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Contents

Viewpoints

Original Papers

Reviews

Editorial

Corrigenda and Addenda

Viewpoint

Counting Bites With Bits: Expert Workshop Addressing Calorie and Macronutrient Intake Monitoring

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Abstract

Background: Conventional diet assessment approaches such as the 24-hour self-reported recall are burdensome, suffer from recall bias, and are inaccurate in estimating energy intake. Wearable sensor technology, coupled with advanced algorithms, is increasingly showing promise in its ability to capture behaviors that provide useful information for estimating calorie and macronutrient intake.

Objective: This paper aimed to summarize current technological approaches to monitoring energy intake on the basis of expert opinion from a workshop panel and to make recommendations to advance technology and algorithms to improve estimation of energy expenditure.

Methods: A 1-day invitational workshop sponsored by the National Science Foundation was held at Northwestern University. A total of 30 participants, including population health researchers, engineers, and intervention developers, from 6 universities and the National Institutes of Health participated in a panel discussing the state of evidence with regard to monitoring calorie intake and eating behaviors.

Results: Calorie monitoring using technological approaches can be characterized into 3 domains: (1) image-based sensing (eg, wearable and smartphone-based cameras combined with machine learning algorithms); (2) eating action unit (EAU) sensors (eg, to measure feeding gesture and chewing rate); and (3) biochemical measures (eg, serum and plasma metabolite concentrations). We discussed how each domain functions, provided examples of promising solutions, and highlighted potential challenges and opportunities in each domain. Image-based sensor research requires improved ground truth (context and known information about the foods), accurate food image segmentation and recognition algorithms, and reliable methods of estimating portion size. EAU-based domain research is limited by the understanding of when their systems (device and inference algorithm) succeed and fail, need for privacy-protecting methods of capturing ground truth, and uncertainty in food categorization. Although an exciting novel technology, the challenges of biochemical sensing range from a lack of adaptability to environmental effects (eg, temperature change) and mechanical impact, instability of wearable sensor performance over time, and single-use design.

Conclusions: Conventional approaches to calorie monitoring rely predominantly on self-reports. These approaches can gain contextual information from image-based and EAU-based domains that can map automatically captured food images to a food database and detect proxies that correlate with food volume and caloric intake. Although the continued development of advanced machine learning techniques will advance the accuracy of such wearables, biochemical sensing provides an electrochemical analysis of sweat using soft bioelectronics on human skin, enabling noninvasive measures of chemical compounds that provide insight into the digestive and endocrine systems. Future computing-based researchers should focus on reducing the burden of wearable sensors, aligning data across multiple devices, automating methods of data annotation, increasing rigor in studying system acceptability, increasing battery lifetime, and rigorously testing validity of the measure. Such research requires moving promising technological solutions from the controlled laboratory setting to the field.

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KEYWORDS

computer vision systems; computing methodologies; diet; energy intake; eating; eHealth; feeding behavior; mHealth; nutritional status; obesity; wearable technology

Introduction

The marked rise in obesity, particularly in the United States, is a complex sociodemographic and public health problem that is largely driven by poor diet, excessive caloric intake, and insufficient caloric expenditure [1]. Weight loss interventions in clinical and research settings have sought to curb this growing health concern by providing recommendations on decreasing caloric intake and increasing caloric expenditure [2]. Thus, subjective diet assessments—including food records, 24-hour dietary recall, and food frequency questionnaires (FFQs)—are often used in weight loss interventions to evaluate diet adherence and behavior change, although they are burdensome and prone to biased measurements of dietary intake and physical activity [3,4]. There is increasing interest in using health and fitness wearable devices to measure eating behaviors as they address the limitations of subjective diet assessments; these devices are set to become a US $48.2 billion market by 2023 [5]. Broad deployment of wearable activity trackers and heart rate monitors in the last decade has coincided with the need to reduce errors and improve our understanding of diet behaviors, calorie count, and nutrient intake. Using wearable technologies not only improves our understanding of diet behaviors but also aids the design of novel interventions to prevent overeating. Although emerging data suggest that diet and exercise programs are more successful at obtaining weight loss and healthy behavior change when they are mobile health (mHealth)–based interventions (ie, delivered via a mobile phone) compared with non-mHealth interventions (controls) [6], the effectiveness of combining mHealth-based interventions with wearable technologies to produce dietary change has yet to be properly studied.

To date, 3 types of technology-enabled wearable domains for calorie and nutrient monitoring have emerged: (1) *image-sensing technology* (eg, cameras coupled with novel algorithms that detect and analyze foods in an image using a food database); (2) *eating action unit (EAU)–based technology* (eg, wrist-worn sensors to capture eating and diet behaviors); and (3) *biochemical measures* (eg, sweat-sensing wearable technology that measures nutrient status). Although their impact on improving care and health outcomes remains untested, the validity of such devices is a prominent concern among researchers. Prior narrative reviews and surveys have focused on describing existing technologies [7-9] and algorithms [10], along with advantages and disadvantages of each type of wearable. Here, we have described the outcomes of a 1-day invitational workshop that identified challenges in developing technology-enabled, automated calorie-monitoring methods and proposed opportunities for future computing research in this field. We have also discussed how technology and objective measurements can support conventional subjective diet assessment approaches.

Methods

An expert, consensus-building 1-day workshop, supported by the National Science Foundation and organized by Northwestern University, was held on June 20, 2017, in Chicago, Illinois. The *primary aim* of the workshop was to discuss the development, evaluation, and use of technology to detect and understand diet behaviors and estimate calorie and macronutrient intake.

A total of 30 participants from 6 universities and from the National Institutes of Health were selected to participate in the workshop. To capture varying perspectives across multiple fields, participants included population health researchers, such as behavioral scientists, nutritionists, obesity epidemiologists, and intervention developers (Bonnie Spring, Lisa Neff, Kevin Hall, and Marilyn Cornelius); computer scientists (Nabil Alshurafa, Adam Hoover, Edward Delp, and Mingui Sun); and engineers in biomedical, material science, and computer technology (Roozbeh Ghaffari, John Rogers, Veena Misra, Adam Hauke, Andrew Jajack, and Jason Heikenfeld). Multimedia Appendix 1 provides a list of participants at the workshop. Owing to the exploratory nature of this workshop, the organizers did not apply a theoretical framework.

A team consisting of at least 2 participants was organized to lead a discussion about one of the following topics: types of technology-enabled calorie and macronutrient monitoring, potential research gaps and technical challenges to advance the capture of energy expenditure, and methods for how technology can assist conventional subjective diet assessments. Workshop participants were also randomly separated into 2 groups to delineate key topics for future research. Overall, there was consensus regarding the need to refine technology-supported calorie- and macronutrient-monitoring approaches. The *primary deliverable* was a set of presentations delineating current gold standards for measuring energy intake and an appraisal of the state of research related to calorie- and macronutrient-monitoring technology. Experts within each technology-enabled wearable domain identified new insights and opportunities from these presentations and conversations, which were used to inform the final recommendations presented in this paper. A final review of the recommendations was performed by the authors of this paper.

Technology-Enabled Domains for Measuring Calorie and Macronutrient Intake

Technology-enabled measures can reduce participant burden and increase granularity of diet data collection through automated measures [11]. We have explained each technology-enabled domain and identified key challenges to advancing the technology in the sections that follow (summarized in Figure 1). Each section also highlights potential research opportunities to advance technology-enabled devices in measuring calorie and macronutrient intake.

Image-Based Sensing

Image-based sensing systems [12,13] that combine wearable or smartphone-based cameras with advanced computational machine learning models, in particular deep learning [14], have the capability to identify pixels in an image that represent foods (this is known as food segmentation), provide accurate timestamps when a meal is consumed (this is known as the metadata associated with the image), estimate consumption duration and frequency, and ascertain geographic eating locations (these 2 are commonly referred to as contextual information of the eating event). To enable these functions, researchers have focused on using image-based systems to identify food types [15]. These systems combine image-processing techniques and big data analytics to estimate energy contents for a meal [16,17] from food and nutrient databases, such as the Nutrition Data System for Research and the Food and Nutrient Database for Dietary Studies (FNDDS) [18]. Thus, image-based systems are unique as they use known foods in a database to guide the estimation of calorie intake and can provide a fairly accurate analysis of the consumed food types. However, accurate estimation of energy and nutrients in an image relies on the system’s ability to distinguish foods from the image background and to identify (or label) food items. Although there are promising advancements, several challenges remain in automating the estimation of calorie intake from cameras (Table 1).

Figure 1. Overview of challenges in developing technology-enabled, automated caloric-monitoring methods.

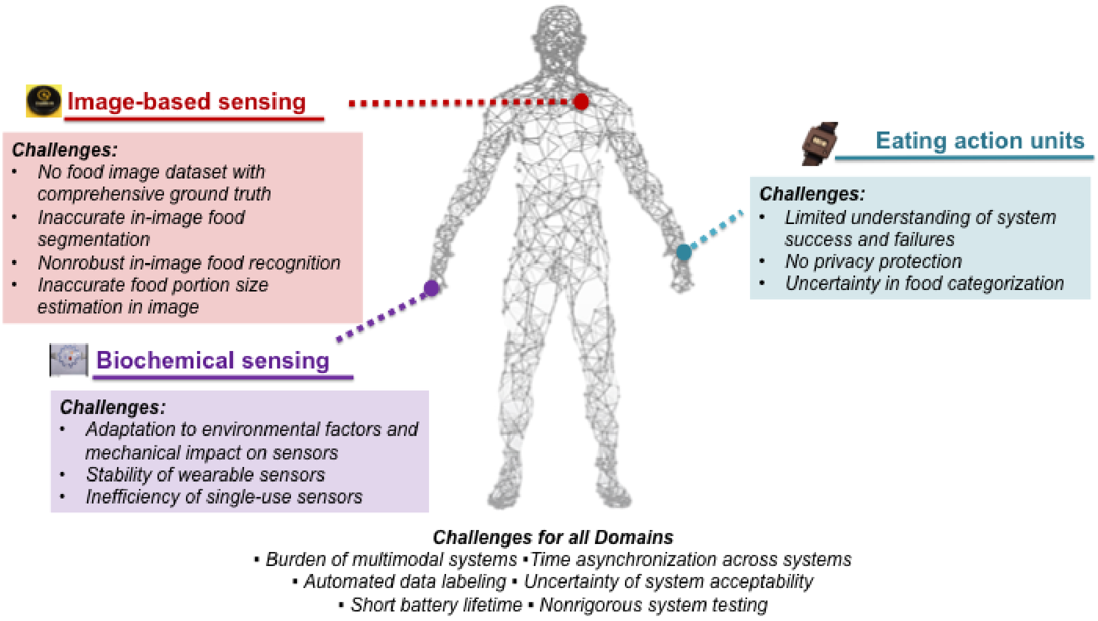

Table 1. Challenges and research opportunities in adopting image-based sensing methods.

Challenge	Research opportunity
Lack of publicly available large-scale food image datasets with comprehensive *ground truth* labels	Develop feasible method to annotate food images crawled from the Web or collected from nutrition studies that can scale up
Inaccurate food image–segmentation algorithms	Reduce the burden of requiring fine-grain pixel-level training data for image segmentation and leverage accurate image or specific image region level information to improve food segmentation performance
Nonrobust food image–recognition systems	Design deep neural network–based models to capture structures in the image that are associated with specific foods and incorporate contextual information to improve robustness
Inaccurate food portion size estimation in image	Develop methods that can directly link food images to portion size; explore 3-dimensional information from newer camera sensors on mobile devices

Challenge: Lack of Publicly Available Large-Scale Food Image Datasets With Comprehensive Ground Truth Labels

A *ground truth* label, derived from observable data, is the objective verification of particular properties of a digital image, used to test the accuracy of automated image analysis processes. The ground truth of food images includes known, fixed features such as pixels representing food objects in the image (used for food segmentation), food types (used for food recognition), and food portion size in grams (used for portion size estimation). Such information is necessary to train the image analysis system to accurately estimate calorie intake from the image. Several publicly available food datasets contain a substantial amount of food images [18] and provide general labels of different food types, but none provide information relative to portion size, segmented food items, or additional context of the image source. To reliably build a machine learning model that automatically maps images to calories, successful image-based systems need large collections of food images (ie, food image datasets) with the necessary *ground truth* labels to improve the learned models. These *ground truth* labels should clearly delineate different food items even if they are on a single plate and should include portion size information for each food item.

Research Opportunities

To address the need for constructing large-scale food datasets with food images that provide comprehensive *ground truth* information, a solution is to merge food images sourced from the internet or from nutrition studies with manual annotation from crowd-sourcing platforms. Amazon Mechanical Turk (AMT) has been used for food image collection and annotation tasks [19,20], although AMT is not tailored for building large food image datasets efficiently with proper labels. This inefficiency may be partly attributed to its high cost and dependency on crowdsource workers unfamiliar with the context in which the data were collected (eg, restaurant food vs homemade meal). There are opportunities to develop novel tools that not only label foods in the image but also remove irrelevant images to aid crowdsource workers in accurately labeling necessary data. These approaches can be developed using a combination of crowd input and advanced automatic image analysis techniques [21].

Challenge: Inaccurate Food Image–Segmentation Algorithms

Image segmentation is the process of partitioning an image using an algorithm into disjointed and coherent regions on the basis of prespecified features. Food image segmentation is important for multifood images in which subsequent analysis, such as recognition and portion size estimation, depends on having accurate segmentation of each food in the image. Owing to the complexity of food images (eg, occlusion, hidden or mixed foods, and shadows), accurate food image segmentation is a difficult task and affects the ability of image-based sensing systems to identify food types. Previous studies [22-26] have used image-segmentation methods such as contour-to-region, graph-based, and superpixel-based approaches. A segmentation method based on deep neural networks has been proposed [27] to reliably build a model that automatically segments foods. However, these models require pixel-level food labels or labeled bounding boxes to indicate regions containing foods, which is time-consuming and computationally expensive.

Research Opportunities

Owing to the inefficiency and high expense, some studies have applied graph-based methods to select regions containing foods [28] or have explored techniques where only image-level labels indicating the presence or absence of foods are required instead of requiring pixel-level labels of food objects [29]. The opportunity to advance such methods remains, as does the main opportunity of creating efficient segmentation algorithms that provide pixel-level labels and training for each image in a food dataset.

Challenge: Nonrobust Food Image Recognition Systems

Research [30-32] in food recognition has analyzed multiple features and classification algorithms (aimed at identifying foods) that are effective but mainly restricted to a known food dataset that has been established a priori. Researchers [27,33,34] use either an end-to-end deep neural network or image features with variations of support vector machine (SVM) [35] classification algorithms to optimize food recognition. However, many studies on food recognition assume that only 1 food item is present in an image and apply a multiclass classification algorithm to identify the foods. In real-world scenarios, there is typically more than 1 food item in an image, where each food item is a segment in the image and is described by handcrafted or deep features and then classified by an SVM classifier [22,36].

Research Opportunities

Robust and accurate food image recognition remains a challenge because many foods have a deformable appearance and thus lack of rigid structures and because there often exists subtle differences in visual features among different food categories. Factors such as food preparation and personal preferences can also affect the appearance of food ingredients. Deep neural network–based approaches provide opportunities to improve the robustness and accuracy of food recognition systems but depend heavily on well-constructed training datasets and proper selections of neural network architectures. However, there is an opportunity to provide contextual information in the food recognition algorithm, which can include environmental cues and previous diet history. There have been advances in restaurant-specific food recognition [23,37,38] where location and menu information are used to assist with recognition. Others [39] have integrated recipe and cuisine as context and prior knowledge to aid automatic food recognition. Food patterns across time and dietary preferences are increasingly being shown to improve food classification accuracy [40]. Incorporating contextual cues can be essential to advancing the robustness of food recognition algorithms.

Challenge: Inaccurate Portion Size Estimation in Image

Estimating food portion size from an image is challenging as preparation and consumption impose large variations on food shape and appearance. Several food portion estimation techniques based on reconstructing the 3-dimensional (3D) models of the foods have been developed, which require users to take multiple images or videos or to modify mobile devices [41-45] to enable reconstruction. These approaches work well for irregularly shaped foods, but they do not work well when there are no strongly matched features (ie, corresponding sets of points) occurring on multiple frames. These approaches also require users to capture multiple images from different angles, making them tedious and unsuitable for long-term health monitoring and data collection. Others have focused on developing methods to estimate food portion size from a single-view image [17,46-49]. These methods use geometric model–based techniques that require food labels and food segmentation masks (ie, pixel location of foods in the image). Errors from automatic food classification and image segmentation can propagate into the final portion estimation. In addition, existing methods have only examined small model libraries consisting of foods with simple geometric shapes (eg, apples, burgers, and pizza). Further research is required to develop more comprehensive model libraries capable of dealing with irregularly shaped foods.

Research Opportunities

Despite some promising results from existing approaches, the performance of current portion estimation methods is not yet satisfactory. More recently, several groups [27,50] have developed portion estimation methods using deep learning. However, these techniques estimate food volumes rather than food energy. With food volumes estimated, food density is still required to compute weights, which can then be mapped to food energy using a food composition resource, such as the FNDDS [18]. Therefore, new approaches [16] that can directly link food images to food energy in the image are desirable.

Depth sensors and dual camera configurations are quickly gaining popularity on consumer mobile devices. More 3D information can be collected without significantly adding to a user's burden capturing the eating scene. For example, mobile phones equipped with depth sensors enable simultaneous capture of image depth and the RGB color model image. For dual camera systems, at least two images are captured from slightly different angles, enabling multiview 3D reconstruction techniques. The additional information captured by the mobile devices may improve the accuracy of food portion estimation by providing additional 3D information on food objects.

Eating Action Unit–Based Sensing

Although existing imaging technologies have shown reasonable success in estimating calorie intake and nutrients from images, there is growing interest in capturing proxies to calorie intake with sensor modalities that have fewer wearer privacy concerns. EAUs (ie, fine-grained activity units that occur during eating) are a mechanism to understand calorie intake patterns and behaviors. Accelerometer- and gyroscope-based inertial measurement units [51,52] are examples of EAUs that assess eating patterns. These techniques have been developed as a result of observing feeding gestures (or bites) and their correlation to calorie intake [53,54]. The underlying assumption of EAUs is that by counting the number of bites and estimating average calories per bite, we can provide a reasonable estimate of overall calories consumed, map the number of bites to calories to determine over- or underconsumption, and enable users to automatically quantify their calorie intake using EAU-based devices [55].

Capturing EAUs enables actionable insight, where information generated can be used by wearers, clinicians, and dietitians in a timely manner. They also enable interventionists to test the efficacy of calorie-informed, just-in-time interventions in close proximity to eating episodes. Although the detection of EAUs has shown promise, several challenges prevent these systems from being adopted in clinical and population settings (Table 2).

Table 2. Challenges and research opportunities in adopting eating action unit–based sensing methods.

Challenge	Research opportunity
Limited understanding of context surrounding system success and failures	Use wearable video cameras to validate contextual information surrounding when sensor–algorithm pairings fail in real-world settings
Privacy protection in *ground truth* data collection methods	Identify novel ways of protecting bystanders and other sensitive information in the field of view of cameras both in hardware and software to ensure wearer privacy concerns are addressed, thereby increasing likelihood of capturing naturally occurring behavior
Inability to accurately distinguish between food categories	Define food categories that are most useful for clinicians and researchers for diet interventions and food recalls

Challenge: Insufficient Understanding of the Context of System Success and Failure

Several systems have shown promise in free-living populations but fall short of delineating the contexts for when and where their systems succeed and fail, which prevents others from building on previous work to advance EAU systems under challenging scenarios. For example, gesture EAUs are confounded by smoking action units; however, few studies attempt to consider other challenging contextual scenarios that can confound eating behaviors [56]. Attempts to advance eating detection while considering challenging contexts are limited primarily because confounding contexts are not clearly delineated. A preliminary study in 8 participants who wore a wrist-worn sensor for a few hours in a free-living situation demonstrated that wearable video cameras have an approximately 38% false-discovery rate, which typically corresponded to phone-related gestures [57]. The false-discovery rate could be mitigated by integrating phone usage information with the system. However, data are limited in the context in which 1 device outperforms the other, limiting our ability to advance EAU-based eating detection systems.

Research Opportunity

Additional data are needed on the strengths and limitations that lead systems to succeed and/or fail in free-living populations. Understanding the context of success or failure enables identification of strengths and weaknesses of various systems and advances both the hardware and algorithm used to solve these challenges. Studies are beginning to identify the context in which sensor-algorithm pairings fail; however, they lack validity through visual confirmation. With the exception of a few recent studies [57-62], few researchers have incorporated wearable video cameras in the field to provide such validation. Researchers should continue using wearable video cameras in free-living populations and clearly state the context within which the system succeeds or fails.

Challenge: Inability to Protect Privacy When Using Wearable Video Cameras in the Field

Evaluation of an eating detection system necessitates testing against visually confirmed (with video) ground truth (ie, means of validating the activity in a real-world setting). Visual confirmation of eating behaviors is the strongest form of ground truth available for EAUs but also one of the most burdensome on the participant and researcher. Many researchers limit their studies to controlled settings primarily because of the limited robustness of the sensor and the time required to manually label video streams to produce ground truth. There is significant time and cost associated with designing a fail-safe device that can function in free-living environments [63]. However, people are generally unwilling to wear wearable video cameras in real-world settings owing to privacy concerns, and the likelihood of behaving naturally in the presence of a video camera is limited [64]. Recent research has shown that, given acceptable levels of incentives and properly orienting the camera, participants are willing to don wearable video cameras in real-world settings for a short period of time. Some researchers bypass the use of wearable video cameras by combining other sources of information, such as food journaling and sensor data [65], commercial electroencephalography (EEG) sensors to produce labels for a wearable EEG device [66], and a GoPro Hero 3 camera mounted on the chest facing the jaw [58].

Research Opportunity

Ensuring a long-lived, minimally intrusive method for capturing ground truth is necessary for capturing realistic data and rigorously testing interventions. As many participants report concerns for bystanders as their main reason for being unwilling to wear a camera all day [64,67,68], researchers may be able to design video cameras that are both privacy-preserving and that aid in validating other body-worn sensors by providing video confirmation of EAUs. Importantly, this will ensure that sensors being deployed adequately validate the behaviors they claim to capture in the settings they are most needed.

Challenge: Inability to Accurately Distinguish Between Food Categories

Similar to image processing, EAU-based sensors have shown success in distinguishing between different food categories. Chewing crunchy chips compared with chewing a banana produces very different sensor signals, and researchers are beginning to capitalize on these variations to distinguish between food items and type. Automatically determining solid versus liquid ingestion has provided some utility in identifying sources of ingestion behavior and intervention design, allowing researchers to investigate this phenomenon [69-71]. This could provide utility in a hospital setting, where foods provided to patients are known a priori, narrowing the food search space. However, this limits utility in free-living populations, and the challenge remains in increasing external system validity.

Research Opportunity

Knowledge of an individual’s diet may narrow the search space, enabling sensors to automatically distinguish between individuals, given their known diet and food environment. An opportunity exists to categorize foods in a way that would be most useful for researchers and clinicians in improving calorie intake estimates. Although distinguishing between liquid and solid consumption may have research utility, it is unknown what other types of food categories may be distinguishable. Within-subject variability of nutrients is influenced by gender, age, and education [72]. Thus, this research opportunity would be most helpful for populations with low-variability diets, particularly among elderly participants or patients on restricted diets.

Biochemical Measure–Based Sensing

There are concerted efforts underway to characterize the biochemical changes in the body that result from food and calorie intake. Novel classes of biochemical and electrochemical sensing systems could be used to analyze changes in metabolic activity observed in interstitial fluid, saliva, or sweat [73,74]. In this section, we have reviewed wearable sweat monitoring systems that have been deployed recently in remote environments (Table 3).

Table 3. Challenges and research opportunities in adopting biochemical measure–based sensing methods.

Challenge	Research opportunity
On-body biochemical monitoring	Apply wearable biochemical sensors to monitor electrolytes, metabolites, and proteins in biological fluids (eg, saliva, sweat, and interstitial fluid)
Stability of wearable sensors under different environmental conditions for metabolites, electrolytes, and proteins	Develop stable biochemical tests to determine concentrations (bioassays) of glucose, lactate, cortisol, ammonium, sodium, chloride, and potassium, which require limited handling and refrigeration with dehydration or freeze-drying methods
Reusable vs single-use wearable sensors	Develop low-cost battery and energy harvesting solutions to enable single-use and multiuse modes of operation

Challenge: On-Body Biochemical Monitoring

Recent efforts have focused on biochemical analysis of eccrine sweat using wearable devices [75-77], which leverage both colorimetric and electronic-based sensors that collect sweat directly from skin pores and measure biomarker concentrations and dynamics (eg, sweat loss and sweat rate) in real time. This opens new possibilities for characterizing electrolyte and metabolite loss during daily activities, which can be correlated with blood metabolites, hormone, proteins, pathogens, and drugs [78,79].

Continuously monitoring biomarkers in sweat requires highly sensitive techniques for extraction and electrochemical analysis. Researchers have devised strategies to reduce the contamination effects of skin in contact with the device, while increasing sweat collection volume. This new class of wearable biochemical sensors could provide viable pathways for creating noninvasive and remote analysis of diet, wellness, and health [75]. However, shelf-life stability of biochemical sensors, susceptibility to contamination, and fundamental limitations in capturing sufficient volumes of sweat remain problematic.

Research Opportunity

Key opportunities lie in the design and deployment of biochemical-sensing devices that can endure temperature changes owing to environmental factors and mechanical impact while maintaining signal quality without degradation over time. Beyond device resiliency, comparisons of sweat and blood analyte levels must be tested across healthy and sick populations to determine validity and applicability of on-body sweat sensing.

Challenge: Enabling Robust Onboard Enzymatic and Chemical Assays (Biochemical Tests and Assays) Under All Environmental Conditions

The rich heterogeneous blend of electrolytes, metabolites, and proteins in sweat represents a unique set of noninvasively collected data. These biomarkers have been shown to correspond to the physiologic state and may serve as the basis for understanding cognitive impairment in the field. To date, most studies have focused on characterizing electrolytes and metabolites (eg, glucose or lactate) using bioassays in controlled laboratory settings. Metabolic biomarkers could change with physical stress and diet during daily activity outside of controlled laboratory settings. The stability of wearable biochemical sensors is thus crucial to maintain over extended time periods in real-world settings.

Research Opportunity

Wearable biochemical sensors that employ onboard dehydrating reagents or buffers that reduce degradation could lead to broad-scale deployment of these systems. Refrigeration is useful in protecting against bioassay degradation, but it requires special instructions and specialized equipment for proper handling and modes of operation. The development of new classes of wearable devices that require limited handling and refrigeration and that can handle enzyme-linked immunosorbent assay and protein-based analysis, using dehydration and freeze-drying steps to promote chemical stability, represents an area of enormous potential for robust remote-based deployment of wearable technologies.

Challenge: Reusable Versus Single-Use Sensors

Continuous monitoring of sweat biomarkers requires flexible electronics modules, memory storage, and onboard batteries to facilitate data capture, signal processing, and transmission. Significant practical considerations, such as sensor corrosion at the interface with ionic fluids, need for cleaning, and the resulting signal degradation that could occur over time limit the utility of reusable systems. Electrochemical sensing systems consisting of a reusable electronics module and single-use electrochemical sensors provide compelling routes to address these challenges. Single-use system designs may circumvent the challenges of long-term wear, fluid–device interface, and signal degradation. However, disposable devices must be carefully engineered to support sufficiently reduced cost to warrant single-use deployment.

Research Opportunity

Sweat is a corrosive biofluid that engenders significant device cleaning to facilitate reuse of the device. Thus, single-use wearable biochemical-sensing systems address important limitations of reusable systems assuming cost constraints are met. Hybrid designs, in which the reusable module mechanically couples to a single-use biochemical sensor, may mitigate the limitations of reusable and single-use systems. Although hybrid systems tend to cost more, they have significantly greater signal processing and battery capacity for long-term continuous monitoring.

Challenges Across Sensing Modalities

Regardless of the type of sensing modality, calorie estimation techniques share a set of common challenges because of the unique role that eating and nutrition play in everyone's lives. These challenges are related to sensor development, validation, and refinement both in controlled and free-living settings.

Challenge: Burden of Multimodal Systems

Although many researchers have studied detecting eating using a single wearable device, several are beginning to combine multiple sensors and context via multiple wearable devices to advance the total accuracy of an eating detection system. Mirtchouk et al [80] showed that using in-ear audio with head and wrist sensors improved accuracy from 67.8% with audio alone to 82.7% and 76.2% for head and wrist sensors, respectively. However, these approaches were mainly tested in a laboratory setting, not in a free-living environment, and it is unknown how well the findings translate to free-living populations. Multimodal sensor studies that attempt to determine utility of sensors in real-world settings are sorely needed.

Wrist sensors coupled with other sensor modalities (eg, GPS and respiratory plethysmography) may aid in distinguishing among smoking, eating, and other activities. Examples of multimodal systems include using a jaw motion sensor, a hand gesture sensor, and an accelerometer [81] and using an airflow sensor, a respiratory plethysmography chest sensor, and a wrist-worn sensor [82]. However, the burden of wearing all these sensors is significant. Thus, novel ways of combining less burdensome sensors and devices or integrating noncontact or noninvasive devices are needed while advancing the accuracy in detecting calorie and macronutrient intake or proxies.

Challenge: Time Asynchronization Across Sensors

A multidevice system brings challenges in coordinating and synchronizing activities and sensing across devices. As each device manages its own internal clock, this network of clocks can become unsynchronized following power failure or reset. Most devices are designed to be standalone and use an internal clock, as opposed to time stamping their data using a nearby smartphone or body sensor unit. Time synchronization in real time has been a long-studied problem; however, automated time-synchronization methods post data collection can enable researchers to test multiple devices simultaneously, without the need to reengineer the device to use a central hub. Without reliable millisecond time-synchronization techniques, annotations from 1 sensor stream (eg, video camera) are not transferable to another sensor stream.

Challenge: Lack of Automation in Data Labeling

Once a sensor is deployed in a real-world setting, a supervised learning model, which aims to categorize data from prior known labels or information (ie, supervised training), is designed to process the data and determine system viability. However, one challenge in building a supervised learning model is providing sufficiently annotated instances or labels to train the model. Prior studies in real-world settings have depended on self-reported annotations [59,83-86], which are burdensome and rarely timely. More recently, studies are using wearable cameras worn by participants to provide annotations through visual activity confirmation poststudy [57-62]. To visually confirm, a data labeler is hired to watch the video and label points in time when the activity occurred, which is time-consuming and prone to error. Computer scientists are beginning to design tools to automatically annotate using active learning systems that attempt to reduce the required number of annotations to build a reliable machine learning model. However, systems currently developed focus on building models that process data with samples that are fixed in time (eg, an image or a minute of data). Active learning systems designed to handle activities with varied durations (eg, eating episodes, feeding gestures, and chewing duration) can fill this gap.

Challenge: Unknown Acceptability of System by Users

For a system to succeed in real-world settings, it must be acceptable for the population of interest. Although several surveys have been designed to assess wearability of systems, there is no validated standard survey or approach to assess willingness to wear and use a device in the nutrition context. Current systems deploy devices for a variable amount of time (eg, 1–2 days, 1 week, or 1 month) and then report comfort based on a Likert scale. Habits regarding technology adoption are not properly understood until at least 1 week (when most individuals stop using an app or a device) [87]. As a result, acceptability must be clearly limited to the number of days the system was actually tested in free-living populations. An important contributor to system acceptability is battery lifetime, which is closely tied to device burden (ie, frequency of recharge).

Challenge: Short System Battery Lifetime

Long battery lifetime is essential for wearable technology to ensure high sensor sensitivity and recall of eating episodes in free-living populations. It is reported to be the most important feature rated by mobile device users [88-90]. Battery lifetime becomes critically important in longitudinal studies where reducing user burden is key to gathering more data and encouraging habituation. If users must recharge a device multiple times a day, this will limit data collection. Moreover, battery lifetime enhancements enable populations who may otherwise not be able to manage a device (eg, pediatric or geriatric populations). There are several software approaches to increase battery lifetime including duty-cycling, high-powered sensors, or triggering with low-power sensors. Reducing computational complexity and designing for specificity also reduces wasted energy. New materials enable batteryless sensing devices powered by energy harvested from the environment, wearer motion, or Wi-Fi gateways. Although these sensors show promise, they are not without challenges, as reliability can be an issue when ambient energy is not readily available. Wearable sensors are increasingly being developed to last several months [91,92], but most commercial sensors last <12 hours [93] when attempting to collect continuous inertial measurement unit data. Low-maintenance sensor solutions must be designed, and careful consideration of battery lifetime must exist in every phase of system and study design.

Challenge: Limited Rigor of System Testing

Although technology development serves as an important contribution to the health community, reproducibility of the results is essential to determine proper construct validity, internal reliability, and test-retest reliability to increase confidence in the potential of a system to work in real-world settings. Most existing wearable sensors and systems show success by their principal investigator but have not extended beyond the laboratories in which they were implemented. To prevent bias in reporting, researchers need to disseminate their systems (hardware, software, and datasets) to other teams to provide independent testing and review. Such rigor in testing of sensing platforms is needed across all sensor modalities.

How Technology-Enabled Devices Can Assist Conventional Subjective Diet Assessment

Conventional diet assessments comprise subjective and objective (eg, double-labeled water and metabolic chamber) approaches [94]. Although both approaches measure calorie and macronutrient intake, subjective diet assessments are more commonly implemented in research and clinical settings [95], in part owing to greater convenience and reduced cost [96]. Subjective diet assessments are not constrained by battery lifetimes and are acceptable for target populations. However, each type of subjective diet assessment introduces unique types of measurement error depending on how the diet data are being collected. A description of each assessment, and its strengths and limitations, is presented in Table 4. We posit that technology—such as image sensing, EAU, and biochemical measures—can assist subjective diet assessments to capture habitual dietary intake and eating behaviors, as systematic and random errors associated with both approaches are fundamentally independent. Replacing subjective diet assessments with technology may be difficult as other limitations could arise, such as ambiguity in identifying food images through image distortion or uncertainty over whether the food was truly consumed [97]. Combining information from technology and subjective diet assessments improves the validity of dietary intake data because the 2 approaches complement each other's strengths and limitations.

Table 4. Conventional subjective measurements of energy and macronutrient intake.

Method	Description	Strengths	Limitations
24-hour diet recalls	Inquiry about everything one had to eat and drink during the previous day (usually midnight to midnight); probes often used to collect more detail and standardize the interview	Open-ended, enabling greater detail about intake and food preparation; good for culturally diverse diets; less burdensome	Memory dependent; error prone in quantifying portion sizes; requires intensive interviewer effort, which can decrease motivation to collect accurate data; repeated measures needed to capture usual intake; can alter eating behaviors if recalls are scheduled in advance
Food records	Detailed list of all foods and drinks consumed over a specified amount of time, written by respondent and ideally using weight scales or measuring tools to determine portion size; provides data about actual intake	Open-ended; does not rely on memory if records are completed on time; allows for self-monitoring	Requires intensive respondent effort, which can decrease motivation to collect accurate data or lead to poor response rate; burdensome on staff to analyze data owing to entering and coding items; repeated measures needed to capture usual intake; can alter eating behaviors since respondents are monitoring their diets
Food frequency questionnaire	Questionnaire asking whether a food item was consumed during a specified period of time; contains 2 components (food list and frequency response question); provides data about relative intake	Measures usual intake; less burdensome on respondent and research staff	Memory dependent; food list is fixed and may not capture usual intake, particularly in a culturally diverse diet; may be difficult to quantify food portions without food images; difficult to inquire about mixed dishes; respondent may have difficulty interpreting the questions

One primary concern for using subjective diet assessments includes intentional or unintentional misreporting of dietary intake [98]. Specifically, 24-hour dietary recalls and FFQs rely on memory, which can depend on age, education, attention during eating, and consistency of diet patterns [94,99]. Many individuals underestimate portion sizes for foods and beverages [100] and are sometimes provided with household items, food scales, and/or 2-dimensional images of foods with anchors to improve portion size accuracy [94]. However, these instruments create additional burden and decrease motivation to accurately capture caloric and macronutrient intake. These limitations have far-reaching implications as investigators would be uncertain if the subjective diet assessments are accurately characterizing true dietary intake [101], correctly identifying whether participants are adhering to specific diet interventions [102], and introducing bias when investigating diet-disease associations [101]. Image-sensing and EAU behavior approaches can minimize misreporting by objectively capturing food images and by identifying timing of eating episodes, allowing individuals and researchers to corroborate information from subjective diet assessments. Furthermore, image-sensing and EAU measures can also serve as visual or verbal cues to assist recall when conducting subjective diet assessments.

A limitation specific to 24-hour dietary recall and food records is the measurement of acute intake and not the usual diet [94]. Multiple measures are needed to capture usual intake, and data collection must occur for every day of the week [94]. However, increasing the number of subjective diet assessments creates greater burden for the individual and the research team. Image-sensing and EAU measures can reduce the number of 24-hour dietary recalls and food records needed to capture the best estimates of absolute dietary intake, while automating the analysis of dietary data. To this end, more research is needed to evaluate the number of images and EAU measures needed to provide the best approximation of absolute dietary intakes.

Biochemical measures can also determine nutrient status of the body. However, biochemical concentrations are not true markers of dietary intake and can reflect how the body absorbs, transports, metabolizes, and excretes the nutrient [103]. Therefore, biochemical measures cannot replace subjective diet assessments since it would be unclear how nutrient status is influenced by dietary intake or in vivo processes. Recent advances in statistical approaches, such as prediction models that use data from technology and conventional subjective approaches, account for measurement errors and can provide more accurate results [104,105].

Technology-enabled devices that measure calories and nutrients can also have far-reaching implications in clinical practice. A recent study reported that providers perceive health-tracking technologies as very useful when reviewing patient data, managing medical visits, and facilitating patient–provider communication [106]. A growing number of patients are also engaging with health technology. According to the National Cancer Institute's 2017 Health Information Trends Survey, 34% reported owning an electronic monitoring device to track their health behaviors [107]. A growing opportunity remains in developing efficient strategies to merge technology with subjective diet assessments toward obesity prevention and treatment efforts.

Discussion and Conclusions

Sensors from the 3 domains presented (image-based, EAU-based, and biochemical measure–based) have the potential to identify markers that improve estimates of calorie intake. However, the technologies still require considerable user input from the end user, scientist, or clinician who may have to label or segment images or metrics from such wearables to train a machine learning system. Fully automating technology-enabled calorie and nutrient monitoring would open the possibility to providing highly informed and validated information to augment recall methods and advance estimates of calorie intake for clinicians and patients.

Wearable-based sensing modalities focused on biochemical processes offer a solution for understanding food nutrients. However, more technical expertise is needed to merge conformal, low battery, secure, and valid technology with appropriate caloric assumptions. Once a stronger correlation can be drawn between biochemical products analyzed and calories consumed, biochemical-based wearables may provide promise in future automated calorie estimation systems. However, as with most wearable technologies, adherence to wearing the device remains problematic. This may be overcome if the value in such technologies pans out.

Although calories and nutrients can be consumed and monitored, it is essential to understand the behavioral choices that drive these decisions and if those behaviors can provide insight into calorie intake. All 3 systems have the potential to provide such information from cortisol levels for stressful eating (using biochemical sensors) to late-night snacking (using image-, physical-, and behavioral-based sensors) and beyond. The biggest challenge then becomes how to use the reliable big data collected from these devices to drive an actionable outcome such as lower calorie consumption or identification of eating behaviors that increase calorie intake.

It is our view that the defined research opportunities regarding calorie intake monitoring apps are the most promising, which may move the science toward a ubiquitous future of such monitoring. Nonetheless, challenges remain to fully introduce such solutions to have the desired health impact that clinicians and patients alike expect. At present, the next logical step is for scientists to improve the functionality of such devices, for human-computer interaction experts to improve usability, and for clinical teams and behavioral scientists to assess what information can be used to improve health behavior interventions given these new advanced technological tools. This translational, multidomain effort will demonstrate whether calorie intake monitoring enables higher quality of life and thus challenges the public health crisis of obesity.

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Authors' Contributions

All authors drafted the paper or critically revised it for intellectual content, gave approval for the final version to be published, and agreed to be accountable for all aspects of the work.

Conflicts of Interest

None declared.

Multimedia Appendix 1
List of attendees including faculty, postdoctoral researchers, and graduate students who participated in the discussions.
[DOCX File , 14 KB - jmir_v21i12e14904_app1.docx]

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Abbreviations

3D: 3-dimensional
AMT: Amazon Mechanical Turk
EAU: eating action unit
EEG: electroencephalography
FFQ: food frequency questionnaire
FNDDS: Food and Nutrient Database for Dietary Studies
mHealth: mobile health
RGB: red green blue
SVM: support vector machine

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Original Paper

A Web-Based Self-Titration Program to Control Blood Pressure in Patients With Primary Hypertension: Randomized Controlled Trial

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Abstract

Background: Hypertension is a major cause of mortality in cardiac, vascular, and renal disease. Effective control of elevated blood pressure has been shown to reduce target organ damage. A Web-based self-titration program may empower patients to control their own disease, share decisions about antihypertensive dose titration, and improve self-management, ultimately improving health-related quality of life.

Objective: Our primary aim was to evaluate the effects of a Web-based self-titration program for improving blood pressure control in patients with primary hypertension. Our secondary aim was to evaluate the effects of that program on improving health-related quality of life.

Methods: This was a parallel-group, double-blind, randomized controlled trial with assessments at baseline, 3 months, and 6 months. We included patients with primary hypertension (blood pressure>130/80 mm Hg) from a cardiology outpatient department in northern Taiwan and divided them randomly into intervention and control groups. The intervention group received the Web-based self-titration program, while the control group received usual care. The random allocation was concealed from participants and outcome evaluators. Health-related quality of life was measured by the EuroQol five-dimension self-report questionnaire. We used generalized estimating equations to evaluate the effects of the intervention.

Results: We included 222 patients and divided them equally into intervention (n=111) and control (n=111) groups. Patients receiving the Web-based self-titration program showed significantly greater improvement in the systolic and diastolic blood pressure control than those who did not receive this program, at 3 months (–21.4 mm Hg and –5.4 mm Hg, respectively; *P*<.001) and 6 months (–27.8 mm Hg and –9.7 mm Hg, respectively; *P*<.001). Compared with the control group, the intervention group showed a significant decrease in the overall defined daily dose at both 3 (–0.202, *P*=.003) and 6 (–0.236, *P*=.001) months. Finally, health-related quality of life improved significantly in the intervention group compared with the control group at both 3 and 6 months (both, *P*<.001).

Conclusions: A Web-based self-titration program can provide immediate feedback to patients about how to control their blood pressure and manage their disease at home. This program not only decreases mean blood pressure but also increases health-related quality of life in patients with primary hypertension.

Trial Registration: ClinicalTrials.gov NCT03470974; https://clinicaltrials.gov/ct2/show/NCT03470974

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KEYWORDS

Web-based; self-titration; blood pressure; hypertension; health-related quality of life

Introduction

The World Health Organization (WHO) reported that hypertension is one of the most common health concerns [1], with an estimated worldwide prevalence of more than 1.3 billion people [2]. The WHO also predicted that hypertension will affect 29% of the world's population by 2025 [3]. In the United States, just about 49% of male patients and 55% of female patients had controlled hypertension between 2009 and 2012 [4]. Similarly, around 24% of the adult population in Taiwan (4.6 million people) had hypertension, and only 58% of hypertension patients had good control [5].

Hypertension is a major cause of mortality, resulting in 10.5 million deaths worldwide annually [6,7]. Death is a consequence of target organ damage due to hypertension, including cardiovascular, cerebrovascular, and kidney diseases [8-10]. In Asia, high systolic blood pressure is the main risk factor for stroke [11]. Hypertension and its comorbidity also affect health-related quality of life (HRQoL) [12]. A meta-analysis of 20 cross-sectional studies showed that patients with hypertension had poor HRQoL compared with normotensive adults [13]. Similar findings were reported from a meta-analysis of 21 observational studies in China [14].

The poor adherence to health behaviors, a significant barrier to optimal blood pressure control [15], is due to treatment regimen complexity, side effects of medicines, psychosocial distress, and poor health literacy [16,17]. Home blood pressure self-monitoring has been shown to improve blood pressure control [18,19] and help health care providers make appropriate treatment decisions [19]. A recent meta-analysis concluded that clinical interventions should be developed to help patients perform accurate self-monitoring of their blood pressure in order to achieve better blood pressure control [20]. Telemedicine could be useful in this regard because it not only allows patients to easily perform self-monitoring at home but also enables clinical professionals to have access to the data and give their feedback to patients immediately [21].

In clinical practice, a cardiologist usually starts antihypertensive therapy by medication titration based on a patient's response and educates patients about self-monitoring and self-adjustment of dosages at home [22]. However, most patients are anxious about how to follow the complicated treatment regimen [22]. Medication titration strategies have been designed to successfully assist patients in self-titration of antidiabetic, oral anticoagulation, and beta-adrenergic receptor blocking medicines [23-25]. The titration process allows patients to perceive how their efforts improve their disease outcomes [26].

Few randomized controlled trials have investigated the outcomes of medication titration on blood pressure control in patients with hypertension. The Telemonitoring and Self-Management in Hypertension 2 (TASMINH2) trial combined telemonitoring with a titration strategy to improve blood pressure control for patients with hypertension [27]. The intervention group had significantly greater decreases in systolic blood pressure (SBP) and diastolic blood pressure (DBP)—3.7 mm Hg (95% CI 0.8-6.6) and 1.3 mm Hg (95% CI 0.3-2.6), respectively—compared with a control group after 12 months. In a second trial, Targets and Self-Management for the Control of Blood Pressure in Stroke and at Risk Groups (TASMIN-SR) [28], patients with secondary hypertension received training in self-titration of antihypertensives. Again, the results showed that patients in the intervention group had significant decreases in SBP (–8.8 mm Hg; 95% CI 4.9-12.7) and DBP (–3.1 mm Hg; 95% CI 0.7-5.5) after 12 months. The TASMINH4 trial evaluated the effectiveness of general practitioner–led titration of antihypertensives with either self-monitoring or self-monitoring plus telemonitoring on blood pressure control [29]. The trial showed that SBP significantly decreased after 12 months in both intervention groups, with differences of –3.5 mm Hg (95% CI –5.8 to –1.2) in the self-monitoring group and –4.7 mm Hg (95% CI –7.0 to –2.4) in the telemonitoring group. Moreover, DBP also decreased in both the self-monitoring group (–1.5 mm Hg, 95% CI −2.7 to −0.2) and the telemonitoring group (−1.3 mm Hg, 95% CI −2.5 to −0.02).

Nevertheless, two previous studies were unable to detect a significant finding of the effects of antihypertensive titration on blood pressure control [30,31]. The first, a two-armed trial, indicated that health coaching with home titration was not superior to usual care for blood pressure control after 6 months [30]. A second study, the Diabetes Risk Evaluation and Microalbuminuria 3 (DREAM 3) trial, assessed the effects of a nurse-lead titration strategy in patients with hypertension, diabetes, and microalbuminuria, but found no significant effect on either SBP or DBP control at 6 and 12 months [31]. Thus, there is no consistent evidence about the efficacy of medication titration on blood pressure control, and there is a notable lack of research data from Asia.

We aimed to evaluate the effectiveness of a Web-based self-titration program on blood pressure control in patients with primary hypertension. Our primary hypothesis was that patients receiving the Web-based self-titration program in the intervention group would have a better control of SBP and DBP than the control group after 3 and 6 months. The secondary hypothesis was that the patients in the intervention group would show greater improvement in HRQoL than those in the control group.

Methods

Study Design

This was a parallel-group, double-blind, randomized controlled trial. Participants were randomly assigned to an intervention group or a control group using a permuted block randomization design with a block size of 4. The random allocation was concealed from participants and outcome evaluators via the use of sequentially numbered opaque envelopes. Data were collected at baseline, 3 months, and 6 months. The study was based on the CONSORT-EHEALTH guidelines (V1.6) [32] and was conducted from February 2017 to August 2018.

Study Setting and Sample

We enrolled patients with primary hypertension from a cardiovascular outpatient clinic of a medical center in northern Taiwan. The inclusion criteria were as follows: age of 20-79 years, diagnosis of primary hypertension with SBP≥130 mm Hg or DBP≥80 mm Hg, intake of less than four antihypertensive agents, access to a sphygmomanometer at home, ownership of a smart phone or personal computer to use, ability to read and understand Chinese or Taiwanese, and will to participate. The exclusion criteria were as follows: SBP≥180 mm Hg or DBP≥100 mm Hg; pregnancy; receipt of a heart transplant, permanent pacemaker, or implantable cardioverter defibrillator; diagnosis of arrhythmia, stroke, thyroid disease, major psychiatric disorder, renal disease, heart failure, acute myocardial infarction, cancer, or terminal disease; intake of antidepressants; or addiction to drugs or alcohol.

The study procedures were reviewed and approved by the Institutional Review Board (IRB 2-104-05-148) of the participating hospital. Before enrollment, the principal investigator explained the research purpose and procedures to the participants and obtained their written informed consent. The participants randomly assigned to the intervention group were trained to use the self-titration platform for 1 month and continuously received the self-titration intervention for 6 months. The participants in the control group received usual care.

Study Procedures

The participants assigned to the intervention group received a 4-week training course before receiving the Web-based self-titration program. First, participants were given a secure account and a unique password of the website platform. We assisted participants with any set-up required on their smartphones or tablets. A stepwise instruction booklet was provided to guide log-in and use the platform. Second, the physicians of these participants set individualized blood pressure targets and explained the tailored medication titration instructions to each participant, who were then asked to rely on their home blood pressure recordings to titrate their medication doses. Third, participants were trained to measure their blood pressure by using automated electronic sphygmomanometers correctly. Finally, all participants received education about the management of hypertension.

When participants began the Web-based self-titration program, they were asked to measure their blood pressure before taking their medications and to report the data on the platform every day. We reviewed the data daily and provided a consultation through a phone call or website platform as needed for each individual participant. The physicians provided instructions to participants for any medication dosage change (increase or decrease), based on the self-monitoring data, through the website platform or clinical visit every month. The participants learned how to modify their lifestyle and manage hypertension by visiting the website repeatedly.

The participants in the control group received usual care, which included routine follow-up treatments for medication, lifestyle modification consultations, and a blood pressure check. Medications were adjusted depending on evaluations from their physicians at each clinical visit.

The principal investigator conducted a meeting to deal with problems arising in the study once a month. The outcomes were evaluated for both groups before starting the intervention and after initiating the intervention, at 3 months and 6 months.

Intervention

Based on a review of the literature [33-35] and our professional experiences, our research team determined that patients able to titrate medications by themselves should be proficient in three areas: the ability to measure blood pressure correctly, the ability to record and understand the blood pressure recordings, and the ability to adjust their dose (add, maintain, or decrease) or adopt emergency interventions based on the instructions. A secure website was designed to assist patients in performing safe self-titration. The website includes five sections: (1) personal information collection, (2) individual physical data recordings, (3) blood pressure recordings, (4) patient education in hypertension, and (5) consultations (Figure 1).

In the personal information section, we required patients to provide the following data: age, gender, education status, employment status, contact information, comorbidity, current medications, and next visit date. In the individual physical data section, we input hematology test data such as low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, triglycerides, and serum creatinine levels through a chart review. Patients were able to access their blood test data through the website.

In the blood pressure recording section, we set up individual blood pressure targets for each patient. The patients measured their blood pressure and recorded the data through the Web. An alarm and reminder system was designed and set up to allow patients to clearly understand the meaning of their current blood pressure readings and how to deal with them (Multimedia Appendix 1) [28,36]. When patients filled in their blood pressure data on the website, reminders popped up according to the blood pressure readings (Figure 2). If a blood pressure reading was below or above normal, the system automatically triggered an alert for the study team to contact the patient. If the blood pressure readings were not entered by 9 PM, the system was designed to send an email notification to remind the study team and either the patient or his/her caregiver to enter the readings. The database was automatically backed up at 12 PM each day.

Outputs of blood pressure data were displayed as curve diagrams showing the 1-month or 3-month trends to patients (Figure 3).

In the patient education section, a video provided information about the management of hypertension and instructions about blood pressure measurements, a healthy diet, and exercise. The video content was designed based on the guidance of five experts from among the cardiologists and nurses. Finally, the patients were able to directly contact the research team through the consultation section.

Figure 1. Screenshot of instruction in self-titration strategy.

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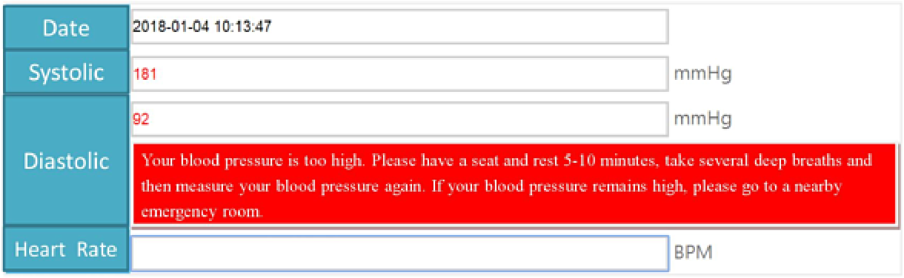
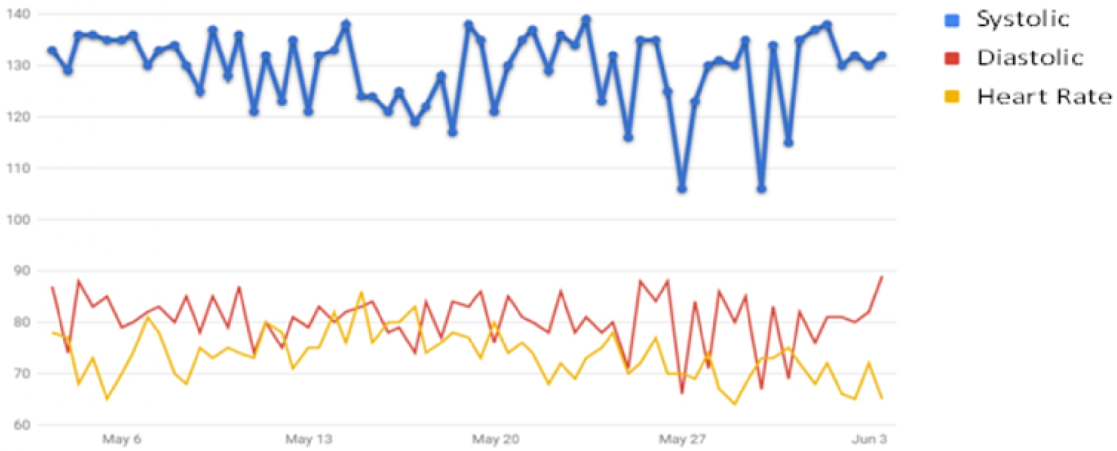
Figure 2. Screenshot of the medication reminder area and medication titration area.



Date	2018-01-04 10:13:47	
Systolic	181	mmHg
Diastolic	92	mmHg
	Your blood pressure is too high. Please have a seat and rest 5-10 minutes, take several deep breaths and then measure your blood pressure again. If your blood pressure remains high, please go to a nearby emergency room.	
Heart Rate		BPM

Figure 3. Screenshot of curve diagram on blood pressure.



Measures

Demographic and Clinical Characteristics

The following data were collected from self-reports and chart review before randomization: age, gender, education, marital status, occupation, smoking habits, body mass index, clinical history, antihypertensive medications, and duration of having hypertension. We calculated the antihypertensive dosage based on the defined daily dose (DDD), as recommended by the WHO, which uses assumed average maintenance doses per day for a drug according to its main indication in adults [37].

Blood Pressure Measurements

Blood pressure was measured with an automatic sphygmomanometer (JPN1; Omron Colin, Kyoto, Japan). According to the guidelines of the Taiwan Society of Cardiology and the Taiwan Hypertension Society, we asked the participants to sit in a quiet and comfortable room for at least 5 minutes before taking their blood pressure. The blood pressure was taken twice at intervals of 1-2 minutes [38]. The average of these two readings was used in the data analysis. In addition, the researchers assisted all participants in checking the accuracy of their own automated electronic sphygmomanometers and evaluated whether the cuffs were appropriately sized for participants' upper arms.

Health-Related Quality of Life

We used the 3-level version of EuroQol five-dimension self-report questionnaire (EQ-5D-3L) [39] to measure variables of HRQoL. The EQ-5D-3L is composed of two parts: (1) the EQ-5D descriptive system and (2) the EuroQol visual analog scale (EQ-VAS) [39]. The EQ-5D descriptive system has five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension is rated on three levels: no problems (level 1), some problems (level 2), and extreme problems (level 3); the scores are converted into a single summary score, which describes a patient's HRQoL. The EQ-VAS records the respondent's self-rated health status on a 20-cm vertical scale (visual analog scale) that ranges from 0, indicating the worst health status, to 100, indicating the best possible health state [39]. The VAS is a quantitative measure of a patient's judgement about their health status. We used the Chinese version of EQ-5D-3L, which has been demonstrated to have adequate validity and reliability [40].

Defined Daily Dose

We calculated the antihypertensive dosage based on the DDD, as recommended by the WHO, a unit of measurement for assumed average maintenance doses per day for a drug according to its main indication in adults. The DDD provides a standardized and objective dose unit, allowing clinicians or researchers to assess drug consumption dosage and compare patients with themselves or other patients. DDDs are only used for medicines after they are assigned Anatomical Therapeutic Chemical Classification System (ATC) codes [37]. For example, the ATC code for amlodipine (5 mg) is C08CA01. This code indicates that the DDD of amlodipine is 5 mg. Therefore, when the prescription of daily dose of amlodipine is 5 mg, the patient is taking 1 DDD of this medicine [37].

Outcomes

The primary outcome was the mean SBP and DBP at 3 months and 6 months. The secondary outcomes were the overall antihypertensive DDD and the two measures for HRQoL at 3 months and 6 months.

Statistical Analysis

We estimated the sample size using G*Power version 3.1 [41]. According to a previous study [28], a sample size of 80 patients per group was estimated for 90% power (two-tailed and at a 5% significance level) to detect a difference of at least 5 mm Hg in systolic blood pressure between the intervention and control groups and assuming an SD of 17 mm Hg. Allowing for a 20% dropout rate during follow-up, the sample size was increased to at least 96 patients for each group.

Data were analyzed by IBM SPSS, Version 21.0 (IBM Corp, Armonk, New York) based on intention-to-treat analysis. The analysis was conducted by a researcher who was blinded to the random allocation. The demographic and clinical characteristics were analyzed as means and SDs or as frequencies and percentages. Independent *t*-tests and Chi-square tests were carried out to examine the homogeneity of characteristics between the two groups. Group differences were examined using the generalized estimating equation (GEE). The outcomes were tested at the 5% two-tailed level of significance.

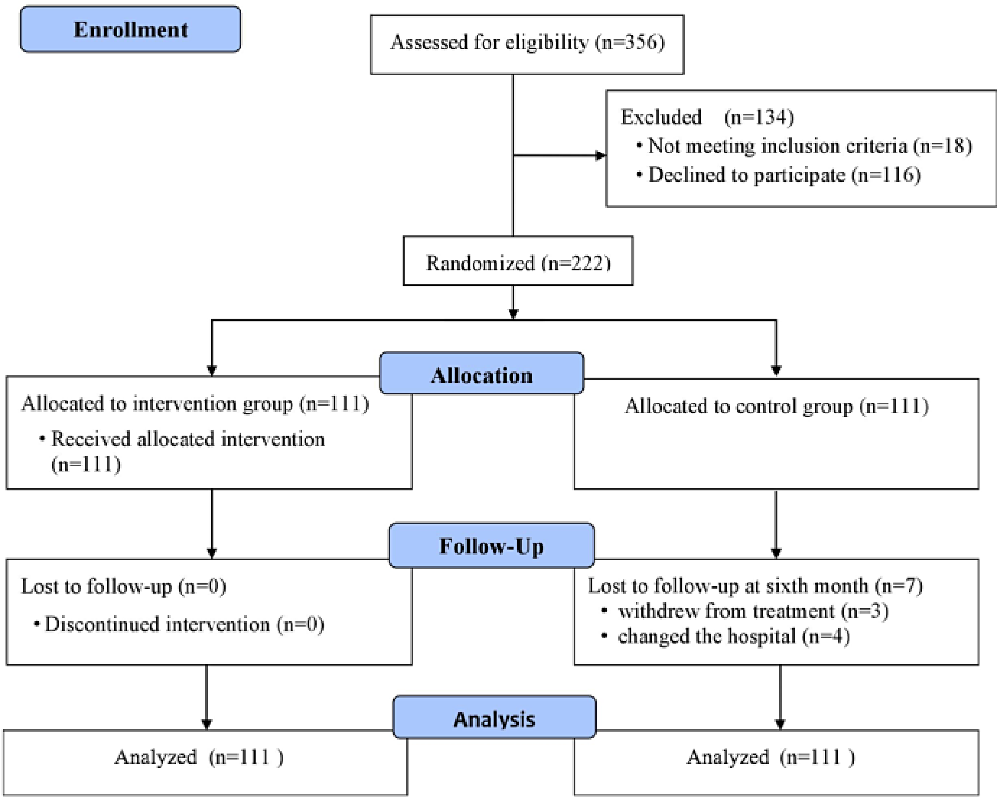
Results

Baseline Participant Characteristics

Of the 356 enrolled patients, 18 did not meet the inclusion criteria and 116 (32.6%) declined to participate. Therefore, a total of 222 patients (62.4%) were included and randomly assigned to the intervention (n=111) or control (n=111) group. Figure 4 shows the flowchart for screening, enrollment, randomization, and follow-up.

The baseline characteristics of participants are summarized in Multimedia Appendix 2. The mean age of participants was 62.7 (SD 9.3) years. Most participants were men (n=114, 51%), married (n=214, 94%), and employed (n=124, 56%); only a few participants were smokers (n=28, 13%). The mean body mass index was 26.44 kg/m^2 (SD 3.79). The average length of hypertension diagnosis was approximately 6 years, and diabetes and hyperlipidemia were the most common comorbidities. The mean SBP and DBP were 143.21 (SD 13.62) mm Hg and 84.18 (SD 10.84) mm Hg, respectively. The overall antihypertensive DDD was 1.80 (SD 1.0) units. Only the demographic characteristic of education differed between groups (*P*<.001); however, there were no significant differences in any clinical characteristics.

Figure 4. Flow diagram of the inclusion of patients in the randomized trial of the two groups.



Effect on Systolic Blood Pressure

We used GEE analysis to examine if there was an effect of the Web-based self-titration program on the control of SBP (Table 1). After adjusting for the baseline difference in education, the GEE model showed that the SBP decreased significantly more for the intervention group than for the control group at the 3- and 6-month follow-ups, as shown in Multimedia Appendix 3. The findings indicated that the Web-based self-titration program resulted in a greater control of participants' SBP.

Table 1. Generalized estimating equation analysis of the effect of the intervention on systolic blood pressure.

Variable	Regression coefficient	SE	χ^2 (df)	*P* value
Group (intervention)[a]	0.12	1.86	0.004 (1)	.95
Time (3 mo)[b]	5.28	1.36	15.2 (1)	<.001
Time (6 mo)[b]	7.99	1.44	30.9 (1)	<.001
Group (intervention) × time (3 mo)[c]	–21.43	1.89	127.7 (1)	<.001
Group (intervention) × time (6 mo)[c]	–27.82	2.10	175.2 (1)	<.001

[a] Reference group: control group.

[b] Reference group: time (baseline).

[c] Reference group: group (control) × time (baseline).

Effect on Diastolic Blood Pressure

GEE analysis examined changes in DBP after controlling for the difference between groups at baseline. The mean DBP for the intervention group significantly decreased more at 3- and 6-month follow-ups (*P*<.001) compared to the control group (Table 2; Multimedia Appendix 4). These findings suggest that patients who participated in the Web-based self-titration program had better control of DBP than patients in the control group who received usual care.

Table 2. Generalized estimating equation analysis of the effect of the intervention on diastolic blood pressure.

Variable	Regression coefficient	SE	χ^2 (df)	*P* value
Group (intervention)[a]	0.536	1.44	0.1 (1)	.71
Time (3 mo)[b]	–1.586	0.83	3.6 (1)	.057
Time (6 mo)[b]	0.477	1.03	0.2 (1)	.64
Group (intervention) × time (3 mo)[c]	–5.442	1.21	20.4 (1)	<.001
Group (intervention) × time (6 mo)[c]	–9.739	1.49	42.6 (1)	<.001

[a] Reference group: control group.

[b] Reference group: time (baseline).

[c] Reference group: group (control) × time (baseline).

Effect on Overall Defined Daily Dose for Antihypertensive Medication

GEE analysis examined the effect of the Web-based self-titration program on changes in overall DDD for antihypertensive medicines. The GEE model, adjusted for the baseline difference between groups, showed that the mean DDD for the intervention group significantly decreased more than that for the control group (*P*<.01) at both follow-up times (Table 3; Multimedia Appendix 5). Our findings indicate that patients who participated in the Web-based self-titration program intervention were able to significantly reduce the dosage of antihypertensive medicine.

Table 3. Generalized estimating equation analysis of the effect of the intervention on overall defined daily dose.

Variable	Regression coefficient	SE	χ^2 (df)	*P* value
Group (intervention)[a]	–0.242	0.16	2.5 (1)	.12
Time (3 mo)[b]	0.132	0.47	8.1 (1)	.004
Time (6 mo)[b]	0.132	0.05	6.9 (1)	.008
Group (intervention) × time (3 mo)[c]	–0.202	0.07	8.9 (1)	.003
Group (intervention) × time (6 mo)[c]	–0.236	0.07	11.3 (1)	.001

[a] Reference group: control group.

[b] Reference group: time (baseline).

[c] Reference group: group (control) × time (baseline).

Effect on Health-Related Quality of Life

GEE analysis of EQ-5D scores examined the effect of the Web-based self-titration program on improving HRQoL (Table 4). After adjusting for the baseline difference between groups, the GEE model showed that the increase of the mean EQ-5D scores for the intervention group was significantly more (*P*<.001) than that for the control group at the 3- and 6-month follow-ups (Table 4; Multimedia Appendix 6). These findings indicate that patients who were provided with the Web-based self-titration program perceived their HRQoL to improve following the intervention and compared to controls who did not participate in the program.

Table 4. Generalized estimating equation analysis of the effect of the intervention on EuroQol five-dimension self-report questionnaire scores.

Variable	Regression coefficient	SE	χ^2 (df)	*P* value
Group (intervention)[a]	–0.074	0.02	17.5 (1)	<.001
Time (3 mo)[b]	–0.076	0.02	23.7 (1)	<.001
Time (6 mo)[b]	–0.108	0.02	40.7 (1)	<.001
Group (intervention) × time (3 mo)[c]	0.216	0.02	113.1 (1)	<.001
Group (intervention) × time (6 mo)[c]	0.275	0.02	171.6 (1)	<.001

[a] Reference group: control group.

[b] Reference group: time (baseline).

[c] Reference group: group (control) × time (baseline).

Effect on Self-Rated Health Status

The EQ-VAS used to measure participants' self-rated health status was also evaluated at the 3- and 6-month follow-ups using the GEE model adjusted for the baseline difference between groups (Table 5). The mean scores on the EQ-VAS increased significantly more for the intervention group than the control group at both follow-up times ($P<.001$) (Table 5; Multimedia Appendix 7). Thus, these findings suggest that the Web-based self-titration intervention resulted in improvement in perception of patients' health status at the 3- and 6-month follow-ups.

Table 5. Generalized estimating equation analysis of the effect of the intervention on self-rated health status.

Variable	Regression coefficient	SE	χ^2 (df)	*P* value
Group (intervention)[a]	–11.247	1.89	35.5 (1)	<.001
Time (3 mo)[b]	–8.252	1.56	28.1 (1)	<.001
Time (6 mo)[b]	–12.820	1.65	60.5 (1)	<.001
Group (intervention) × time (3 mo)[c]	24.459	1.92	163.0 (1)	<.001
Group (intervention) × time (6 mo)[c]	36.883	2.08	314.4 (1)	<.001

[a] Reference group: control group.

[b] Reference group: time (baseline).

[c] Reference group: group (control) × time (baseline).

Discussion

Principal Findings

This randomized clinical trial examined the effects of a web-based self-titration program on the control of blood pressure and HRQoL in patients with primary hypertension. The principal findings of this trial demonstrated that our Web-based self-titration program significantly improved blood pressure control, overall DDD for antihypertensive medicine, HRQoL, and self-rated health status at 3- and 6-month follow-ups compared to baseline measures. In addition, these improvements were significantly better than those seen in the control group at both follow-ups. Additionally, no harmful events occurred in our cohort.

Our results on the control of SBP and DBP are consistent with the findings of previous studies on the benefits of self-titration of antihypertensive medication for blood pressure control [27,28]. In our study, we designed a program to assist patients with hypertension to self-monitor their blood pressure in their home every day; self-manage their life style; and, when needed, self-titrate their antihypertensive medication through an internet website. The self-monitoring of blood pressure has been identified as an effective means of blood pressure control [18]. Moreover, a meta-analysis of 25 clinical trials suggested the implementation of self-monitoring in conjunction with co-interventions, such as lifestyle counselling and systematic medication titration by doctors, pharmacists, or patients, leads to better clinical blood pressure control for patients with hypertension [20]. Our Web-based intervention program resulted in significant blood pressure reduction in patients with hypertension. Our findings provide further support that daily patient self-management of treatment and lifestyle through a website can lead to better control of blood pressure for patients with hypertension.

Another notable finding of our study was that the overall antihypertensive DDD was significantly reduced in the intervention group compared with the control group. No other studies have reported similar findings. The significant reduction in antihypertensive DDD for patients in the intervention group may have been a result of consultations and reminders from clinical professionals through the Web-based program. This support may have helped patients not only modify their lifestyle, but also persist in carrying out healthy behavior. Empowerment for lifestyle self-management and self-titration of their own medication has been shown to positively impact patient compliance [27]. Therefore, a more positive attitude of commitment to these aspects could have been promoted by an increased sense of autonomy and control over the disease. Regardless of the reason, this finding appears to be in line with international guidance that adherence to both lifestyle change and medication are equally important in blood pressure control [20].

HRQoL is frequently used to examine the beneficial effects of interventions and treatments [13]. Earlier studies in patients with hypertension indicated that poor blood pressure control negatively affected HRQoL [13-15]. Hypertensive patients with poor blood pressure control have greater stresses resulting from the disease itself and the treatments, and therefore, they may have worse HRQoL as a result of coping with related stress [13,42]. In this study, we found that patients with hypertension in the intervention group who received the Web-based self-titration program had greater improvement in their HRQoL at the 3- and 6-month follow-ups compared with the patients in the control group. We suggest that control of blood pressure for patients with hypertension in the intervention program helped in improving their quality of life. The patients in the intervention group reported that the Web-based self-titration program led them to engage in monitoring their blood pressure more regularly and empowered them to self-manage their clinical interventions and lifestyle. The educational component of the intervention provided patients with knowledge about the relationship between blood pressure and health status. They felt that they benefited from the support offered through the online consultations, where they could communicate problems with blood pressure control immediately. Therefore, they felt more confident that they may control their blood pressure and life.

Our results also showed that patients who engaged in the Web-based self-titration program perceived a significant improvement in their health status at the 3- and 6-month follow-ups. Health status is challenging to improve because it is a patient-centered outcome. The symptom burden significantly predicts worse health status [43]. In this study, patients were empowered to self-manage their blood pressure and achieved a positive outcome. The reduction in symptoms, owing to the control of their blood pressure, may have improved their perceived health status. In addition to symptom burden, HRQoL is another principal component of health status [44]. The hypertensive patients who received the Web-based self-titration program reported a significant improvement in their HRQoL, which may have also advanced in their health status.

Limitations

The potential limitations in this study should be considered. First, our follow-up period was only 6 months, which meant that we could not detect the long-term consequences on cardiovascular events, or indeed, whether the initial successes would be sustainable in the long term. Nevertheless, the initial improvements in blood pressure control have a clear potential to reduce cardiovascular complication rates. Second, we used telemedicine to support the medication titration, which excluded patients without a computer or smartphone access. Third, we were not able to blind the patients' physicians, which could have introduced bias. Finally, we only recruited participants from one medical center, which limits our ability to generalize the findings. These limitations should be addressed in future research.

Conclusions

There is limited research examining the effects of a Web-based self-titration program on blood pressure control in patients with primary hypertension. The results of this study support both our hypotheses: (1) patients with primary hypertension who received the Web-based self-titration program had significant control of SBP and DBP, and (2) the HRQoL of patients was significantly improved through this Web-based program. In addition, the intervention group had significant reductions in DDD for antihypertensive medications and improvements in the perception of their health status. Thus, we believe that the Web-based self-titration program may assist patients with primary hypertension to self-manage their treatments and healthy lifestyle in their home. This Web-based intervention program also has the benefit of reducing the amount of time required for patients to visit an outpatient clinic or hospital for care. Taken together, the intervention program could improve the quality of care for patients while reducing health care costs.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Alarm and Reminder system: Definitions of blood pressure readings and actions.
[DOCX File , 16 KB - jmir_v21i12e15836_app1.docx]

Multimedia Appendix 2
Demographic and clinical characteristics of participants and differences between groups.
[DOCX File , 17 KB - jmir_v21i12e15836_app2.docx]

Multimedia Appendix 3
Change in systolic blood pressure between two groups at 3 times.
[PNG File , 17 KB - jmir_v21i12e15836_app3.png]

Multimedia Appendix 4
Change in diastolic blood pressure between two groups at 3 times.
[PNG File , 17 KB - jmir_v21i12e15836_app4.png]

Multimedia Appendix 5
Change in the overall antihypertensive defined daily dose between two groups at 3 times.
[PNG File , 79 KB - jmir_v21i12e15836_app5.png]

Multimedia Appendix 6

Change in scores of EQ5D between two groups at 3 times.
[PNG File , 62 KB - jmir_v21i12e15836_app6.png]

Multimedia Appendix 7
Change in scores of ED-VAS between two groups at 3 times.
[PNG File , 67 KB - jmir_v21i12e15836_app7.png]

Multimedia Appendix 8
CONSORT‐EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 8588 KB - jmir_v21i12e15836_app8.pdf]

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Abbreviations

DBP: diastolic blood pressure
DDD: defined daily dose
EQ-5D-3L: 3-level version of EuroQol five-dimension self-report questionnaire
EQ-VAS: EuroQol visual analogue scale
GEE: generalized estimating equation
HRQoL: health-related quality of life
SBP: systolic blood pressure
WHO: World Health Organization

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Original Paper

Exploring the Views of Osteogenesis Imperfecta Caregivers on Internet-Based Technologies: Qualitative Descriptive Study

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Abstract

Background: Osteogenesis imperfecta (OI) is a rare genetic condition that can lead to frequent debilitating bone fractures. Family caregivers of children with OI face unique challenges in providing care, which may include limited access to information about the condition, feelings of distress, and experiences of social isolation. Internet-based technologies (IBTs) have been useful for supporting other types of caregivers. However, the views of OI caregivers on IBTs have not been explored.

Objective: This study aimed to explore the views of OI caregivers on the uses of IBTs to support them in caring for their children with OI.

Methods: A qualitative descriptive study was conducted. Caregivers of children with OI were recruited at a pediatric hospital in Montreal, Canada. Interviews were used to explore each caregiver's views on the applicability of IBTs in supporting their caregiving needs. The interviews were transcribed verbatim and thematically analyzed.

Results: A total of 18 caregivers participated. The caregivers shared that IBTs were useful for facilitating the following activities: daily activities of caregiving (such as providing physical care, supporting relationships, supporting self-care and hope, and managing the logistics of caregiving), OI medical information seeking, and OI social networking. However, they also revealed concerns about the health consequences of IBT use and the quality of IBT content. Concerns regarding IBTs varied somewhat with caregivers' geographies. Caregivers offered suggestions and strategies for how IBTs can be optimized for caregiving.

Conclusions: Family caregivers of children with OI face unique challenges in providing care, which may include lacking access to information about the rare condition and feeling socially isolated. OI caregivers use IBTs to overcome some of these challenges and to support their specific caregiving needs. These findings contribute to the paucity of knowledge by offering varied IBT strategies to support caregiving activities, which may be beneficial for other caregivers. Participants' suggestions for IBT services can inform the development of new resources for OI caregivers and potentially for other caregivers of children living with rare conditions.

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KEYWORDS

smartphone; caregivers; pediatrics; rare diseases; telemedicine; quality improvement; social media; chronic disease; osteogenesis imperfecta

Introduction

Background

Osteogenesis imperfecta (OI) is a rare genetic condition (affecting 1 in 10,000 births) that alters collagen production [1,2]. OI is characterized by increased bone fragility and reduced bone mass, which increase the risk of fractures [1,2]. Although many OI types are distinguished in the genetic literature, the majority of individuals with OI are diagnosed with OI type I, which has the mildest disease severity [1]. OI type II is deadly in the neonatal period. OI type III is the most severe form of OI that is compatible with long-term survival. OI type IV is of moderate disease severity [1]. OI types V, VI, and VII are newer classifications that present with different bone and tissue phenotypes; these variants have a mild-to-moderate risk for bone fractures [1,2]. At present, there is no cure for OI; thus, ongoing and frequent physiotherapy, occupational therapy, surgery, and bisphosphonate medications remain to be the course of treatment [1,3,4].

Caregiving and Osteogenesis Imperfecta

In chronic conditions such as OI, family caregivers (*caregivers*) play a critical role in providing safe, effective, and supportive care for patients [5]. For many caregivers, although positive experiences can result from raising a child with OI [3,6], the diagnosis itself is often “devastating” [3], leading to subsequent “ups and downs” [3] as families adjust to the diagnosis. The challenges faced by OI caregivers can include financial difficulties, transportation and accessibility challenges, a lack of knowledgeable health care providers, suspicions of child abuse leading to the diagnosis, social isolation, and a lack of social support [3,6-8].

Caregiving and Internet-Based Technologies

Caregivers of patients with various other childhood- and adult-onset conditions have found that internet-based technologies (IBTs), such as websites, email, social media, mobile apps, and video calls, facilitate knowledge exchange and provide social support in their caregiving support needs [5,9-13]. Research on the uses of IBT for caregivers of children with special needs is an emerging field [13-15]. By understanding these caregivers’ views on IBTs, future platforms may be created to meet their unique needs [13,16]. As far as we are aware, no researchers have studied the uses of IBTs among caregivers of children with OI. Therefore, the aim of this study was to explore the views of caregivers of children with OI on the uses of IBTs in supporting their caregiving needs.

Methods

Design

A qualitative descriptive study [17] was conducted at a university-affiliated, pediatric orthopedic hospital in Montreal, Canada, where health care services are provided both in English and French to patients. Ethical approval was received from McGill University’s institutional review board (study number A05-B39-17B) and the study site before setup and recruitment.

Recruitment

Purposive sampling was used to recruit adults (older than 18 years) who brought a patient (aged between 0 and 21 years) with OI to the study site for an OI-related appointment and who considered themselves to be a caregiver for the child. A nonauthoritative member of the team approached clinicians who had appointments with patients with OI to mediate an introduction to the study. If caregivers expressed an interest in learning more about the study, then a member of the research team described the study and informed the caregiver of the potential consequences of participating. If the caregiver provided their written consent to participate, then an interview was scheduled at the caregiver’s convenience.

Data Collection

Each of the caregivers participated in 1 individual semistructured interview that took place in person at the hospital or by telephone or videoconferencing. All interviews were audio taped. Either the first author (AC) or the research assistant (KC) conducted the interviews by using an interview guide for caregivers who identified as IBT users (Multimedia Appendix 1). We prepared a second guide for interviewing caregivers who might not consider themselves to be regular users of IBTs; however, all caregivers who agreed to be interviewed identified as regular IBT users, so this second guide was never used. Demographic data were collected in a short demographic survey. Field notes were recorded after each interview.

Data Analysis

Demographic data were analyzed using descriptive statistics in Microsoft Excel. Audio recordings were transcribed by the researchers who conducted the interviews (AC and KC). The French interviews were transcribed in French and open coded into English by KC, who is fluently bilingual in both English and French. The transcribed data and field notes were uploaded into Excel where they were open coded and thematically analyzed by AC, with additional intercoder verification by KC [18]. In regular meetings with the bilingual principal investigator (AT), the research team shared and discussed progress and interpretations of the data and the ongoing inductive development of the codebook [19]. These codebooks and meeting notes were recorded in a research journal, as were the ongoing research reflections of the first author (AC). The carefully anonymized research journal, larger samples of coded data, and the codebook may be made available for audits upon request.

To improve the trustworthiness of this qualitative research, we were guided by Lincoln and Guba’s [20] 4 criteria of credibility, dependability, confirmability, and transferability. The reflexive journaling by AC, the audio taping of interviews, and the research team’s regular peer debriefing enhanced the credibility of our research [21]. Carefully documenting our team’s discussions and decisions in our research journal and making the anonymized research journal, coding samples, and codebook available for audit enhanced the dependability of this study [21]. The carefully documented decision trail in our research journal and our frequent team debriefings supported the confirmability of this study [21]. The team development of our codebook and intercoder checks, our field notes, and our inclusion of thick descriptions and quotes support the transferability of our research [21].

Results

Demographic Data

A total of 18 adult caregivers from 14 families were interviewed for this study (Table 1). The interviews ranged from 15 min to 1.5 hours. These interviews resulted in 13.05 hours of audio recordings. Most of the caregivers (16/18) had the support of another adult providing care assistance at home. Functional abilities of their children ranged from having no need for any mobility assistance devices to using a wheelchair full time outside the home.

Internet-Based Technology Views: Uses, Concerns, Strategies, and Suggestions

All families in our study had access to the internet at home. Most felt confident in their ability to navigate the internet and mobile apps. Furthermore, in their survey, 14 of the 18 participants responded that they had a generally positive view of using IBTs in relation to caring for their child with OI; in addition, 2 of them had a neutral view of IBTs and 2 had a negative view of IBTs. Caregivers described multiple uses of IBTs, reported some concerns, and shared their strategies and suggestions for optimizing future IBT development.

We used the following identification format to refer to specific participants throughout this paper: (Caregiver type) (Family number)-(OI type). Caregiver types were fathers (F), mothers (M), and legal guardians (G).

Uses of Internet-Based Technologies

Facilitating Daily Activities Related to Caregiving

Providing Physical Care

Caregivers described using IBTs to support physical caregiving activities by promoting rest and immobilization after fractures or surgeries and by being a tool for distracting their child. As a mother explained, “TV and the tablet is a hell of a distraction for pain” [M5-III]. For another family, the biggest challenge in caring for their 19-month old with OI was in trying to keep her immobilized for several weeks after her leg surgeries:

> *She got her [femur-rodding] surgery two weeks ago...she used to be able to crawl everywhere she wanted to...So, what we did most recently is, with the advice from a social worker here at [the study site] she said, “you know, you can have all these opinions about electronics, but you know, for those couple of weeks she’s going to be immobilized, we don’t need to feel bad about making her use electronics, or watching more TV than usual.” And that’s exactly what we did.* [F1-IV]

For these parents, Web-based videos and new computer tablet games provided calming distractions to help prevent their child from moving around when he or she needed to rest. In addition, caregivers found video streaming apps to be very helpful for occupying their children when the local environment was unsafe (eg, slippery mopped floors) and for distracting their children from pain after a fracture, during splinting, or during intravenous procedures.

Table 1. Demographic data were collected from the caregiver participants.

Demographic traits	Values[a]
Individuals interviewed (number of families represented)	18 (14)
Relationship to child with OI[b] (N=18 caregivers), n	
Mother	11
Father	5
Other: legal guardian	2 (same family)
Language of interview (N=18 caregivers), n	
English	12
French	6
Caregivers' median age in years (age range)	37.5 (24-57)
Caregiver’s sex (N=18 caregivers), n	
Female	13
Male	5
Residential region (N=14 families), n	
Local (<2 hours’ drive from Montreal)	7
Within Quebec, not local	1
Other Canadian region	3
International	3
Highest level of education (N=18 caregivers), n	
Some postsecondary (university or college)	5
Received university or college diploma	11
Postgraduate	2
Marital status (N=18 caregivers), n	
Married or common law	14
Single (never married)	2
Separated or divorced	2
Estimated family income (N=14 families), n (Can $)	
<$25,000	3
$25,000-$50,000	1
$50,000-$80,000	1
>$80,000	7
Do not know	1
Prefer not to answer	1
Child’s OI type (N=14 families), n	
I	3
III	4
IV	6
VI	1
Ages of children with OI (17 children with OI), n	
Baby (0-12 months)	2
Toddler (13 months-3 years)	1
Preschool (4-5 years)	1

Demographic traits	Values[a]
School aged (6-12 years)	11
Teenager (13-18 years)	2
Family history of OI (N=14 families), n	
Yes	3
No	11
Internet access at home (N=14 families), n	
Yes	14
No	0
Comfort using the Internet (N=18 caregivers), n	
Very comfortable	14
Somewhat comfortable	3
Neutral	1
Somewhat uncomfortable	0
Uncomfortable	0
General thoughts on using the internet for OI care (N=18 caregivers), n	
Positive	14
Neutral	2
Negative	2

[a] Values represent the number of individuals, unless otherwise indicated.

[b] OI: osteogenesis imperfecta.

Supporting Relationships

Caregivers also described how they used IBTs to bond with their children and extended families. A father explained how he used IBTs for low-impact activities, such as listening to audiobooks when he put his daughters to bed each night, doing Web-based yoga videos, and playing Pokémon Go in new cities for father-daughter dates. Traveling presented additional difficulties for families of children with fragile bones. One mother explained how her toddler stays connected with her grandparents through video calling even though those grandparents live farther away:

> *FaceTime with my parents—she actually does that a lot! "Mommy, mommy! I want to see Pappi!"...she asks for them. When my father's not home to do that FaceTime, it's like "Where is he?! Why?!"* [M1-IV]

For some families, visiting other individuals' houses posed a fear of fractures being caused by furniture or wobbly objects. Instead of visiting these houses in person, OI caregivers used Web-based videoconferencing tools, such as Skype and FaceTime, to connect with friends and family and to keep their children in a safer environment.

Supporting Self-Care and Hope

Caregivers used IBTs for their own self-care and feelings of hope. Smartphone games, video streaming services, music apps, and social media for personal use were all popular tools. A common challenge for caregivers was experiencing boredom as they waited through numerous medical appointments and lengthy recoveries from surgeries. Caregivers used IBTs, such as video streaming apps and smartphone games, as distractions during these times. One mother used a relaxation app to help her focus on her breathing, which lessened her anxiety. Some caregivers used Web-based resources to find inspiration. One caregiver watched inspirational YouTube videos posted by families with OI to help *motivate* her daughter and herself (M6-III). Another mother, whose school-aged child had experienced over 150 fractures, explained:

> *On YouTube, I find there's a lot of inspirational videos that are nice to watch. Experiences that turn out to be good and [show] that there's hope.* [M5-III]

Managing the Logistics of Caregiving

Caregivers used IBTs to manage the logistics of coordinating medical appointments. There were 2 caregivers who specifically mentioned using their calendar apps to keep track of the many health care appointments that came with caring for a child with brittle bones. Caregivers generally agreed that IBTs had made accessing health care services much easier. Caregivers used emails to contact potential clinicians and make appointments, texted their social workers and physiotherapists, and sent x-ray pictures to their treating physicians. A few caregivers created their own digital medical records by compiling their emails, x-ray photos, and other documents into one digital location, such as an emails folder or a photo album.

Some families used internet tools and apps to find community and care resources. Caregivers discussed using the internet to assess an environment's wheelchair accessibility (eg, Kijiji's images helped them assess the accessibility of rental housing).

Several families used IBTs to research products and services that could help with caring for a child with OI. One mother explained how she used the internet to research an appropriate stairlift for their home once their children were too big to be carried upstairs:

> *I think, yes, sometimes [the Internet] helps. Like the stairlift. We didn't have any idea how we would do this. And then internet search[ing], we saw that all these different companies were selling these stairlifts for different price [sic]. So yeah, I think that's helped.* [M3-IV]

Other examples included caregivers watching Web-based video reviews of potential wheelchairs to buy and researching OI-appropriate activities and adapted sports for their children to engage in.

Finally, caregivers used IBTs to continue managing their careers. One father, whose family travelled far to receive treatment for their 2 children with OI, explained he often used video calling to call his children after surgeries when he was unable to be physically present. This father also had to give up his business providing income tax services because it was not flexible enough to meet his family's needs. Instead, he became a taxi driver who supplemented his income as an Uber driver. Another father explained that the internet allowed him to resolve a workplace emergency remotely while he was waiting for his daughter's planned surgery at the hospital.

Facilitating Osteogenesis Imperfecta Medical Information Seeking

Caregivers noted that a common activity relating to OI care was seeking information about the condition. Caregivers were selective in how they used IBTs for finding medical information. They preferred to receive medical and prognostic information from clinicians, but they would often seek information regarding day-to-day OI care activities using Web-based resources. However, as a mother from a country with limited access to OI support explained, for some families, the internet was their only accessible source for OI information:

> *To me, I think [IBT is] good. It is really helping. Because if you should look at where I'm coming from...and where the kind of information that I can even access back home, I think it's excellent. It bridges the gap. Even though we are far apart, we are able to know most of the things going on.* [M6-III]

For some caregivers with limited access to OI expertise, wading through OI websites found on the internet was their only option for learning about their child's medical needs.

Facilitating Osteogenesis Imperfecta Social Networking

Caregivers, primarily mothers, were strategic in how they used OI social media. Most preferred social media for meeting other OI families. They shared day-to-day care information rather than using it for specific information on prognoses or treatments. Some caregivers were more interested in answering others' questions than in having their own questions answered. Several caregivers expressed an interest in meeting and conversing with other families with OI to learn more about each other's OI experiences, and in doing so, these caregivers formed strong connections through social media. One mother, although cautious regarding specific pieces of OI information being shared on social media, kept in touch with over 200 people from the OI community on Facebook. Another mother explained:

> *[The OI Parents Facebook group is] a huge, huge, huge—if not the biggest help, with [OI son] and being a caregiver for him. The parents, the families that are on there, are awesome. Everybody is just—so helpful.* [M9-III]

Caregivers who frequently participated on OI social networks also used these platforms for sharing practical advice with each other:

> *Useful tips and tricks to help after rodding, after a fracture, adjusting the wheelchair—like, those types of things.* [M13-III]

One mother explained that OI parents were the ones who know practical day-to-day care strategies, such as where to find adaptive clothing and winter boots that would fit her child's physique. Web-based caregivers could receive faster answers to questions from multiple sources, such as information on how to splint a new fracture, than if they sought out input from their health care providers. For a few of these families, the first time they learned about the study hospital site being an OI treatment center was through OI social networks rather than through a health care professional.

Concerns of Internet-Based Technologies

Caregivers' concerns about IBTs typically fell into 2 categories: health and screen time concerns and concerns regarding the quality of IBT content. Geographic differences in these IBT concerns were noted.

Health and Screen Time Concerns

Caregivers expressed concerns about the potential negative mental and physical health effects of too much screen time for themselves and for their children. One mother shared:

> *The OI Parents group can be really good. [But] I've excused myself from following it on my newsfeed because it was all I saw, all day... I found that all OI, all of the time, was making that our life. Instead of OI being a part of our life, it was taking over.* [M13-III]

Some caregivers were concerned about Web-based predators. Others worried about cyberbullying directed toward their children or cyber judgement from other OI parents. Although caregivers consistently expressed concerns regarding both themselves and their children spending too much time on their devices, a few explained that they were somewhat less strict with IBT use for their children with OI because they could not do as many physical activities as other children, especially during a fracture, immobilization, or a painful period.

Quality of the Internet-Based Technology Content

The most prominent concern regarding IBT was the quality of the content available. Several families described their disturbing experiences of trying to find information about OI on the Web.

When 1 mother tried to find more information on OI through a search engine, she found the following:

> *Angulated limbs, like fresh fractures, bone through skin, those kinds of things, which was terrible for a postpartum mother to see about their tiny little baby. So, I have stopped [searching].* [M13-III]

Oftentimes, what caregivers found first on the Web were the worst-case scenarios that were not applicable to their own children.

Families preferred to speak with expert clinicians about the medical treatment and prognostic aspects of OI. Several caregivers explained that as there is so much variation in the presentation of OI, Web-based prognostic information relevant to their own cases was limited. It also cost caregivers a lot of time to determine which websites and tools had accurate high-quality information. Conflicting information and disinformation led to a few caregivers seeking clinical OI information solely from the study hospital site. They preferred to explore Web-based resources recommended from trusted health care institutions.

Geographic Differences in Internet-Based Technologies Concerns

Caregivers who had easier access to the study hospital site appeared to have more concerns regarding OI social networks and Web-based resources. For instance, a father who had lived with OI and near the study site most of his life explained that he probably had no interest in OI social media for 2 reasons: he had searched on social media for OI once and believed the information to be very inaccurate and because “for us, [OI is] known. And that’s the big difference” [F1-IV]. In contrast, when asked about her views on IBTs, a mother from a country with limited accessible OI care options shared:

> *I want anybody that has OI should have internet access. Because it gives fast access to people you’re supposed to connect [with], once you have an emergency.* [M12-IV]

This mother learned of OI treatment and the study hospital site through an international social media group for OI families. Before learning about this group, she felt isolated, as if she was the only parent ever who had a child with brittle bones. Through the Web-based group, other international members connected with her and sent her bisphosphonate treatments. With bisphosphonates, her school-aged daughter’s bones strengthened, and she was able to mobilize more freely, enabling her to attend school. The Web-based group also managed to connect this mother with a local sponsor so her daughter could receive surgical treatments at the study site.

Strategies and Suggestions for Optimizing Internet-Based Technologies

Advice to Other Caregivers Regarding Internet-Based Technology Strategies

Caregivers shared the IBT advice they would share with other caregivers on how to use IBTs optimally with their children and for themselves. They recommended using Web-based videos and apps for distracting their children when they are in pain or immobilized. Websites that some caregivers suggested for learning more about OI included YouTube videos about the OI experience, OI Facebook groups, and the OI Foundation and Shriners Hospitals for Children—Canada websites and social media pages. They advised that caregivers should monitor the content their children view and that caregivers should be somewhat skeptical consumers of Web-based content. They also stressed the importance of being role models to their children when using IBTs, such as by limiting parents’ and children’s screen time.

Suggestions for Internet-Based Technology Development

OI caregivers offered many ideas for desirable IBT products and services to better support their needs (Textbox 1). In general, caregivers desired child-friendly and age-appropriate IBTs, and they wanted these resources to be available on the Web to regularly inform caregivers about research and medical updates. Caregivers said that when a service is meant to provide answers to questions, it should be interactive and quickly responsive. Francophone families particularly emphasized that there were not enough resources in French, limiting their access to support. Some caregivers suggested they would be interested in social media resources to understand what adulthood experiences of OI are like. A few families said they had never been told about nor had they found any OI-specific IBT resources. These caregivers wanted expert OI institutions to recommend more Web-based OI resources. Caregivers stated that resources should be offered in multiple languages, with Web-based and offline capabilities, with geographically specific listings, and in both short summaries and more extensive reports or videos.

Textbox 1. Internet-based technologies that caregivers would like to see developed to facilitate caregiving.

Internet-based technologies (IBTs) to facilitate daily activities related to caregiving and logistics:

- An email coordinating service that sends caregivers' emailed questions to the correct medical department or contact
- The option to schedule appointments on the Web
- A Web-based platform informing caregivers of relevant government financial aids and services
- The option to have videoconferencing consultations with clinicians

IBTs to verify medical information:

- Web-based, regularly updated information on the gold standards of care and treatment for osteogenesis imperfecta (OI)
- Downloadable software for OI families with descriptions of the condition, available resources, new treatments, and recent research updates
- Web-based home fracture-splinting videos with diverse techniques for every fracture possible
- Web-based videos portraying OI patients before and after various treatments
- A Web-based listing of a group of trusted parents and clinicians who caregivers can contact
- A gamified app to teach children occupational therapy and physiotherapy

IBTs to engage in social networking and share experiences with OI families:

- An OI social network where parents can share practical knowledge and videos of caregiving techniques with each other
- A way to organize the OI Parents Facebook group content so that the information it contains is easier to navigate
- A website to donate medical equipment, such as wheelchairs, to other families

Discussion

Principal Findings

We found that OI caregivers were using IBTs to care for themselves and for their children with OI. Yet, although caregivers generally held positive views of IBTs, they were also concerned about the potential negative health effects of IBTs and the quality of IBT content. Caregivers offered suggestions for how other OI caregivers could optimize the use of IBTs in their caregiving lives and for how clinicians and software developers could build better IBTs to support caregivers.

Caring for a child with OI may lead to physical, relational, and self-care challenges [6,22]. Our study found that caregivers were facing similar challenges, but it also revealed the benefits of using IBTs to manage these challenges. For example, OI caregivers used IBTs as a distraction to manage the physical challenges associated with treating their child's pain. Social challenges, such as social isolation from family members and friends, were being partially overcome through videoconferencing support. Caregivers' physical, emotional, and self-care challenges were being addressed through IBT support. New IBT platforms may also target these needs.

Researchers have described the many logistical challenges of caring for a child with OI, such as coordinating appointments, finding resources, and communicating with clinicians [6,7]. These logistical challenges were also noted in this study. Smartphone apps are presently being developed for caregivers of other chronically ill children to communicate with other family members and health care teams to coordinate care [23-25]. Other potential platforms for addressing these logistical challenges include teleconferencing with clinicians and Web-based appointment scheduling [13]. Similar apps may be developed to support OI caregivers.

Several caregivers in this study experienced difficulties in finding health care providers who were knowledgeable about OI. These difficulties have been previously reported by OI caregivers [6,22]. For medical information on OI, such as treatments and fracture prognoses, caregivers much preferred information that came from a knowledgeable OI health care provider or institution. However, when knowledgeable providers were not available, caregivers turned to the internet. This is a similar strategy used by other rare disease populations to fulfill their information needs [12,14]. Web-based resources serve as sources of information and support, particularly when specialists are not accessible [12-14].

Caregivers' views on IBTs for social and medical information seeking appeared to depend, in part, on their relative access to the study site's OI specialist center: if caregivers did not have easy access to OI medical specialists (eg, because of geographical constraints), they relied more on Web-based OI resources and communities. This pattern corresponds with research suggesting caregivers of children with special needs have more of an impetus to seek information on the Web than do caregivers of children without special needs [14,15]. This pattern suggests that IBTs may be most useful for caregivers who have internet access but do not have regular or easy access to experts. Still, similar to the OI caregivers in our study, many caregivers have concerns regarding the health effects and quality of the content of IBTs [14,26]. Leading OI institutions should work to develop and share Web-based services, ensuring they provide high-quality information and content.

Clinical and Research Implications

Clinicians should inquire about families' current uses of IBTs and help link families to other credible sources [12,27]. The study site's recent adoption of the *Upopolis* platform, which helps children with medical support needs find information and connect with other friends and families, is an example of a credible existing tool being shared by clinicians [28]. Families, clinicians, and researchers should work together to create resources using participative approaches. Using participatory design approaches to build new interventions increases the likelihood that end users will accept the interventions when they are launched [16,29]. Recent examples in OI include the creation of the Good2Go MyHealth Passport, a tool for optimizing the transfer of pediatric patients to adult health care services and prototype development of a tool to engage children with OI in their care [30-32]. OI caregivers' suggestions and strategies for supportive IBTs should be used to improve clinical practice and to develop future IBT services for families with OI [33].

Study Limitations and Strengths

Our study has several limitations. Regarding our data collection and analysis methods, ideally for the 6 French interviews, we would have independently back translated the English translations into French to ensure that the translations were trustworthy [34]. Owing to time and resource limitations, we did not do this, as 5 of the 6 team members and coauthors were fluently bilingual. One of the coauthors, KC, is fluently bilingual in English and French and has a rich personal knowledge of the subject material [34]. She was responsible for open coding all the French interviews into English. Regarding our sample, this study was conducted at an internationally renowned treatment center for OI. Therefore, we were conducting interviews with caregivers who had the resources to access this center. The demographic survey data revealed that most participants were financially well off and had at least some postsecondary education. Future research should work to explore the IBT views and needs of OI caregivers who do not have access to international treatment centers and who have even more diverse socioeconomic backgrounds than these caregivers did.

Strengths of the study design include a rich description of the setting and of the participants. These data add context to the study, helping the reader to decide if and whether the results and interpretations are relevant to their own situation or research [35]. The interviews were comprehensive (lasting between 15 min and 1.5 hours), and the sampling was purposive to include a range of OI caregiver experiences, creating a deep dataset for analysis. Finally, as far as we are aware, this is the first study to research in depth how caregivers of children with OI view and use IBTs to support their caregiving activities. Our research offers a starting point for future researchers to build more supportive caregiving technologies.

Conclusions

Through this study, we have a better understanding of how OI caregivers can use specific IBTs to facilitate daily activities, information seeking, and social networking in relation to OI. We also have a better understanding of their concerns regarding IBTs and how future IBT projects may be built to optimize the benefits of IBTs while reducing the concerning aspects of IBTs. Clinicians should share the strategies that OI caregivers recommend for optimizing IBT use in caregiving with families newly diagnosed with OI. Some of these strategies may also be useful for other caregivers caring for youths with rare or chronic conditions. Clinicians should work toward developing IBTs that meet the needs and suggestions of the caregiver participants in this study so that the benefits of IBTs may be realized for more caregivers, while diminishing the potential harms of IBTs.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide for interviews with caregivers who identified as internet-based technology users.
[DOCX File , 22 KB - jmir_v21i12e15924_app1.docx]

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Abbreviations

IBT: internet-based technology
OI: osteogenesis imperfecta

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Original Paper

Validation of Single Centre Pre-Mobile Atrial Fibrillation Apps for Continuous Monitoring of Atrial Fibrillation in a Real-World Setting: Pilot Cohort Study

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Abstract

Background: Atrial fibrillation is the most common recurrent arrhythmia in clinical practice, with most clinical events occurring outside the hospital. Low detection and nonadherence to guidelines are the primary obstacles to atrial fibrillation management. Photoplethysmography is a novel technology developed for atrial fibrillation screening. However, there has been limited validation of photoplethysmography-based smart devices for the detection of atrial fibrillation and its underlying clinical factors impacting detection.

Objective: This study aimed to explore the feasibility of photoplethysmography-based smart devices for the detection of atrial fibrillation in real-world settings.

Methods: Subjects aged ≥18 years (n=361) were recruited from September 14 to October 16, 2018, for screening of atrial fibrillation with active measurement, initiated by the users, using photoplethysmography-based smart wearable devices (ie, a smart band or smart watches). Of these, 200 subjects were also automatically and periodically monitored for 14 days with a smart band. The baseline diagnosis of “suspected” atrial fibrillation was confirmed by electrocardiogram and physical examination. The sensitivity and accuracy of photoplethysmography-based smart devices for monitoring atrial fibrillation were evaluated.

Results: A total of 2353 active measurement signals and 23,864 periodic measurement signals were recorded. Eleven subjects were confirmed to have persistent atrial fibrillation, and 20 were confirmed to have paroxysmal atrial fibrillation. Smart devices demonstrated >91% predictive ability for atrial fibrillation. The sensitivity and specificity of devices in detecting atrial fibrillation among active recording of the 361 subjects were 100% and about 99%, respectively. For subjects with persistent atrial fibrillation, 127 (97.0%) active measurements and 2240 (99.2%) periodic measurements were identified as atrial fibrillation by the algorithm. For subjects with paroxysmal atrial fibrillation, 36 (17%) active measurements and 717 (19.8%) periodic measurements were identified as atrial fibrillation by the algorithm. All persistent atrial fibrillation cases could be detected as “atrial fibrillation episodes” by the photoplethysmography algorithm on the first monitoring day, while 14 (70%) patients with paroxysmal atrial fibrillation demonstrated “atrial fibrillation episodes” within the first 6 days. The average time to detect paroxysmal atrial fibrillation was 2 days (interquartile range: 1.25-5.75) by active measurement and 1 day (interquartile range: 1.00-2.00) by periodic measurement (*P*=.10). The first detection time of atrial fibrillation burden of <50% per 24 hours was 4 days by active measurement and 2 days by periodic measurementThe first detection time of atrial fibrillation burden of >50% per 24 hours was 1 day for both active and periodic measurements (active measurement: *P*=.02, periodic measurement: *P*=.03).

Conclusions: Photoplethysmography-based smart devices demonstrated good atrial fibrillation predictive ability in both active and periodic measurements. However, atrial fibrillation type could impact detection, resulting in increased monitoring time.

Trial Registration: Chinese Clinical Trial Registry of the International Clinical Trials Registry Platform of the World Health Organization ChiCTR-OOC-17014138; http://www.chictr.org.cn/showprojen.aspx?proj=24191.

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KEYWORDS

atrial fibrillation; photoplethysmography; continuous detection; accuracy; smartphone; smart band; algorithm

Introduction

Atrial fibrillation (AF) is the most common recurrent arrhythmia in clinical practice, occurring in 1%-2% of the general population [1]. Two epidemiological studies found an AF prevalence rate of approximately 0.7% in the Chinese population nearly a decade ago [2,3]. Other studies found that the prevalence of AF increased 20-fold and that of AF-related stroke increased 13-fold in the southwest of China from 2001 to 2012 [4]. As such, it was estimated that there were 10 million patients with AF in China in 2016 [5]. When identified clinically, AF is asymptomatic in at least one-third of patients [6]. Some patients experience very brief episodes, associated with vague symptoms. Therefore, it is possible that these epidemiological numbers are underestimated, as many patients with asymptomatic or paroxysm AF could be undetected [7,8]. However, the prevalence of AF is expected to increase significantly in the next 30-50 years due to an ageing population. The prevalence of AF in Korea is expected to be 5.81% in 2060, while its prevalence in Taiwan is estimated to be 4.01% in 2050 [9,10]. Furthermore, AF is an important risk factor for stroke, increasing the stroke risk five-fold, and accounts for nearly one-third of all stroke cases [11-13]. Thus, AF is likely to become a significant public health issue in the future. Early diagnosis and anticoagulation therapy could reduce the number of AF-related strokes by approximately two-thirds [14], making it particularly important to effectively detect AF as early as possible.

However, paroxysmal AF could be underdiagnosed because there is possibly no onset in the hospital [15]. Mobile health could provide a promising solution [16]. The popularity and high-speed updating capabilities of smartphone apps and wearable fitness trackers have made continuous self-monitoring of health indicators possible in real-world settings. Patients and clinicians can utilize these technologies for proactive health care. For example, people can use smartphone apps and smart bands to count steps, measure sleep time, and continuously monitor heart rate/rhythm.

Photoplethysmography is an optical method to measure changes in tissue blood volume through the skin capillary bed, which can be performed using a smartphone in conjunction with a smart band/watch without any additional peripherals [17,18]. Smartphones and wearable devices have leveraged optical detection of photoplethysmography signals to track heart rate/rhythm from the finger and wrist, achieving high sensitivity and specificity for AF detection [19,20]. Thus far, most studies examining this method of AF detection have used single-point tests. Our previous study confirmed the feasibility of single-point photoplethysmography measurement of smartphones for AF detecting too [21]. A real-world study of patients with AF outside hospital context is limited. The application of photoplethysmography-based smart devices in continuously and automatically monitoring AF risk is unknown. The objectives of this study were to validate the accuracy and sensitivity of continuous detection of AF with photoplethysmography-based smart devices and to investigate the underlying clinical factors impacting the detection.

Methods

Study Population

Subjects for this pilot study were recruited from the community and the outpatient department of the Chinese PLA General Hospital from September 14, 2018, to October 16, 2018. We included adult participants aged ≥18 years who were able to provide informed consent and were willing to wear the smart wearable device. Individuals were excluded from the study due to the presence of a pacemaker or implantable defibrillator or if they were unable to use smart wearable devices.

Study Procedures

Three types of smart wearable devices were used in this study. These included the Huawei WatchGT [22], the Honor Watch [23], and the Honor Band4 [24]. The matching smartphone app was used (Honor9; Huawei Device Co, Ltd, Shenzhen, China). The Huawei smart wearing devices were freely provided for the subjects.

All subjects received active measurement with smart band/watch upon enrollment. Measurement with the devices was taken immediately following doctor diagnosis, and each participant used two of three devices. If the initial two measurements failed, additional measurements were taken. Participants were helped with band/watch placement and instructed to keep their arms still by resting them on a table. The photoplethysmography signal was record for 45 seconds, and a result was provided to detect the single-point heart rhythm.

After active measurement, each of the 200 participants who owned Huawei smart phones were provided with an Honor Band4 to continuously monitor heart rate/rhythm during a 14-day period. Each participant was given assistance in downloading the app to his/her smartphone by a member of the study team. Participants were also trained on how to use the device. They were instructed to actively take two measurements per day and wear the smart band as long as possible in order to record the most automatic periodic measurement data possible. The periodic measurement was automatically taken every 10 minutes, irrespective of whether the subject walked or rested, and 60-second photoplethysmography signals were continuously collected. However, the algorithm was first performed to identify whether the signal quality was good enough to do further analysis. Thereafter, the photoplethysmography algorithm was carried out to screen irregular pulse rhythm. At least a 30-second AF was needed to meet the definition of AF.

This was a single-center pilot study of AF screening and part of the pre-mAFA II registry. The pre-mAFA studies examined mobile health technology for improved screening, patient involvement, and optimization of integrated AF care. The Medical Ethics Committee of the Chinese PLA General Hospital and the China Food and Drug Administration approved this study protocol (approval number: S2017-105-02). Further, this study was registered in the Chinese Clinical Trial Registry, which was part of the International Clinical Trials Registry Platform of the World Health Organization (ChiCTR-OOC-17014138).

Atrial Fibrillation Detection and Confirmation

AF diagnoses were independently confirmed with medical history, physical examination, and electrocardiogram by two doctors. Patient data such as medical history, physical examination, and electrocardiogram were collected when subjects were enrolled. Doctors used a dual earpiece stethoscope to confirm cardiac rhythm of the same subject. If the doctors disagreed on the diagnosis obtained via the dual earpiece stethoscope and pulse check, the subject was further exposed to a 12-lead electrocardiogram that was examined independently by two additional doctors.

Paroxysmal AF was defined as self-terminating, in most cases, within 48 hours. Some AF paroxysms might continue for up to 7 days. AF episodes that were cardioverted within 7 days were considered to be paroxysmal [25].

Persistent AF was defined as AF that lasted longer than 7 days, including episodes that were terminated by cardioversion, either with drugs or by direct current cardioversion, after 7 days or more [25].

Photoplethysmography Algorithm

One of the efficient machine learning methods, boosting, was used to train the model to screen AF. Sensitive features extracted from the waveforms and the peak-to-peak intervals of the photoplethysmography were utilized in the model. The peak-to-peak intervals of photoplethysmography were uniform for sinus rhythm data but chaotic for AF episodes. For example, the variance, entropy, etc, derived from the peak-to-peak intervals were fluctuating for AF episodes (Multimedia Appendices 1 and 2). Three smart devices were used to investigate if the layout of the photoplethysmography sensor position influences the accuracy of photoplethysmography algorithm to detect AF.

Statistical Analyses

Continuous variables were tested for normality by the Kolmogorov-Smirnov test. Data with normal distributions were presented as mean (SD). Data with non-normal distributions were analyzed using a Mann-Whitney U test and were presented as median (interquartile range [IQR]). Categorical variables were analyzed using Pearson chi-square test or Fisher exact test.

Sensitivity and specificity were calculated by periodic interpretation of smart wearable devices compared with physician diagnoses. Kappa coefficients were assessed for diagnostic agreement, which was performed using MedCalc 12.6.1.0 (MedCalc Software BVBA, Ostend, Belgium). Excellent agreement was defined as a kappa coefficient >0.80.

A two-sided *P* value<.05 was considered statistically significant. The 95% CIs were calculated, and statistical analysis was performed using IBM SPSS Statistics, version 25.0 (SPSS Inc, Chicago, Illinois).

Results

Baseline Characteristics and Atrial Fibrillation Diagnoses

There were a total of 361 subjects (median age 50 years; IQR=36-62 years); 178 (49.3%) were female, excluding 12 subjects with poor pulse signals. There were 20 diagnoses of paroxysmal AF, 11 of persistent AF, and 330 of sinus rhythm confirmed by doctors via medical history, physical examination, and electrocardiogram upon enrollment.

Active Measurement by Photoplethysmography

All 361 subjects received a 45-s photoplethysmography active measurement with at least two kinds of smart wearable devices, with a total of 735 valid pulse waveform recordings. Among the 735 valid photoplethysmography signals, 77 signals were classified as AF and 658 were classified as sinus rhythm (Figure 1).

The sensitivity of all of three smart devices with the 45-s photoplethysmography active measurement in predicting AF was 100%, the specificity ranged from 98.93% to 99.16%, the positive predictive value ranged from 91.67% to 93.10%, and the negative predictive value was 100%. Three kinds of smart wearable devices exhibited kappa coefficients ranging from 0.95 to 0.96 to detect AF against the reference standard in the single-point heart rhythm detection. There was no significant difference in further statistical analysis of the results from different smart devices compared with the diagnosis of the doctors (*P*=.97; Table 1).

Figure 1. Participant flow diagram of the study. AF: atrial fibrillation，SR: sinus rhythm.

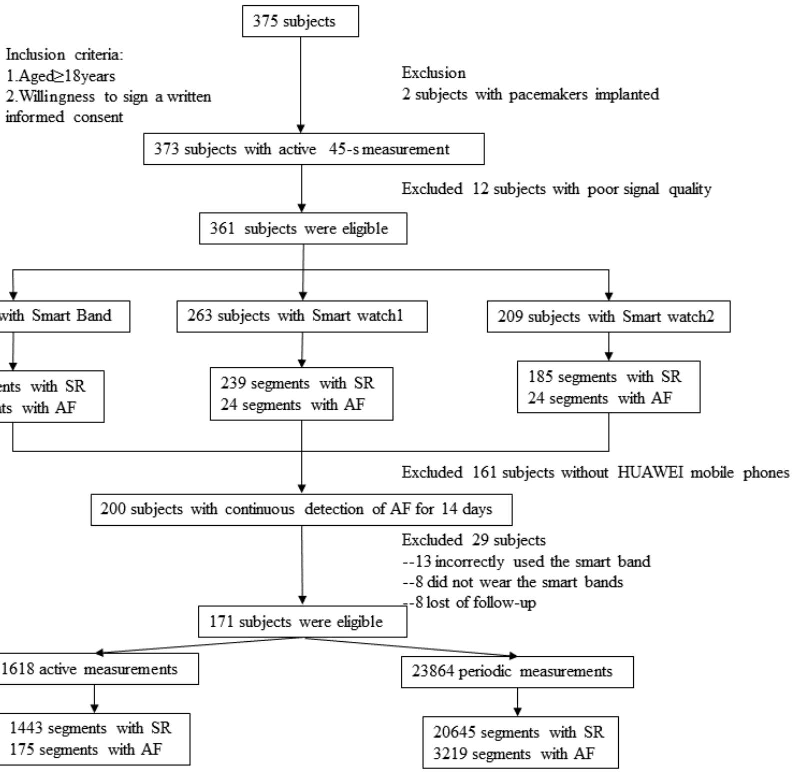


Table 1. Detailed diagnostic performance of the photoplethysmography algorithm for atrial fibrillation screening in different smart devices.

Index	Smart band (n=263)	Smart watch 1 (n=263)	Smart watch 2 (n=209)
Sensitivity, % (95% CI)	100 (87.23-100)	100 (85.75-100)	100 (84.56-100)
Specificity, % (95% CI)	99.15 (96.97-99.90)	99.16 (97.01-99.90)	98.93 (96.19-99.87)
Positive predictive value, % (95% CI)	93.10 (77.23-99.15)	92.31 (74.87-99.05)	91.67 (73.00-98.97)
Negative predictive value, % (95% CI)	100 (98.44-100)	100 (98.46-100)	100 (98.03-100)
Kappa (95% CI)	0.96 (0.91-1)	0.96 (0.90-1)	0.95 (0.88-1)

Continuous Photoplethysmographic Detection of Atrial Fibrillation

A total of 171 subjects (mean age 53.23 years, SD 13.58 years), 85 (50%) women, finished 14 days of continuous monitoring with a smart band, resulting in 25,482 valid photoplethysmography waveform signals. These signal results were recorded from11 cases of persistent AF, 20 cases of paroxysmal AF, and 140 cases of sinus rhythm, all of which were confirmed by doctors with clinical data (Figure 1, Table 2).

Hypertension was present in 47 (28%) patients; diabetes mellitus, in 23 (14%) patients; coronary artery disease, in 14 (8%) patients; current smoking, in 24(14%) patients; and current drinking, in 32(19%) patients. The prevalence of other diseases such as heart failure was less than 5%. The median CHA2DS2-VASc (congestive heart failure, hypertension, age ≥75 years [doubled], diabetes mellitus, stroke [doubled], vascular disease, age 65-74 years, female sex) score was 1 (IQR=0.75-2.00), while the median HAS-BLED (hypertension, abnormal renal function, abnormal liver function, stroke, bleeding, labile INR [international normalized ratio], age >65 years, drugs or alcohol) score was 0 (IQR=0.00-1.00; Table 2).

We finally collected a total of 1618 photoplethysmography active measurement signal segments and 23,864 photoplethysmography periodic measurement signal segments from the 171 participants during the 14-day period (Figure 1). There were 127 (97.0%) active monitoring signals and 2240 (99.2%) periodic monitoring signals suggesting AF during 14 days for patients with persistent AF (Figure 2), while 36 (17%) active monitoring signals and 717 (19.8%) periodic monitoring signals suggested AF for patients with paroxysmal AF (Figure 3). The proportion of AF cumulative episodes to total measurements for 14 days demonstrated significant differences between the persistent AF group and the paroxysmal AF group (periodic measurement: *P*<.001, active measurement: *P*=.001).

The ability of active and periodic measurements to predict AF (median time to first notification of AF) was 1 day (IQR=1.00-1.00) for patients with persistent AF (*P*=.65). For paroxysmal AF, 12 (60%) patients were identified as having AF with periodic measurement and 8 (40%) patients were identified as having AF with active measurement during the 14-day study period, while 14 (70%) patients were identified as having AF within the first 6 days with combined active and periodic measurements (*P*=.15). Median time to first detection of AF was 1 day (IQR=1.00–2.00) and 2 days (IQR=1.25-5.75) by periodic and active measurements, respectively (*P*=.10).

Table 2. Baseline characteristics of the continuously monitored participants (N=171).

Characteristics	Total
Demographics	
Age (years), mean (SD)	53.23 (13.58)
Female, n (%)	85 (50)
Medical history	
Heart failure, n (%)	1 (1)
Hypertension, n (%)	47 (28)
Diabetes mellitus, n (%)	23 (14)
Previous stroke/SE[a]/TIA[b], n (%)	4 (2)
Coronary artery disease, n (%)	14 (8)
Vascular disease, n (%)	8 (5)
Renal dysfunction, n (%)	2 (1)
Bleeding history or predisposition, n (%)	4 (2)
Sleep apnea, n (%)	8 (5)
Hyperthyroidism, n (%)	1 (1)
Current smoking, n (%)	24 (14)
Current drinking, n (%)	32 (19)
CHA_2DS_2-VASc[c] score, median (IQR[d])	1 (0.75-2.00)
HAS-BLED[e] score, median (IQR)	0 (0.00-1.00)
Medications, n (%)	
Oral anticoagulant	19 (11)
Antiplatelet drug	11 (6)
Calcium channel blockers	3 (2)
ACEI/ARB[f]	10 (6)
Diuretic	4 (2)
Digoxin	1 (1)
Antiarrhythmic drugs, n (%)	
Class I	3 (2)
Betablocker	3 (2)
Class III	5 (3)
Class IV	3 (2)

[a] SE: systemic arterial embolism.

[b] TIA: transient ischemic attack.

[c] CHA2DS2-VASc: congestive heart failure, hypertension, age ≥75 years (doubled), diabetes mellitus, stroke (doubled), vascular disease, age 65-74 years, female sex.

[d] IQR: interquartile range.

[e] HAS-BLED: hypertension, abnormal renal function, abnormal liver function, stroke, bleeding, labile international normalized ratio, age>65 years, drugs or alcohol.

[f] ACEI/ARB: angiotensin-converting-enzyme inhibitor, angiotensin receptor blockers.

Figure 2. (A) Cumulative active measurement of patients with persistent AF during the 14-day period. (B) Cumulative periodic measurement of patients with persistent AF during the 14-day period. AF: atrial fibrillation.

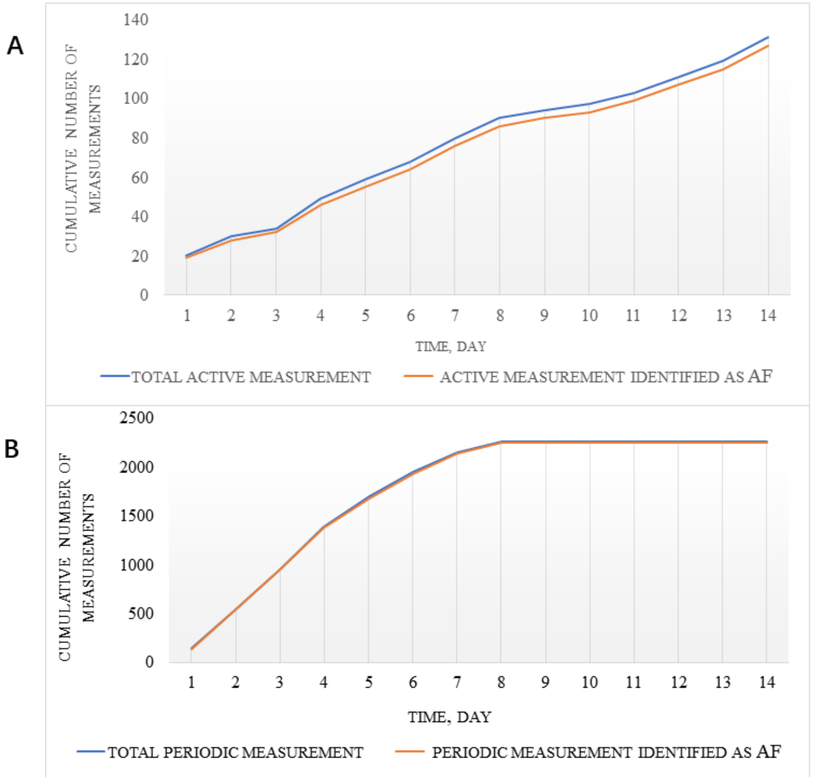
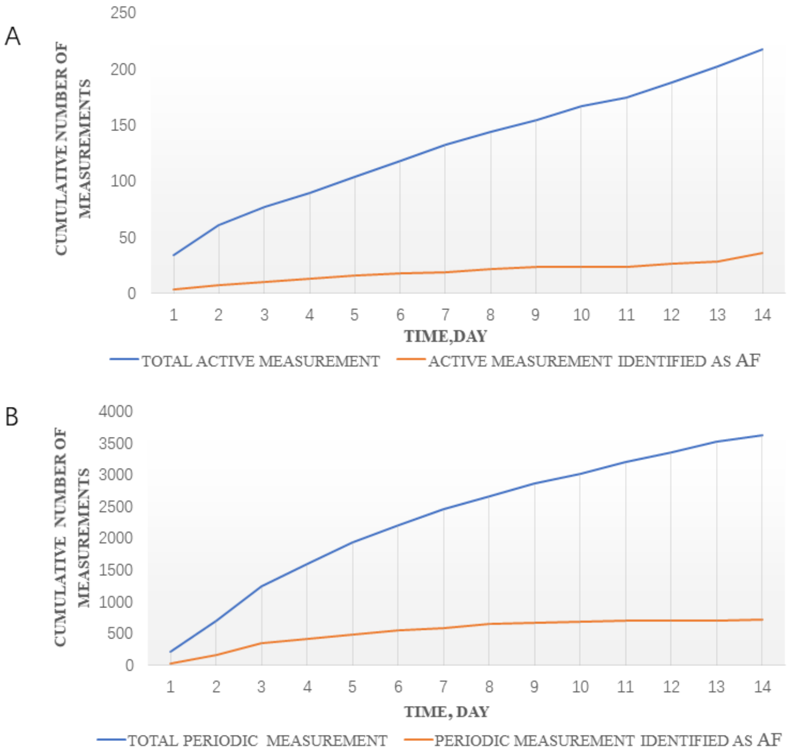


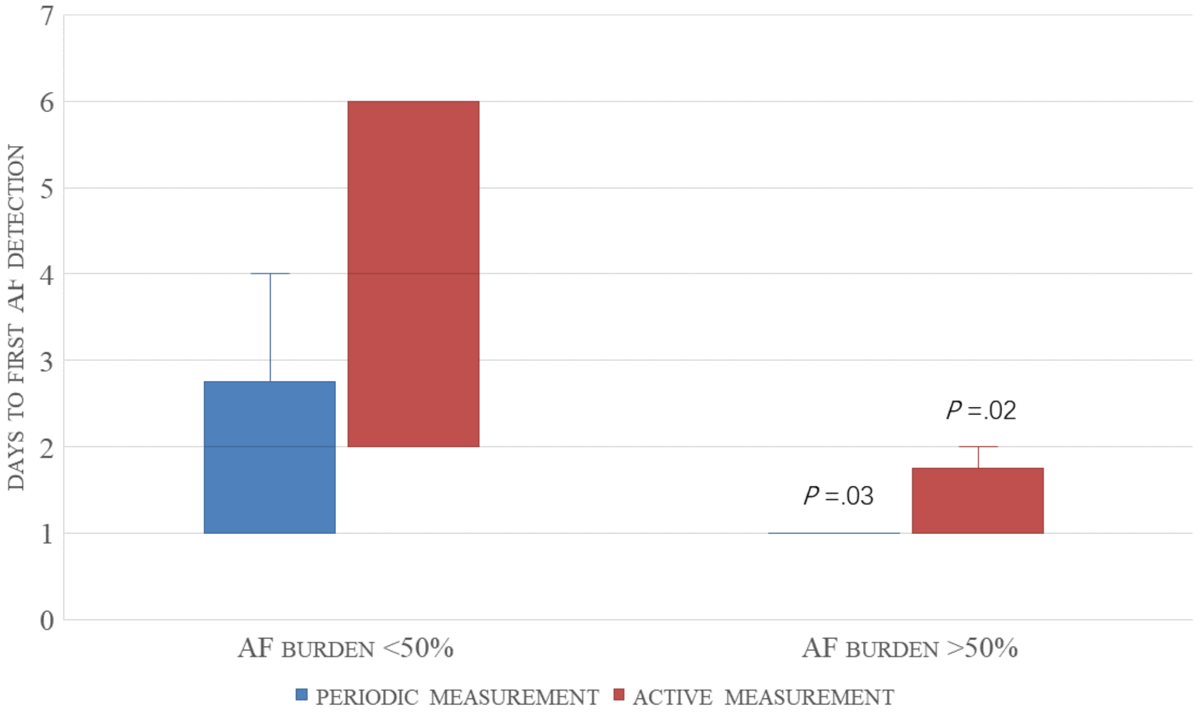
Figure 3. (A) Cumulative active measurement of patients with paroxysmal AF during the 14-day period. (B) Cumulative periodic measurement of patients with paroxysmal AF during the 14-day period. AF: atrial fibrillation.



Atrial Fibrillation Burden and Photoplethysmography Monitoring

AF burden was defined as the ratio of the number of episodes of AF monitored to the total number of measurements for 24 hours. For those with AF episodes sustained less than 50% per 24 hours, the median number of days to first detection of AF was 4 (IQR=2.00-6.00) by active measurement and 2 (IQR=1.00–2.75) by periodic measurement. However, for individuals with AF episodes sustained more than 50% per 24 hours, the median number of days to first detection of AF was 1 for both active (IQR=1.00-1.75) and periodic (IQR=1.00-1.00) measurements. The median number of days to first detection of AF between the two groups demonstrated significant differences (active measurement: *P*=.02, periodic measurement: *P*=.03; Figure 4).

Figure 4. Time to the first detection of AF (quartile box-whisker plot). AF: atrial fibrillation.



Discussion

Principal Findings

This study found that photoplethysmography-based smart devices (watch/band) could effectively detect AF episodes, with active or periodic measurement. However, detection of paroxysmal AF exhibited a longer duration, and therefore, continuous periodic measurement was recommended.

Accuracy and Sensitivity of Photoplethysmography-Based Smart Device for Detection of Atrial Fibrillation

We analyzed 735 valid photoplethysmography signals acquired by active measuring from 361 participants, excluding 12 subjects with poor pulse signals. Results indicated that the three kinds of smart wearable devices (two watches and one band) exhibited a very high kappa coefficient (0.95-0.96) to detect AF with active measurement against the reference standard diagnosed by doctors. Sensitivity was 100% and specificity ranged from 98.93% to 99.16%, which were higher than the statistics reported by previous works. Tison et al [26] showed that among 51 patients undergoing cardioversion, smart watches based on the photoplethysmography technique can diagnose AF with a sensitivity of 98.0% and a specificity of 90.2% compared to the standard 12-lead electrocardiogram. Rozen et al [27] designed a study to evaluate use of a smartphone app as a method of detecting AF before and after electrical cardioversion in 97 patients and achieved a sensitivity of 93.1% and a specificity of 90.9%.

Feasibility of Photoplethysmography-Based Smart Device for Continuous 14-Day Monitoring of Atrial Fibrillation

We analyzed a total of 25,482 valid photoplethysmography waveform signals acquired from 171 participants by active and periodic measurements for 14 days. Results showed that periodic measurement can achieve high AF diagnostic accuracy in the real world as well. For patients with persistent AF, 127 (97.0%) and 2240 (99.2%) photoplethysmography signal segments were identified as AF by active and periodic measurements, respectively. These numbers were much higher than those of patients with paroxysmal AF, with only 36 (17%) active monitoring photoplethysmography signals and 717 (19.8%) periodic monitoring photoplethysmography signals suggesting AF. These are consistent with the disease characteristics of persistent and paroxysmal AF; even in patients with persistent AF, there is possibly short sinus rhythm among AF episodes. Periodic measurements seemed to be more sensitive in detecting AF than active measurements. Much frequency monitoring of periodic measurements is likely to “catch” the AF episodes, which also need to be further validated in a large study. In addition, previous studies have shown that 60.3% patients had their first arrhythmia after the first 48 hours of monitoring [28]. In this study, the median time to first AF diagnosis with persistent AF by the two types of measurements were both 1 day. The high accuracy of periodic measurement shows a strong benefit of continuous monitoring. This is important, as patients can not only detect heart arrhythmias at the onset of symptoms such as palpitations via active measuring, as previously mentioned in other studies [29,30], but also improve the identification rate of asymptomatic AF through continuous periodic monitoring.

Factors Impacting the Continuous 14-Day Detection of Atrial Fibrillation

In a previous study, the mean interval to first detection of AF was inversely proportional to total AF burden [28]. We also compared the time to first detection of AF between different degrees of AF burden. For patients with AF episodes sustained less than 50% in 24 hours, the median number of days to first detection of AF was 4 by active measurement and 2 by periodic measurement. However, the median number of days to first detection of AF was 1 for both measurements for patients presenting with AF episodes sustained more than 50% in 24 hours. This suggested that the less AF occurred, the longer the latency to AF detection (active measurement: P=.02, periodic measurement: P=.03). Steinhubl et al [31] reported immediate continuous monitoring with a home-based, wearable electrocardiogram sensor patch compared with delayed monitoring, which resulted in a higher rate of AF diagnosis. We found that, with the extension of monitoring time, the number of patients identified with AF gradually increased, especially for patients presenting with paroxysmal AF. As such, paroxysmal AF may require a longer duration of measurement to reach a diagnosis. Moreover, it seems to be a trend that combining active and periodic measurements was more effective in identifying AF than using either of them alone, although this result was not statistically significant. When the two methods were combined, 11 (100%) patients with persistent AF could be detected in the first day. In addition, 14 (70%) patients with paroxysmal AF could be detected within the first 6 days, and no more new patients with AF were detected after 6 days, based on continuous photoplethysmography monitoring data.

Limitations and Future Directions

There were several limitations to this study. First, the sample size was relatively small. Second, some participants did not complete the active measurement twice a day in strict fidelity with the study requirements. Additionally, the plateau in periodic measurements, resulting from the lack of measurements after the eighth day in patients with persistent AF, could possibly be associated with the discontinuation of smart devices use, which might impact the detection of AF. Third, in 31 (16%) participations diagnosed with sinus rhythm at baseline, AF episodes were detected during the 14-day continuous monitoring. However, these “suspected AF” cases were lost to follow-up, and we could not identify the cardiac rhythm. Fourth, there was no timely 12-lead electrocardiogram monitoring data synchronized with photoplethysmography data in this study. Finally, in 12 (3%) subjects, the recorded quality of photoplethysmography signals was poor. The inadequate signal quality possibly was associated with the deep color, perfusion of the skin, inappropriate wearing, etc. To develop a photoplethysmography-based screening approach, a photoplethysmography algorithm was developed, tested, and optimized among 394 cases in the stage 1 and stage 2. Subsequently, the photoplethysmography algorithm and different smart devices were validated among 375 cases in a real-world settings with 14-day monitoring (stage 3), which was performed in this study. Thereafter, the photoplethysmography algorithm and smart devices would be further validated in the general population with at least 10,000 subjects (stage 4, mAFA II study).

Conclusions

Photoplethysmography-based smart devices are accurate in the continuous detection of AF outside the hospital. The accuracy is similar between the active and periodic measurements. In addition, this method is simple and accessible. For asymptomatic patients with low AF burden, prolonged continuous monitoring time might increase the detection rate of AF. This technology can extend the diagnosis, monitoring, and risk assessment of AF beyond the hospital, providing a new way for doctors and patients to manage AF together.

Acknowledgments

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Authors' Contributions

HZ conducted data collection and analysis and wrote the initial draft of the manuscript. Y-TG and Y-DC are supervisors of this project as well as joint senior authors. JZ, H-BL, Y-XC, and BY provided the PRO AF photoplethysmography algorithm. All coauthors contributed revisions to the manuscript and approved the final manuscript.

Conflicts of Interest

JZ, H-BL, Y-XC, and BY are employees of Huawei Device Co, Ltd. The Huawei Heart Health Research Team developed and optimized the photoplethysmography algorithm.

Multimedia Appendix 1
Electrocardiogram and photoplethysmography in patients with sinus rhythm.
[PNG File , 564 KB - jmir_v21i12e14909_app1.png]

Multimedia Appendix 2
Electrocardiogram and photoplethysmography in patients with atrial fibrillation.
[PNG File , 612 KB - jmir_v21i12e14909_app2.png]

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Abbreviations

ACEI/ARB: angiotensin-converting-enzyme inhibitor, angiotensin receptor blockers
AF: atrial fibrillation
CHA2DS2-VASc: congestive heart failure, hypertension, age ≥75 years (doubled), diabetes mellitus, stroke (doubled), vascular disease, age 65-74 years, female sex
HAS-BLED: hypertension, abnormal renal function, abnormal liver function, stroke, bleeding, labile international normalized ratio, age>65 years, drugs or alcohol
IQR: interquartile range
SE: systemic arterial embolism
TIA: transient ischemic attack

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Original Paper

Effectiveness of Smartphone App–Based Interactive Management on Glycemic Control in Chinese Patients With Poorly Controlled Diabetes: Randomized Controlled Trial

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Abstract

Background: In recent years, the rapid development of mobile medical technology has provided multiple ways for the long-term management of chronic diseases, especially diabetes. As a new type of management model, smartphone apps are global, convenient, cheap, and interactive. Although apps were proved to be more effective at glycemic control, compared with traditional computer- and Web-based telemedicine technologies, how to gain a further and sustained improvement is still being explored.

Objective: The objective of this study was to investigate the effectiveness of an app-based interactive management model by a professional health care team on glycemic control in Chinese patients with poorly controlled diabetes.

Methods: This study was a 6-month long, single-center, prospective randomized controlled trial. A total of 276 type 1 or type 2 diabetes patients were enrolled and randomized to the control group (group A), app self-management group (group B), and app interactive management group (group C) in a 1:1:1 ratio. The primary outcome was the change in glycated hemoglobin (HbA_{1c}) level. Missing data were handled by multiple imputation.

Results: At months 3 and 6, all 3 groups showed significant decreases in HbA_{1c} levels (all $P<.05$). Patients in the app interactive management group had a significantly lower HbA_{1c}level than those in the app self-management group at 6 months ($P=.04$). The average HbA_{1c} reduction in the app interactive management group was larger than that in the app self-management and control groups at both months 3 and 6 (all $P<.05$). However, no differences in HbA_{1c} reduction were observed between the app self-management and control groups at both months 3 and 6 (both $P>.05$). Multivariate line regression analyses also showed that the app interactive management group was associated with the larger reduction of HbA_{1c} compared with groups A and B at both months 3 and 6 (all $P>.05$). In addition, the app interactive management group had better control of triglyceride and high-density lipoprotein cholesterol levels at both months 3 and 6 compared with baseline (both $P<.05$).

Conclusions: In Chinese patients with poorly controlled diabetes, it was difficult to achieve long-term effective glucose improvement by using app self-management alone, but combining it with interactive management can help achieve rapid and sustained glycemic control.

Trial Registration: ClinicalTrials.gov NCT02589730; https://clinicaltrials.gov/ct2/show/NCT02589730.

(J Med Internet Res 2019;21(12):e15401) doi:10.2196/15401

KEYWORDS

app; self-management; interactive management; guidance; glycated hemoglobin A1c; diabetes

Introduction

Effectiveness of Smartphone Apps on Glycemic Control

The rapid development of mobile medical technology has provided multiple ways for the long-term management of chronic diseases, especially diabetes [1]. As a new type of management model, smartphone apps are global, convenient, cheap, and interactive. Compared with traditional computer- and Web-based telemedicine technologies [2,3], apps may have unique advantages in diabetes management [4-6]. Recent studies have proved that apps are effective at improving glycated hemoglobin (HbA_{1c}) levels and could be considered as an adjuvant intervention to diabetes management [7-11].

Demand for Further and Sustained Glycemic Control

China has the world's largest population with diabetes [12] but a shortage of physicians. Under such special national conditions, scientific and effective diabetes management models are urgently needed for better outcomes. Although apps were proved to be effective at glycemic control, how to gain a further and sustained improvement is still being explored. Welltang, designed in Chinese language, is the most widely used app for diabetes management in China. It was previously reported in a 3-month randomized controlled trial that diabetes patients using the Welltang app achieved statistically significant improvements in HbA_{1c}, with an average decrease of 1.95%, whereas the reduction in HbA_{1c} was just 0.79% in the control group [9]. However, the duration of this previous study was relatively short, and there was a lack of a professional health team to provide interactions with patients beyond medical adjustment, such as diet, exercise, and diabetes education.

Aim of This Study

Therefore, this single-center, open-labeled, prospective randomized controlled trial was conducted in Chinese patients with poorly controlled diabetes, including both type 1 and type 2 diabetes, to investigate the effectiveness of an app-based interactive management model on glycemic control and to explore an individualized method for diabetes management in China.

Methods

Trial Design

This study was a 6-month long, single-center, open-labeled, prospective randomized controlled trial. Participants were recruited from the outpatient clinic of the Department of Endocrinology and Metabolism of Shanghai Jiao Tong University Affiliated Sixth People's Hospital from July 2015 to February 2016. According to the type of diabetes mellitus (type 1 or 2 diabetes), the stratified randomization method was used to generate a random number table, and participants were randomized into 3 groups in a 1:1:1 ratio: group A (control group), group B (smartphone app self-management group), and group C (smartphone app interactive management group). This study was registered at ClinicalTrials.gov, number NCT02589730.

Study Patients

Outpatients diagnosed with type 1 or 2 diabetes (aged 18-65 years) were enrolled according to the 2010 American Diabetes Association criteria [13], with a duration ≥6 months and HbA_{1c} ≥8% within 3 months before enrollment. To be eligible, patients had to be able to use a smartphone, be willing and able to perform daily self-monitoring of blood glucose (SMBG), and be willing and able to visit a physician at months 3 and 6.

Patients were excluded according to the following criteria: (1) insulin pump users; (2) pregnant or plan to be pregnant during the study period; (3) excessive drinking or drug users; (4) used drugs that might affect blood sugar in the 3 months before enrollment, such as glucocorticoids and thyroid hormones; (5) psychotic and were receiving treatment; (6) severe complications or systemic diseases; (7) experienced cardio- or cerebrovascular events in the 6 months before enrollment; (8) severe hearing or visual impairment; (9) unable to access the Web or unable to learn to use the app on the smartphone; and (10) unsuitable for the study according to the judgment of the researchers.

The study was approved by the Ethics Committee of the Shanghai Jiao Tong University Affiliated Sixth People's Hospital and conformed to the provisions of the Declaration of Helsinki. All participants provided written informed consent before enrollment.

Interventions

The smartphone-based diabetes management platform in this study was Welltang, which was designed by Shanghai Geping Information and Technique Company Ltd, and it was used by both patients and clinicians. For patients, Welltang mainly comprises 4 parts: education, self-management (including records of SMBG, diet, exercise, medication, body weight, and other diabetes data), patient community, and communication between patients and clinicians. For clinicians, Welltang mainly provided the real-time uploading of data from patients.

In group A, patients received usual care and did not install Welltang on their smartphone. They learned diabetes-related knowledge and skills by self-learning and summarizing, and they adopted lifestyles and behaviors voluntarily.

In group B, each patient was requested to install Welltang on their smartphone. They learned diabetes-related knowledge and skills by using the app, including glycemic control, diet, exercise, medication, and the use of insulin. There was no other staff involved in the care of this group, except for 1 clinician.

In group C, besides app self-management, patients received interactive management online (service for stable glucose×180 days). After randomization, a third-party professional diabetes health care team comprising 1 dietician and 1 health manager conducted interactive management with patients through the Welltang platform. The dietician was responsible for daily dietary guidance and the health manager for comprehensive interventions, such as exercise, glucose monitoring, and diabetes education based on the data uploaded by the patients. The service had a standardized operation process. During the first month, centralized management was conducted for reasons of poor glycemic control to help patients develop good habits of glucose control. Afterward, patients were evaluated monthly. When blood glucose (BG) fluctuated greatly, the causes of fluctuation were analyzed to improve glycemic control. When the patients achieved certain improvements and gained inertia, reminders were provided promptly to prevent large fluctuations. Finally, this team also assisted patients with achieving a relatively stable period of managing diabetes by themselves. During the service, a glucose control report was generated every week, and appropriate suggestions were provided according to the report.

After enrollment, each patient was provided an optimal glucose control target according to the *Guidelines for the Prevention and Treatment of Type 2 Diabetes in China (2013 Edition)* [14] and received basic diabetes education, including diet control, adequate exercise, SMBG, and regular follow-up. All patients could contact clinicians by telephone during the follow-up, but those who had installed the app were encouraged to contact clinicians online. Clinicians were blind to the patients' groups. The dietician and health manager could view all patients' clinical variables and provide real-time interventions and adjustments on the basis of these data.

Each patient was equipped with a designated BG meter and an adequate number of test strips. Patients in the app self-management and app interactive management groups were asked to regularly record the glucose results in Welltang; patients in the control group were asked to record their glucose results in a log book. The frequency of SMBG that was required was at least 6 times a week, without a maximum limit. Test trips were provided by the investigators for free.

Data Collection

The follow-up duration was 6 months. At baseline, all patients were asked to complete a questionnaire about demographic characteristics, personal history, and medical history. Anthropometric and clinical measurements were collected from all patients at baseline and at months 3 and 6 after the intervention.

Body mass index (BMI) was calculated as BMI=weight (kg)/height^2 (m^2). Blood pressure was measured with a mercury sphygmomanometer after the subject had rested for at least 10 min. Waist circumference (W) was measured midway between the lowest rib and the iliac crest with the subject in the standing position.

Venous blood was collected in the morning after a 10-hour overnight fast. The levels of fasting plasma glucose (FPG), HbA_{1c}, total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol (HDL-c), low-density lipoprotein cholesterol (LDL-c), alanine aminotransferase, aspartate aminotransferase, gamma-glutamyl transpeptidase, creatinine, uric acid, and albumin-to-creatinine ratio were assessed with standard methods, as described previously [15].

Adverse Event

In this study, the major adverse event was hypoglycemia. Hypoglycemia was defined as BG ≤3.9 mmol/L. Each patient had received related education and treatment measures after enrollment and could call physicians when they needed. All adverse events were recorded.

Outcomes

The primary outcome was glucose control, including the changes (from baseline to months 3 and 6) in the HbA_{1c} level. The secondary outcomes included the changes in FPG, body weight, and lipids.

Sample Size

In a small-sample (n=9) observational study conducted before this trial, the reductions of HbA_{1c} in the control, app self-management, and app interactive management groups after 3 months of follow-up were 0.9% (SD 0.9%), 1.3% (SD 1.1%), and 1.6% (SD 1.3%), respectively. On the basis of these results from the small-sample observational study, with alpha=.05 and beta=.10, we calculated a required sample size of 65 patients per group by PASS 11.0 (NCSS LLC) software. Considering a dropout rate of 20%, a sample size of 78 patients per group was required.

Statistical Analysis

The statistical analysis was performed based on the intention-to-treat principle. Missing data were handled by multiple imputation [16,17]. The R multivariate imputation by chained equation package was used to impute 5 sets of complete dataset with 50 iterations per imputation. Predictive mean matching was used for continuous variables. All findings are presented based on multiply imputed data, unless otherwise indicated.

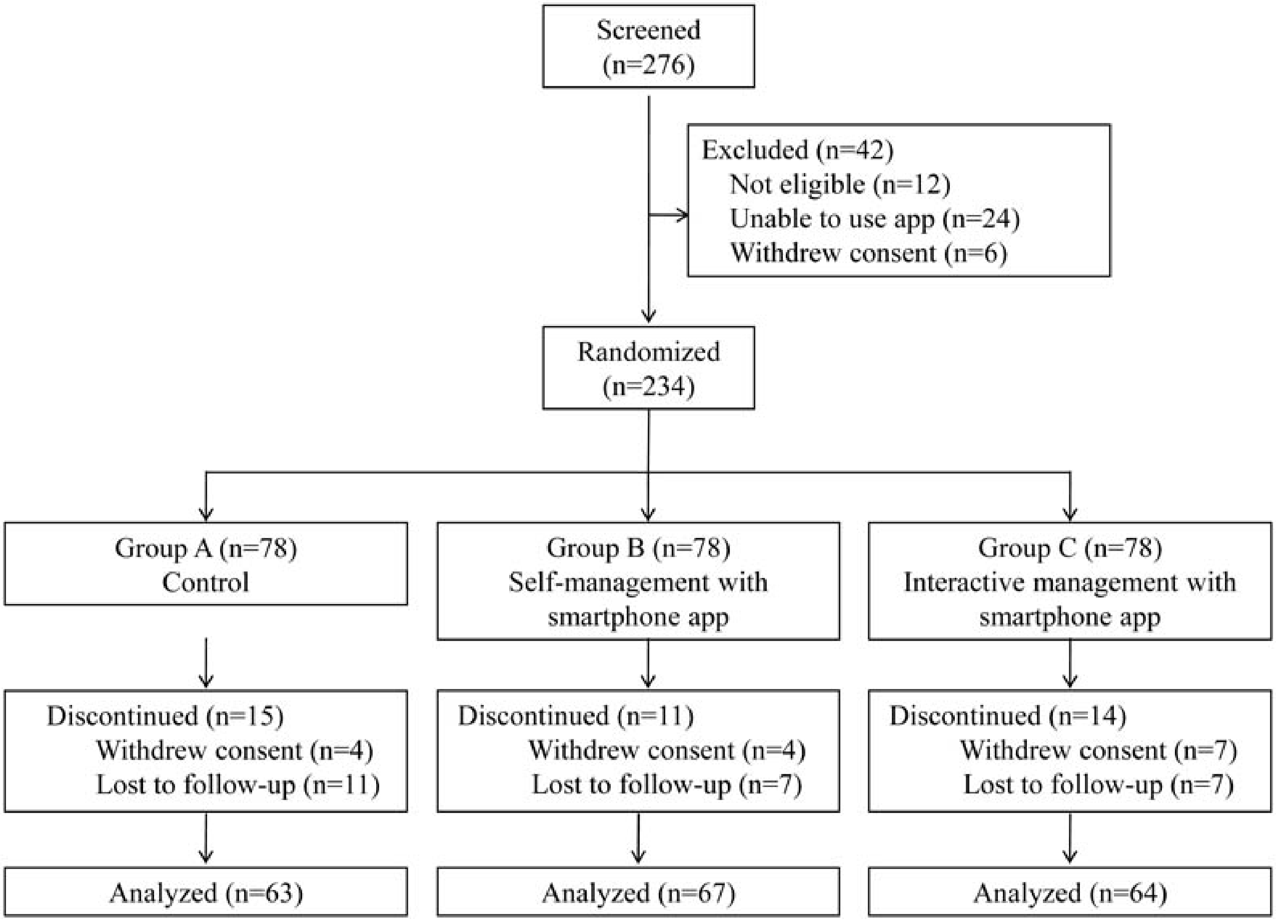
The data are reported as the mean (SD), unless otherwise stated. Intergroup comparisons were conducted with the unpaired Student *t* test, Kruskal-Wallis test, and chi-square test for normally distributed data, skewed data, and categorical variables, respectively. The paired Student *t* test was used to evaluate the differences in continuous variables from baseline to months 3 and 6 of follow-up in each group. The multiple linear regression analyses were applied to explore the associations of HbA_{1c} level reduction and different models of diabetes management. All data analyses were conducted by SPSS version 19.0 (SPSS). A 2-tailed *P* value of <.05 was considered indicative of a statistically significant difference.

Results

Baseline Characteristics of Study Participants

Of the 276 participants who underwent screening in this study, 234 were enrolled and randomized to groups A (n=78), B (n=78), or C (n=78). Of these, a total of 209 (209/234, 89.3%) completed the third month visit and 194 (194/234, 82.9%) completed the sixth month visit. After randomization, 15 patients from group A, 11 from group B, and 14 from group C discontinued the study because they either withdrew their consent or were lost to follow-up (Figure 1).

Figure 1. Study design and participant flow diagram.



The demographic and baseline clinical characteristics of the 3 groups are presented in Table 1. Among the patients enrolled, the mean age was 53 (SD 11) years, mean diabetes duration was 11.3 (SD 6.1) years, 8.9% (21/234) had type 1 diabetes, 38.0% (89/234) were female, 46.2% (108/234) had junior college or higher education, and 58.1% (136/234) were working. The average BMI at baseline was 25.03 (SD 3.36) kg/m^2, and the average FPG and HbA$_{1c}$ levels were 10.02 (SD 3.03) mmol/L and 9.45% (SD 1.36%), respectively.

Table 1. Baseline characteristics of study participants of the 3 groups.

Baseline characteristics	Group A[a]	Group B[b]	Group C[c]
Gender (men/women), n	78 (49/29)	78 (50/28)	78(46/32)
Age (years), mean (SD)	55 (11)	52 (10)	52 (12)
Diabetes duration (years), mean (SD)	12.7 (7.1)	11.2 (5.6)	10.1 (5.5)
Type 1 diabetes, n (%)	7 (9)	7 (9)	7 (9)
Body mass index (kg/m^2), mean (SD)	24.63 (2.79)	25.36 (3.32)	25.09 (3.88)
Waist circumference (cm), mean (SD)	85.2 (7.7)	87.2 (8.9)	87.0 (10.6)
Blood pressure (mmHg), mean (SD)			
Systolic	127 (13)	127 (12)	127 (15)
Diastolic	79 (9)	81 (9)	80 (7)
Fasting plasma glucose (mmol/L), mean (SD)	9.86 (3.17)	10.06 (3.03)	10.14 (2.92)
Glycated hemoglobin (%), mean (SD)	9.27 (1.25)	9.46 (1.18)	9.58 (1.62)
Total cholesterol (mmol/L), mean (SD)	4.92 (1.10)	4.65 (0.87)	5.01 (0.79)
Triglyceride (mmol/L), mean (SD)	1.84 (1.05)	1.87 (1.14)	2.39 (1.63)
Lipoprotein density (mmol/L), mean (SD)			
High	1.11 (0.27)	1.08 (0.27)	1.07 (0.28)
Low	2.97 (0.94)	2.79 (0.75)	2.90 (0.79)
Aminotransferase (U/L), mean (SD)			
Alanine	27 (19)	28 (24)	35 (28)
Aspartate	21 (8)	22 (12)	25 (15)
Gamma-glutamyl transpeptidase (U/L), mean (SD)	36 (21)	39 (25)	40 (23)
Creatinine (µmol/L), mean (SD)	65 (16)	64 (13)	62 (13)
Uric acid (µmol/L), mean (SD)	303 (67)	305 (78)	305 (78)
Education, n (%)			
Junior college or higher	32 (41)	38 (48.)	38 (48)
High school	27 (34)	25 (32)	28 (35)
Primary school or less	19 (24)	15 (19)	12 (15)
Working, n (%)	39 (50)	50 (64)	47 (60)
Insulin, n (%)	33 (42)	33 (42)	41 (52)
Hypertension, n (%)	29 (37)	23 (29)	28 (35)
Current smoker, n (%)	18 (23)	13 (16)	14 (17)
Current drinker, n (%)	13 (16)	6 (7)	11 (14)

[a] Group A: control group.

[b] Group B: app self-management group.

[c] Group C: app interactive management group.

Primary Study Outcomes: The Change in the Glycated Hemoglobin Level

Only a significant difference in HbA_{1c} levels was observed between groups A and C at baseline (average change in HbA_{1c} in groups A vs group C: 9.14% [SD 1.13%] vs 9.60% [SD 1.44%]; $t_{125}=-1.995$; *P*=.048). Compared with baseline, all 3 groups showed significant decreases in HbA_{1c} levels at both months 3 and 6 (all *P*<.001). At month 3, the mean HbA_{1c} levels in groups A, B, and C were 8.12% (SD 1.21%), 7.94% (SD 1.35%), and 7.59% (SD 0.95%), respectively. Intergroup comparisons only showed a significant difference between groups A and C ($t_{125}=2.732$; *P*=.007). At month 6, the mean HbA_{1c} levels in groups A, B, and C were 7.80% (SD 1.14%), 8.04% (SD 1.38%), and 7.57% (SD 1.18%), respectively. Intergroup comparisons showed that HbA_{1c} levels in group C were significantly lower than those in group B ($t_{129}=2.072$; *P*=.04; Multimedia Appendix 1).

To further compare the improvement of glycemic control in the 3 different management groups, we analyzed the mean HbA$_{1c}$ level reduction from baseline to months 3 and 6. We found that at the end of month 3, the average decrease in HbA$_{1c}$ levels in group C was larger than that in groups A and B (group C vs group A: −2.00% [SD 1.45%] vs −1.01% [SD 1.42%]; t_{125}=3.876; P<.001; group C vs group B: −2.00% [SD 1.45%] vs −1.46% [SD 1.52%]; t_{129}=2.091; P=.04). At month 6, the HbA$_{1c}$ reduction in group C was still significantly larger than that in groups A and B (group C vs group A: −2.03% [SD 1.56%] vs −1.34% [SD 1.50%]; t_{125}=2.515; P=.01; group C vs group B: −2.03% [SD 1.56%] vs −1.37% [SD 1.48%]; t_{129}=2.488; P=.01). However, no differences were observed between groups B and A at both months 3 and 6 (both P>.05; Multimedia Appendix 1).

Multivariate linear regression analyses defined HbA$_{1c}$ reduction as a dependent variable and the group A or group B as reference. After adjustment of age, gender, W, BMI, diabetes duration, systolic blood pressure, diastolic blood pressure, TC, TG, HDL-c, and LDL-c, the results showed whether at months 3 or 6, group C was associated with the larger reduction of HbA$_{1c}$, compared with groups A and B (all P<.05). But this association was not significant between groups B and A at both months 3 and 6 (both P>.05; Table 2).

Table 2. Multivariate linear regression analyses of glycated hemoglobin reduction.[a]

Diabetes management models	Beta value	SE	Standardized beta (95% CI)	P value
At 3 months				
Model 1				
Group A[b] (reference)	—[c]	—	—	—
Group B[d]	−.242	0.259	−.076 (−0.752 to −0.268)	.35
Group C[e]	−.826	0.260	−.258 (−1.339 to −0.314)	.002
Model 2				
Group B (reference)	—	—	—	—
Group C	−.585	0.250	−.182 (−1.078 to −0.092)	.02
At 6 months				
Model 3				
Group A (reference)	—	—	—	—
Group B	.097	0.267	.030 (−0.431 to 0.625)	.72
Group C	−.553	0.269	−.169 (−1.083 to −0.023)	.04
Model 4				
Group B (reference)	—	—	—	—
Group C	−.650	0.258	−.199 (−1.159 to −0.140)	.01

[a] Independent variables originally included the following: age, gender, W, BMI, diabetes duration, systolic blood pressure, diastolic blood pressure, TC, TG, HDL-c, and LDL-c.

[b] Group A: control group.

[c] Do not have statistical data.

[d] Group B: app self-management group.

[e] Group C: app interactive management group.

Secondary Study Outcomes: Fasting Plasma Glucose, Body Weight, and Lipid Levels

At the end of month 3, group C experienced significant improvement in FPG levels (mean FPG at month 3 vs baseline: 8.12 [SD 2.07] mmol/L vs 9.91 [SD 2.93] mmol/L; t_{63}=4.251; P<.001), whereas the difference was not significant in both groups A and B (P=.86 and P=.21, respectively). Intergroup comparisons found that the FPG level in group C was lower than that in groups A and B (mean FPG in group C vs group A: 8.12 [SD 2.07] mmol/L vs 9.10 [SD 2.78] mmol/L; t_{125}=2.235; P=.03; group C vs group B: 8.12 [SD 2.07] mmol/L vs 9.14 [SD 2.61] mmol/L; t_{129}=2.469; P=.02). At month 6, still only group C had a significantly lower FPG level than that at baseline (mean FPG at month 6 vs baseline: 7.87 [SD 2.07] mmol/L vs 9.91 [SD 2.93] mmol/L; t_{63}=4.920; P<.001). The FPG level in group C was still significantly lower than that in both groups B and A at month 6 (mean FPG in group C vs group A: 7.87 [SD 2.07] mmol/L vs 8.91 [SD 2.81] mmol/L; t_{125}=2.372; P=.02; group C vs group B: 7.87 [SD 2.07] mmol/L vs 9.08 [SD 2.91] mmol/L; t_{129}=2.731; P=.007). No differences were observed between groups B and A at both months 3 and 6 (both P>.05).

All 3 groups had better control of HDL-c levels at both months 3 and 6 (all P<.05). Group C had better control of TG and HDL-c levels at both months 3 and 6 compared with those at baseline (all *P*<.05). There were no significant differences among the 3 groups for body weight, TC, TG, and LDL-c at both months 3 and 6 (all *P*>.05; Multimedia Appendix 2).

Blood Glucose Test Rate, Frequency of App Usage, and Guiding Time

No significant differences in the BG test rate were reported among the 3 groups at both months 3 and 6. After 3 months of follow-up, the average weekly frequencies of BG test rates in groups A, B, and C were 10.9 (SD 7.8) times, 10.1 (SD 9.5) times, and 11.1 (SD 8.9) times, respectively, and were 10.5 (SD 7.5) times, 10.1 (SD 9.3) times, and 9.4 (SD 6.9) times at the end of month 6, respectively.

The frequencies of app usage in groups B and C were 10.7 (SD 9.5) times per week in group B and 11.1 (SD 7.3) times per week in group C, and the difference was not significant (*P*=.83).

In group C, each patient received an average of 30.5 (SD 3.6) times of interactive management during the whole follow-up, with an average guiding time of 458 (SD 54) min.

Adverse Events

The major adverse event in this study was hypoglycemia. Hypoglycemia was defined as a BG ≤3.9 mmol/L. At the end of month 6, the frequency of hypoglycemia was similar in the 3 groups (average frequency in group A: 6.9 [SD 6.3] times per person, group B: 6.7 [SD 6.2] times per person, and group C: 5.7 [SD 4.9] times per person). During the follow-up, none of the patients dropped out because of hypoglycemia.

Discussion

Summary of Principal Findings

This study found that the app interactive management group had a greater improvement in HbA_{1c} levels compared with both the app self-management and control groups. However, no significant differences were observed between the app self-management and control groups in the reduction of HbA_{1c} levels, indicating that when using the app for diabetes management, only self-management is not enough, and the combination with interactive management can provide better glycemic control and a longer effect.

Recent studies have shown that a smartphone-based app was a feasible and an effective tool for diabetes management [4,7,18-20]. Waki et al [21] used an app named *DialBetics* in a 3-month randomized study, which enrolled 54 patients with type 2 diabetes, and found that HbA_{1c} decreased with an average of 0.4% (from 7.1% [SD 1.0%] to 6.7% [SD 0.7%]) in the DialBetics group, whereas it increased with an average of 0.1% (from 7.0% [SD 0.9%] to 7.1% [SD 1.1%]) in the non-DialBetics group. Another randomized trial conducted in 185 Chinese patients with type 2 diabetes also found that the implementation of the app *Diabetes-Carer* was effective at improving the proportion of type 2 diabetes patients with a HbA_{1c} <7% [8]. In this study, consistent with the previous studies, the app interactive management group had a better improvement in HbA_{1c} levels compared with both the app self-management and control groups after 6 months of follow-up, however, no significant differences were observed between the app self-management and control groups at both months 3 and 6. These results indicated that the effect of app self-management may not be significantly superior to usual care. Limited by the large number of diabetes patients but a shortage of medical staff in China, clinicians and nurses always lack time to provide normative and continuous management for diabetes patients. In addition, test strips are not covered by most health care insurances, which may cause a heavy financial burden for most of the patients. Considering these factors, this study also provided equally basic diabetes education to the control group and provided adequate test strips to all patients for free. Therefore, the benefits of glycemic control may be because of the management in diabetes patients themselves rather than the unique role of the app. In addition, the better control of BG in the app interactive management group than the control and app self-management groups might be able to reflect the importance of guidance rather than the provision of free test strips only. With better control of BG, patient's health and quality of life might also improve.

In most of the previous diabetes management–related apps, clinicians could view the data and queries uploaded by patients on the app platform; however, the interventions were limited to drug adjustments in most of the cases [5,17,22]. However, lifestyle adjustments, including healthy diet and regular exercise, are equally important for glycemic control and prevention of diabetes-related complications [23-26]. Owing to a shortage of medical staff in China, it is very difficult to provide comprehensive and effective guidance to every diabetes patient. Therefore, based on the use of Welltang, we introduced a third-party professional health care team to actively interact with patients online to provide a full range of guidance. The results showed that after 6 months of follow-up, HbA_{1c} levels in group C had decreased by an average of 2.03%, which was significantly higher than that in group B, with an average decrease of 1.37%. In addition, compared with that at baseline, group C achieved better control of TG and HDL-c levels at both months 3 and 6, whereas the differences were not significant in group B. These findings indicated that app self-management combined with a professional health team could achieve better glycemic and lipid control. The interactive management model may be one of the models that truly promote diabetes management in the future.

In addition, we also found that in the third month of follow-up, all 3 groups showed significant decreases in HbA_{1c} levels. However, in the following 3 months, there was no significant improvement in HbA_{1c} levels. In group C, the HbA_{1c} level decreased an average of 0.03%, whereas it increased an average of 0.09% in group B. Interestingly, in group A, the HbA_{1c} level decreased an average of 0.33%. Our results indicated that the app was able to achieve a quick and effective improvement in HbA_{1c} levels in a short time. However, in the following 3 months, the effects appear to have a *platform period*, and group A even had a nearly equal effect compared with group B. Similar phenomena have been observed in previous studies [8,27]. Interestingly, in a review of diabetes education, researchers also found that group and individual education had an equal impact on HbA_{1c} at 12 to 18 months [28]. Patients' inertia after receiving management for a relatively long time and different glycemic control targets from clinicians may contribute to this phenomenon.

In this trial, each participant was equipped with a BG meter and sufficient test strips. During the follow-up, the frequency of SMBG in the 3 groups was almost the same, which was approximately 11 times a week. Web-based care management in patients with poorly controlled diabetes showed that a larger number of website SMBG data uploads was associated with a larger decline in HbA_{1c} [29]. Another study *Engaging and Motivating Patients Online With Enhanced Resources for Diabetes*, which was aimed to evaluate an online disease management system supporting patients with uncontrolled type 2 diabetes, also demonstrated that participants who tested their glucose at home and uploaded their results more often were more likely to have improved at 6 and 12 months than those who did not [2]. In this study, group C had a full-time third-party diabetes health team reviewing all patients' uploaded data every week and making recommendations about diet and exercise management, which could help further improve glycemic control.

Limitations

There are still some limitations in this study. First, it was a single-center study, and the follow-up duration was only 6 months. Considering the chronic and long-term characteristics of diabetes, the study was unable to assess the long-term effects of a smartphone-based app on diabetes management; further multicenter studies with longer follow-up are needed to evaluate the long-term benefits of smartphone apps on diabetes management. Second, owing to the trial requiring that patients be able to use a smartphone phone, only those aged less than 65 years were enrolled. The results may not entirely reflect the characteristics of all diabetes populations. Third, the sample of type 1 diabetes patients in this study was small; further studies in different types of diabetes are needed to provide more detailed results. Finally, this study also provided equally basic diabetes education and adequate test strips to the control group, which might cause the control condition to not be a true treatment as usual condition.

Conclusions

In conclusion, we found that the effect of app self-management alone in Chinese diabetes patients with poor glycemic control was not superior to routine management, and the combination with interactive management can help achieve rapid and sustained glycemic control.

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Authors' Contributions

YB and JZ designed the study. LZ, HY, and JP helped with recruitment of the participants. WZ and YS collected the data. LZ and XH performed the statistical analysis and wrote the paper. YB and JZ revised the paper and contributed to the discussion. LZ and XH contributed equally to this paper and were the guarantors.

Conflicts of Interest

None declared.

Multimedia Appendix 1
(A) Glycated hemoglobin (HbA_{1c}) levels during 6 months in the 3 groups. (B) The average reductions of HbA_{1c} levels during 6 months in the 3 groups. Group A: control group, Group B: app self-management group, and Group C: app interactive management group. HbA_{1c}: glycated hemoglobin.
[PNG File , 125 KB - jmir_v21i12e15401_app1.png]

Multimedia Appendix 2
Levels of fasting plasma glucose, Body Weight and Lipids during the follow-up.
[DOCX File , 19 KB - jmir_v21i12e15401_app2.docx]

Multimedia Appendix 3
CONSORT-EHEALTH checklist (V1.6.1).
[PDF File (Adobe PDF File), 301 KB - jmir_v21i12e15401_app3.pdf]

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Abbreviations

BG: blood glucose
BMI: body mass index
FPG: fasting plasma glucose
HbA$_{1c}$: glycated hemoglobin
HDL-c: high-density lipoprotein cholesterol
LDL-c: low-density lipoprotein cholesterol
SMBG: self-monitoring of blood glucose
TC: total cholesterol
TG: triglyceride
W: waist circumference

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Original Paper

Peer Mentorship via Mobile Phones for Newly Diagnosed HIV-Positive Youths in Clinic Care in Khayelitsha, South Africa: Mixed Methods Study

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Abstract

Background: Youths in South Africa are poor utilizers of HIV health services. Medecins Sans Frontieres has been piloting youth-adapted services at a youth clinic in Khayelitsha, including a peer virtual mentorship program over mobile phones, piloted from March 2015 to May 2016.

Objective: The objective of this study was to evaluate the effect of the peer mentorship program on youth engagement with HIV services and explore the acceptability of the program to both mentors and mentees.

Methods: Antiretroviral initiation, retention in care (RIC), and viral load suppression were compared between youths engaged in the virtual mentorship program and two matched controls. In-depth interviews were also conducted for 5 mentors and 5 mentees to explore acceptability and impact of the program.

Results: A total of 40 youths were recruited into the virtual mentorship program over the study period. Of these, data were obtained for 35 and 2 matched controls were randomly sampled for each. There was no difference in baseline demographics (eg, age, gender, and CD4 count). Mentees had increased antiretroviral initiation (28/35, 80% vs 30/70, 42% in matched controls) and viral load completion (28/35, 80% vs 32/70, 45%); however, no differences were found in viral load suppression or RIC at 6 or 12 months. Mentors reported being motivated to participate in the program because of previous personal struggles with HIV and a desire to help their peers. Mentees reported fears of disclosure and lack of acceptance of their status as barrier to accessing services, but they felt free to talk to their mentors, valued the mentorship program, and indicated a preference for phone calls.

Conclusions: Peer mentorship in youths is acceptable to both mentors and mentees and appears to increase linkage to care and viral load completion rates.

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KEYWORDS

youth; HIV; peer influence; retention in care; mobile phone; patient navigator

Introduction

HIV in Youths in South Africa

There are an estimated 20 million youths aged 15 to 25 years in South Africa according to the 2011 census. In 2012, only 50% of the youths knew their HIV status [1]. Of the youths that test positive (estimated at 7%) [2], only 28% are accessing antiretroviral therapy (ART), 83% of which link to and are retained in care in the first 2 years and 81% of which achieve viral load suppression [3]. Adapting services to be youth-friendly overcomes many of the barriers with youths accessing care [4,5], and hence, in the urban informal settlement of Khayelitsha, Medecins Sans Frontieres (MSF) supports a stand-alone youth-only clinic, with youth-adapted services, including in-facility youth-friendly adherence clubs, point-of-care CD4 testing, and young counselors. This youth-friendly model of care has managed to achieve 50% ART initiation rates [6], an improvement on national figures, but still short of the World Health Organization's 90-90-90 goals. Furthermore, many youths still start ART late in the course of HIV disease, even if their status is known, leading to a poorer outcome [7].

Youths and the Role of HIV-Positive Peers

One measure that can increase linkage to care in newly diagnosed patients is to link them to peers living with HIV. The role of the peer is to act as a navigator through the health system, provide peer support and basic counseling, and visit the patient to encourage return to care [8]. Just 1 visit from a navigator can increase long-term linkage to care substantially [8]. Using navigators can be effective in youth-cohorts [9], not only for linkage to care but also for peer-to-peer support and health promotion [10]; however, there are high potential stigma and disclosure problems among youths (from family, friends, and the community), especially with home visits, as many youths have not disclosed their status to their family [11,12].

Youths and Mobile Technology

The use of mobile technology for health-related functions by HIV-positive youths is increasingly common [13]. Primarily, mobile phones have been used to disseminate youth-adapted health information, link youths to health care services [14], and provide peer support networks. The mobile chat app platform Mixit has been used in South Africa for a variety of HIV- and health-related interventions targeting youths, from digital counseling support to health promotion [15]. The platform is principally chat room–based, with either public chat rooms or password-protected private ones, and also includes functionality such as quizzes and video content; however, since the introduction of more popular social media platforms such as Facebook, it has reduced in popularity substantially [16]. In South Africa, youths have expressed a desire to receive health information and health services via mobile technologies [15], and in 2012, MSF introduced mobile phone–based support groups (WhatsApp group chat rooms) ,to supplement existing in-person youth-adherence clubs , which were frequently used and valued by the youths [16].

The Virtual Mentors Program

On the back of this success, a peer-to-peer mobile phone–based system, known as the Virtual Mentors program, was introduced in 2015 to link newly diagnosed youths with stable youths in care. The aim of this program was to determine if peer-to-peer mentorship, specifically between newly diagnosed HIV-positive youths and HIV-positive youths stable in care, could be successfully implemented using mobile phones as the primary means of communication. This virtual mentor approach catered more strongly toward the mobile phone–based online communication desires of the youths [17]. It also obviated the need for a physical home visit.

Recruitment and Role of Mentors

Virtual mentors were recruited annually from existing HIV youth-adherence clubs, on a voluntary basis, and underwent a 1-day training session conducted by MSF to capacitate them on their roles as navigators. Mentors could volunteer for more than 1 year, a minimum of 6 mentors were active at any given time, and a total of 19 mentors were used throughout the study. The virtual mentor would interact with the mentee via a mobile interface (SMS text messaging, call, or WhatsApp messenger) and was provided with 50 South African Rand (approximately US $3.50) per mentee to cover any data or airtime costs. The mentor was required to send 2 greeting messages to the mentee upon receiving their contact details. If the mentee did not respond after 3 days, the mentor then contacted the counselor to confirm the contact details of the mentee, and if these were correct, they informed the counselor that their mentee had not responded.

Once the mentor had made contact with the mentee, there were no stringent guidelines for their interaction (duration or content); however, mentors were provided with a messaging template (Multimedia Appendix 1) to guide them in their interactions with the mentee, which stipulated the minimum required engagement. The mentorship would conclude with the mentor inviting the mentee to attend their next HIV youth-adherence club. By visiting the mentor's club, the mentee got an idea of what the youth-adherence club entails and would potentially be encouraged to join their own youth-adherence club. The youth-adherence club visit date also acted as a fixed date for the termination of the mentorship program, and as such, mentees could receive anywhere from 2 to 8 weeks of mentorship depending on their recruitment date, although continued communication beyond this point remained an option if the mentor so desired or if the counselor felt it necessary and requested it of the mentor.

Recruitment of Mentees

All patients who were aged between 12 and 25 years, who were newly diagnosed HIV positive at either clinic site, who at diagnosis either did not agree to start ART or were ineligible for treatment based on CD4 guidelines, and who declined to join an HIV youth-adherence club were eligible for the study. The counselor performing the HIV test offered the option of a peer mentor and would explain to the patient that the mentor was a young person also living with HIV who attended the clinic, would not come to their place of residence, and would not disclose their status. Consenting patients were added to a mentee sign-up sheet, which included their name, contact details, and preferred platform of communication (eg, WhatsApp and SMS). Mentees were then assigned to appropriate mentors by the youth-counselor coordinator, who attempted as much as possible to match mentors and mentees based on similar demographics or circumstances (eg, a pregnant mentee with a woman who had 1 or more children).

This paper investigates whether the virtual mentorship program was acceptable to youths, both mentors and mentees, through in-depth interviews and describes the mentees' HIV- and ART-related outcomes in comparison with the matched controls.

Methods

Study Design

A mixed methods design was employed. A matched case-control quantitative component was used to assess if the virtual mentorship increased ART initiation of the newly diagnosed patients and positively affected their retention in care (RIC). An in-depth qualitative interview component was used to determine if the mobile phone mode of communication was a preferable means of peer support for the youths.

Study Setting

The study was conducted at 2 stand-alone youth clinics in a high HIV prevalence context, the periurban informal settlement of Khayelitsha, Cape Town. The study was conducted from March 11, 2015, to May 24, 2016. This study was approved by the University of Cape Town's Human Research Ethics Committee (Reference: 245/2016).

Descriptive Data Collection and Analysis

Descriptive data for the virtual mentees cohort were collected from the Prehmis electronic medical record database, including demographic, headcount, and RIC statistics. Viral load data were collected through direct lookup of patient data via the National Health Laboratory Service's online portal. Patient clinic folder audits were conducted for any missing data fields.

For each virtual mentee analyzed, we selected 2 matched controls who tested positive at the same facility. Mentees were matched to the 2 patients with the nearest HIV counseling and testing (HCT) dates, without replacement. All patients with missing HCT data were dropped. The outcomes measured are detailed in Table 1.

No statistical comparisons were calculated between the intervention group and the matched controls, which are presented as an approximate indication of the outcomes of youths in standard of care.

Table 1. Descriptive data outcomes measured in mentees and matched controls.

Outcome to be measured	Calculation
Linkage to ART[a] care	Number of patients who tested positive and initiated ART/number of patients tested positive
Median time to linkage to ART care	Of those who initiated ART, difference between the date of HIV counseling and testing and the date of ART initiation
Median time out of care pre-ART	Of those who did not link within the first 6 months, total number of days late for pre-ART appointments
Retention in care on ART	Number of patients retained in care at 6 and 12 months/number of patients who initiated ART
Viral load completion	Number of viral load results available/number due for a viral load at 4 months
Viral load suppression	Number of patients with suppressed viral load (<400 copies/ml)/number of viral load results available

[a] ART: antiretroviral therapy.

In-Depth Interviews and Analysis

Participants were selected for in-depth interviews based on their age and gender to get a representative sample of all the mentees and mentors recruited and to ensure that at least one male and one female and an older (>18 years) and a younger (<18 years) participant were included. The in-depth interviews followed the guide outlined in Multimedia Appendix 2. The in-depth interviews were held in a private room at the clinic, at a location of the mentee's convenience, or telephonically. Written informed consent was obtained for all participants, or verbal informed consent was obtained in the case of telephonic interviews. Interviews were conducted in a mixture of English and Xhosa; however, audio transcripts of the interviews were transcribed into English by the interviewer before analysis. The in-depth interviews were analyzed through a grounded theory approach. Transcripts were coded for emergent themes by 2 researchers. Lists of the emergent themes were then compared and condensed into key themes.

Results

Descriptive Data

A total of 40 youths were recruited into the Virtual Mentors program from March 2015 to May 2016. As detailed in Figure 1, 5 participants had missing HCT data and hence were excluded from analysis. Therefore, 70 matched controls with similar HCT dates were randomly drawn for comparison.

The mentees and the matched controls had similar demographic features and baseline CD4 counts, as detailed in Table 2.

Linkage to ART care at any point after diagnosis was substantially higher in the virtual mentees cohort (Figure 2 and Table 3). Both groups had very large ranges in terms of the number of days between diagnosis and initiation of ART. RIC on ART at both 6 and 12 months was similar for both groups. Both groups had similar viral load suppression at the 4-month stage; however, the virtual mentees cohort had a much higher viral load completion rate.

Figure 1. Exclusion criteria flow diagram. HCT: HIV counseling and testing; LTF: lost to follow-up; mo: months; RIC: retention in care; TFO: transferred out; ART: antiretroviral therapy.

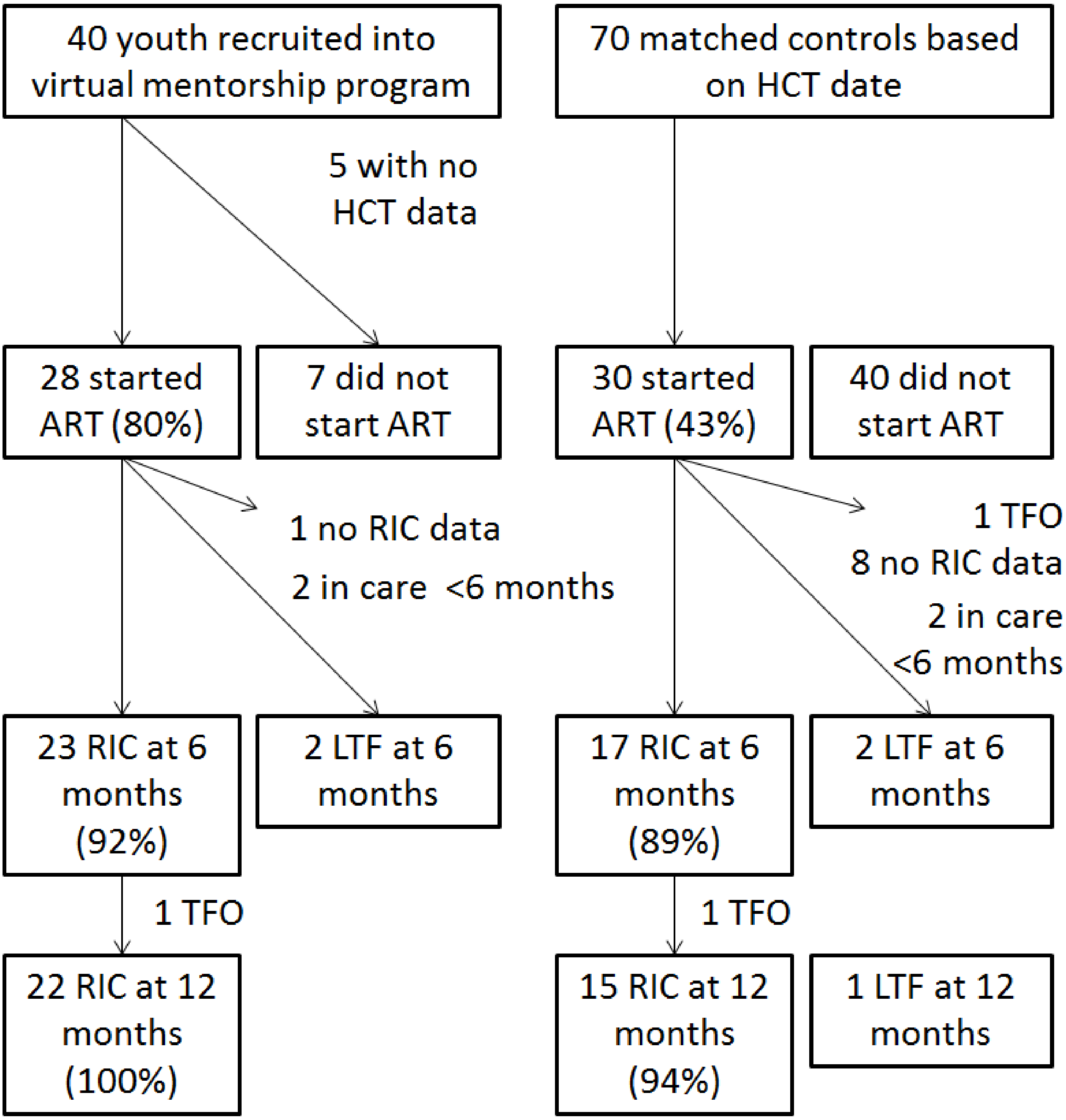

Table 2. Demographic data between groups.

Demographic	Virtual mentees cohort (N=40)	Matched controls cohort (N=70)
Gender, n (%)		
Male	2 (5)	6 (9)
Female	38 (95)	64 (91)
Age at diagnosis, median (IQR[a])	20 years 5 months (3 years 4 months)	22 years 7 months (3 years 6 months)
Baseline CD4, median (IQR); n	496 (378-592); 29	443 (307-638); 6

[a] IQR: interquartile range.

Figure 2. Antiviral therapy initiation, retention, and viral load completion by group. ART: antiretroviral therapy; VL 1: first viral load.

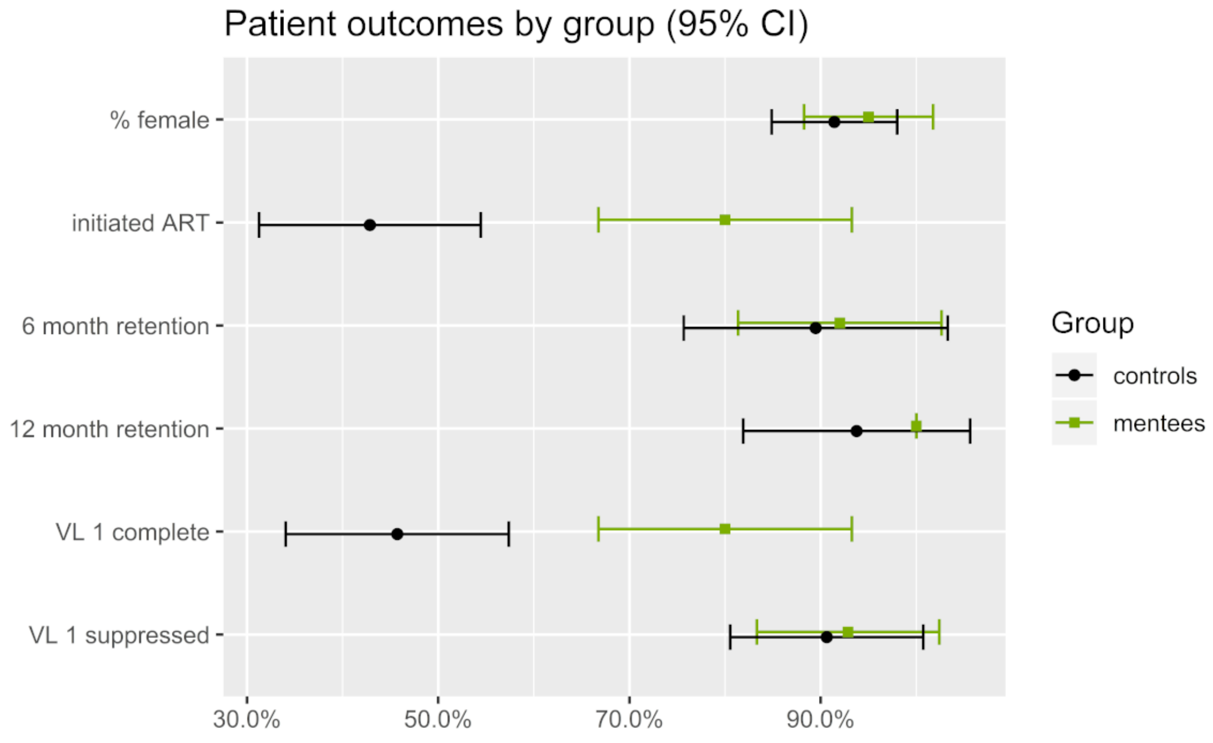

Table 3. Linkage, retention in care, and viral load outcomes.

Metric	Virtual mentors (VM)	Matched controls (MC)
Linkage to ART[a] care, n (%)	28 (80)	30 (43)
Of those linked, Days to linkage to ART care, median (IQR[b])	217.5 (32.5-467.75)	49.5 (7-333.25)
Days out of care pre-ART, median (IQR); n	38 (1-350); 17	200 (29-337.5); 11
Retention in care on ART at 6 months (for VM, N=45; for MC, N=19), n (%)	23 (92)	17 (89)
Retention in care on ART at 12 months (for VM, N=22; for MC, N=16), n (%)	22 (100)	15 (94)
First viral load completion (for VM, N=35; for MC, N=70), n (%)	28 (80)	32 (45)
First viral load suppression (<400 copies/ml; for VM, N=28; for MC, N=32), n (%)	26 (93)	29 (91)

[a] ART: antiretroviral therapy.

[b] IQR: interquartile range.

Qualitative Data

Mentors

In total, 2 themes emerged from discussion with the mentors: (1) most mentors felt motivated to be a mentor because of previous personal struggles with their HIV status and (2) mentors saw the value in having a peer to speak to when newly diagnosed:

> *I decided to be a mentor because I was once a victim or was diagnosed with something and it was not easy for me to speak to anyone.* [Participant 4]
>
> *You see so I decided to take this and change other scared children you see to take their treatment and accept their status it is not easy to accept all of this you would think that you will die same time and how will you disclose at home you even need a person to speak to and you will not have so at least when you have someone your age who will speak the same language as you, you would feel better that is why I decided to take a step forward and be able to mentor other children.* [Participant 1]

Mentees

In total, 5 themes emerged from the interviews with the mentees: (1) a lack of acceptance acted as a barrier to care, (2) a fear of accidental disclosure to the community, (3) mentees felt free to talk openly with their mentors, (4) mentees had a positive view of the mentors asking them questions, and (5) direct phone calls and face-to-face interactions between mentors and mentees was higher than expected.

First, there were 2 major issues identified as barriers to care for youths: (1) lack of acceptance of their HIV status and (2) fear of disclosure if they attended the clinic or the support groups:

> *Problem I am scared of people they always check what you coming to do so I am avoiding that.* [Participant 3]
>
> *I was scared of here at Site C there can be someone from my area who will identify me know about my HIV, and go tell my parents about my involvement in the group I was scare to be known my HIV status and I had not yet accepted my HIV positive status so it was hard to attend support group I felt like hiding myself at home and be unknown.* [Participant 2]

The mentees had a very positive regard for the mentorship program and reported being able to talk to their mentors about disclosure issues and accepting their HIV status. The 2 major themes emerging were feeling free to talk openly to the mentor and a positive view of the mentors asking them questions:

> *She use to call me and ask things that I wished they were being asked by my mom or my older sister or something then I would speak with her and like I was free with her.* [Participant 1]
>
> *We were chatting nicely since she was a mentor who was supporting people who wanted people to accept their condition she was supportive towards people.* [Participant 2]
>
> *She was all right conversing encouraged me saying when you are HIV positive there are a lot of people who survive if they eat their treatment correctly but if you are not taking your treatment correctly HIV can kill you.* [Participant 3]

Finally, the primary modes of communication between mentors and mentees skewed toward direct phone calls and also included face-to-face interactions:

> *Yes I used to call her when there is something I do not understand.* [Participant 3]
>
> *She constantly phoned me and encouraged me to come to the group but I could not because I was stressed.* [Participant 2]
>
> *Ha a we used to meet when I am not fetching pills or coming to the club like when she asked to see me like if have come to fetch pills today she would say ok she will be free at a certain time and ask me to come tomorrow if there is nothing I am doing so we can talk nicely then I would come so that is how we were meeting.* [Participant 5]

Discussion

Principal Findings

Virtual Mentorship May Increase Antiretroviral Therapy Initiation and Mentees Have Good Retention in Care

Traditional adult patient navigator programs do not work well in the case of youths [9]. Our study shows that adopting the patient navigator role to be more youth friendly, that is, using peers and platforms acceptable to youths, is effective at linking youths to ART care. Youth-friendly peer navigators have been used successfully as part of the Red Carpet Program in Kenya [9] and the Health Connectors project currently underway in South Africa. The Health Connectors project also incorporates a mobile health (mHealth) element to their peer navigation [18]. The Virtual Mentors program described here differs from these interventions in that it comprises only of a peer mentor interaction over a mobile phone for a limited length of time. It is less resource intensive than either the Red Carpet Program or the Health Connectors project; however, it still had a positive impact, with substantially more youths linking to ART care than controls. In the virtual mentors group, there does appear to be a longer delay before linkage to care, and this could be a bias in the selection of mentees for the program or a result of the program itself. Of those who did not link within the first 6 months, the mentees were less likely to miss a pre-ART clinic visit.

Virtual Mentorship Is Acceptable to the Youth Mentors and Mentees and Counselors

The use of mHealth for youths in South Africa is well documented and has generally been well accepted across a variety of interventions [15]. The youths reported liking the virtual mentorship program, as they found the peers relatable and inspiring, which allowed them to freely talk to and ask questions of their mentors.

The mentors themselves were pleased to do the mentorship, and none of them reported it being an undue burden or that they felt out of their depth or unable to provide peer support to the newly diagnosed youths.

Limitations

This study was limited by a small sample size. There were some challenges with sign up as only a small proportion of youths were signed up to the virtual mentorship program, given the large number of youths who were diagnosed positive at the clinic over the study period. It is unclear if these youths refused or if they were not offered the service.

The matched controls also displayed high levels of RIC, and these 2 factors made it difficult to elucidate any impact of the virtual mentors on long-term outcomes. Both the mentees and matched controls were also overwhelmingly female. This may limit the applicability of such a program to young males, a key population with poor access to HIV services; however, it is not indicative of a female preference for the program as the control group had a similar gender distribution.

Recruitment into the virtual mentees cohort was also at the discretion of both the counselor and the participant, and hence, there are likely strong selection biases at play. Counselors may have identified higher-risk individuals for recruitment into the program; conversely, participants with poor health-seeking behavior may have declined the services of a mentor. This may have biased both the virtual mentees cohort and the matched controls cohort (which either were not offered the service or refused). However, the lack of differences in baseline CD4 suggests that the youths accepting mentorship were at no higher or lower risk than the matched control.

There may have been a similar selection bias and recall bias for the in-depth interviews. Participants who defaulted treatment, or were not linked to care, were harder to contact and hence were underrepresented in the sample. So, it was difficult to understand the circumstances where the mentorship did not work.

Conclusions

A peer-to-peer navigator program for newly diagnosed HIV-positive youths, conducted via mobile phone, might have increased linkage to ART care but had no impact on RIC. Mentees believed the program to be beneficial and supportive, and the mentors implementing the intervention were happy to do it.

Implications for Policy and Practice

The benefit of community and peer health care workers in South Africa is well documented, and scale up of these services is a national policy [19]. Part of their role is to act as patient navigators [19-21]. There is also a greater recognition of the importance of adapting health care services to be youth friendly [22]. It is, therefore, vital that peer navigator services are also adapted to be youth-friendly. The virtual mentorship pilot presented in this paper has demonstrated a peer navigator approach, acceptable to both youth mentors and mentees, that could supplement or enhance any clinic wishing to implement youth-friendly services into their package of care.

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Authors' Contributions

DH designed and managed the study and was the lead author. ZM was responsible for implementation and qualitative evaluation of the program. TC assisted with quantitative evaluation of the program. PR was responsible for implementation of the program at the pilot sites. All authors contributed to the conceptualization of the study and provided feedback on the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Virtual mentors messaging template.
[DOCX File , 29 KB - jmir_v21i12e14012_app1.docx]

Multimedia Appendix 2
In-depth interview guide.
[DOC File , 27 KB - jmir_v21i12e14012_app2.doc]

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Abbreviations

ART: antiretroviral therapy
HCT: HIV counseling and testing
mHealth: mobile health
MSF: Medecins Sans Frontieres
RIC: retention in care

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Original Paper

Pregnancy-Related Information Seeking and Sharing in the Social Media Era Among Expectant Mothers: Qualitative Study

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Abstract

Background: Social media has become the most popular communication tool used by Chinese citizens, including expectant mothers. An increasing number of women have adopted various forms of social media channels, such as interactive websites, instant messaging, and mobile apps, to solve problems and obtain answers to queries during pregnancy. Although the use of the internet by pregnant women has been studied extensively worldwide, limited research exists that explores the changing social media usage habits in China, where the 1 child policy ended in 2015.

Objective: This study aimed to (1) present the status quo of pregnancy-related information seeking and sharing via social media among Chinese expectant mothers, (2) reveal the impact of social media usage, and (3) shed light on pregnancy-related health services delivered via social media channels.

Methods: A qualitative approach was employed to examine social media usage and its consequences on pregnant women. A total of 20 women who had conceived and were at various stages of pregnancy were interviewed from July 20 to August 10, 2017. Thematic analysis was conducted on the collected data to identify patterns in usage.

Results: Overall, 80% (16/20) of participants were aged in their 20s (mean 28.5 years [SD 4.3]). All had used social media for pregnancy-related purposes. For the seeking behavior, 18 codes were merged into 4 themes, namely, gravida, fetus, delivery, and the postpartum period; whereas for sharing behaviors, 10 codes were merged into 4 themes, namely, gravida, fetus, delivery, and caretaker. Lurking, small group sharing, bad news avoidance, and cross-checking were identified as the preferred patterns for using social media. Overall, 95% (19/20) of participants reported a positive mental impact from using social media during their pregnancy.

Conclusions: It is indisputable that social media has played an increasingly important role in supporting expectant mothers in China. The specific seeking and sharing patterns identified in this study indicate that the general quality of pregnancy-related information on social media, as well as Chinese culture toward pregnancy, is improving. The new themes that merge in pregnancy-related social media use represent a shift toward safe pregnancy and the promotion of a more enjoyable pregnancy. Future prenatal care should provide further information on services related to being comfortable during pregnancy and reducing the inequality of social media–based services caused by the digital divide.

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KEYWORDS

pregnant women; social media; information seeking; consumer health information; China

Introduction

Social Media Engagement in Pregnancy-Related Topics Worldwide

Pregnancy-related information is in great demand worldwide. A qualitative study conducted in the United States implied that pregnancy-related information, such as that relating to healthier lifestyles, childbirth, infant care, and being a good mother, were major unmet needs of pregnant women, where technologies for use during pregnancy could be significantly improved [1]. Similarly, China has faced such challenges because of its comparatively lower health literacy rates [2]. This situation has intensified since the termination of the 1 child policy in 2015, with the population of pregnant women being on the rise as well as their information needs; this is especially true in the case of older pregnant women.

The internet has been widely used as an effective tool to meet health information needs across the world, and pregnancy-related information is no exception [3,4]. A systematic review on the internet usage by pregnant women found that fetal development and nutrition during pregnancy were highly mentioned topics [3]. In China, pregnant women mainly evaluate the information obtained via the internet by consulting various online sources before drawing conclusions, and they perceive information found on the internet to be generally reliable [5]. With the evolution of internet-based technologies, social media has penetrated all walks of human life as well as prenatal care [6]. Social media is defined as “a group of Internet-based applications that build on the ideology and technological foundations of Web 2.0” [7,8], which enables the creation and exchange of information, allowing users to become the content generators rather than solely the receivers of content. Social media forms are not limited to websites but include blogs, online forums, online discussion boards, and various other apps or platforms. As an alternative source of pregnancy-related information, social media has become hugely popular as an instrument for obtaining desired health information, sharing concerns felt during pregnancy, and communicating with other pregnant women [9,10]. Compared with offline methods of communication, pregnancy-related information retrieved via social media is deemed much more convenient, detailed, practical, customized, and unbiased [9,11]. A survey conducted in Australia showed that almost three-quarters (73%) of expectant mothers had used pregnancy-related apps [12]. Similarly, the United States and European countries have evidenced the popularity of pregnancy-based social media usage [13,14]. In addition, several social media channels have featured *father-to-be* campaigns to encourage participation by expectant fathers during pregnancy [15].

Pregnancy-Related Engagement in China’s Social Media Platforms

In China, research into online pregnancy-related information retrieval is limited, with currently available research mainly focused on statistics obtained from websites and descriptions for specific geographic populations. Gao et al [5] explored pregnancy-related information searches in southeastern China and found that more highly educated women tended to assign higher credibility to online health information. In addition, they also noticed that a relatively low percentage of participants would discuss the online health information they had found with their caregiver or health professionals, in-person. A recent systematic review of available literature found a low presence of strong evidence for low- and middle-income countries in terms of the impact resulting from internet usage by pregnant women, considering their large volume of users [16,17]. In China, the most frequently used pregnancy-related apps are *MeetYou* and *BabyTree*. Various types of pregnancy-related information across different stages of child birth have been integrated into 1 software application, as along with the ability to search for health information and engage in interactive discussion forums and shopping.

It is recognized that pregnant women have individual health information needs and preferred sources for identifying this information. By accessing health information on social media, pregnant women become better informed about their health condition. An increasing number of studies have started to reveal the prevalence of social media usage by pregnant women, including their adoption, usage patterns, and impact. However, little analysis has been conducted on the current status quo of seeking and sharing pregnancy-related information on social media, in the context of China. Furthermore, most recent studies have focused on developed countries when exploring the functionality and rationality for social media usage by pregnant women. To fill this gap, this research extensively examined the search strategies, sharing patterns, and their impact on expectant mothers in China. As searching for suitable pregnancy-related information or sharing relevant pregnancy-related information is deemed important for expectant mothers, this study provided insight into how pregnant women in China use social media and its corresponding effects. By using the results of this study, enterprises with a special interest in pregnant women can better tailor their online services. The findings also encourage public or authoritative medical institutes to offer more personalized pregnancy-related information services via social media and other communicative tools.

Methods

To achieve the aims of this study, a qualitative methodology was adopted. Qualitative methods were chosen for their ability to obtain firsthand data that could shed light on the culture and context of online pregnancy-related information searches from the study population [18]. The consolidated criteria for reporting qualitative research checklist was adhered to when considering the most appropriate method of study [19].

Study Design

Interviews were targeted toward expectant mothers in China who use social media to obtain and synthesize information during pregnancy; this included exploring information seeking and sharing behaviors and their consequences. The inclusion criteria for interviewees were as follows: aged over 18 years, married, located in China, have known about their pregnancy for a period of at least one month, and used social media for pregnancy-related purposes at least once in the past month. The exclusion criteria were as follows: not residing in China, aged under 18 years, unmarried, have known about their pregnancy for a period of less than one month, and did not use social media for pregnancy-related purposes at all during the past month. Participants were selected based on a snowball sampling process. Initially, potential participants were solicited from the pools of acquaintances of the researchers via social media posts (eg, QQ and WeChat), whereas new participants joined if existing participants nominated participants that met the inclusion criteria. This study followed common practices in China for protecting the privacy of participants. As a recent quantitative study [20] revealed that young, first time expectant mothers, with a higher education level (ie, bachelor's degree or above) were more likely to use social media–based pregnancy apps, we prioritized participants who were of a young age, had a higher education degree, and were experiencing pregnancy for the first time.

The interviews were completed by the fifth author (HRR), who is a young lecturer in a university and mother of a 3-year-old child. She has used social media for more than 10 years, with extensive experience of seeking and sharing pregnancy-related information on social media across different pregnancy cycles. Before participation, all participants were informed of the study's aim, process, and the benefits and potential risks of partaking in the research. All participants agreed to participate in the interview process and consented to the interview data being recorded anonymously. All interviews were conducted face-to-face at a comfortable place for the participants, mostly near or at their homes. The interview phase was conducted from July 20 to August 10, 2017. Each interview lasted for at least 30 min.

Data Collection and Analysis

All interviews were conducted in Chinese. Interviews were recorded and were transcribed later for analysis. The interview framework included the following areas of questioning: (1) participants' description of their background and frequency of using social media during pregnancy, (2) description of their social media use, particularly on pregnancy-related information seeking and sharing, and (3) the reported impact of social media usage during pregnancy. Questioning began by asking the participants' demographic information, such as age, educational level, occupation, pregnancy cycle, and their daily use of social media during their pregnancy. The focus then shifted to their experience of pregnancy-related information seeking and sharing on social media channels. In this section, our study was interested in the types of pregnancy-related information that were sought or shared, including their preferred social media channels and with whom. The participants were also asked to recall a situation when they sought or shared their pregnancy-related information on social media. In the last section, participants were queried about their personal reflection on the social media use for pregnancy-related purposes. This focused on their physical health and mental health as well as their relationship with caretakers. Before each interview, a list of pseudonyms was provided to the participants to select 1 and use them for documentation to protect their identity, and the researchers made all efforts to secure the participants' privacy throughout the entire study. Table 1 shows the characteristics of the participants.

All participants were in their first marriage. Furthermore, 80% (16/20) were aged in their 20s (mean 28.5 years [SD 4.3]), with 1 participant aged 20 years and 1 participant over 40 years. In this study, most participants were primigravida (pregnant for the first time; 18/20, 90%). In terms of the stage of pregnancy cycle, many (16/20, 80%) were in their last trimester (over 28 weeks), whereas only 1 woman was in the early stage of pregnancy. With regard to their educational background, 60% (12/20) had obtained at least a bachelor's degree, whereas 20% (4/20) had achieved a high school–level education or equivalent. Overall, 65% (13/20) of participants were employed, with their occupation varying from primary, middle, high, or vocational school teacher; university lecturer; support staff; assistant researcher; bank associate; accountant; to traffic police officer. In addition, with regard to monthly family income, 50% (10/20) of participants earned over 10,000 Renminbi (RMB), whereas 5 (25%) participants earned less than 10,000 RMB.

For the analysis of the seeking and sharing behaviors, thematic analysis of the transcript was conducted using recommended procedures [21], which included (1) familiarization with the data, (2) generation of initial codes, (3) searching for codes, (4) reviewing themes, (5) defining and naming themes, and (6) writing the results. An initial coding framework was developed with randomly selected texts from 5 interviews and the codebook was updated after each analysis. The codes were checked rigorously to ensure their fit to the original text. The codes with shared themes were merged and modified, if required.

After the analysis of the 19th interview transcript, new data did not emerge from the data collection. To ensure confidence and verification of the data saturation, the researchers followed a recent practice [22] and conducted another interview for confirmation. For the 20th interview, no additional codes were generated. It was clear that the data provided a clear saturation point and the interviews were then ceased. In total, 21 codes and 5 themes were identified after a redundancy check and discussion.

Table 1. Characteristics of the participants (N=20).

Characteristics	Participants, n (%)
Age (years)	
18-20	1 (5)
21-30	16 (80)
31-40	2 (10)
>40	1 (5)
Education level	
Bachelor’s degree or above	12 (60)
College degree	3 (15)
High school or equivalent	4 (20)
Unrevealed	1 (5)
Occupation	
Employed[a]	13 (65)
Unemployed/housewife	7 (35)
Monthly family income (Renminbi)	
≤10,000	5 (25)
10,001-15,000	6 (30)
15,001-20,000	4 (20)
Unrevealed	5 (25)
Childbearing history/parity	
Primipara	18 (90)
Multipara	2 (10)
Pregnancy cycle	
First trimester (≤12 weeks)	1 (5)
Second trimester (13-27 weeks)	3 (15)
Last trimester (>27 weeks)	16 (80)

[a] Their occupations were teachers (n=8), university support staff (n=1), research assistant (n=1), bank associate (n=1), accountant (n=1), and traffic police (n=1).

Results

General Overview

All participants reported using social media for pregnancy-related purposes, but with different intensities. When asked about their frequency of use in the past month, 80% (17/20) reported that they used social media almost every day and the others reported less usage frequency, ranging from every other day to 3 to 4 days interval. The highly mentioned instant messaging platforms were WeChat and Weibo, whereas pregnancy apps were *BabyTree* and *MeetYou*. With regard to the seeking behavior, 18 codes were merged into 4 themes, namely gravida, fetus, delivery, and postpartum period. We identified 7 subcategories within the gravida category, 4 subcategories within the fetus category, 4 subcategories within the delivery category, and 3 subcategories within the postpartum period category. Table 2 presents these details. Among them, the most frequently sought information was related to fetal development, with 90% (18/20) of participants mentioning this while using social media during pregnancy. Nutrition during the postpartum period was the least mentioned, with 10% (2/20) of participants recalling their search. In addition, pregnancy taboo, nutrition during pregnancy, sex of fetus, and pregnancy-related complications were highly cited.

Table 2. Pregnancy-related information seeking categories, subcategories, and excerpted examples.

Categories	Number of mentions by participants	Example quotes
Gravida		
Pregnancy taboo	15	"I learned that I can eat shrimp but not crab via the *Health Mothers*." (WeChat public account)
Nutrition during pregnancy	12	"I asked in the WeChat group what vitamins they were supplied."
Pregnancy-related complications	10	"I was too frightened of encountering gestational diabetes, and I could not help but search it everywhere…"
Antenatal care	8	"The schedule of pregnancy check on *MeetYou* was what I wanted exactly."
Pregnancy symptoms	6	"Although the doctor said that intense vomiting is not a problem, I still searched comments from others with similar conditions for comfort."
Amusement and sports	6	"Sometimes I just felt bored and browsed other gravida's posts to see if they had anything interesting happening."
Super-cool pregnancy-related goods	3	"I found a comfort pillow on the *Little Red Book*. It was worth it!"
Fetus		
Fetal development	18	"…It informed me when my baby began to have a heartbeat and could hear me…I followed the app since my pregnancy."
Sex of fetus	12	"The doctor did not tell me, I searched clues from other mothers' experiences."
Antenatal training	8	"I played the music in *Baby Tree*."
Baby's name	7	"I looked into answers about their naming techniques."
Delivery		
Preparation for delivery	12	"I started to compare the maternity packages on the platform since my seven-month pregnancy."
Mode and process of delivery	8	"When I learnt of the term painless labor, I searched it for further details."
Delivery stories	4	"I am scared about delivery, and luckily found a lot who were sharing their experiences on *MeetYou*."
Hospital and doctor choices	4	"I looked at many comments online and choose the doctor I favored."
Postpartum period		
Infant care	8	"I also compared the mother-baby care center on social media…"
Maternal recovery and sex life	5	"I looked particularly for information on weight loss and muscle exercises."
Nutrition during postpartum period	2	"I hardly checked the nutrition and vitamins after childbirth."

With regard to the sharing behavior of expectant mothers, public sharing of pregnancy-related information was hardly seen on social media. However, some participants expressed their habit of sharing within closed groups and engaging in private conversations with friends or relatives on social media channels. A total of 10 codes were identified, which emerged into 4 themes, namely, gravida, fetus, delivery, and caretaker. Furthermore, 4 subcategories within the gravida category, 2 subcategories in fetus, delivery, and caretaker, respectively were found. In Table 3, further details are provided. Among them, the most shared information related to their husbands (10 out of 20 participants), whereas the sex of fetus (2 out of 20 participants) was the least referred to topic. In addition, announcement of pregnancies, preparation for delivery, pregnancy symptoms, mode and process of delivery, and other topics about their mother-in-law/mother were also highly discussed on social media.

Table 3. Pregnancy-related sharing categories and subcategories.

Categories	Number of mentions by participants
Gravida	
Pregnancy announcement	9
Pregnancy symptoms	6
Pregnancy-related complications	5
Super-cool pregnancy-related goods	5
Fetus	
Fetus pictures	3
Sex of fetus	2
Delivery	
Preparation for delivery	8
Mode and process of delivery	6
Caretaker	
Husband	10
Mother-in-law/mother	6

Preferred Seeking and Sharing Patterns

Lurking on Social Media

On the basis of our interviews, 90% (18/20) of participants noted that they review pregnancy-related information on social media. As one participant stated:

> *I had a strong prenatal reaction with continued vomiting and dizziness, much stronger than my mother-in-law and my mother had experienced or expected...I wasn't assured until I found that many similar cases were uploaded by other expectant mothers…I saw one recommendation of several public accounts on social media for pregnancy-related information, and I subscribed to some of them for regular updates.*

In addition, 95% (19/20) of participants had not actively engaged in pregnancy-related conversations initiated by other strangers on social media. As one participant expressed:

> *I do not want to talk with other pregnant women I am not familiar with. I think pregnancy is a personal matter and I do not want to share too much with others I do not know. If I cannot find the health information I need, I will quickly switch to other channels or online conversations to look for more precise answers.*

Small Group Sharing

All participants believed that they did not need to publicly share information about their pregnancy on social media app. They perceived pregnancy to be a private affair, feeling reluctant to share their news with everyone. However, many participants said that they would use social media channels to connect with close female friends, particularly those who are pregnant, and they showed varying degrees of dependence on pregnancy groups hosted on social media channels. As one participant mentioned:

> *I was not a social media fan, nor did I want others know about my pregnancy. I felt it unnecessary to post it on social media, and I have not seen any of my friends ever post their pregnancy news on social media…But, I like to share it privately with my girls via WeChat. We have a WeChat group with some pregnant women. We talk about everything during our pregnancy, every day. Sometimes, we Tucao (uncover some foolish story) about our husbands. I felt much relief chatting with them.*

Bad News Avoidance

Notably, although participants acknowledged the importance of obtaining health information via pregnancy apps, half (10/20, 50%) of the participants also tried to avoid bad news posted by others. For example, one participant revealed that:

> *This is my first pregnancy and I am very worried about my medical reports, as my doctor said that two core factors are relatively lower, considering my situation. The doctor instructed me to take pills every day during pregnancy, as my diagnosis was preabortion. I was so scared regardless of my doctor's explanation. Then, I went on to the Meetyou application and joined a chat group that featured my core indictors. Some of the conversations really horrified me. Meanwhile, when I compared my situation with theirs, I felt lucky. One said that this can never be a small thing, and her last child abortion was a lesson.*

This feeling was confirmed by another participant who stated that extreme cases were frequently discussed on social media channels; however, most pregnant women do not possess serious conditions. She also added that usually women over the age of

35 years had more serious concerns, as well as those who had previously experienced child abortion.

Cross-Checking of References

All participants applied similar search strategies, often searching for the same pregnancy-related information multiple times to obtain a comprehensive understanding of the problem encountered. For example, if an answer received more likes or follows, it could be deemed more convincible. In addition, if the online description of the problem coincided with their real experiences, many participants tended to believe them. If many sources presented similar results, they were likely to be right. One participant stated:

> *When I searched my symptoms online, I compared the results on different sources. With social media, I can easily see the number of followers, comments, as well as the identity of the providers. For example, I visited Zhihu, a knowledge exchange social networking website, to find out the reason why I became very itchy after several months of my pregnancy. I looked at one conversation on this topic and saw a lot of answers. I can easily identify the reliable ones by comparing the number of Zan (followers). On Zhihu, some people claimed that they were experienced doctors of Obstetrics and Gynecology. I valued their information very much.*

Impact of Social Media Use

In general, participants were satisfied with pregnancy-related information found via social media channels and reported a positive impact. All participants agreed that the health information they had found via online channels had greatly empowered them to make more informed decisions during pregnancy. Overall, 95% (19/20) of participants were moderately or very satisfied with the current pregnancy-related provision. For firsthand knowledge on pregnancy-related topics offered via social media, participants were much appreciative:

> *My mother used to tell me about her experience. However, I found that was not practical for me…Thanks to social media, I can connect with my friends who have experienced childbirth. Also, with the range in applications, I can know almost everything going on in my body during the whole pregnancy period.*

In addition, 95% (19/20) of participants reported a positive impact from using social media during their pregnancy. Only 1 participant stated that no impact had occurred during pregnancy; however, all primipara participants expressed that health information found via social media was of great value for them and made their first pregnancy a smooth experience. Furthermore, they also believed that social media had created a communicative platform for allowing them to chat with other pregnant women and get timely support. This contributes to the reduction of anxiety and loneliness during pregnancy. As one participant said:

> *Social media not only helps me with finding pregnancy-related information, but it also makes me more confident about my pregnancy and puts me in a good mood…If I get bored, I can read funny stories or play small virtual games embedded on the MeetYou application, to kill time.*

Discussion

Principal Findings

This study aimed to understand the social media usage of pregnant women in China, including its adoption, manifestation, and its impact. Similar to studies conducted in developed countries [12,23], this study, focused on China, the largest developing country, has also employed a qualitative approach to reveal the status quo of social media use for pregnancy-related purposes.

First, the frequency of using social media and the topics concerned are distinct between seeking and sharing behaviors among Chinese expectant mothers. This study revealed that seeking happened more frequently than sharing on social media. This may attribute to the ease of the 2 behaviors. For seeking behavior, it does not involve new knowledge or information creation. In the case of seeking pregnancy-related information, the process of information retrieval could be achieved in minutes. However, in the case of sharing, it creates new information, takes time before sharing, and has almost immediate consequences. Sharing pregnancy-related information requires efforts in organizing language as well as concerns for safety and privacy. The high utilization of social media for pregnancy-related information seeking means that pregnant women in general have insufficient knowledge about their pregnancy and have a general anxiety; this is especially the case for first-time expectant mothers. The increasing division between provision and demand of pregnancy-related information may contribute to the frequent use of social media. From the perspective of provision, this implies that there is a failure in health education for pregnant women during the new baby–born peak, when China abandoned the 1 child policy. It is worthwhile for hospitals or other medical institutions to utilize various means to engage with expectant mothers who are seeking health-related knowledge, for example, providing the latest pregnancy-related information on popular social media channels, including Weibo, WeChat, and short-video platforms, to reach a large audience of expectant mothers.

With regard to the topics, seeking behavior focused on the expectant mother and fetus, whereas the postpartum period was less concerning, which coincides mostly with previous studies on Chinese pregnant women seeking health-related information [5]. In addition, several new seeking intentions appeared, such as amusement, sex of fetus, and super-cool pregnancy-related goods. This variation may imply a change in perception of pregnancy, calling for more enjoyable pregnancy experiences rather than merely safe pregnancy. As for information sharing, the most mentioned topics were related to husband and pregnancy announcement. This is different from the sharing habits of pregnant women in the United States, where information about husbands is not on their sharing list [23]. With regard to sharing information specifically about their husbands, the most highly mentioned topic related to foolery or funny things happening during the caretaking process by the husband. This sharing could be interpreted as fun or anxiety relieving to gain peace of mind [24].

Second, pregnant women are silent on public social media channels in general but do actively engage in small online groups. Traditionally, pregnancy in Chinese culture is a personal affair and one which is shared only in closed groups. This may attribute to the general notion that pregnancy is a vulnerable state in Chinese culture [25]. In particular, pregnancy is regarded as high-risk within the first 3 months; thus, Chinese pregnant women often do not share their news openly on social media during this early stage, rather they prefer to announce their pregnancy only to close relatives and friends after their condition has become stable. Usually, the husband is the first to learn of the pregnancy, then other family members or close friends are informed. A comparative study between Australian and Chinese pregnant women showed a significant cultural difference in terms of beliefs, attitudes, barriers, and intentions toward exercise during pregnancy [26]. When considering pregnancy taboos that are deeply rooted in Chinese culture, expectant mothers in China are generally much more careful than those in Western countries [14], which leads to their lack of engagement on social media.

Previous anthropology studies have demonstrated that the sharing nature of women has been passed on through generations and historical experiences, such as childbirth, child rearing, and feeding the family and guests [27,28]. For pregnant women, their ability to share or engage in conversation is evident on social media, but in a much more private manner. This may be because of the hierarchy of trust as indicated by Fei et al [29], where closer relationships deserve more trust. Compared with random conversations with pregnant women they are not familiar with, Chinese expectant mothers prefer to share their concerns, talk about their experiences, and offer instant help within their social circle of close family members or friends who share childbearing experiences. In addition, certain pregnancy-related inquiries could be deemed intimate, such as questions relating to sexual activity during pregnancy. A possible strategy for social media–based prenatal care would be to encourage participation for sharing information by initiating public conversation and inviting opinions from leaders, for example, health professionals in renowned hospitals or people with influences in the online community. Increased participation in return brings more users and, thus, increases the market.

Third, avoiding bad news and cross-checking reference were involuntary seeking habits among Chinese pregnant women. Pregnant women have a tendency to avoid bad news presented by others online and refuse to read the details on subjects such as miscarriage or stillbirth. Two explanations for this phenomenon are fear and sensitivity. The physical changes experienced by women during pregnancy lead them to a heightened awareness of their surrounding environment. If a negative story is found, pregnant women could easily relate this to their own situation and put themselves in the mind of the storyteller; for example, a topic on nausea and vomiting during pregnancy posted on social media. The online comments could be varied relating to the etiology and corresponding treatment [30], which may involve extreme cases and bad outcomes. A review of them is likely to cause discomfort and fear. This is consistent with previous studies that have explored negative stories surrounding childbirth, pregnancy, or baby care, which could result in stress, effects on everyday life, and avoidance of childbirth or pregnancy altogether [31]. Despite the internal feelings experienced when reading such stories, negative outcomes could also be related to interpersonal or service-related problems such as tension in the patient-clinician relationship or postponing a clinical encounter [32]. Risk aversion is in the nature of human beings and this also applies to pregnant women. However, there is no guarantee to keep pregnant women from experiencing any negative outcomes as the information found on social media is hard to avoid. Health professionals or supporters of social media usage during pregnancy could help expectant mothers establish scientific mindsets to reduce the negative outcomes from social media usage; for example, expectant mothers could share and discuss with their physicians.

Our study also showed that the evaluation of health information by pregnant women followed similar principles: searching, but never fully sourcing it from one place. This may be because of the chaotic nature of pregnancy-related information provided online, where no specific standards are currently implemented. As not all pregnancy-related information on social media is deemed helpful, pregnant women must be cautious in applying the knowledge they retrieve in their daily lives. With constant criticism from media about false or fake information from social media channels, pregnant women in China are quite aware of the side effects of social media. As pregnancy in Chinese culture is a critical family business rather than a personal experience, pregnancy attracts great attention either from the expectant mother or from her family [33]. There is no doubt that a small problem experienced during pregnancy could be amplified, requiring careful checking for consistency in information obtained from social media using an offline approach such as seeking health professionals' advice. Indeed, through decades of efforts in national prenatal care, the general health literacy level among pregnant women has increased significantly [34], which also makes pregnant women more confident in using online pregnancy-related information.

Finally, although reported impacts were positive, the digital divide of providing pregnancy-related information deserves practical attention. Although almost all participants in this study claimed a positive result in using social media during pregnancy, it cannot be assumed as a generalized conclusion that social media provides benefits for all pregnant women on all occasions in China. Many pregnant women with a lower level of education, poor health literacy, and unemployment do not use social media for pregnancy-related purposes. As this group of pregnant women align to the profile of expectant mothers living in rural areas of China, with access to limited medical resources and a neighborhood with all known acquaintances, they do not feel the need or desire to use social media for pregnancy-related purposes as often their relatives and friends, who have experienced childbirth, live close by and can share their experiences on a personal level. Some, in fact, may go to a hospital for the purpose of delivery only. In our study, the participants were mostly highly educated, comparatively affluent, representing the largest group of users among all pregnant women in China. The positive outcomes experienced from social media is likely to be connected with their comparable advantages in internet expertise and health information literacy [35]; this may lead to a *digital divide* in the quality of health care provision among pregnant women with different socioeconomic statuses. To maximize the benefit of social media for expectant mothers, it is worth employing marketing strategies that target pregnant women with lower literacy or lower incomes and exploring further social media–enabled online consultation methods designed specifically for these users [11].

Conclusions

This study investigated the current adoption and behavioral habits of using social media by Chinese expectant mothers when seeking and sharing pregnancy-related information. We interviewed 20 pregnant women, applying thematic analysis to summarize the major themes regarding how pregnant women use social media and the perceived impact of its use. Generally, pregnancy-related information seeking behaviors are more frequent than sharing behaviors. The top pregnancy-related information seeking and sharing topics were related to fetal development and about the expectant father during pregnancy. In terms of specific patterns, lurking, small group sharing, bad news avoidance, and cross-checking of references were identified. Most expectant mothers reported positive outcomes from social media usage for pregnancy-related purposes.

Our study had some limitations. First, all participants were healthy without any complications accompanied with their pregnancy [36], such as being overweight or having hypertension or type 2 diabetes. For pregnant women with complications, their condition may be major, making them more likely to be unsatisfied about the medical consultation received, which may lead to a different pattern of social media usage and impact. A focus on pregnant women with specific conditions and various severities may desire future exploration [37]. Second, this study concerns pregnant women in China exclusively and did not distinguish between women whose medical resources are constrained and those with abundant medical resources. Further research could explore those with medical resource deficiency and compare pregnant women in such areas with those having affluent resources. Finally, this research may have overlooked the other online seeking habits and sharing behaviors of pregnant women, which could be of critical importance; for example, their sentiments with their husbands, mothers-in-law, and other caretakers [1,15].

There is no doubt that by using social media, Chinese expectant mothers are extensively empowered to realize and seek better prenatal care. Thus, social media not only serves to provide health knowledge for pregnancy safety but also guides pregnant women during their journey to motherhood, being wary of their own situation and becoming more joyful during their pregnancy [24].

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

RMB: Renminbi

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Original Paper

Understanding the Function Constitution and Influence Factors on Communication for the WeChat Official Account of Top Tertiary Hospitals in China: Cross-Sectional Study

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Abstract

Background: Widespread adoption and continued developments in mobile health care technologies have led to the improved accessibility and quality of medical services. In China, WeChat, an instant messaging and social networking app released by the company Tencent, has developed a specific type of user account called WeChat official account (WOA), which is now widely adopted by hospitals in China. It enables health care providers to connect with local citizens, allowing them to, among other actions, send regular updates through mass circulation. However, with the diversity in function provided by WOA, little is known about its major constitution as well as the influence factors on the WeChat communication index (WCI). The WCI has been widely used in social media impact ranking with various types of WeChat content to fully reflect the dissemination and coverage of tweets as well as the maturity and impact of WOA.

Objective: There are two typical WOAs available to users, namely, WeChat subscription account (WSSA) and WeChat service account (WSVA). The biggest difference between them is the frequency of messages transmitted. This study aimed to explore the function constitution of WSVA adopted by top tertiary hospitals in China and the major contributors of the WCI score.

Methods: A total of 681 top tertiary hospitals were selected from the Hospital Quality Monitoring System; the WOA of every top tertiary hospital was retrieved in the WeChat app. We divided core functional items of WSVAs using categorical principal component analysis. To elicit the factors that influenced the use of WSVA, quantile regression was employed to analyze the WCI score.

Results: From the 668 WOAs identified, adoption of WSVAs (543/668, 81.3%) was more than that of WSSAs (125/668, 18.7%). Functional items of WSVAs were categorized into four clusters: (1) hospital introduction, (2) medical services, (3) visiting assistants, and (4) others. With regard to the influence factors on the WCI, the impact of the activity index of WSVA and the total visiting number of outpatients and emergencies on WCI were statistically significant and positive in all quantiles. However, the year of certification, the type of hospital, the year of public hospital reform, and the number of beds merely affected the WCI at some quantiles.

Conclusions: Our findings are considered helpful to tertiary hospitals in developing in-depth functional items that improve patient experience. The tertiary hospitals should take full advantage of times of posting and provide high-quality tweets to meet the various needs of patients.

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KEYWORDS

WeChat official account; WeChat service account; social media; function constitution; tertiary hospital; tertiary care centers; health care; WeChat communication index; mobile health; telemedicine

Introduction

Background

Mobile technologies and internet-connected devices hold great potential for improving health care delivery and services [1,2]. According to a report released by the Business Communications Company in 2017, the global market for mobile health technologies is expected to grow at an annual rate of 28.6% [3]. Among others, social media, an important part of mobile apps, is defined by Kaplan and Haenlein [4] as "a set of Internet-based applications built on Web 2.0 ideas and technologies that allow for the creation and exchange of user-generated content." Social media has changed the nature of interaction between individuals and health care providers. It also provides a medium for the public, patients, and health care professionals to communicate on health care issues [5].

With developments in internet capabilities, such as speed and widespread connectivity, social media has continued to manifest its influence. An increasing amount of research involved in the effects of social media on the health care industry has been observed [6-8]. Some researchers have evaluated the academic influence of WeChat [9]. Gan [10] conducted a survey to explore the adoption of WeChat in Chinese public libraries. In the health care field, many researchers have investigated the application of social media within and outside hospitals (eg, hospital apps [11,12], health care apps [13], Facebook [14,15], and WeChat [16]). Others have reported interventions and assistance using social media for particular patients (eg, orthodontic patients [17] and glaucoma patients [18]). In addition, some scholars have concentrated on the use of health care apps by older Germans [19].

WeChat Official Account and WeChat Communication Index

WeChat is the most popular social media mobile app in China, providing over 1 billion daily active users with a multipurpose messaging and mobile payment app [20,21]. The app has rapidly become an integral part of people's daily life, with citizens now using it to message, share updates, find people in their local community, transfer money, and pay utility bills in real time [22]. One of the main accounts available to users on WeChat, since 2012, is the *WeChat official account (WOA)*, which is a lightweight app on WeChat and which targets celebrities, government agencies, and businesses to facilitate cooperation and promotion. WOA transmits messages, including real-time adverts to WeChat users, thus reducing propagation costs and raising brand popularity, among others. According to a report issued by iResearch in 2015, 79.2% of WeChat users subscribe to certain WOAs [23].

There are 2 typical kinds of WOAs: WeChat subscription account (WSSA) and WeChat service account (WSVA). WSSA provides a means to reach the subscribers by information propagation. In contrast, WSVA provides entities, such as governments and businesses, with more powerful business services and user management capabilities. One of the main differences between the 2 accounts is frequency of message transmission. Specifically, WSSA can send out 1 group of messages every day, whereas WSVA can only send out 4 groups of messages every month [24].

The WeChat communication index (WCI), released in March 2017 as an integral feature of the WeChat app, provides users with the ability to measure the popularity of keywords based on their search volume and appearance within articles or shared stories [25], which is currently one of the most important media reports in China. Users can track the popularity of keywords over a 7-, 30-, or 90-day period, identifying a WCI score. The WCI score is derived from a series of complex and rigorous calculation formulas, which consist of 4 dimensions, that is, *overall communication power,average dissemination power,headline communication power,* and *peak dissemination power* [26] (for the detailed calculation formula of WCI, see Multimedia Appendix 1). Owing to its comprehensiveness, transparency, and openness, the WCI has high credibility and authority in the Chinese industry and has been widely used in various types of social media impact ranking of WeChat content. The WCI can fully reflect the dissemination and coverage of messages released by WOAs as well as the maturity and impact of WOAs, with it currently being adopted by over 20,000 institutions. Besides, WCI has been updated over time, with the latest version being 13.0 at present.

Classification and Reform for Public Hospital in China

According to the *Regulation of Medical Institutions*, released by the National Health Commission of the People's Republic of China (NHC-PRC) [27], there are different types of medical institutions, including comprehensive hospitals (CHs), specialized hospitals (SHs), maternal and child health center, integrative traditional Chinese and western medicine hospitals, township health centers, and ethnicity hospitals. The CHs and SHs play a leading role in China in terms of the number and scale of medical services provided; the main difference between them is that the CHs have complete departments, whereas the SHs only provide one or a few medical specialties. Furthermore, hospitals in China are classified into 3 tiers according to the present Hospital Grading System: tier 1 (primary), tier 2 (secondary), and tier 3 (tertiary), each of which is further divided into 3 levels, including level 1, level 2, and level 3 [28]. The tertiary hospitals with level 3 represent the most advanced level of service provided in China. In addition, the diction *tertiary hospitals with level 3* is simplified as *top tertiary hospitals* in some literature [29-31].

According to *Guiding Opinions on the Pilot Reform of Public Hospitals*, released by NHC-PRC [32], the hospital reform was phased in and implemented in all public hospitals in 5 consecutive batches from 2010. The reform endeavored to improve the availability, accessibility, quality, and efficiency of medical services in public hospitals. The application of WSVA and the derived WCI was related to and contributed to fulfilling these purposes.

Objectives

WOAs are now seen as an essential marketing and branding tool by government agencies, celebrities, and businesses alike. Citizens in China are connecting with their favorite brands to receive real-time updates and important information, making it a crucial element of everyday life, with no exception in the health care field in China [33,34]. It is perceived as an ideal medium for implementing a *patient-centered* approach to health care. Specifically, the WOA of electrocardiogram remote consultation for township health center was established in Guandong province in China, through which timely medical service can be provided to address poor diagnostic quality in primary health institution [35]. The design and establishment of a mobile medical consumables management system based on WOA is helpful to manage medical consumable materials more conveniently and efficiently [36]. However, much remains unknown with regard to the main functional items and impact factors on the WCI for WOAs. To improve our understanding of the use of WOAs by top tertiary hospitals in China, the following 3 research questions are identified:

1. What was the status quo regarding the application of WOAs used by the top tertiary hospitals in China?
2. What was the major function constitution of WOA?
3. What were the factors that influence the WCI and their effects on WCI at different levels?

Methods

Sample and Data Collection

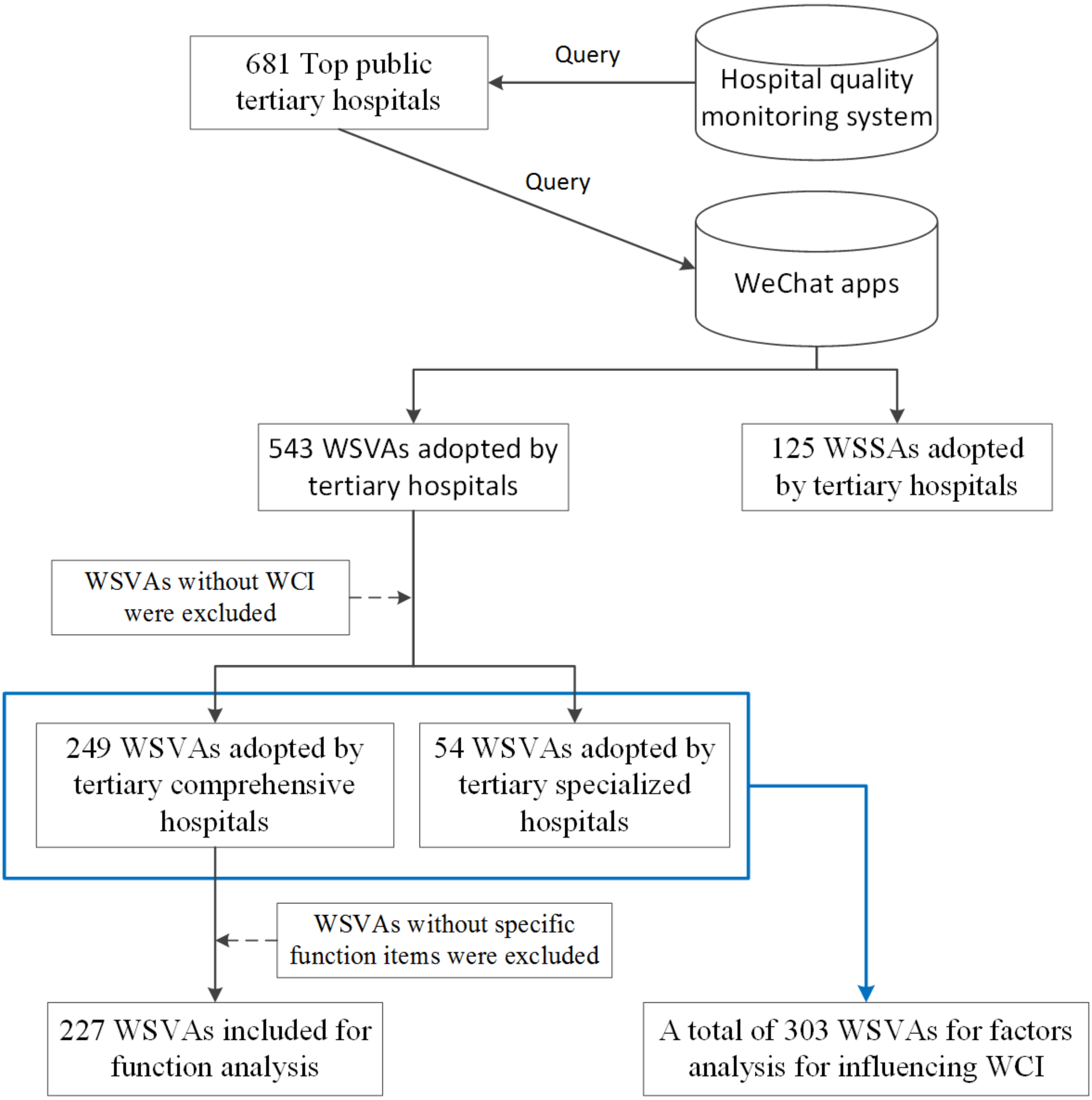
The process used for identifying the WOAs of top tertiary hospitals in China is shown in Figure 1. Specifically, 3 stages were completed, as follows, regarding the data collection of this study.

First, through interrogation of the Hospital Quality Monitoring System developed by NHC-PRC [37], 681 top tertiary, comprehensive or specialized, hospitals were identified on May 3, 2018. The hospitals were then classified into different groups based on different regions of China [38], that is, Western China (WC), Central China (CC), and Eastern China (EC), which corresponds to a gradually incremental population density and economic development level. Among the top tertiary hospitals, each of 3 research assistants had access to 227 (681 divided by 3) official websites. They collected the *number of beds* and *total visiting number of outpatients and emergency room* in 2017 from each hospital official website and confirmed whether each website of tertiary hospital presented the official quick response (QR) code of WOA. The number of beds mainly refers to the number of open beds representing the capacity of the hospital, which is counted in thousands. However, the number of authorized beds, which relates to the governmental subsidy to each public hospital, was used to replace the number of open beds when the latter could not be found. Moreover, the total visiting number of outpatients and emergencies reflects the quality of medical service to some extent. The research assistants used smartphones to search and subscribe to the WOAs of each hospital to ascertain the type and the year of certification. As a result, 543 WSVAs and 125 WSSAs were identified and verified for further analysis.

Second, 3 research assistants searched these WSVAs on the official website of the Qingbo Index, obtaining the average WCI, number of posting times, and the total number of posted tweets, for each WSVA in April 2018. Here, the average WCI was the sum of the WCI generated by each posting divided by the number of posting times in April 2018. Considering that most WSSAs have no WCI, 303 WSVAs, including 249 WSVAs adopted by tertiary CHs, were chosen for subsequent analysis.

Finally, as for 249 WAVAs, these 3 research assistants randomly chose a certain province located in each region in China and subscribed to all WSVAs in the province, and thereafter, they listed all the specific functional items of each WSVA. As some WSVAs have no specific functional items, a total of 227 WSVAs were identified from 249 WSVAs for function analysis. Then, a list of 15 functions of WSVAs was identified, following discussions and resolution of any discrepancies or disagreements. Eventually, 1 research assistant proceeded to record the functional items of the remaining WSVAs. In addition, 303 WSVAs were employed for analysis of influence factors on the WCI.

Figure 1. Process for identifying the WeChat official accounts adopted by tertiary hospitals. WCI: WeChat communication index; WSSA: WeChat subscription account; WSVA: WeChat service account.



Measure of Factors Influencing the WeChat Communication Index

We investigated 6 indicators: (1) the year of certification of the WSVA, (2) the type of hospital, (3) the year of public hospital reform involved, (4) the number of beds, (5) the total number of visiting outpatients and emergency patients, and (6) the activity index of the WSVA. The impact of these indicators on the WCI was considered. Herein, the certification of the WSVA is optional and officially authorized and approved by the Tencent company. In addition, the certification is not free. After certification is granted, more rights of the WSVA will be given to the owner, which is helpful for the development and utilization of the functional items of the WSVA. We used the following formula to calculate the activity index of each WSVA [9], which partly represents the emphasis from the tertiary hospitals on WOA and is conducive to promoting users' stickiness:

Activity index = 0.5*ln (number of posting times a month + 1) + 0.5*ln (number of posted tweets a month + 1)

In addition, the variance inflation factor of each independent variable is less than 2. All independent variables and their descriptions and references are listed in Table 1.

Table 1. Description of variables that influence WeChat communication indexes.

Variable name	Description and coding	References
CertificationYear	The initial year of certification of the WSVA[a]. The coding is listed as follows: 1=never certified, 2=certification during 2014 to 2016, 3=certification in 2017, and 4=certification in 2018	Gan, 2016 [10], Xu et al, 2015 [39], and Zhang, 2015 [40]
HospitalType	The type of hospital. The coding is listed as follows: 1=specialized hospital and 2=comprehensive hospital	Huang et al, 2019 [41], Chen et al, 2009 [42], Tatro et al, 2019 [43], and Plantier et al, 2017 [44]
ReformYear	The year of public hospital reform involvement. The coding is listed as follows: 1=2010, 2=2014, 3=2015, 4=2016, and 5=2017	Lin et al, 2014 [45]
BedNumber	The number of beds per top tertiary hospital	Lin et al, 2014 [45]
TotalVistingNumber	The total number of visiting outpatients and emergency patients in 2017	Fuller et al, 2019 [46]
ActivityIndex	The activity index of the WSVA	Zhao et al, 2017 [9]

[a] WSVA: WeChat service account.

Method of Visualization for Distribution of WeChat Official Accounts of Tertiary Hospitals

EChart is an open-source visualization library, implemented in JavaScript, that provides intuitive, highly customizable data visualization charts [47]. We developed a program based on EChart library, using the Java language, which demonstrated the geographical distribution of the WOAs of tertiary hospitals in China. As the map produced is 3 dimensional, the number of WOAs in each province in China is displayed together with the color depth and height of the pillars. Furthermore, the yellow, green, and blue portions of the map represent WC, CC, and EC, respectively.

Statistical Analysis

Function Coding and Categorical Principal Component Analysis

As for each functional item, we coded *1* for having such functional item in WSVA and *2* for having no such function. Then, categorical principal components analysis (CATPCA), a variable-centered method aimed to correlate variables based on the relationship between each other, was used to reduce the dimensionality while accounting for as many of the patterns of variation as possible [48,49]. In CATPCA, categorical variables are optimally quantified in the specified dimensionality. As a result, nonlinear rather than linear relationships between variables can be modeled. The CATPCA was completed using SPSS 20.0 (IBM). In addition, the function constitution presents what functions 227 WSVAs of top tertiary CHs provide and what categories these functions can be roughly divided into using CATPCA.

Quantile Regression

Quantile regression, as introduced by Koenker and Bassett, is used to extend the explanation of the conditional mean in ordinary least squares (OLS) regression to the estimation of conditional quantile functions models in which conditional quantiles of the response variable are expressed as functions of observed covariates [50-52]. One advantage of quantile regression, relative to the OLS regression, is that the quantile regression estimates are more robust against outliers in the response measurements, so as to allow a nonnormally distributed response variable. As such, quantile regression could identify heterogeneous effects of independent variables on different conditional quantiles. Therefore, quantile regressions are gradually being recognized as a helpful technique in the case of skewed (non-normal) distribution, which can explain response measurement more accurately and comprehensively than classical methods [53]. The conditional quantile function of y_i given x_i can be specified as $Q_\tau(y_i \mid x_i) = x_i\beta_\tau$, with $Q_\tau(y_i \mid x_i)$ being the conditional quantile function at quantile τ, with $0 < \tau < 1$, and β_τ representing the vector of parameters to be estimated [54].

Given that the mean WCI score of 303 WSVAs was 510.67 (SD 220.61) and that WCI did not satisfy normal distribution, with the *P* value of Shapiro-Wilk normality test being .03, we analyzed the factors influencing the WCI using quantile regression performed by R 3.5.1, which offers several packages implementing quantile regression analysis. We now have 11 covariates, plus an intercept. For each of the 12 coefficients, we plotted the 9 distinct quantile regression estimates for τ=(0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, and 0.9) as the black solid curve with filled dots as well as the relevant 95% interval estimates shown by the shaded gray area. For each covariate, the point estimates may be interpreted as the impact of a 1-unit change of the covariate on the relevant conditional WCI quantile, holding other covariates fixed. Thus, each of the plots has a horizontal quantile of the WCI, or τ scale, and the vertical scale indicates the covariate effect. Meanwhile, the red solid line and dashed line in the visualization map of quantile regression analysis show the OLS point, and 95% CI estimates on the conditional mean were reported. Where the shadow area intersects with the black solid line, it suggests that the effect of the covariate on the relevant conditional WCI is not statistically significant because the coefficient corresponding to that quantile is no different from zero.

Results

Basic Statistical Information

Distribution for Top Tertiary Hospitals

Among the 681 tertiary hospitals, there are 145 SHs and 536 CHs. As shown in Table 2, 307 hospitals were located in EC, accounting for nearly half of the total. Obviously, there exist geographical differences in the distribution of tertiary hospitals.

Table 2. Distribution of top tertiary hospitals in different types and regions.

Type of region	Specialized hospital (N=145), n (%)	Comprehensive hospital (N=536), n (%)	Total (N=681), n (%)
Western China	31 (21.4)	130 (24.3)	161 (23.6)
Central China	38 (26.2)	175 (32.6)	213 (31.3)
Eastern China	76 (52.4)	231 (43.1)	307 (45.1)

Distribution of WeChat Official Accounts Adopted by Top Tertiary Hospitals

A total of 668 hospitals hold WOAs, accounting for 98.0% (668/681) of the total number of top tertiary hospitals (for the list of WOAs in all provinces of China, see Multimedia Appendix 2). This shows that most top tertiary hospitals attach great importance to the role of their WOAs. In addition, we found that there are merely 397 hospitals that provide QR codes of their WOAs on the official hospital website, showing that some top tertiary hospitals are still lacking the publicity of their WOAs.

As shown in Figure 2, the EC held 307 WOAs, accounting for nearly half (307/668, 46.0%) of the total of tertiary hospitals, followed by the CC and the WC. Meanwhile, 259 WSVAs adopted by top tertiary hospitals were located in the EC, accounting for 47.7% (259/543) of the total of tertiary hospitals, followed by the CC and the WC. However, the number of WSSAs in the 3 regions is roughly the same. In total, the number of WSSAs or WSVAs adopted by CHs is more than that of SHs because there are more CHs in our dataset. Figures 3 and 4 display the spatial distribution of the sample throughout mainland China. The number of WSVAs is mainly concentrated in the CC and EC. Guangdong province holds the largest number of WSVAs.

Figure 2. Distribution of WeChat official accounts operated by top tertiary hospitals.

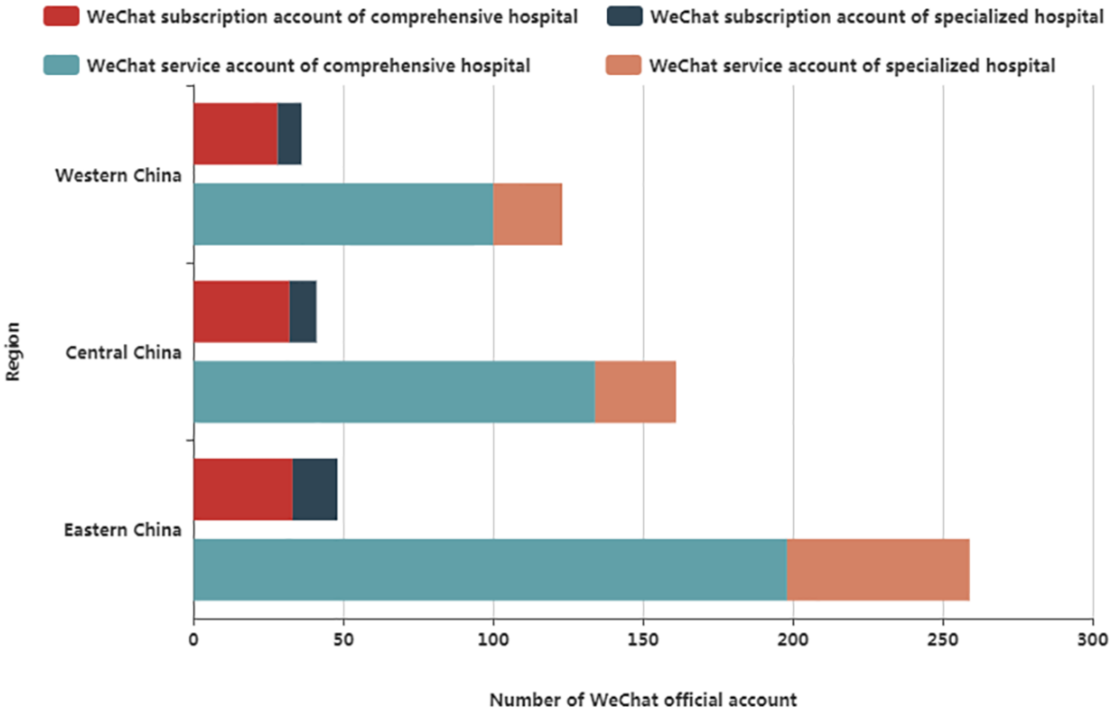


Figure 3. Spatial distribution of WeChat subscription accounts operated by top tertiary hospitals.

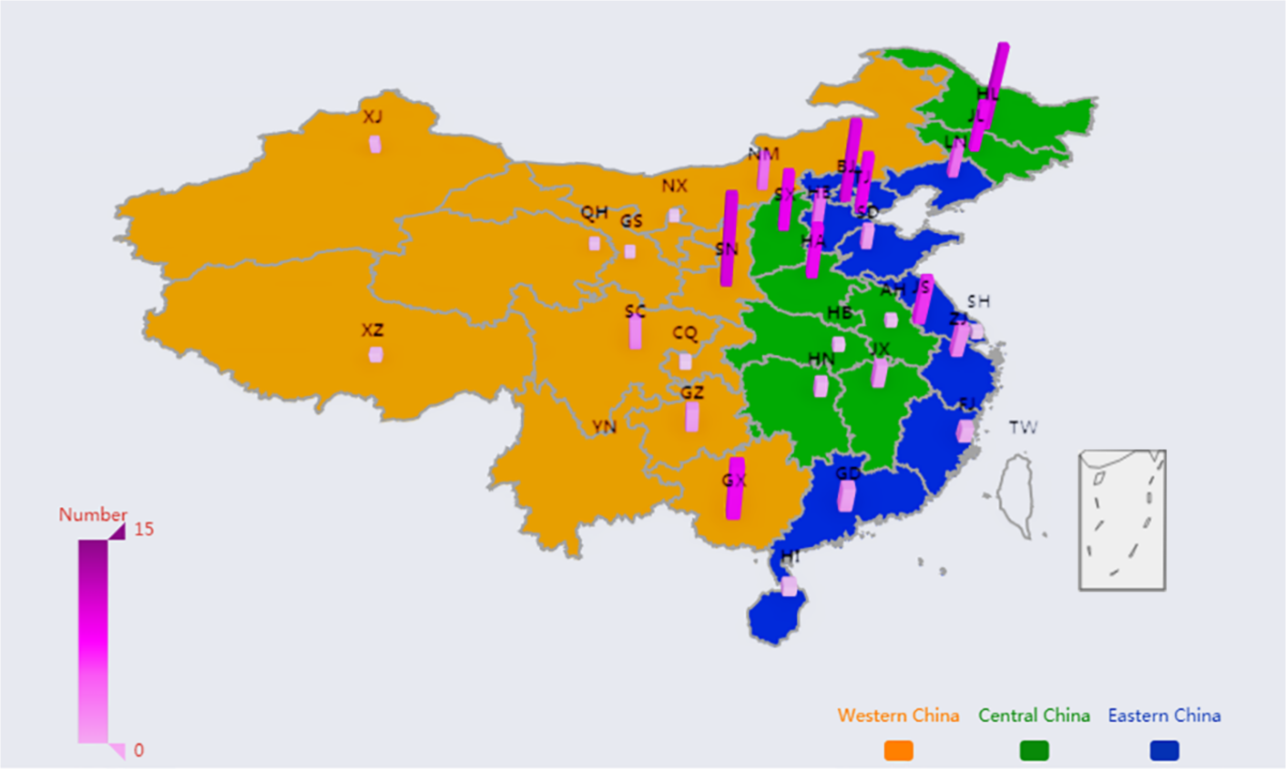
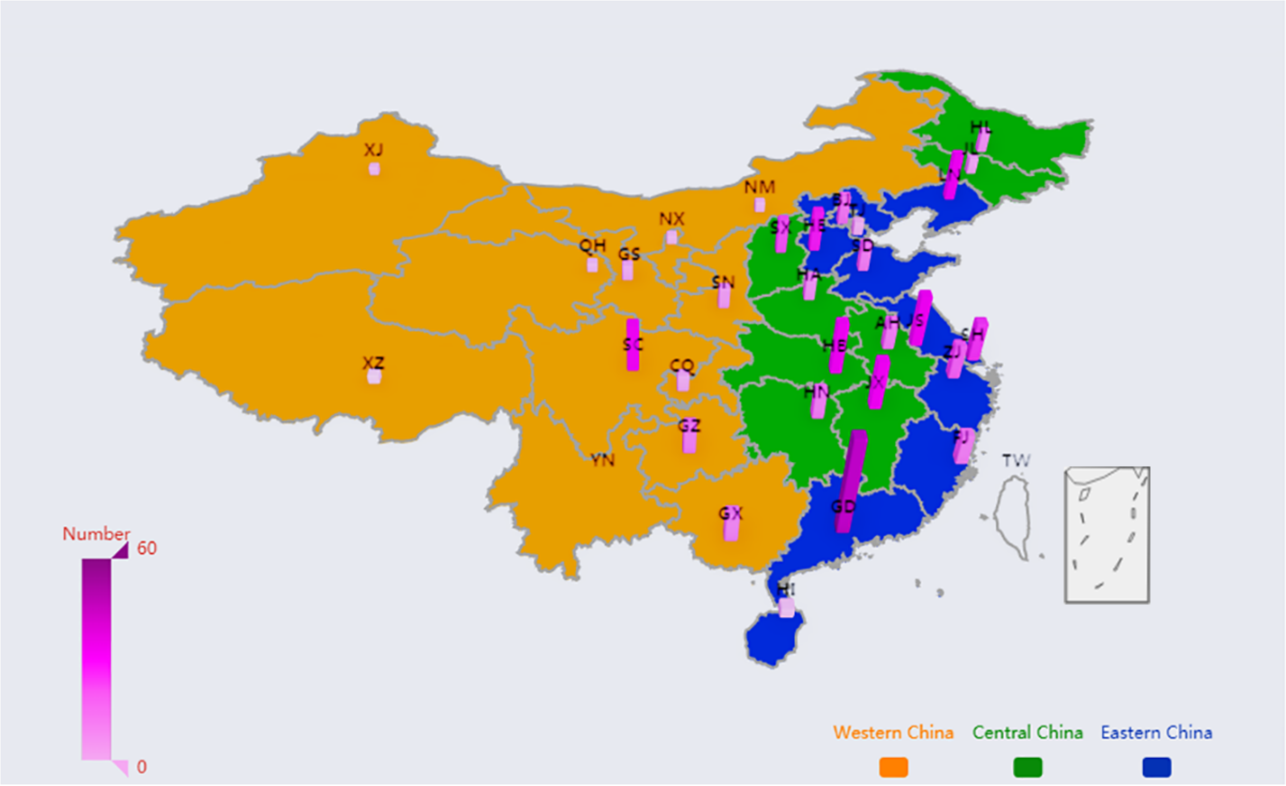


Figure 4. Spatial distribution of WeChat service accounts operated by top tertiary hospitals.



Function Analysis for WeChat Service Account Adopted by Top Tertiary Comprehensive Hospitals in China

Function Distribution for WeChat Service Account

Table 3 summarizes the distribution of 15 functional items available in the 227 WSVAs of top tertiary hospitals in China. The average function number of each tertiary hospital is 7.44. It can be seen that the most widely available function across the different regions of China is visiting appointment, followed by the function inquiry, suggesting that most top tertiary hospitals give priority to appointments and patient inquiries. However, the function online consultation was still underdeveloped (17/227, 7.5%) in most top tertiary hospitals.

Table 3. Function distribution of WeChat service account operated by top tertiary hospitals.

Function item	Western China (N=41), n (%)	Central China (N=71), n (%)	Eastern China (N=115), n (%)	Total (N=227), n (%)
Hospital brief	24 (59)	50 (70)	65 (56.5)	139 (61.2)
Introduction of department and experts	15 (37)	34 (48)	56 (48.7)	105 (46.3)
Information bulletin	21 (51)	29 (41)	59 (51.3)	109 (48.0)
Medical guide	18 (44)	35 (49)	65 (56.5)	118 (52.0)
Hospital navigation	16 (39)	22 (31)	47 (40.9)	85 (37.4)
Visiting appointment	36 (88)	65 (92)	98 (85.2)	199 (87.7)
Inquiry	28 (68)	53 (75)	92 (80.0)	173 (76.2)
Medical charge payment	18 (44)	36 (51)	68 (59.1)	122 (53.7)
Online consultation	3 (7)	7 (10)	7 (6.1)	17 (7.5)
Intelligent guidance	13 (32)	24 (34)	23 (20.0)	60 (26.4)
Personal information management	27 (66)	51 (72)	87 (75.7)	165 (72.7)
Health education	14 (34)	28 (39)	36 (31.3)	78 (34.4)
Advice and feedback	17 (41)	31 (44)	52 (45.2)	100 (44.1)
Related links	17 (41)	35 (49)	67 (58.3)	119 (52.4)
Others	14 (34)	28 (39)	59 (51.3)	101 (44.5)

Function Categorization for WeChat Service Accounts

Owing to the insufficient employment of the function *online consultation*, we used the remaining 14 functional items for the subsequent analysis using CATPCA. Notice that the eigenvalue for a dimension should be larger than 1, when all variables are single nominal. Therefore, there was a 4-dimensional solution, accounting for 50.06% of the total variance (for more details, see Multimedia Appendix 3).

To form a clearer observation, the plane coordinate maps were chosen and drawn for dimensions 1 and 2, and dimensions 1 and 3, respectively, as shown in Figures 5 and 6. As can be seen, 14 functional items could be categorized into 4 clusters by using CATPCA, each of which refers to the adoption of functional items of the WSVA at the same time, owing to the higher correlation within each cluster. The name of each cluster was refined based on the functional items in the respective cluster.

As shown in Figure 5, cluster 1 is located in quadrant I with the name of visiting assistance, which contains visiting guide, advice and feedback, and intelligent guidance. Cluster 2 is referred to as medical services, covering inquiry, personal information management, visiting appointment, medical charge payment, and related links, all of which are present in quadrant IV. Cluster 3, named hospital introduction, is in quadrant II, which includes the hospital brief, introduction of department and expert, information bulletin, hospital navigation, and health education. Cluster 4 is in quadrant III, which merely holds 1 functional item *others*, as shown in Figure 6.

Figure 5. Component loadings of 14 functional items of WeChat service accounts between dimensions 1 and 2.

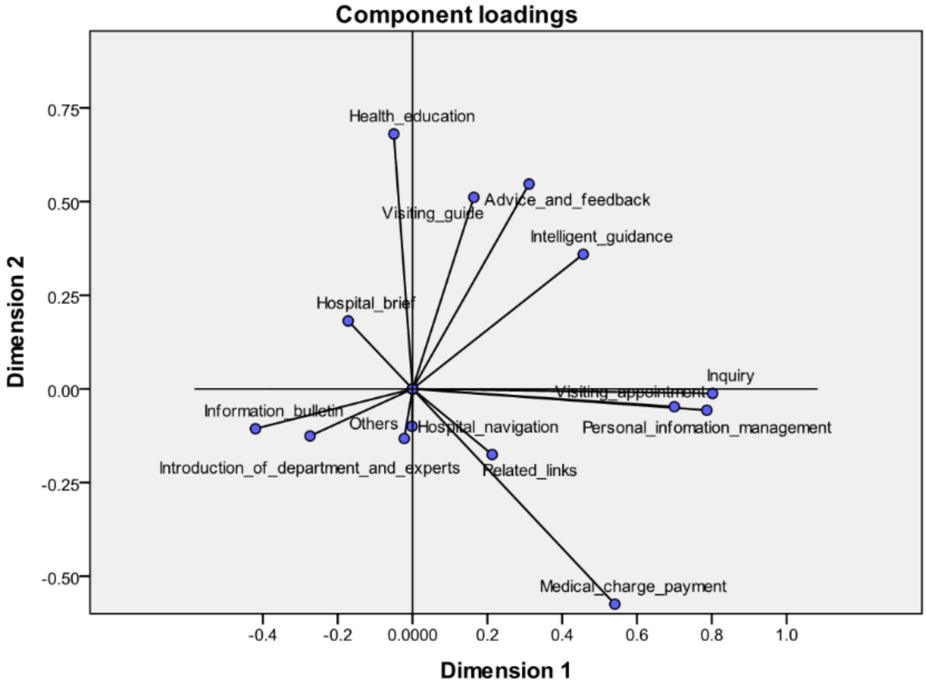
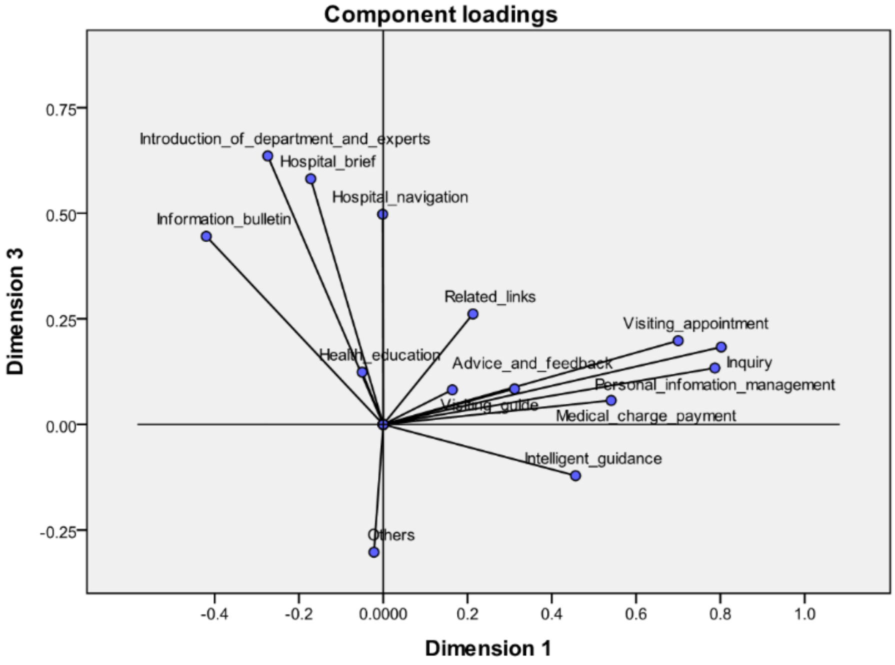


Figure 6. Component loadings of 14 functional items of WeChat service accounts between dimensions 1 and 3.



Influence Factors on the WeChat Communication Index

Descriptive Statistics for Influence Factors

The tertiary hospitals with the 10 highest WCIs are shown in Table 4. As seen, 6 of these WSVAs of tertiary hospitals were certificated in 2018. There are 8 CHs and 2 SHs. In terms of regional distribution, 9 tertiary hospitals are located in EC and CC, except 1, which is based in WC. Except from the 2 hospitals with low activity index, which are affiliated to Sun Yat-sen University, the remaining 8 hospitals have a high activity index. The *West China Hospital, Sichuan University* ranks highest, far ahead of other tertiary hospitals.

The basic information for independent variables is presented in Table 5. It is observed that most WSVAs operated by top tertiary hospitals were certificated in 2017 or 2018, making up 94.4% (287/303) of the total. CHs comprised 79.5% (241/303) of the total. Most hospitals (163/303, 53.8%) are located in EC. As of 2017, all tertiary hospitals were involved in public hospital reform.

Table 4. Top 10 WeChat communication indexes of top tertiary hospitals.

No	Name of top tertiary hospital	Average WCI[a]	Certification year	Hospital type	Region type	Activity index
1	West China Hospital, Sichuan University	1233.49	2014	CH[b]	WC[c]	2.004
2	Hunan Children's Hospital	1099.34	2018	SH[d]	CC[e]	2.087
3	The First Affiliated Hospital, Sun Yat-sen University	1074.46	2018	CH	EC[f]	1.498
4	Guangzhou Women and Children's Medical Center	1026.92	2017	SH	EC	1.966
5	Tongji Hospital, Tongji Medical College, Huazhong University of Science & Technology	1012.37	2017	CH	CC	2.047
6	Qilu Hospital of Shandong University	996.97	2018	CH	EC	2.124
7	The Third Affiliated Hospital, Sun Yat-sen University	991.86	2017	CH	EC	0.693
8	The First People's Hospital of Foshan	981.47	2018	CH	EC	2.465
9	Yichang Central People's Hospital	951.52	2018	CH	CC	2.538
10	Shanghai Ninth People's Hospital, School of Medicine, Shanghai JiaoTong University	949.48	2018	CH	EC	2.159

[a] WCI: WeChat communication index.

[b] CH: comprehensive hospital.

[c] WC: Western China.

[d] SH: specialized hospital.

[e] CC: Central China.

[f] EC: Eastern China.

Table 5. Basic information for independent variables influencing WeChat communication index.

Variable name	Values
CertificationYear (N=303), n (%)	
Never certificated (reference category)	7 (2.3)
Certification during 2014 to 2016 (CertificationYear1)	9 (3.0)
Certification in 2017 (CertificationYear2)	173 (57.1)
Certification in 2018 (CertificationYear3)	114 (37.6)
HospitalType (N=303), n (%)	
Specialized hospital (reference category)	62 (20.5)
Comprehensive hospital (HospitalType1)	241(79.5)
ReformYear (N=303), n (%)	
Involved in 2010 (reference category)	51 (16.8)
Involved in 2014 (ReformYear1)	30 (9.9)
Involved in 2015 (ReformYear2)	74 (24.4)
Involved in 2016 (ReformYear3)	54 (17.8)
Involved since 2017 (ReformYear4)	94 (31.0)
BedNumber, mean (SD)	1.83 (1.06)
TotalVisitingNumber, mean (SD)	153.09 (116.43)
ActivityIndex, mean (SD)	1.99 (0.45)

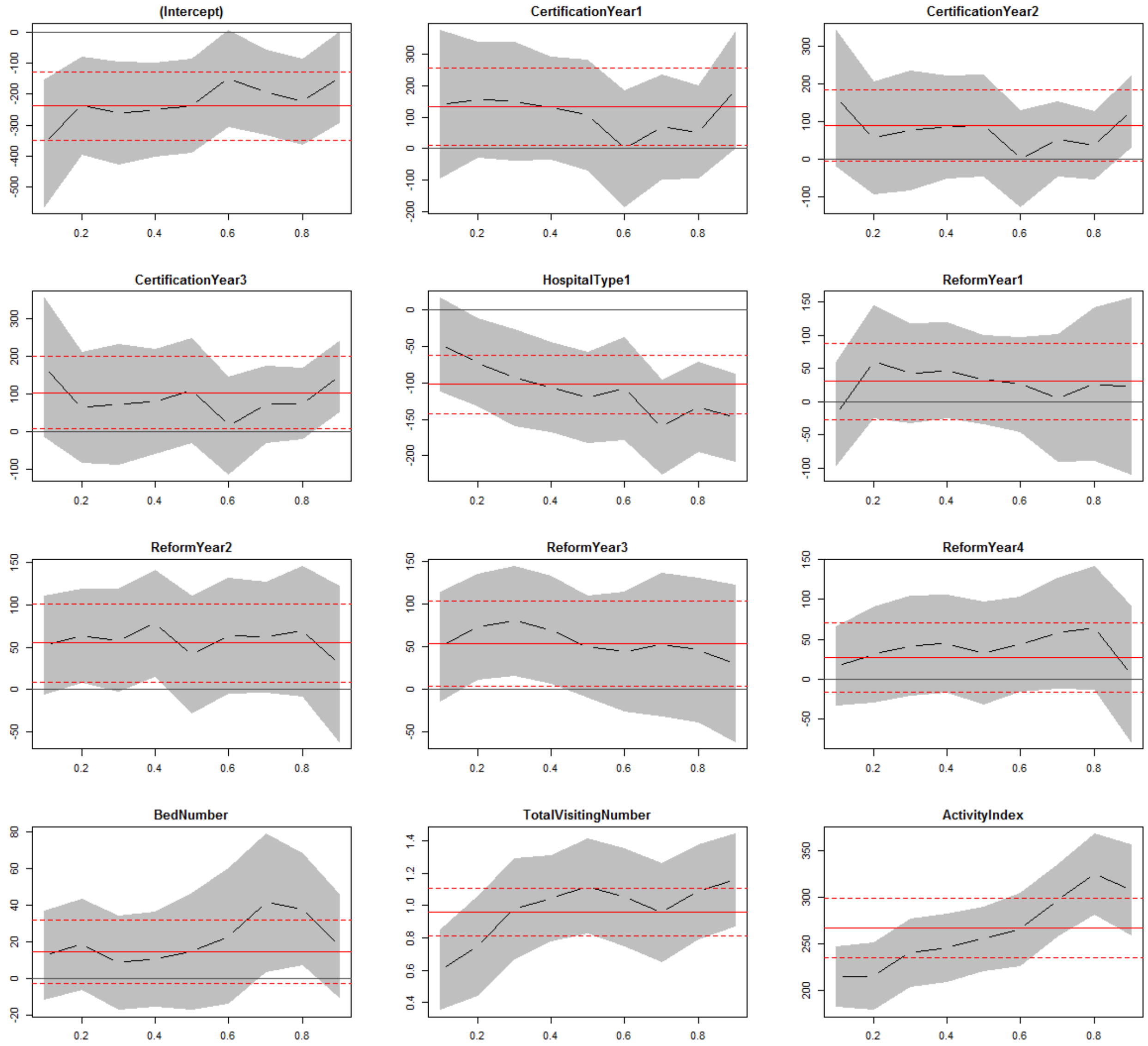
Quantile Regression Analysis for WeChat Communication Index

A summary of the quantile regression results for WCI, with each quantile in 0.10 increments, is shown in Figure 7 (for more detailed results of quantile regression, see Multimedia Appendix 4). The dummy variables, including the year of certification of WSVA, the type of tertiary hospital, and the year of public hospital reform involved, were generated. In general, it can be seen that all dummy variables did not have a statistically significant effect on WCI, except the type of tertiary hospital, although there were some significant effects on WCI at some quantiles.

Specifically, we took uncertification as the reference category of the year of certification for WSVA. The impact of the different years of certification on WCI was seen as positive, but insignificant, with a relatively less fluctuation across the different quantiles of WCI. CHs are seen to have a negative impact on WCI, in comparison with SHs, with a downward trend as the quantile increases. In essence, the higher the WCI was, the bigger the effect difference on WCI between CH and SH had. Namely, SHs place more emphasis on WSVA than CHs. It should also be noted that the type of tertiary hospital has a significant impact on WCI after 0.20 quantile and beyond. The impact of the year of the public hospital reform involved on WCI takes 2010 as the reference category; the impact on WCI is generally positive in different periods because one of the purposes of the reform in public hospitals is to benefit the population by the wide adoption of various technologies. However, the effects remain statistically significant at some quantiles, although the impact varies across the different quantiles of WCI.

In addition, there are 3 continuous variables affecting the WCI. Specifically, the effect of the number of beds on WCI is positive for all quantiles but only significant from the 0.70 quantile to the 0.90 quantile, although the effect can no longer be found in the median level. Moreover, the total visiting number of outpatients and emergency patients and the activity index of WSVA both have a significant positive effect on WCI for all quantiles. Figure 7 also shows an overall upward trend, that is, the higher the quantile of WCI, the higher the positive effect of activity index on WCI, whereas the effect of the total visiting number of outpatients and emergencies shows fluctuation.

Figure 7. Ordinary least squares and quantile regression estimates for WeChat communication index model. Vertical axes show coefficient estimates of named explanatory variable; horizontal axes depict the quantiles of the WeChat communication index variable; the red plain line and the red dashed line represent the ordinary least squares point and 95% CI estimates on the conditional mean, respectively; the black dashed lines represent conditional quantile estimates.



Discussion

Principal Findings

This study presented the distribution of WOAs operated by top tertiary hospitals in China and 4 clusters of the functional items of WSVA using CATPCA. The factors influencing the WCI were analyzed using quantile regression. The effects of the total number of visiting outpatients and emergency patients and the activity index of WSVA on the WCI are significant and positive for all quantiles. However, 3 dummy variables are seen to have no significant effect on the WCI.

First, the WOAs, especially WSVAs, have been widely adopted in top tertiary hospitals in China, indicating that they are supportive and aligned to the improvement of the efficiency for medical services and facilitating health care. To the best of the authors' knowledge, one of the main reasons for this is that mobile reading and WeChat reading have already been included in the Chinese national reading category. According to the recent Chinese National Reading Survey, released by the China Press and Publication Research Institute, the proportion of WeChat reading has grown rapidly [55,56]. In addition, it seems that there are more provinces in the WC, but the number of WOAs is generally rare. However, after normalizing the number of WOAs operated by top tertiary hospitals targeted to every province in China, it can be found that there was no significant difference in WSSA adoption between the normalized value sets from WC, CC, and EC, with the P values more than .05 calculated using the Kruskal-Wallis test. All these results demonstrate that the wide application and mutual reference of mobile health technologies between tertiary hospitals make adoption of WOA similar.

In addition, there may still be some drawbacks in the application and promotion of WOAs. The QR code of the WOAs should be provided to facilitate patient scanning on the official website of the tertiary hospital. Some tertiary hospitals have not yet paid much attention to the application of WOAs, with uncreated or uncertified accounts or insufficient functions being provided. However, the WOAs will be an important part of communication if the hospital wants to improve its quality of medical services and influential power. In light of the trend reflected by the year of certification, the application of WOA to top tertiary hospitals is still in its infancy, which should be developed with more functional items and provide better services after certification.

Second, more functional items in the WSVAs should be developed to meet the various demands of patients. Currently, functional items of WSVAs are varied; the focus is generally on visiting appointments and inquiries, although there are 4 clusters of functional items observed. Another worthwhile function is medical charge payments. With the widespread popularity of mobile payment in China, online payments for medical services will undoubtedly be applied. However, with respect to security interface settings of WSVAs, there are still certain risks that have yet to be ameliorated.

Furthermore, it should be noted that interactive functions for medical services should be given more attention for development, although WOAs have increasingly integrated some functional items from mobile health care apps. With the improved expectation for medical service, some interactive functional items between doctors and patients should be strengthened or developed to further alleviate "the difficulties and high costs of obtaining medical services in China" and meet the higher medical service demands. The development of the functional item *online consultation* in the WSVA will further support patient-centered medical services. Certainly, there is a need for mechanisms to ensure that doctors participate in online counseling services in the context of the shortage of medical resources in China, for example, involving this service in the performance of doctors. The widespread application of such functions will alleviate the difficulty in seeing a doctor to some extent. This is consistent with *Healthy China 2030 Planning* [57], *Guidance on actively promoting the "Internet +" initiative* [58], *Opinions on Promoting the Development of "Internet + Medicine"* [59], and other relevant policies released by the State Council of China, which suggest speeding up the construction of smart hospitals to further facilitate patients.

Third, the top tertiary hospitals should post high-quality messages as much as possible to expand the influence of WOAs operated by top tertiary hospitals. As shown from the results of the above quantile regression analysis, the total number of visiting outpatients and emergency patients and activity index can promote the communication power of WSVAs. Therefore, it is necessary to take full advantage of the 4 times of posting, optimize the column settings of tweets, and improve the quality and originality of tweets that meet the demands of patients, which is similar to the operation of other social media in the health care field [60,61]. In addition, consumer health vocabulary and health literacy should also be developed and improved to help patients better understand messages [62-64], which will enhance the attractiveness and the degree of activity on WOAs. However, there are some top tertiary hospitals that have no WOAs. Accordingly, it is necessary for those hospitals without WOAs to set up a department or form a team to maintain the system and post high-quality messages. Therefore, all these measures will provide a valuable means to expand the influence of WSVAs and, in return, improve the patient experience, which is consistent with the aim of the reform of health care system in China.

In addition, CHs should also strengthen the construction of WSVAs, which typically apply to large tertiary hospitals at higher quantiles. First, the influence of the type of hospital on the WCI is statistically significant at the higher quantiles, suggesting that the type of tertiary hospital is a sensitive indicator of high WCI scores. From the above results, tertiary hospitals with different WCI scores should take the significant influence factors in the corresponding quantile regression into consideration to quickly improve the influence of their WSVAs. Second, the number of beds represents the size of the hospital. As the size of tertiary hospitals in China continues to expand, its impact on WCI decreases after the 0.70 quantile, the reason for which might be that the hospital staff might be busy and have no motivation to improve the impact of the WCI. Furthermore, tertiary hospitals with a large numbers of beds should take advantage of their size and develop chronic disease management and health education aimed at specific populations

[65] by introducing new health care technologies using WSVAs, which will ease the conflicts between doctors and patients and establish a harmonious relationship between them.

Limitations

Several potential limitations are worth noticing, and further research will be optimized on the basis of these. First, some bias might exist because we merely collected data from tertiary hospitals. Therefore, the results may not be truly representative of all hospitals in China. In addition, the hospital name and the name of WOA do not correspond in some instances, which means that some WOAs could not be found. Obviously, this affects the accuracy of the distribution of WOAs in China.

Second, the advantage of the CATPCA method is that it can grapple with various types of data, but these 14 functional items are summarized based on a certain amount of investigation and discussion, which might have effects on the categorization of the functional items of WSVA.

Finally, this study collected number of open beds as well as the total number of outpatients and emergency patients in 2017 from the homepages of tertiary hospitals. The time-lag updating of these data might lead to the bias of the result of quantile regression analysis. There also exists the different time of posting messages with the limitations of 4 times, but the relevant data were captured by Qingbo Index system at a fixed date, which may influence the result of the quantile regression analysis. Future research might be started based on panel data.

Conclusions

In this study, the distribution of WOAs was presented. CATPCA was conducted with the data source from the WeChat app using SPSS 20.0. Quantile regression was used to explore and understand the factors that influenced the WCI, performed by the R 3.5.1. Obviously, quantile regression analysis can provide more abundant information by describing the different effects of independent variables on the dependent variable at different quantiles, which ensure better accuracy and robustness of the regression results. On the basis of the aforementioned results and discussion, some valuable and reasonable results for WOAs, including function constitution and influence factors on the WCI, were identified. With the widespread application of WOA, it is reasonable to believe that WOAs will be an important medium in the future to publicize hospitals and enhance the accessibility of medical care for patients, thereby improving patient experiences.

In addition, the results of this study are useful for tertiary hospitals for a better understanding of how to update the function of their WSVAs and improve the impact of their WCI. Specifically, this study’s results of the function constitution of WOAs will primarily help hospitals learn from each other. Subsequently, the hospitals, in partnership with the developer of WOAs, constantly optimize the interface and enrich the functional items of WOAs so as to form a complete, convenient, and integrated medical service for patients, which will alleviate the pressure of patients queuing for medical treatment. Meanwhile, on the basis of exploring the main factors influencing the communication of WOAs, the hospital may take targeted improvement measures to further enhance the timeliness, richness, and readability of health care–related information, which will further enlarge the hospital’s publicity on social media, cultivate positive usage intention, and increase the content experiences.

Acknowledgments

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Authors' Contributions

LS, the first author, designed and conducted the study into the factors influencing the WCI using quantile regression. SW, the second author, contributed to the research by helping with data collection and function analysis of WSVAs. WC, the third author, contributed to the distribution of WOAs operated by top tertiary hospitals in China. QF, the fourth author, contributed to the statistical analysis. RE, the fifth author, contributed to the language polishing and proofreading. JX, the eighth author, reviewed the draft. ZZ, the corresponding author, designed the study and finalized the draft. All other authors contributed to the preparation and approval of the final accepted version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The detailed calculation formula of WeChat communication index.
[DOC File , 35 KB - jmir_v21i12e13025_app1.doc]

Multimedia Appendix 2
The list of WeChat official accounts in all provinces of China.
[DOC File , 67 KB - jmir_v21i12e13025_app2.doc]

Multimedia Appendix 3

Component loadings of 14 function items of WeChat service accounts.

[DOC File , 44 KB - jmir_v21i12e13025_app3.doc]

Multimedia Appendix 4

The detailed results of quantile regression.

[DOC File , 46 KB - jmir_v21i12e13025_app4.doc]

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Abbreviations

CATPCA: categorical principal components analysis
CC: Central China
CH: comprehensive hospital
EC: Eastern China
NHC-PRC: National Health Commission of the People’s Republic of China
OLS: ordinary least squares
QR: quick response
SH: specialized hospital
WC: Western China
WCI: WeChat communication index
WOA: WeChat official account
WSSA: WeChat subscription account

WSVA: WeChat service account

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Review

Criteria to Measure Social Media Value in Health Care Settings: Narrative Literature Review

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Abstract

Background: With the growing use of social media in health care settings, there is a need to measure outcomes resulting from its use to ensure continuous performance improvement. Despite the need for measurement, a unified approach for measuring the value of social media used in health care remains elusive.

Objective: This study aimed to elucidate how the value of social media in health care settings can be ascertained and to taxonomically identify steps and techniques in social media measurement from a review of relevant literature.

Methods: A total of 65 relevant articles drawn from 341 articles on the subject of measuring social media in health care settings were qualitatively analyzed and synthesized. The articles were selected from the literature from diverse disciplines including business, information systems, medical informatics, and medicine.

Results: The review of the literature showed different levels and focus of analysis when measuring the value of social media in health care settings. It equally showed that there are various metrics for measurement, levels of measurement, approaches to measurement, and scales of measurement. Each may be relevant, depending on the use case of social media in health care.

Conclusions: A comprehensive yardstick is required to simplify the measurement of outcomes resulting from the use of social media in health care. At the moment, there is neither a consensus on what indicators to measure nor on how to measure them. We hope that this review is used as a starting point to create a comprehensive measurement criterion for social media used in health care.

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KEYWORDS

social media; information systems; health care; value; measurement; criteria

Introduction

Background

The use of social media in health care settings is increasingly becoming prevalent [1,2]. Social media used in health care settings can broadly be grouped into 2 categories—general purpose Web-based social networks and online health communities [3]. General purpose Web-based social networks include most Web 2.0 websites and applications such as Facebook and Twitter that enable users to create and share content or to participate in social networking. Online health communities, on the contrary, are special purpose platforms such as PatientsLikeMe and MedHelp that provide a means for health care professionals, patients, and their families to share information about an illness, seek and offer support, and connect with others in similar circumstances.

Social media refers to internet-based applications that enable the creation and exchange of user-generated content [4]. It is a complex combination of sociology and technology [5]. Social media facilitates social interaction and allows the creation of virtual communities. In terms of technology, social media is underpinned by Web 2.0 technology that enables people to create, share, collaborate, and communicate. Use cases of social media in health care can broadly be categorized into 4 major types, namely professional to professional (P2P), professional to consumer (P2C), consumer to consumer (C2C), and consumer to professional (C2P) [3]. P2C represents a situation in which a health care professional provides support to a health consumer; C2P represents health consumers who provide support to health care professionals by way of contributing their experience and opinions; and P2P and C2C represent interactions and exchange of support among members of the respective Health 2.0 user groups.

Social media has become a tool of choice for members of the medical profession who see it as a medium to connect, engage, and influence their audience [6]. In many organizations, social media serves both as a medium to communicate with customers and as a medium to communicate internally [7]. Thus, it has become a medium for the health care community to network, develop their skills, and forge their identity [8]. Health care professionals leverage social media to build, reinforce, and maintain professional relationships with colleagues and to share information [9]. Health care providers use social media to promote their organizations, amplify word-of-mouth effects, build strong relationships with both existing and potential customers, improve brand awareness, and increase volume of traffic to website [10,11]. Patients can also access information relevant to their condition through social media [1]. Such medical information may include links to health resources or images or videos with relevant health content [12].

Objectives

Research to date on the value of social media in health care settings has largely focused on the use and value of the application to health care providers [1,13-15] and patients [16-21]. Fewer studies have focused on measuring the value of social media in health care settings. As health care becomes more patient centered and outcome driven, stakeholders need to be able to report and measure outcomes arising from social media use [2,22,23]. In health care settings, there is considerable interest in exploring how best to ascertain value derived from social media initiatives [2,22-24]. However, measuring the value of social media is a conundrum [5,7,25,26]. The value of an information system (IS) is often linked with its ability to satisfy specific needs [27]. Some have argued that the value of social media has to do with its effectiveness as a marketing tool and suggest that metrics such as hit rate and follower numbers that measure the marketing reach be used to measure social media value [28,29]. However, in health care settings, the use of marketing-based metrics alone may not be sufficient to measure the value of social media, given that, in health care, ensuring better health outcomes for patients rather than attracting more patients is the paramount objective. Furthermore, the impact of social media on patient outcomes can be subtle; thus, it may not be measurable using traditional IS metrics alone [30].

Although relevant literature reveals a kaleidoscope of approaches that can potentially be used to measure the value of social media in health care settings, there is little consensus on what indicators to measure or on how to measure them [15,31]. To clarify this complex phenomenon, we explored different approaches to measure the value of social media in health care settings proposed in previous studies. We deployed a taxonomic approach to elucidate the measurement criteria and to present them in a way that illustrates common features. This allowed the classification of diverse measurement approaches according to a predetermined system, with the resulting catalog being used to provide a conceptual framework for discussion, analysis, and information retrieval. Taxonomies related to social media use have been identified to be critical to understanding the state of the art in research in this area [32].

Many measurement criteria of health care social media identified in the relatively few literatures on the subject are confusing and difficult to apply [33]. To date, however, there is no scholarly paper (known to the authors) that reviews the current knowledge, including substantive findings, and theoretical and methodological contributions in this area. This paper fills this gap. By reviewing and elucidating current measurement criteria propounded in the relevant literature, we hoped to contribute to a better understanding of the value of social media in health care.

The aim of this study was to elucidate how the value of social media in health care settings can be ascertained and to taxonomically identify the steps and techniques in social media measurement from a review of relevant literature.

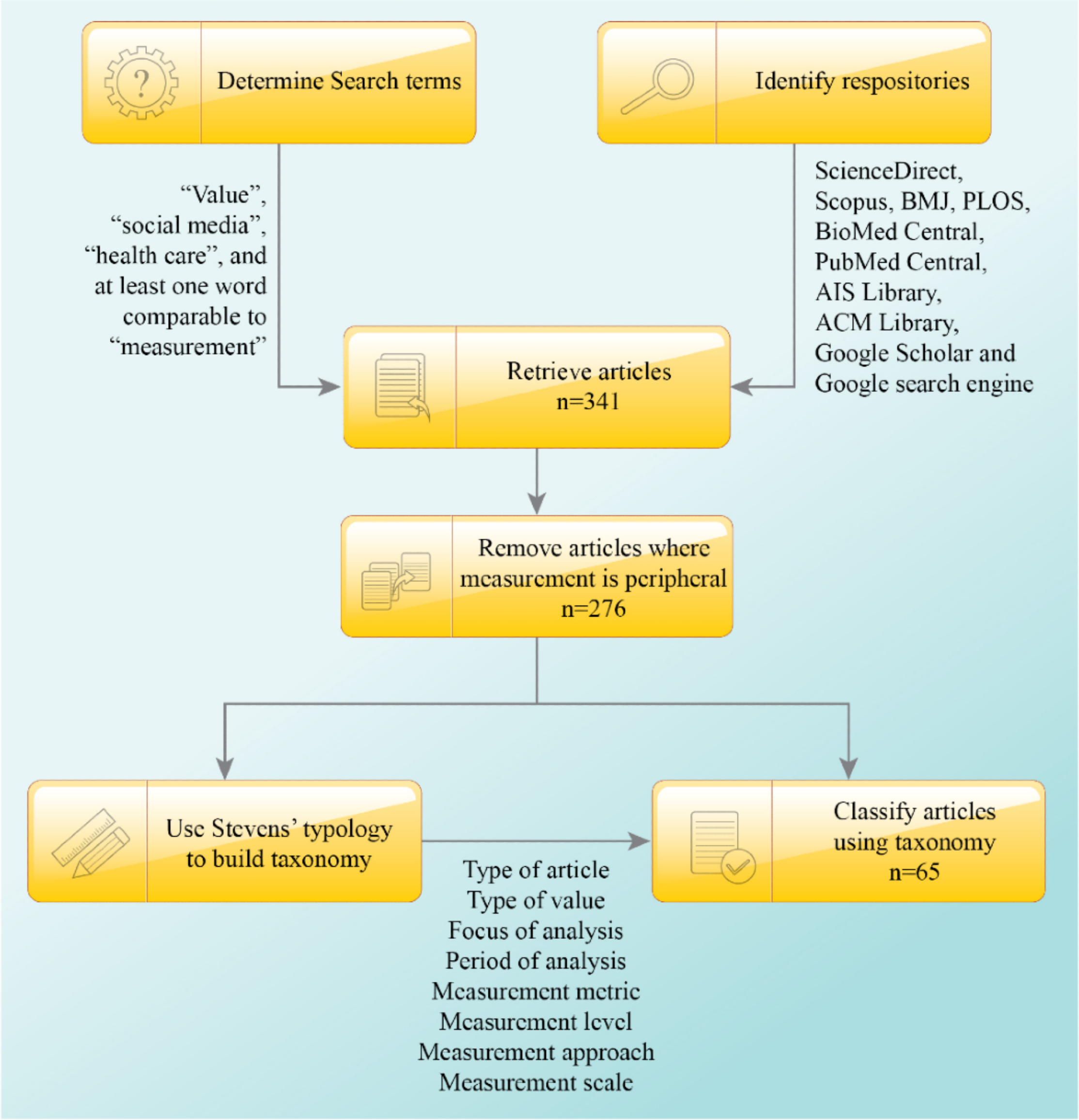
Methods

Overview

To address the objective of this study, we sought to understand existing research [34] from a theoretical and contextual point of view [35]. Although it is not a requirement for narrative review articles to list the types of databases and methodological approaches used to conduct the review or the evaluation criteria for inclusion of retrieved articles [35], we provided this information to ensure methodological transparency.

Repositories containing the full text of relevant research articles were first identified. Search terms described below were constructed and applied to retrieve articles from the repositories. Retrieved articles were culled so that only the articles that were specifically related to measuring value in health care, ISs, and social media deployments remained. We then performed an analysis of the retrieved articles guided by Stevens' [36] measurement typologies also described in the following section. Figure 1 illustrates the activities performed to arrive at a taxonomy and apply the taxonomy to published studies related to determining value from social media use in health care settings.

Figure 1. Sequence of activities in taxonomy development.



Search Criteria

We included articles in journals, conference proceedings, and reports published in English that specifically or broadly discussed measuring ISs value, measuring social media value, and measuring value in health care. Only papers published since 2009 on measuring the value of social media in health care settings were included. Given that the literature on social media use in health care settings is scattered across repositories, the search was not limited to specific databases. Rather, relevant literature was collected from a variety of online databases, that spanned IS, medical informatics, medical and business journals, and conference proceedings and reports [37]. Databases searched included ScienceDirect, Scopus, BMJ, BioMed Central, PubMed Central, PLOS, AIS Library, and ACM Library and Google Scholar as a general database. Furthermore, the Google search engine was used to identify other articles that might not have been accessible in the online databases. To identify published articles pertaining to measuring the value of social media in health care, academic databases were probed using multiple search terms. All searches included the following terms: "value," "social media," "health care" and at least one word comparable to "measurement." This ensured that the review covered substantial relevant literature on the subject and was not confined to one research methodology, one set of journals, or one geographic region [38].

Article Selection and Analysis

The titles and abstracts of 341 articles were reviewed. After sorting through the articles, papers merely discussing the definitions and types of social media, without suggesting the value or measurement criteria, were deemed not relevant to the review, and thus were excluded. At the end, only relevant publications (n=65) were included in the review.

The intent of reviewing the relevant literature on the subject was not to conduct a systematic review; rather, the intention was to enhance the quality of the arguments and assertions presented herein by reviewing a sufficient amount of the literature [39], given that suitable measurement criteria for social media have to be underpinned by relevant theory and embedded in the literature [40].

A narrative review of the published literature that describes measurement criteria for health care social media was conducted after selecting relevant articles. A narrative review approach ensured that the narrative thread would not be lost in the restrictive rules of a systematic review and that issues that require the wider scoping of a narrative review are addressed [41]. While qualitatively analyzing and synthesizing relevant literature, a conscious effort was made to avoid simply repeating ideas presented in the reviewed articles without elucidating how they apply to the subject matter. Thus, this study makes an academic contribution by synthesizing the available material and offering a scholarly analysis [34].

Guideline for Analysis

The phenomenological nature of value and its various perspectives and viewpoints make it challenging to develop suitable measurement criteria for evaluation [42,43]. This study tries to make sense of the different approaches and to make relevant recommendations accordingly. As is usually the case with narrative review articles, this paper does not adopt methodological approaches that would answer specific quantitative questions [35]. Rather, it uses qualitative methods, using headings and subheadings, to discuss the phenomenon that is the focus of the paper being reviewed [35].

To have a consistent basis to compare and contrast the distinct yardsticks used in the measurement of health care social media, a taxonomic approach was adopted, using Stevens' [36] measurement typologies as a guideline. Stevens introduced a theory of levels of measurement in 1946. Level of measurement or scale of measure is a classification that describes the nature of information within the values assigned to variables. According to Stevens, all measurements could be conducted using at least one of four different types of scales called *nominal*, *ordinal*, *interval*, and *ratio* [36]. His measurement scales allow for both qualitative and quantitative measurements and are widely used by researchers. In this study, we used the scales as a framework for taxonomizing the various measurement criteria for social media in health care. This taxonomy would enable a better understanding of how health care providers can measure their social media.

Results

Taxonomy and Criteria

A variety of approaches for measuring the value of social media in health care settings were identified in this review. We have argued that the choice of measurement yardstick depends on the context, that is, the objective that underpins a health care provider's use of social media.

The following sections present the conclusions reached based on the literature reviewed. Table 1 illustrates the taxonomy derived from relevant literature. It describes the content and characteristics of relevant literature, including the objectives, focus of analysis, period of analysis, measure of value adopted, and the type of value identified. It also presents how Stevens' [36] measurement typologies can facilitate a better understanding of the existing measurement criteria for health care social media.

Table 1. Taxonomy derived from the literature on measuring health care social media value.

Taxonomic class	Category A[a]	Category B[a]	Category C[a]	Category D[a]
Type of article	• IS[b] or IT[c] • Business • Medical • eHealth	• Peer reviewed • Non–peer reviewed	—[d]	—
Type of value	• IS value • Health value	• Utilitarian value • Hedonic value	• Instrumental value • Intrinsic value	• Contextual value
Focus of analysis	• Value of health care social media and the need for its measurement	• Measurement of outcomes resulting from the use of health care social media	• Deriving health information from measuring social media data	—
Period of analysis	• Pre–social media adoption	• Post–social media adoption	—	—
Measurement metric	• Monetary value	• Non–monetary value	—	—
Measurement level	• Micro • Aggregate	• International • National • Industry • Organizational • Individual	—	—
Measurement approach	• Quantitative[e]	• Qualitative[f]	• Mixed method[g]	—
Measurement scale	• Nominal[h]	• Ordinal[i]	• Interval[j]	• Ratio[k]

[a] Category, as used here, refers to alternatives within a taxonomic class, in no particular order.

[b] IS: information systems.

[c] IT: information technology.

[d] Some taxonomic classes have fewer categories, hence the empty cells.

[e] Quantitative measurement involves the use of an interval or a ratio scale.

[f] Qualitative measurement involves the use of a nominal or an ordinal scale.

[g] The mixed method approach involves the use of both quantitative and qualitative methods.

[h] A nominal scale is used for classification or grouping (eg, = or ≠).

[i] An ordinal scale is used for comparison and sorting (eg, > or <).

[j] An interval scale is used to determine difference or affinity (eg, + or −).

[k] A ratio scale is used to determine magnitude or amount (eg, x or /).

Type of Article

The analysis of the literature shows that existing literature relevant to the value of social media in health care settings broadly fits into 2 categories: peer reviewed sources and non–peer reviewed sources. Peer reviewed sources outnumbered non–peer reviewed sources.

Furthermore, the literature on the subject can be categorized based on the discipline toward which the publication leans. Some of the relevant literature were published in IS publications, business publications, medical publications, and medical informatics publications, which discuss issues that intersect IS and health care. Most articles cited in this review are from medical informatics publications.

Type of Value

The concept of *value* is multidimensional and its conceptualization depends on the perspective used [44]. When measuring the value of social media in health care, the dilemma is often what metric to use, whether to use metrics that measure IS value or health value, whether to use metrics that measure utilitarian or hedonic value, or whether to measure instrumental or intrinsic value, as outlined below. The type of value to measure depends on the context of use.

Information System Value and Health Value

IS researchers view value as the worth, desirability, or utility of IS artifacts [43], as happy endings in terms of system impact [45] or as the positive outcome that is created through user-system interaction [46]. In health care, however, value has been conceptualized as *the health outcomes achieved per dollar spent* [30,47,48] or as patient outcomes divided by total costs for providing care [49]. Value in health care is evidenced by the outcomes achieved [30]. However, some health care outcomes may not be immediate, and thus, they may be difficult to measure.

A good measurement criterion for health care social media should reflect its technological features and health care context.

As an IS artifact, social media needs to be evaluated based on outcomes achieved after user-system interaction. However, given that the context is health care, these outcomes should be wellness. On the basis of this argument, the value of health care social media seems to be the positive outcomes it delivers to the intended recipient after interaction with the application.

Utilitarian and Hedonic Value

Effective social media platforms are *sticky*, meaning that users visit them frequently and also spend a fair amount of time on them [50]. Continuing to use a social networking platform indicates that the user must experience some benefits or satisfaction from it [51]. After signing up for social media, the value of the services becomes a factor in their continued usage. Users must receive some perceived value or benefits for using the network, otherwise there would not be any motivation for users to continue using the network after joining [51]. The value users derive from using health care social media could reflect hedonic or utilitarian value.

IS value can be analyzed based on the type of value the IS artifact being studied delivers, that is, whether they provide hedonic or utilitarian value [43]. Hedonic value has to do with a product's entertainment-related or emotional benefits, whereas utilitarian value has to do with what the product does or what it allows the user to do [52].

The literature reviewed suggests that users usually do not use health care social media for entertainment. Rather, they use the application because they see it as a medium to complete some necessary tasks, such as accessing or sharing health-related information. People that use social media for health-related activities have a clear intent for using the application; thus, they deliberately choose media that will satisfy given needs in terms of knowledge, social interactions, companionship, diversion, or escape [53]. In other words, social media is used in health care because of its functional value. Functional value represents value derived from effective task fulfillment [44].

Instrumental and Intrinsic Value

The value of social media in health care settings can be considered either instrumental or intrinsic. Instrumental value is the property that allows something to serve as a means toward getting something else that is valuable [54]. A growing number of the literature [1,13,15] discuss how using social media in health care settings could yield value. Such uses can be said to be instrumentally valuable given that it serves as a means toward getting value. From this perspective, using social media in health care is not valuable in itself but valuable because it leads to other benefits. One way of measuring the instrumental value of social media in health care settings is to evaluate its capacity to develop engaged audiences in health promotion settings [24]. In this example, the use of social media is not valuable in itself, but a means to achieving the desired value which is an engaged audience.

On the contrary, intrinsic value is the property that makes something valuable in itself, as opposed to being a means to something else [54]. From this philosophical point of view, social media can be said to have intrinsic value in health care settings. In health care settings, the intrinsic value of social media can be measured by evaluating its impact on health care [22,55,56].

Contextual Value

Value does not automatically arise from the properties of an IS, rather it results from the interaction of a user and a given IS in a particular context [44]. In IS research, technology is always linked with context. An IS such as health care social media can be used in different contexts; therefore, it is important to clarify what the use context is to ascertain its value [31]. To understand the value of an IS, it is essential to identify what is important to its users, that is, the value that users desire [44]. Clarifying the use case of an IS when studying its value yields clearer results [43,57,58]. That said, in health care, stakeholders often have numerous mutually exclusive objectives such as access to services, high quality, cost containment, safety, convenience, patient-centeredness, and satisfaction [30].

Although users' objectives and contexts of use are relevant to understanding the value of an IS, many IS value research studies have failed to address the impact of contextual factors [58]. The literature exploring this subject as it relates to the use of social media in health care is scarce. However, a few studies [1,13,15] explored why social media is used in health care and identified 9 categories of reasons: public health promotion, organizational promotion, professional networking, professional education, patient care/education, research, peer support, crowdsourcing health initiatives, and harnessing patients' feedback. This information is important because understanding what users are ultimately trying to accomplish is a prerequisite to defining the appropriate measurement criteria and which measurement tools to use [26].

Focus of Analysis

IS value research broadly fits into 3 categories based on their objectives: improving design, making IS yield consistent benefits, and creating and deriving value from IS [43]. The first category of IS value research seeks to improve design and implementation by elucidating users' motivations, the impact of IS on behavior, and how IS creates utility for users. The second type of IS value research investigates how to make expensive IS investments yield effective and consistent benefits; thus, they explore the impact of IS on the employees, processes, customers, and society. The third research strand, among other things, is concerned with how value is created and derived by users. Most literature reviewed for this study falls into the second category, as most explored the impact of social media on health care providers [6], processes [59], patients [60], and the wider society, for example, in public health surveillance [61,62].

Broadly speaking, on the basis of the focus of their analysis, 3 streams of the literature on measuring the value of social media in health care emerged from the review. The first stream described the potential value of social media in health care [6] and the need to measure the outcomes of social media initiatives [15,31]. The second stream focused on how to measure the value of social media used in health care settings based on outcomes resulting from its use [22,55,63,64]. Finally, the third stream presents how data derived from social media can be used for measurements relevant to health care [65-67].

Period of Analysis

IS value research can also be categorized based on the period of an IS artifact's life cycle that is the focus of analysis. To this end, there are 2 types of IS value research: preadoption IS value research and postadoption IS value research [43,58,68].

Preadoption

Preadoption IS value research helps decision makers to understand which of the available IS options will most likely yield desired results. Going by the literature reviewed in this study, less or no research studies have focused on the preadoption of social media in health care, probably because trying to measure upfront does not yield much [5]. This suggests that many health care providers are adopting and using social media without knowing whether they are choosing the correct option for their context. If that is the case, then more research needs to be conducted in the area of preadoption of health care social media to help decision makers to understand which of the available social media options (eg, general purpose social media vs online health community) will most likely yield desired results.

Postadoption

Postadoption IS value research investigates the extent to which IS investments have actually yielded the desired value [43,58,68]. Virtually, all the literature reviewed in this study fits into this category. Most of the available literature examined the value of social media to health care providers that are already using the application. Postadoption value research is important because it yields information that allows health care providers to determine whether they have derived value from their social media initiatives.

Metric for Measurement

IS value can be appraised either by using monetary measures or by using nonmonetary measures [43]. Although many advocates that metrics that measure monetary value be used to measure the value of social media in health care, however, metrics that measure nonmonetary value are equally relevant given that a substantial part of IS value is nonfinancial or intangible in nature [58]. Furthermore, health care providers are often not profit seeking; thus, the value of the use of social media in health care may not be effectively measured using only monetary metrics.

Monetary

When used for organizational promotion, the impact of social media on a health care practice can be determined using metrics that measure return-on-investment (ROI), that is, the gain or loss generated on the application relative to the amount of money invested [2,28]. Similarly, one can also measure the value of social media in health care by examining how social media compares with alternative mediums of professional medical education using cost analysis, that is, by comparing the ratio of benefits over costs [69]. Furthermore, medical literature [30,48,49] proposes that value be measured in health care settings based on outcomes achieved per money spent. This suggests that the value of social media in health care may be measured based on outcomes achieved from using the application per amount of money spent on social media initiatives. However, there is a need to distinguish between performance, which is measured by means of monetary indicators, and its (potentially different) values in terms of the subjective interpretation of (different) stakeholders [58]. In other words, the subjective nonmonetary perceptions of stakeholders are an element of value.

Nonmonetary

There are a wide variety of nonmonetary yardsticks that can be used to measure the value of social media in health care. For example, when used for public health promotion, the value of social media in health care can be measured based on its impact [70] and reliability [61]. Furthermore, the value of social media in health care can be analyzed in terms of its ability to capture patient-generated information [62] or based on health outcomes resulting from the use of the application [56,60,71] Other nonmonetary yardsticks for appraising the value of social media in health care include measuring its leveragability to drive health improvement [72,73], appraising the extent to which it increases outreach [74], or evaluating it based on the extent to which it facilitates audience engagement [24].

Measurement Level

The value of social media in health care can be measured either at the micro or at the aggregate level. Alternatively, the value of social media in health care can be measured at the international, national, industry, organizational, or individual levels.

Micro and Aggregate Level

When measuring the value of social media, it is important to measure at different levels to see big picture results and see more granular results [26]. The value of social media can be appraised at the micro or aggregate levels [43].

Analysis of value at the micro level focuses on the *individual* or *organization*, whereas analysis at the aggregate level focuses on the *network* or *society* [43]. For instance, at the individual level, users' perspectives are paramount when exploring the value of social media use [15,27]. At the organizational level, on the contrary, it is a bit more complicated to establish the value of social media use; thus, a taxonomic approach is recommended to facilitate a better understanding of the phenomenon [32]. Finally, at the societal level, the measurement complexity is more pronounced; thus, it is very difficult to measure the impact of digital artifacts such as social media on the society at large [75].

International, National, Industry, Organizational, and Individual Level

IS value research evaluates the worth, desirability, or utility of artifacts at various levels, such as the society, firm, organizational network, and individuals [43]. The value of an IS can be analyzed at the international, national, industry, organizational, and individual level [76]. Thus, the value of social media in health care can be analyzed at the international, national, industry, organizational, and individual level.

At the international level, the value of social media in health care can be viewed in terms of the ability of the application to support the creation of online health communities that allow health care providers from around the world to interact, without the limitation of geographical location [9]. At the national level, the value of social media in health care can be measured by, for example, evaluating the social media performance of hospitals in a particular country [77]. At the industry level, there are different plausible ways to explore the value of social media in health care, for example, by measuring to see whether hospitals' social media ratings reflect their actual level of competence [66], by measuring to determine the value of social media to the medical profession [6], or by evaluating the potential benefits of using social media to facilitate continuing medical education[69,73]. At the organizational level, the value of social media can be understood in terms of its value in organizations [32], by, among other approaches, measuring the ROI on the application [2]. Finally, at the individual level, the value of social media in health care can be measured by, among other options, exploring the motivations and consequences of its use [27] or by comparing outcomes with the value users desire from the application [15].

Measurement Approach

When measuring the value of social media in health care, it is important that the right measurement approach is chosen. There are various approaches to measurement that are available for measuring the value of social media in health care. There is the choice of using a qualitative, quantitative, or mixed method approach.

Quantitative

The quantitative approach to measurement is the systematic empirical investigation of observable phenomena via statistical, mathematical, or computational techniques [78]. Most relevant theoretical and empirical research papers appear to be concerned with quantifying impact in health care settings. At the basic level, social media impact can be measured by quantifying the number of hits, page views, visits, return visits, unique visitors, cost per unique visitor, time spent, and interaction rate [79]. Some of the other quantitative methods suggested in the literature reviewed include calculating to determine the ROI of social media [2,28], determining the online influence of a health care provider that uses social media by calculating their Klout score [80], and using a cost-benefit analysis to determine the value of social media in health care [69]. Another quantitative metric for measuring value in health care settings is to calculate health outcomes achieved per dollar spent [30,48,49].

Qualitative

The qualitative approach to measurement is a systematic method of observation that is used to gather nonnumerical data [78]. This type of research identifies meanings, concepts, definitions, characteristics, metaphors, symbols, and description of things and not to their counts or measures [78]. The qualitative method is particularly relevant to measuring the value of social media in health care because its value may manifest in ways that quantitative metrics alone would be unable to capture. Intangible value created by IS artifacts is as important as other types of IS value [58]; therefore, relying solely on traditional measures such as hit counts or other quantitative methods to measure IS value may yield less accurate results than if some level of qualitative analysis is incorporated in the measurement process [40]. Some of the qualitative methods that have been used to explore the value of social media in health care include sentiment analysis [65], taxonomy [3,15], and analysis based on uses and gratification [53].

Mixed Method

An alternative to both quantitative and qualitative methods is the mixed method research approach. Mixed method is a research approach that uses multiple methods—more than one research method or more than one worldview [81]. It may combine quantitative and qualitative research methods in the same research inquiry to develop rich insights into various phenomena of interest that cannot be fully understood using only one research method [81].

The review of relevant literature suggests that mixed method is relevant to investigating the value of social media in health care settings, especially in instances where one method alone may not effectively capture the outcomes resulting from using the application. For instance, using mixed method to research the value of social media in health care allows one to measure the level of audience engagement, determine what resonates with the audience, and changes resulting from behavioral and educational interventions [72]. Some of the ways mixed method has been used in health care social media research include combining social network analysis with content analysis [82], combining content, thematic, and comparative analysis [83], and combining experiment with qualitative analysis [84].

Measurement Scale

Beyond choosing whether to adopt a qualitative or quantitative approach to measurement, those seeking to measure the value of social media in health care would need to choose the specific scale of measurement to adopt. According to Stevens [36], all types of measurement can fit into at least one of the following measurement typologies: nominal, ordinal, interval, and ratio.

Nominal Scale

The nominal scale is an unrestricted assignment of numerals, words, or letters to events or objects simply as labels or unique identifiers to indicate distinct types [36]. The nominal scale is regarded as the most basic form of measurement and is used to categorize and analyze data in many disciplines. When measuring the value of an IS, the scale level of a value item does not necessarily have to be *cardinal* when it is difficult or even impossible to find reliable numerical data [58]; hence, an alternative yardstick such as the nominal scale could be used.

The literature review revealed that the nominal scale is relevant to appraising social media in health care, as it is used for categorization. For instance, health care social media can be grouped into 2 broad categories, namely, general purpose Web-based social networks and online health communities [3]. general purpose Web-based social networks are websites such as Facebook, Twitter, Instagram, and YouTube that enable mass collaboration. Although these platforms are not designed specifically for patients and health care–related communication, their features and functionalities make them suitable for health-related communication [3]. online health communities, on the contrary, are social media websites such as MedHelp and PatientsLikeMe, which are specifically designed for health-related communication [3]. Going further, the use context of social media in health care can be categorized into 4 broad categories based on participants: P2P, P2C, C2C, and C2P [3] At the granular level, the uses of social media in health care can be grouped into 9 contexts of use: professional networking, harnessing patients' feedback, public health promotion, professional education, patient education, organizational promotion, crowdfunding health initiatives, research, and peer support [15].

The advantage of using a nominal scale is that it can help with classification of types of social media used in health care and the context in which they are used. It can be used to determine mode; for example, the most used type of social media (eg, general purpose or online health communities or Facebook, Twitter, and others) in health care. From reviewing relevant literature, it is apparent that general purpose social media are some of the most used type of social media in health care. The general-purpose social media most referred to in the literature are Facebook [56,66,83] and Twitter [24,65,82].

Ordinal Scale

Ordinal level of measurement is the second of the 4 measurement scales. It is used to measure a categorical, statistical data type where the variables have natural, ordered categories but the distance between the categories is not known [36]. Ordinal scales are relevant to measuring health care social media in situations where there is a need to compare phenomena. For example, anecdotal evidence suggests that some health care providers use social media more effectively than others [31]. Going by that assertion, health care providers that use social media can be ranked based on how effectively they use the application: highly effective user, effective user, and ineffective user. This kind of ranking allows data regarding health care social media to be sorted; however, it does not allow the relative degree of difference between them to be determined. On the basis of the ranking, one can tell that one user is more effective than the other at using social media; however, the extent to which a highly effective user is better than an effective user cannot be described. Similarly, patients' perceived quality of care could be measured based on Twitter data [65]. Speculating based on that assertion, patients' perceived quality of care can be ranked based on quality level, for example, high quality, medium quality, and low quality. The median can be determined in this way, but the average cannot. The rankings indicate the patient's perceived quality of care received but does not provide sufficient information to determine the exact difference in quality between the various categories.

Interval Scale

The interval scale is a *quantitative* measurement scale in which the order and the exact differences between the values are known, but that does not imply the existence of a *true* zero point [36]. The interval scale allows for the degree of difference between items to be determined, but not the ratio between them, for instance, date when measured from an arbitrary epoch such as anno Domini (AD) or before Christ (BC. Using these scales, it may be misleading to say that one value is twice or some other proportion greater than another.

Interval scales are relevant for measuring social media in health care. Any measurement criteria that include time or date, technically include an interval scale, since hours and days are all interval measurements. For instance, interval scales can be used to identify optimal times for engagement and to tailor strategy so the right content is posted at the right time (when the audience is most active) and the best days of the week. Through Facebook insights, one can view their followers' daily activity over the past week and can go further and narrow it down to individual days to see how engagement shifts by the hour. By being able to see how audience engagement with their social media changes over a designated period, one can determine which periods are best for bringing in new fans. Using an interval scale to measure social media, one could find that evenings are better than mornings or that weekends are better than weekdays when it comes to audience engagement. That would allow for the degree of difference between these periods to be known but not the ratio between them, given that terms such as *weekdays*, *weekends*, *mornings*, and *evenings* are ambiguous.

Ratio Scale

The ratio scale is a quantitative variable measurement scale that allows comparisons to be made between intervals or differences. Ratio scales are used to estimate *the ratio between a magnitude of a continuous quantity and a unit magnitude of the same kind* [85]. Unlike the interval scale, the ratio scale possesses a nonarbitrary zero value; thus, most measurements in the physical sciences fall under this category.

Ratio scales are widely used in social media measurement, and most social media metrics are examples of the ratio scale. For instance, ratio scales allow social media managers to measure the number of page views, visits, return visits, unique visitors, cost per unique visitor, time spent, and interaction rate [79]. Furthermore, when measuring social media performance, ratio scales can be used to calculate the impressions-to-interactions ratio [28]. Ratio scales can be used to determine how much (magnitude and amount) of something. In health care settings, for instance, the magnitude of a research recruiter's influence can be determined by calculating their Klout score [80]. Influence in this context refers to a measure of a user's ability to drive action from their posts or social interactions. In financial terms, ratio scales can be used to determine the amount of financial benefit a health care provider derives from using social media. For instance, a health care provider can use the ratio scale to calculate the ROI of social media to their practice [2,28].

Ratio scales can also be used to determine how many (count) of something. For example, ratio scales can be used to determine how many health care providers use social media or a particular type of social media [86,87].

Discussion

Summary of Findings

The following taxonomic categories were created based on the literature reviewed: type of article, type of value, period of analysis, measurement metric, measurement level, measurement approach, and measurement scale. From the review of relevant literature, we found the following:

1. Articles on social media value can be derived from IS/information technology (IT), business, medical, or medical informatics literature.
2. Value to measure when appraising health care social media could be IS/IT value or health value, utilitarian or hedonic value, instrumental or intrinsic value, or contextual value.
3. The value of social media in health care can be analyzed pre–social media adoption or post–social media adoption.
4. Metrics used to evaluate the value of social media in health care can measure for either monetary or nonmonetary value.
5. In health care settings, the value of social media can be measured at the micro or aggregate level. Alternatively, it can be measured at the international, national, industry, organizational, and individual levels.
6. The measurement approaches for measuring social media value in health care settings can be quantitative, qualitative, or mixed method in nature.
7. One or more of the following measurement criteria is used in the measurement of health care social media: nominal scale, ordinal scale, interval scale, and ratio scale.

Significance of Study

Research aimed at developing measurement criteria for health care social media is important for both theory and practice. From a theoretical standpoint, investigating the measurement criteria of social media supports the accumulation of knowledge in this emerging domain [40]. From a practice point of view, identifying useful measures of social media outcomes enables managers to evaluate the consequences of social media initiatives vis-à-vis the objectives, enabling them to manage social media strategies from positions that are less reactionary and more grounded in established knowledge or theory [40].

Although there are many papers that describe plausible yardsticks for measuring the value of social media in health care settings, this paper is the first to provide a taxonomic review that covers the types of literature on the subject, the period of analysis, and the focus of analysis. It also covers types of value, metrics for measurement, levels of measurement, approaches to measurement, and scales of measurement.

This study aimed to resolve the dilemma regarding what to measure and how to measure by reviewing and synthesizing relevant literature on the subject. This review paper constructively informs stakeholders about what has been learned, what patterns have emerged from the literature, and how research builds upon previous findings [38]. The findings of this study will help health care managers to ascertain the role of social media in health care and to design social media strategies that can yield tangible results.

This study lays the foundation for the development of a framework to help health care providers measure the outcomes of their social media initiatives by explaining current metrics, yardsticks, and tools for measuring its effectiveness. This is critical because without metrics derived from a theoretical understanding of the underlying processes and objectives, the suitability of the framework may be contestable [40].

Limitations

This work aimed to analyze the literature related to social media value to solicit a taxonomy of ways in which value has been conceptualized. The literature reviewed was not intended to be a systematic review, and it is possible that a wider review may have identified articles that suggest additional concepts for the taxonomy.

Conclusions

This review confirmed a diversity of criteria for measuring social media in health care settings. The most important findings being that users are not sure what types of value to look for, what scale of measurement to deploy, what type of measurement to conduct, when to measure, what metrics to use, and whether to measure at the micro or macro level.

At this time, there is no definitive literature or comprehensive set of methods for measuring the short-, medium-, and long-term impacts of social media on health care quality and safety [72]. Addressing these gaps through more (robust) research is likely to uncover simplified criteria for measuring all types of social media and all contexts of use. Furthermore, as social media is only a tool among several digital technologies that are used in health care, it could be difficult to tease out the specific contributions of social media. However, this seeming challenge of measurement should not be perceived as an obstacle but rather an opportunity to design and develop suitable yardsticks for measuring the contributions of social media in health care settings.

As social media continues to permeate health care, having the measures available and in place to monitor and evaluate outcomes over time will help ensure the effective use of social media in health care improvement.

Recommendations

At the start of a health care social media initiative, a comprehensive measurement approach should be put in place. This will ensure that attention is focused on the objectives and enable the verifiability of outcomes [26]. Users need to clearly define what success will look like [26]. Articulating the objective will help define the appropriate metric to adopt and which measurement tools to use [26]. A starting point could be to understand what others are doing with social media and compare strategies [5].

To determine an appropriate measurement criterion for health care social media, there is a need to define the objectives of the social media initiative, the target audience, and the outcome desired from a social media campaign [72]. Thus, when choosing a measurement framework, it is important to define the metrics to capture in terms of the use cases, importance, and specific objectives [26].

We recommend that this review be used as a starting point to further elucidate and create appropriate measurement criteria for health care social media. Relevant steps in this direction would include the identification of value items with which the respective value can be measured and the identification and development of methodologies that allow measurement [58].

Authors' Contributions

CU conceptualized the study and wrote the manuscript. AS reviewed the manuscript and provided scholarly advice. CU and AS jointly addressed the comments of the Editor and Reviewers.

Conflicts of Interest

None declared.

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Abbreviations

C2C: consumer to consumer
C2P: consumer to professional
IS: information system
IT: information technology
P2C: professional to consumer
P2P: professional to professional
ROI: return-on-investment

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Original Paper

Comparison of YouthCHAT, an Electronic Composite Psychosocial Screener, With a Clinician Interview Assessment for Young People: Randomized Trial

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Abstract

Background: Psychosocial problems such as depression, anxiety, and substance abuse are common and burdensome in young people. In New Zealand, screening for such problems is undertaken routinely only with year 9 students in low-decile schools and opportunistically in pediatric settings using a nonvalidated and time-consuming clinician-administered Home, Education, Eating, Activities, Drugs and Alcohol, Sexuality, Suicide and Depression, Safety (HEEADSSS) interview. The Youth version, Case-finding and Help Assessment Tool (YouthCHAT) is a relatively new, locally developed, electronic tablet–based composite screener for identifying similar psychosocial issues to HEEADSSS

Objective: This study aimed to compare the performance and acceptability of YouthCHAT with face-to-face HEEADSSS assessment among 13-year-old high school students.

Methods: A counterbalanced randomized trial of YouthCHAT screening either before or after face-to-face HEEADSSS assessment was undertaken with 129 13-year-old New Zealand high school students of predominantly Māori and Pacific Island ethnicity. Main outcome measures were comparability of YouthCHAT and HEEADSSS completion times, detection rates, and acceptability to students and school nurses.

Results: YouthCHAT screening was more than twice as fast as HEEADSSS assessment (mean 8.57 min vs mean 17.22 min; mean difference 8 min 25 seconds [range 6 min 20 seconds to 11 min 10 seconds]; *P*<.01) and detected more issues overall on comparable domains. For substance misuse and problems at home, both instruments were roughly comparable. YouthCHAT detected significantly more problems with eating or body image perception (70/110, 63.6% vs 25/110, 22.7%; *P*<.01), sexual health (24/110, 21.8% vs 10/110, 9.1%; *P*=.01), safety (65/110, 59.1% vs 17/110, 15.5%; *P*<.01), and physical inactivity (43/110, 39.1% vs 21/110, 19.1%; *P*<.01). HEEADSSS had a greater rate of detection for a broader set of mental health issues (30/110, 27%) than YouthCHAT (11/110, 10%; *P*=.001), which only assessed clinically relevant anxiety and depression. Assessment order made no significant difference to the duration of assessment or to the rates of YouthCHAT-detected positive screens for anxiety and depression. There were no significant differences in student acceptability survey results between the two assessments.

Nurses identified that students found YouthCHAT easy to answer and that it helped students answer face-to-face questions, especially those of a sensitive nature. Difficulties encountered with YouthCHAT included occasional Wi-Fi connectivity and student literacy issues.

Conclusions: This study provides preliminary evidence regarding the shorter administration time, detection rates, and acceptability of YouthCHAT as a school-based psychosocial screener for young people. Although further research is needed to confirm its effectiveness in other age and ethnic groups, YouthCHAT shows promise for aiding earlier identification and treatment of common psychosocial problems in young people, including possible use as part of an annual, school-based, holistic health check.

Trial Registration: Australian New Zealand Clinical Trials Network Registry (ACTRN) ACTRN12616001243404p; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=371422.

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KEYWORDS

mass screening; adolescents; anxiety; depression; substance-related disorders; primary health care; school health services; eHealth

Introduction

Psychosocial problems and risky health behaviors are significant issues for young people worldwide. In New Zealand, one-third of adolescents are affected by anxiety and depression [1]; the highest rate of suicide is among youth aged 15 to 24 years [2], and approximately one-fourth of high school students engage in hazardous alcohol use [3]. Mental health issues and risky health behaviors can lead to costly long-term health and social outcomes [4-6], and as such, local and World Health Organization policies emphasize the value of developing more effective tools and appropriately targeted and accessible services to identify and address the needs of young people [7-9]. At the same time, young people want a greater say in how services are designed and delivered and expect services to be diverse, contemporary, and responsive [10].

Home, Education, Eating, Activities, Drugs and Alcohol, Sexuality, Suicide and Depression, Safety (HEEADSSS) assessment is a clinician-administered interview-based assessment of young people that can identify mental health and substance use problems [11,12]. Currently, all year 9 (usually 13-year-old) students in low-decile schools (those with the highest proportion of students from low socioeconomic communities) and some attendees at primary care and pediatric services in New Zealand are screened for psychosocial problems via HEEADSSS assessment. Although HEEADSSS offers a straightforward, holistic, and gradual approach to assessing young people across many domains, it is a psychosocial interview rather than a screening tool. Drawbacks include its lack of validation for problem identification, the cost of resourcing, time required for administration (up to an hour per person), and variable quality depending on the skill and experience of the assessor.

The Youth version, Case-finding and Help Assessment Tool (YouthCHAT) [13,14] is a self-report, electronic screener that covers the following domains: smoking, drinking, recreational drug use (based on the Substances and Choices Scale, SACS) [15], problematic gambling, depression (based on the Patient Health Questionnaire-Adolescent Version, PHQ-A) [16,17], anxiety (based on the Generalized Anxiety Disorder-7 scale, GAD-7), sexual health, general stresses, exposure to abuse, behavior problems, anger management problems, eating problems, and physical activity [18]. For each positive domain screened, there is a *help* question that asks participants if they would like help either today or later. Responses to the *help* question support conversations between young people and their health providers about the issues they would like addressed, which facilitates shared decision-making, with increased likelihood that real sustained changes will be made (Figures 1 and 2).

Students complete YouthCHAT electronically on a device, and a summary report is immediately available for the nurse or other health provider through the electronic health record at the point of care. This includes positive or negative responses for each module, and where positive, the score and its interpretation when applicable (eg, depression: PHQ-A score 24=severe depression [20-27 out of a possible 27]) as well as whether help is wanted either now or later is included. A positive PQA-9 question triggers a red alert for self-harm. Where YouthCHAT indicates serious issues such as suicidal ideation, the nurse will intervene even when the students indicate they do not want help. Health providers using YouthCHAT are provided with stepped care resources for each module, tailored to their setting. Although detection of positive issues may increase referral rate and hence workload, this applies equally to HEEADSSS assessment.

YouthCHAT was developed via co-design with young people in primary care, youth, and school settings [13,14,19-22], and previous research has demonstrated its acceptability among young people of New Zealand European, Māori, and Pacific Island ethnicities [23] and identified that some students prefer disclosing sensitive information via electronic means rather than face-to-face means [14,24-27].

Electronic screening has been shown to provide consistent results and can lead to more disclosures and reduce staff time [28,29]. Arguments have been made for and against screening for mental health issues such as depression; however, screening has been found to be effective as long as it is linked to evidence-based interventions, not conducted as a *stand-alone* activity [30].

This study aimed to compare the performance and acceptability of YouthCHAT screening and HEEADSSS assessment for 13-year-old students attending a nurse-led clinic in a high school setting.

Figure 1. Participant flow diagram.

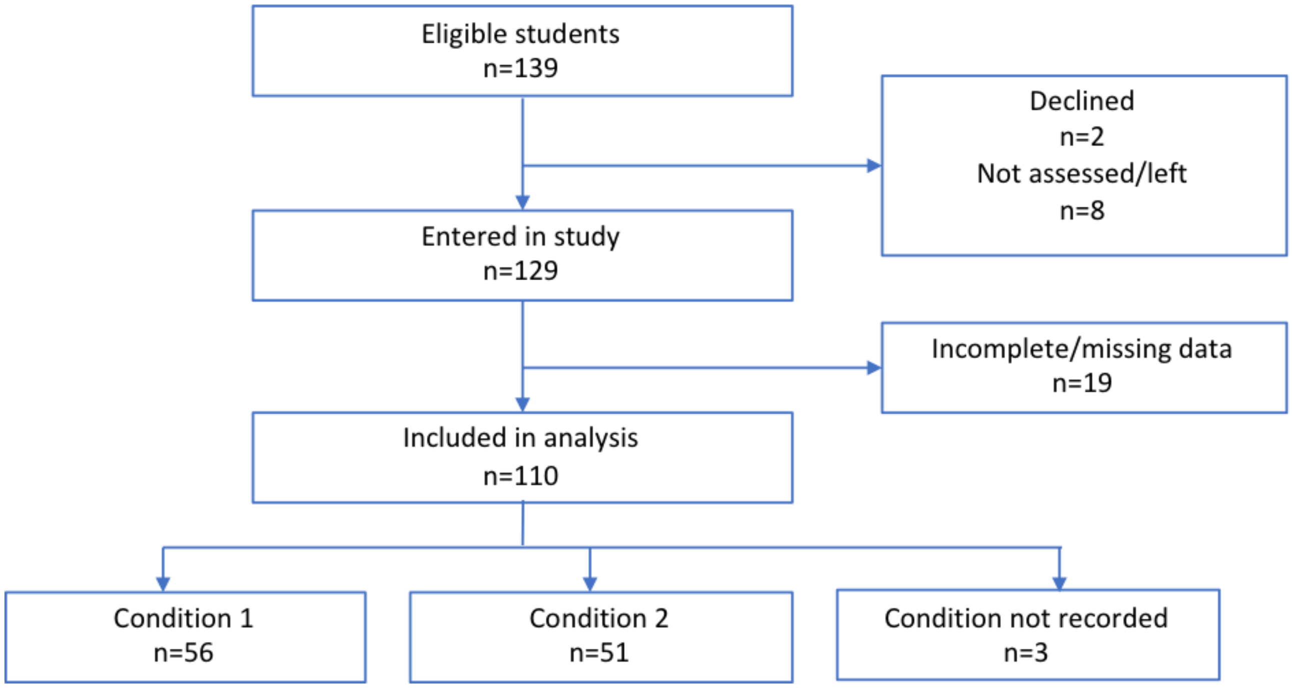
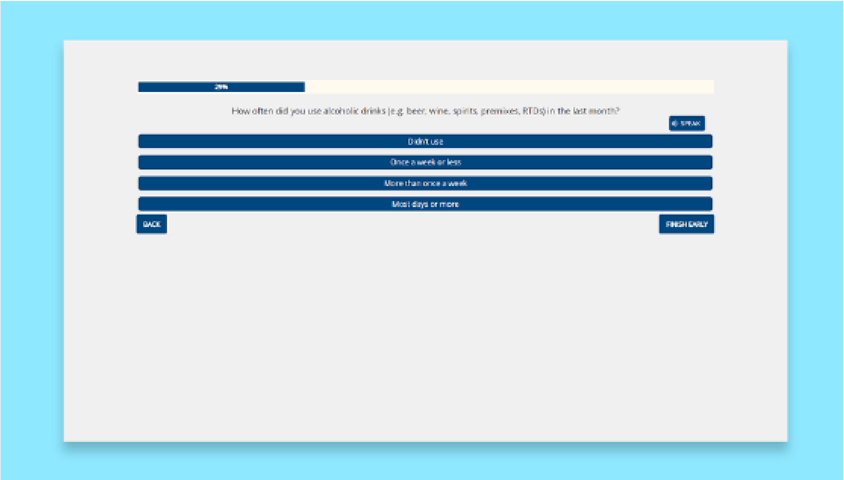


Figure 2. Youth Case-finding and Help Assessment Tool questions example.



How often did you use alcoholic drinks (e.g. beer, wine, spirits, premixes, RTDs) in the last month?

Methods

Trial Design

A randomized trial using a counterbalanced design was employed to deliver YouthCHAT screening either before or after face-to-face HEEADSSS assessment.

Mapping of Youth Version, Case-Finding and Help Assessment Tool and Home, Education, Eating, Activities, Drugs and Alcohol, Sexuality, Suicide and Depression, Safety

Although YouthCHAT and HEEADSSS contained similar areas of assessment, it was necessary to map specific domains to each other for comparison of results. HEEADSSS includes domains on substance misuse, problem eating, sexual health, and physical activity, which are approximately equivalent to YouthCHAT modules. Questions regarding problems at home and safety were mapped for comparison (see Table 1). Although HEEADSSS *mental health* domain includes a number of nonspecific items such a sadness, grief, and difficulty sleeping, YouthCHAT mental health modules only comprised screening measures for depression and anxiety.

Table 1. Mapping Youth version, Case-finding and Help Assessment Tool (YouthCHAT) and Home, Education, Eating, Activities, Drugs and Alcohol, Sexuality, Suicide and Depression, Safety (HEEADSSS) assessment.

Item	YouthCHAT module	HEEADSSS domain
Substance misuse	Smoking or substance misuse (alcohol and drugs)—positive for A Stop *Smoking* In Schools Trial (ASSIST) or Substances and Choices (SACS) Scale	Positive responses to questions on alcohol and drugs
Problems with eating	Positive for problem eating module	Positive responses to questions on eating and weight
Mental health or distress	Depression or anxiety—positive for Patient Health Questionnaire-Adolescent Version (PHQ-A) or Generalized Anxiety Disorder-7 (GAD-7) scale	Positive responses to questions on low mood, self-harm, anxiety, suicidal thoughts, unresolved grief, sadness of historical event, and difficulty sleeping
Problems at home	Positive for "relationships with specific people in your life" or "issues at home, school or work"—from stress module	Positive responses to questions on problems at home
Sexual health	Positive response for sexual orientation, risky sexual behavior, and unwanted sex	Positive responses to questions on sexuality issues
Safety	Positive response to abuse or anger module, to questions on being bullied, or to violence in the stress module	Positive responses to questions on bullying, drunk driving, and other risky behaviors
Physical inactivity	Positive response to physical inactivity	Negative responses to questions on engaging in physical activity

For HEEADSSS assessment, there are no threshold scores—the assessor decides whether the response is positive for that domain or not. For YouthCHAT, responses are clearly positive or negative for each domain. Where there are added tools, cutoff points are as follows:

- ASSIST: 3 to 26 at risk of health and other problems from current pattern of smoking and greater than 26 at high risk of experiencing severe problems (health, social, financial, legal, and relationship) as a result of current pattern of smoking and likely to be dependent;
- SACS: 2 to 3 low-level problems with alcohol or drugs requiring further assessment and more than 3 problems with alcohol or drugs probably requiring treatment;
- PHQ-A: 10 to 14 moderate depression, 15 to 19 moderately severe depression, and 20 to 27 severe depression; and
- GAD-7: greater than 9 general anxiety disorder.

Participants

All year 9 (13- to 14-year-old) students at a low-decile high school in Auckland, New Zealand, were invited to participate following the provision of written information about the study at the start of the school year and the completion of paired informed parental consent (using an opt-out process) and individual participant assent (as all students were aged <16 years). No students were excluded from the study. HEEADSSS assessment is mandatory for all year 9 students regardless of the study.

Recruitment and Randomization

Participants were randomized to receive either HEEADSSS assessment by a school nurse followed by an electronic YouthCHAT screen (condition 1) or YouthCHAT followed by HEEADSSS assessment (condition 2). Clinic staff were provided with a random list from a computer-generated random numbers table, with consecutive sampling until all enrolled students had completed assessment. This took place during a planned break from class time when students receive their annually required HEEADSSS assessment. Review of results and any necessary follow-up was arranged by the school nurse immediately following the completion of YouthCHAT screening and HEEADSSS assessment.

Outcomes

Primary outcome measures were (1) the time taken to complete YouthCHAT and HEEADSSS, (2) comparative detection rates for YouthCHAT and HEEADSSS for each issue, and (3) acceptability of YouthCHAT to students and staff. YouthCHAT data were collected electronically (completed on an electronic tablet by students), and encrypted results were securely stored on a central database. HEEADSSS results were entered into the electronic health record by school nurses. A subset of students completed paper-based acceptability questionnaires, and the 3 school nurses were interviewed individually.

Analyses

Quantitative data were analyzed using Microsoft Excel 2013 and Statistical Package for the Social Sciences version 25 (SPSS v25). Analyses included basic descriptive statistics, between-intervention analyses undertaken with paired *t* tests (for numeric variables) or McNemar tests (for categorical variables), and between-condition nonparametric analyses undertaken with Mann-Whitney *U* tests. Distributions were checked for normality throughout.

Qualitative data were analyzed using a general inductive approach [31], with collated text independently coded by 2 researchers (HT and FG) to identify emerging themes. Discrepancies were resolved through an adjudication session.

Further methodological details are described in our trial protocol [32]. The study was approved by the New Zealand Northern Region Ethics Committee (16/CEN/137/AM03).

Results

Description of Participants

From the 139 eligible students, 129 assented. Electronic screening and face-to-face assessments were conducted between

March and November 2017. There were incomplete or missing data for 19 students, giving a total sample size of 110 for analysis (81%; see Figure 1).

In addition, 63% (71/113) of the participants were of Pacific ethnicity, 29% (33/113) were of Māori ethnicity, and the remaining 8% (9/113) were of New Zealand European or other ethnicity. Moreover, 51% (58/113) of the participants were male, and the randomized condition numbers were similar, with 49% in condition 1 and 51% in condition 2. From the 32 students invited to participate in a focus group (8 during each term), 21 (66%) attended, with 3 groups of 5 participants and 1 group of 6 participants.

Time Taken to Complete Youth Version, Case-Finding and Help Assessment Tool and Home, Education, Eating, Activities, Drugs and Alcohol, Sexuality, Suicide and Depression, Safety Assessment

HEEADSSS time data were missing for 19 students; therefore, the comparative time to complete analyses were conducted for 94 students. YouthCHAT took an average of 8 min 57 seconds (range 1 min 45 seconds to 54 min 15 seconds) to complete, compared with HEEADSSS with an average nearly double at 17 min 22 seconds (range 3 min to 45 min), giving a mean difference of 8 min 25 seconds (range 6 min 20 seconds to 11 min 10 seconds; *P*<.01). For several students, the Wi-Fi connection was lost for YouthCHAT, which may be reflected in the outlier durations of 25 min to 54 min, whereas the vast majority took 10 min or less.

Detection Rates of Complete Youth Version, Case-Finding and Help Assessment Tool and Home, Education, Eating, Activities, Drugs and Alcohol, Sexuality, Suicide and Depression, Safety Assessment

The comparative detection rates are presented in Table 2. The 2 assessments had roughly similar detection rates for substance misuse and problems at home, but YouthCHAT detected significantly more issues around problems with eating or body image perception, safety, physical inactivity, and sexual health (all *P*<.01). HEEADSSS *mental health* category had a greater detection rate when compared with YouthCHAT-detected positive responses to the depression and anxiety tests (*P*<.01); however, no direct comparison between the assessments for only depression and anxiety rates was possible.

Table 2. Comparison between Youth version, Case-finding and Help Assessment Tool (YouthCHAT) screening and Home, Education, Eating, Activities, Drugs and Alcohol, Sexuality, Suicide and Depression, Safety (HEEADSSS) assessment.

Module/domain	YouthCHAT positive, n (%)	HEEADSSS positive, n (%)	*P* value[a]
Substance misuse	10 (9.1)	10 (9.1)	.99
Problems with eating or weight	70 (63.6)	25 (22.7)	<.01
Mental health/distress	11 (10.0)	30 (27.2)	.01
Problems at home	30 (27.3)	29 (26.3)	.72
Sexual health	24 (21.8)	10 (9.1)	.01
Safety	65 (59.1)	17 (15.4)	<.01
Physical inactivity	43 (39.1)	21 (19.1)	<.01

[a] *P* value from McNemar test.

Effects of Randomization Order

The order in which students received YouthCHAT and HEEADSSS (condition 1 vs condition 2) made no significant difference to the duration of YouthCHAT assessment. For YouthCHAT, condition 1 took an average of 8 min 37 seconds (SD 6 min 54 seconds) and condition 2 took an average of 9 min 24 seconds (SD 8 min 26 seconds). For HEEADSSS, condition 1 took an average of 16 min 13 seconds (SD 8 min 42 seconds) and condition 2 took an average of 18 min 7 seconds (SD 9 min 49 seconds).

Similarly, the order made no significant difference to YouthCHAT-positive depression PHQ-A screen rates (both condition 1 and condition 2 had 5 positive screens; $\chi^2_{0.95}=0.0$) or to anxiety GAD-7 rates (condition 1 had 3 screens and condition 2 had 2 screens; $\chi^2_{0.68}=0.25$).

Acceptability of Youth Version, Case-Finding and Help Assessment Tool and Home, Education, Eating, Activities, Drugs and Alcohol, Sexuality, Suicide and Depression, Safety Assessment

The results of the student acceptability survey completed by 21 students are shown in Table 3. There were no significant differences.

Table 3. Student acceptability of Youth version, Case-finding and Help Assessment Tool (YouthCHAT) screening and Home, Education, Eating, Activities, Drugs and Alcohol, Sexuality, Suicide and Depression, Safety (HEEADSSS) assessment (students attending focus groups, n=21).

Item	YouthCHAT, n (%)	HEEADSSS, n (%)	*P* value[a]
Agreed to item			
Works for people my age	18 (85.7)	16 (76.1)	0.4
I have time to think about my responses	16 (76.1)	11 (52.3)	>.99
I felt safe answering the questions	14 (66.7)	12 (57.1)	0.5
I talked about things that I wouldn't have mentioned	11 (52.3)	9 (42.9)	0.7
It's easier to open up about my unhealthy behaviors and feelings	13 (61.9)	11 (52.3)	0.5
It helped me identify the unhealthy behaviors and feelings I need help with	14 (66.7)	12 (57.1)	0.5
Allowed my nurse to know about my unhealthy behaviors & feelings	13 (61.9)	14 (66.7)	0.7
Has too many questions	6 (28.6)	6 (28.6)	0.99
Questions are too personal	5 (23.8)	8 (38.1)	0.5
I worried about the privacy of my information	9 (42.9)	6 (28.6)	0.3
Takes too long	4 (19.0)	6 (28.6)	0.7
Questions were difficult to understand	2 (9.5)	3 (14.2)	0.6
Questions did not relate to me	1 (4.8)	2 (9.5)	0.6
Is boring	2 (9.5)	3 (14.2)	0.6
I felt embarrassed to talk to my nurse about my answers	6 (28.6)	7 (33.3)	0.7
My nurse was judgmental about things I opened up about	1 (4.8)	2 (9.5)	0.6
Objected to specific questions			
Substance misuse	9 (42.9)	4 (19.0)	0.2
Problems with eating	0 (0.0)	2 (9.5)	0.99
Problems at home	2 (9.5)	1 (4.8)	0.99
Sexual health	8 (38.1)	3 (14.2)	0.8
Safety	6 (28.6)	1 (4.8)	0.1
Physical inactivity	2 (9.5)	1 (4.8)	0.99

[a] *P* value from chi-squared calculation with rates correction where n<10.

A total of 4 key themes emerged from the analysis of the 3 nurse interviews (Table 4): (1) valuable tool, (2) difficulties with use, (3) comparing YouthCHAT with HEEADSSS, and (4) additional uses for YouthCHAT. In summary, students found YouthCHAT easy to understand, nurses liked its look and feel, it helped identify students at risk, and nurses found the summary report and the help question useful (Figures 2 and 3). Students did identify some difficulties with use, including Wi-Fi connectivity problems at times, and some students had literacy, language, or cognitive ability issues that were a barrier to its use. In comparison with HEEADSSS, nurses found YouthCHAT easier for students to answer, faster to administer, and helped students subsequently answer face-to-face questions. Nurses suggested additional uses, including repeating annually for a longitudinal picture and using opportunistically with at-risk students in all year groups.

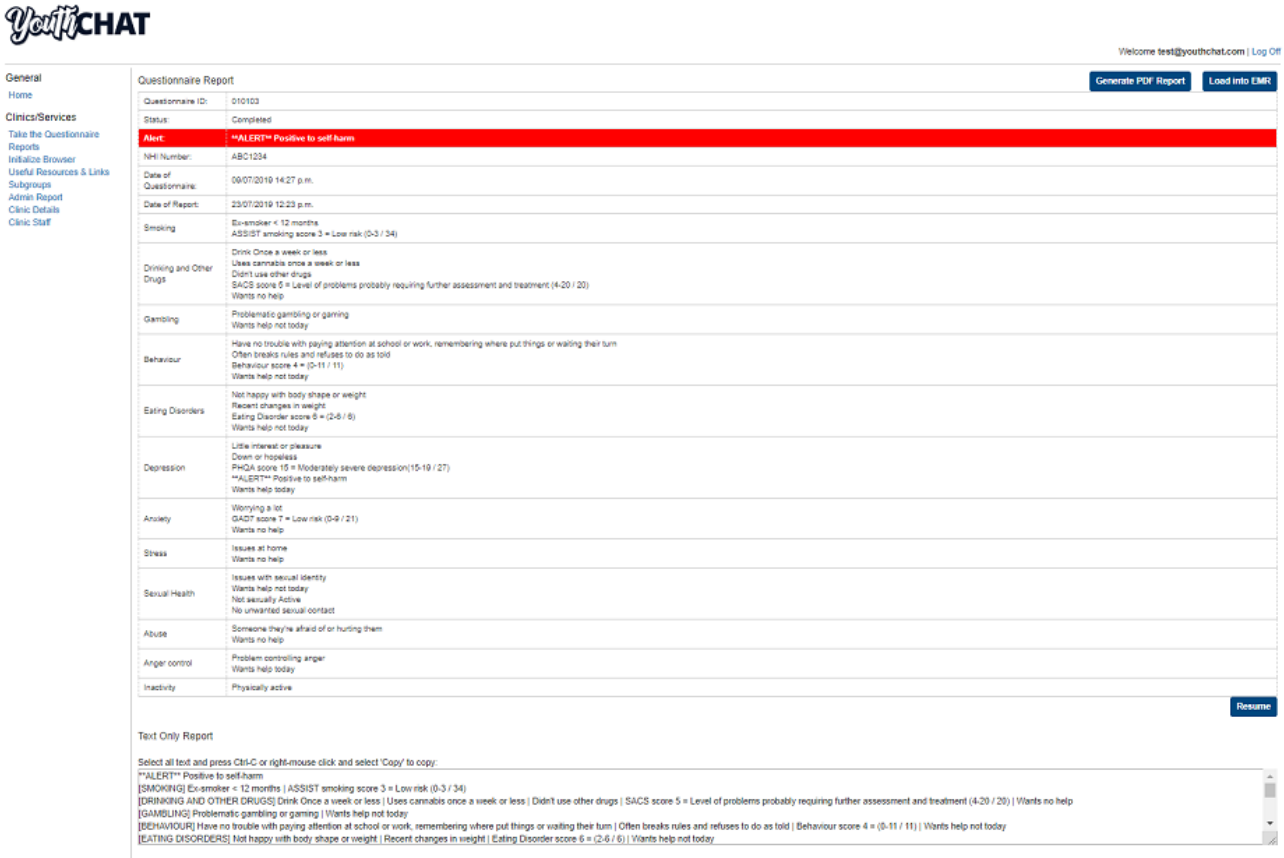
Table 4. Nurses' (N) views on Youth version, Case-finding and Help Assessment Tool.

Theme and subtheme	Example
Valuable tool	
Questions easy to understand	"Most of the kids were able to answer the questions easily." [N2]
Look and feel	"The introductory video was awesome, was really nice and relaxed and helped the students engage." [N3]
Identifies students at risk	"Gathers information that you sometimes forget to ask." [N1]
Useful summary report	"I really liked the clinical summary at the end of YouthCHAT.1Other staff members (e.g., counsellors) thought it was excellent as well. A lot of information is extracted in 15 minutes, more than I could do 1:1." [N2]
Help question is useful	"I love the fact that it asks 'Do you want help today…or in the future' – we all know that nobody is going to change unless they want to, so it's a good way of saving my time and theirs." [N2]
Difficulties with use	
Connectivity (Wi-Fi) issues	"We had some issues with connectivity." [N1]
Student literacy issues	"Literacy issues – those are the kinds of kids that give up early." [N3]
Hearing, language, cognitive ability, and other issues	"One guy with a hearing issue and the volume couldn't go up high enough for him" [N3]; "Some of them had English skills that were not too good because they had just come over from the islands. Sometimes I get an interpreter in." [N2]
Comparing YouthCHAT [a] with Home, Education, Eating, Activities, Drugs and Alcohol, Sexuality, Suicide and Depression, Safety	
Easier to answer electronically	"Kids love [using e-tablet]. I think it is easier to say yes on an e-tablet (than face to face)." [N1]
Faster to administer	"For me to do a HEEADSSS[b], it takes so long and then to write it up, whereas YouthCHAT is so quick." [N2]
Helps with subsequent answering of face-to-face questions	"I think it's better to give YouthCHAT first before talking with them face to face as it gets them in the groove, gives them time to get used to answering questions." [N2]
Additional uses for YouthCHAT	
Opportunistically with other school year groups	"Good to capture kids coming into the school halfway through the year. In fifteen minutes we can quickly capture where they are in their lives." [N2]; "I would do it yearly." [N1]
Longitudinally, for example, repeat annually	"Be good to...follow up with them the next year." [N1]
Use by other staff	"I'd really like the rest of the school health team (counsellors, social workers, nurses, psychologist, addiction workers, GP) to be able to administer YouthCHAT, not just school nurses." [N2]

[a] YouthCHAT: Youth version, Case-finding and Help Assessment Tool.

[b] HEEADSSS: Home, Education, Eating, Activtableities, Drugs and Alcohol, Sexuality, Suicide and Depression, Safety.

Figure 3. Youth Case-finding and Help Assessment Tool summary report.



Questionnaire Report

Questionnaire ID:	010103
Status:	Completed
Alert:	**ALERT** Positive to self-harm
NHI Number:	ABC1234
Date of Questionnaire:	09/07/2019 14:27 p.m.
Date of Report:	23/07/2019 12:23 p.m.
Smoking	Ex-smoker < 12 months ASSIST smoking score 3 = Low risk (0-3 / 34)
Drinking and Other Drugs	Drink Once a week or less Uses cannabis once a week or less Didn't use other drugs SACS score 5 = Level of problems probably requiring further assessment and treatment (4-20 / 20) Wants no help
Gambling	Problematic gambling or gaming Wants help not today
Behaviour	Have no trouble with paying attention at school or work, remembering where put things or waiting their turn Often breaks rules and refuses to do as told Behaviour score 4 = (0-11 / 11) Wants help not today
Eating Disorders	Not happy with body shape or weight Recent changes in weight Eating Disorder score 6 = (2-6 / 6) Wants help not today
Depression	Little interest or pleasure Down or hopeless PHQA score 15 = Moderately severe depression(15-19 / 27) **ALERT** Positive to self-harm Wants help today
Anxiety	Worrying a lot GAD7 score 7 = Low risk (0-9 / 21) Wants no help
Stress	Issues at home Wants no help
Sexual Health	Issues with sexual identity Wants help not today Not sexually Active No unwanted sexual contact
Abuse	Someone they're afraid of or hurting them Wants no help
Anger control	Problem controlling anger Wants help today
Inactivity	Physically active

Text Only Report

Select all text and press Ctrl-C or right-mouse click and select 'Copy' to copy:

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**ALERT** Positive to self-harm
[SMOKING] Ex-smoker < 12 months | ASSIST smoking score 3 = Low risk (0-3 / 34)
[DRINKING AND OTHER DRUGS] Drink Once a week or less | Uses cannabis once a week or less | Didn't use other drugs | SACS score 5 = Level of problems probably requiring further assessment and treatment (4-20 / 20) | Wants no help
[GAMBLING] Problematic gambling or gaming | Wants help not today
[BEHAVIOUR] Have no trouble with paying attention at school or work, remembering where put things or waiting their turn | Often breaks rules and refuses to do as told | Behaviour score 4 = (0-11 / 11) | Wants help not today
[EATING DISORDERS] Not happy with body shape or weight | Recent changes in weight | Eating Disorder score 6 = (2-6 / 6) | Wants help not today
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Discussion

Principal Findings and Comparison With Prior Work

Our results indicate that YouthCHAT is a timesaving, effective, and acceptable psychosocial screener for use in a high school setting. Even with the occasional Wi-Fi glitch, it was significantly faster to use.

In general, YouthCHAT had similar or significantly higher detection rates than HEEADSSS. Although the detection rate for mental health problems or distress was higher with HEEADSSS, this reflects poor mapping of the 2 assessments for this issue. YouthCHAT *mental health* consisted solely of positive scores for depression or anxiety on the PHQ-A or GAD-7, whereas the HEEADSSS domain also included many nonspecific issues such as low mood, distress, unresolved grief, sadness about a historical event, and difficulty sleeping; hence, it is to be expected that more students will score higher for *mental distress* than score positive for depression or anxiety with YouthCHAT. Rates of depression, anxiety, and substance use problems identified via YouthCHAT were in line with expectations for this age group [33,34].

Students revealed significantly more concerns via YouthCHAT than in their HEEADSSS assessment about sensitive issues such as their body weight and sexual health and safety issues such as bullying, violence, and anger. This is consistent with evidence that youth prefer to disclose sensitive information via electronic means, without fear of being judged [24-27]. Electronic screening helps them structure their thoughts and prioritize the issues for which they want help [24]. Despite the difference between groups not being statistically significant, students' concerns regarding privacy of information and being asked questions about sensitive issues suggest that screening for psychosocial issues should always be undertaken in a careful manner and an appropriate setting.

To date, no other screening instrument has been shown to be effective for comprehensively identifying multiple psychosocial problems in young people. Reviews of individual instruments for identifying common psychological problems in young people have identified strengths and weaknesses of different psychometric tests and recommended that these instruments are reserved for targeted use within clinical settings [35,36]. Overall, 3 HEEADSSS-based electronic screeners, TickIT [37], myAssessment [38], and the Headspace Assessment Interview [39], have recently been demonstrated to be acceptable to users in hospital and youth clinic-based settings but have not been evaluated regarding their detection rates.

Given the temporally evolving and fluctuating nature of psychosocial issues during adolescence [40,41], routine (eg, annual) YouthCHAT screening is likely to increase the chance of early detection and intervention. Conducting YouthCHAT before a scheduled HEEADSSS assessment means that the latter needs to focus only on domains where YouthCHAT is positive. Such a *targeted* HEEADSSS approach will reduce the time taken and hence the cost of this assessment. Embedding YouthCHAT screening within a regular *holistic* school health check may also increase mental health literacy [42], normalize the management of psychosocial issues, and reduce stigma about help seeking [43]. Downstream benefits of early intervention may include improved social relationships, better engagement in education and employment, reduced involvement with the justice system, and lower rates of youth suicide [44].

Strengths and Limitations

Strengths of this study include the comparison of YouthCHAT with an existing means of evaluating young people for psychosocial problems, the high response rate, and the collection of both student and staff perspectives on the use of electronic screening within a school environment. The restriction of participants to 13- to 14-year-olds and 3 school nurses from a single high school limits the generalizability of our findings. Owing to the variability in the time taken to complete both tests being considerably less than anticipated (ie, smaller SDs for the time taken to complete YouthCHAT screening and HEEADSSS assessment than expected), our power to detect a difference between the 2 interventions was higher than anticipated. Furthermore, there is a clear statistical difference between the interventions based on this sample; therefore, our final sample size was sufficient to answer our primary research questions. The inclusion of predominantly Māori and Pacific Island participants is both a strength and weakness of this study. Māori and Pacific people comprise 20% and 11%, respectively, of New Zealanders aged 10 to 17 years; hence, these ethnicities are oversampled. However, Māori and Pacific Island youth have higher rates of emotional difficulties [45,46], including depression [47] and suicide [48], yet they access specialist services at lower rates than other ethnicities [49], so early identification and intervention for these youth is key. Finally, the inability to directly map all the YouthCHAT modules to the HEEADSSS assessment domains limited the scope of comparison.

Conclusions

YouthCHAT has been shown to be significantly quicker than HEEADSSS to administer, has a high detection rate of a range of psychosocial issues, and is acceptable to both students and staff. Its potential use is for both opportunistic and routine annual screening of high school students, especially those of low socioeconomic status. Next steps include its evaluation with students of different ages and in different types of school settings. Current evidence supports its use as a first-line screening instrument, which can be followed by a targeted HEEADSSS assessment where indicated.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 98 KB - jmir_v21i12e13911_app1.pdf]

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Abbreviations

GAD-7: Generalized Anxiety Disorder-7
HEEADSSS: Home, Education, Eating, Activities, Drugs and Alcohol, Sexuality, Suicide and Depression, Safety
PHQ-A: Patient Health Questionnaire-Adolescent Version
SACS: Substances and Choices Scale
YouthCHAT: Youth version, Case-finding and Help Assessment Tool

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Original Paper

A Customized Social Network Platform (Kids Helpline Circles) for Delivering Group Counseling to Young People Experiencing Family Discord That Impacts Their Well-Being: Exploratory Study

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Abstract

Background: It has often been reported that young people are at high risk of mental health concerns, more so than at any other time in development over their life span. The situational factors that young people report as impacting their well-being are not addressed as often: specifically, family discord. Kids Helpline, a national service in Australia that provides free counseling online and by telephone to young people in distress, report that family discord and well-being issues are one of the major concerns reported by clients. In order to meet the preferences that young people seek when accessing counseling support, Kids Helpline has designed and trialed a custom-built social network platform for group counseling of young people experiencing family discord that impacts their well-being.

Objective: In this exploratory study, we communicate the findings of Phase 1 of an innovative study in user and online counselor experience. This will lead to an iterative design for a world-first, purpose-built social network that will do the following: (1) increase reach and quality of service by utilizing a digital tool of preference for youth to receive peer-to-peer and counselor-to-peer support in a safe online environment and (2) provide the evidence base to document the best practice for online group counseling in a social network environment.

Methods: The study utilized a participatory action research design. Young people aged 13-25 years (N=105) with mild-to-moderate depression or anxiety (not high risk) who contacted Kids Helpline were asked if they would like to trial the social networking site (SNS) for peer-to-peer and counselor-to-peer group support. Subjects were grouped into age cohorts of no more than one year above or below their reported age and assigned to groups of no more than 36 participants, in order to create a community of familiarity around age and problems experienced. Each group entered into an 8-week group counseling support program guided by counselors making regular posts and providing topic-specific content for psychoeducation and discussion. Counselors provided a weekly log of events to researchers; at 2-week intervals, subjects provided qualitative and quantitative feedback through open-ended questions and specific psychometric measures.

Results: Qualitative results provided evidence of user support and benefits of the online group counseling environment. Counselors also reported benefits of the modality of therapy delivery. Psychometric scales did not report significance in changes of mood or affect. Counselors and users suggested improvements to the platform to increase user engagement.

Conclusions: Phase 1 provided proof of concept for this mode of online counseling delivery. Users and counselors saw value in the model and innovation of the service. Phase 2 will address platform issues with changes to a new social network platform. Phase 2 will focus more broadly on mental health concerns raised by users and permit inclusion of a clinical population of young people experiencing depression and anxiety.

Trial Registration: Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12616000518460; https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=370381

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KEYWORDS

social media; social networking; online counseling; family discord; well-being

Introduction

The demand for Australian online counseling services by young people experiencing family discord and the impact on emotional well-being are substantial and unabating; 8.18% (12,052) and 9.04% (13,322) of the 147,424 contacts recorded by *yourtown* Kids Helpline in 2018 were related to family relationship problems and emotional wellness, respectively [1]. Family discord is defined as disharmony among family members, which may or may not include the child; this can include persistent arguments, controlling behaviors, intimidations, and threats [2]. Improved service reach using online platforms, such as group counseling via a secure social network, is a cost-effective approach to solving consumer demand owing to its accessibility to tech-savvy young people and it gives them the ability to respond en masse. However, challenges in ensuring appropriate user engagement, delivering high-quality evidence-based counseling, and maintaining the confidentiality and safety of clients are key to determining the efficacy of an online mental health service.

It is established that the most popular online resource young people are attracted to is social networking [3-5] and, yet, such platforms are currently not used at scale by mental health services to support young peoples' mental health. This may be largely due to the problem with a lack of evidence-based implementation of social networking as a means of e-mental health service provision. Specifically, they are fraught with safety and privacy issues (ie, maintaining user anonymity as well as allowing counselors to monitor and intervene where necessary with *at-risk* clients). Of major note, globally, no research has been conducted in order to establish evidence-based policy and practice guidelines on how to group-counsel young people via a social network. Given this, online mental health support has typically been provided via chat, Web forum, or email-based counseling in a one-to-one, typically peer-to-peer, format by various mental health services. However, demand by young people for a secure and mobile phone-accessible mental health social networking service, where they can connect to counselors as well as peers experiencing similar issues, is growing given their online communication preferences [4,6]. In this study, we will use a custom-built social networking site (SNS) to address consumer demand as well as user preference for engaging with those with lived experience of family discord. While retaining the option to access counseling experts, this research aims to establish the viability and usability of Kids Helpline Circles (KHL Circles) as an innovative, purpose-built SNS delivered by *yourtown* Kids Helpline for Australian youth.

Kids Helpline is the leading national service in telephone and online counseling in Australia, given that it is the only 24/7 counselor-monitored service (ie, not a peer-to-peer counseling service). Consumers who receive help via the service often wish to revisit in order to receive ongoing counseling support, not just one-time counseling or further referral to other services. Garcia [7] reported that there were more than 70,000 attempts to contact Kids Helpline in the first half of 2019 that were not answered due to the service not having enough online and telephone counselors to meet the increasing demand. To provide more flexibility in meeting demand, Kids Helpline is now focused on providing a professionally facilitated online community for long-term support of clients between the ages of 13 and 25 years, to provide continuous connection and ongoing counseling support to prevent relapse. However, the concept of a purpose-built, secure, private, and counselor-controlled e-mental health-focused SNS needs to be piloted in order to ensure its efficacy before launching it as a new support service for Australian young people.

This participatory action research (PAR)-designed exploratory study [8] sought to develop the evidence base to validate the proof of concept for KHL Circles: a purpose-built, private, and secure SNS, designed to provide 24/7 group counseling to young people in Australia experiencing family discord. This study draws on evidence that young people already seek out others via their private social network choices (eg, Facebook and Instagram) for peer support, in order to feel they are not alone with their problems [4]. However, there are serious concerns that seeking help from peers online who are strangers and nonexperts may expose young people to inaccurate or misleading information and hostile or derogatory comments, which may have a negative impact on their mental health [9]. KHL Circles seeks to address these concerns by providing clients with evidence-based mental health information and support delivered via group counseling. If needed, counselors can direct young people to community services to access legal, financial, disability, or employment advice. KHL Circles also facilitates peer support by connecting clients with other clients of a comparative age who are experiencing similar issues to share stories and support each other; it is facilitated and monitored by professionally trained and accredited counselors who are part of their closed, small-group, social network. This supportive, moderated, online approach has been identified as theoretically optimal in several recent studies that have proposed SNS as an adjunct to online mental health interventions [6,10,11]. However, no research has yet determined a working model for utilizing a private and secure, purpose-built, e-mental health social network for ongoing group counseling to support young people experiencing family discord and mental well-being concerns.

Methods

Participants

A total of 105 participants were recruited from the Kids Helpline telephone and Web-chat counseling service, as well as from their website and social media posts. The participants initially contacted the service to seek help for their concerns and upon counselor interview and assistance for their immediate concerns, they were introduced to the option to join KHL Circles as volunteer participants. The inclusion criteria were as follows: (1) aged 13-25 years and of any gender identity, (2) newly contacting or previously engaged (ie, returning client) with Kids Helpline via one-on-one phone and/or Web counseling, (3) seeking support specifically for issues related to family discord and emotional well-being (eg, at-home psychological abuse, distress, or communication problems with family members), and (4) able to speak English (ie, required under ethical approval for the study, as no translator for other languages could be provided within the counselor-mediated social network). The mean age of participants was 16.2 years (SD 2.9) and the majority were female (86/105, 81.9%). The age, gender, and location breakdowns of participants are presented in Table 1. A total of 81.9% (86/105) of the sample spoke only English. Other languages also spoken included Mandarin, Cantonese, Dutch, Bosnian, Telugu, Punjabi, Bisaya, Korean, and Japanese.

Table 1. Participant demographics and response count.

Demographic	Participants (N=105), n (%)
Age (years)	
13-15	50 (47.6)
16-18	36 (34.3)
19-21	10 (9.5)
22-24	8 (7.6)
25	1 (1.0)
Gender	
Female	86 (81.9)
Male	10 (9.5)
Trans or gender diverse	6 (5.7)
Other	1 (1.0)
Missing	2 (1.9)
Location	
New South Wales	32 (30.5)
Victoria	22 (21.0)
Queensland	22 (21.0)
South Australia	4 (3.8)
Tasmania	1 (1.0)
Western Australia	1 (1.0)
Australian Capital Territory	3 (2.9)
Missing	15 (14.3)

Design and Procedures

This exploratory study used a single-group, PAR, mixed-method design [8] to assess the acceptability, safety, user experience, and potential mental health benefits of KHL Circles. There were six *Circles* (ie, Groups) conducted over a 12-month period, from May 2017 to May 2018. There were 9 participants in Groups 1 and 2 (conducted concurrently), 8 participants in Group 3, and 13 participants in Group 4 (conducted concurrently with Group 3). After the first four groups were completed, the number of participants per group was increased to 32 for Group 5 and 34 for Group 6 in response to qualitative feedback from participants and to increase engagement and activity within each Circle.

Volunteer participants who contacted a Kids Helpline phone or Web counselor received immediate one-to-one counseling (ie, standard care model for the service). While in one-to-one counseling, they were asked if they would be interested in joining the study trialing the peer-support social network, KHL Circles. Those who indicated they wanted to join the trial were informed that they may not be able to join one of the Circles in the social network immediately and, if this was the case, they would be asked to wait for the next group to begin. Potential volunteer participants were screened for severe mental health problems (ie, high-level depression and anxiety) or risk of self-harm behaviors before being permitted into the online group-counseling environment. Screening was conducted through counselor interview. Those who were deemed high risk were provided with one-to-one counseling via Kids Helpline's regular telephone or Web counseling services. Once suitable participants were assigned to a KHL Circle, they completed an entrance survey containing psychometric tests to measure baseline depression, anxiety, self-esteem, and perceived social support.

All volunteer participant members of KHL Circles were asked to use pseudonyms in order to protect their identities from each other. The counselor facilitating the group was the only group member aware of their true identities. Participants were instructed not to reveal any identifying information during the trial, including any identifying photos or images. Those recruited were asked to give electronic consent if they were 16 years of age or older, or consent and optional assent from a parent or guardian if 15 years of age or under. Participants were also asked to read the Kids Helpline policy and agree that during their time in KHL Circles, if they choose to start their own social network support group on a non-Kids Helpline service (eg, Facebook), that Kids Helpline would not be liable for the safety and running of those groups.

Participants completed a baseline survey in the week prior to joining their Circle containing psychometric tests measuring levels of depression, anxiety, self-esteem, and perceived peer support. Participants were also asked to complete a *check-in* survey at the end of weeks 2, 4, and 6, and a final survey at the conclusion of the study (ie, end of week 8); all surveys contained the same four psychometric tests, along with open-response questions on their experiences of KHL Circles. Counselors provided weekly reports on their perceptions of group engagement and any group-counseling concerns or functional issues regarding the online platform. All participants were informed prior to joining KHL Circles that their Circle would be closed at the end of the 8-week cycle, after which each member may revert to one-to-one counseling using Kids Helpline telephone and Web counseling services.

The research protocol was approved by The University of Sydney Human Research Ethics Committee (HREC) (Project #2016/132) and registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) (ACTRN12616000518460).

Kids Helpline Circles Platform

KHL Circles was developed by a team of researchers, psychologists, and programmers following consultation and beta testing with young Kids Helpline clients and using PAR design principles [8]. The platform was developed using the open-source social networking software Elgg [12], which was customized by a team of Web developers and graphic designers to meet the requirements of the service. The platform was available to participants via any Internet-enabled computer or mobile device. The mobile version of the site was adjusted to fit the size of the screen being used by the participant but included all the same components as the desktop version. Participants could log in to KHL Circles anytime throughout the trial. The platform was run on Kids Helpline's own private servers and monitored by Kids Helpline counselors 7 days a week. Clients were also asked to report any risk they foresaw or major conflict within the group by contacting Kids Helpline via telephone or Web counseling services.

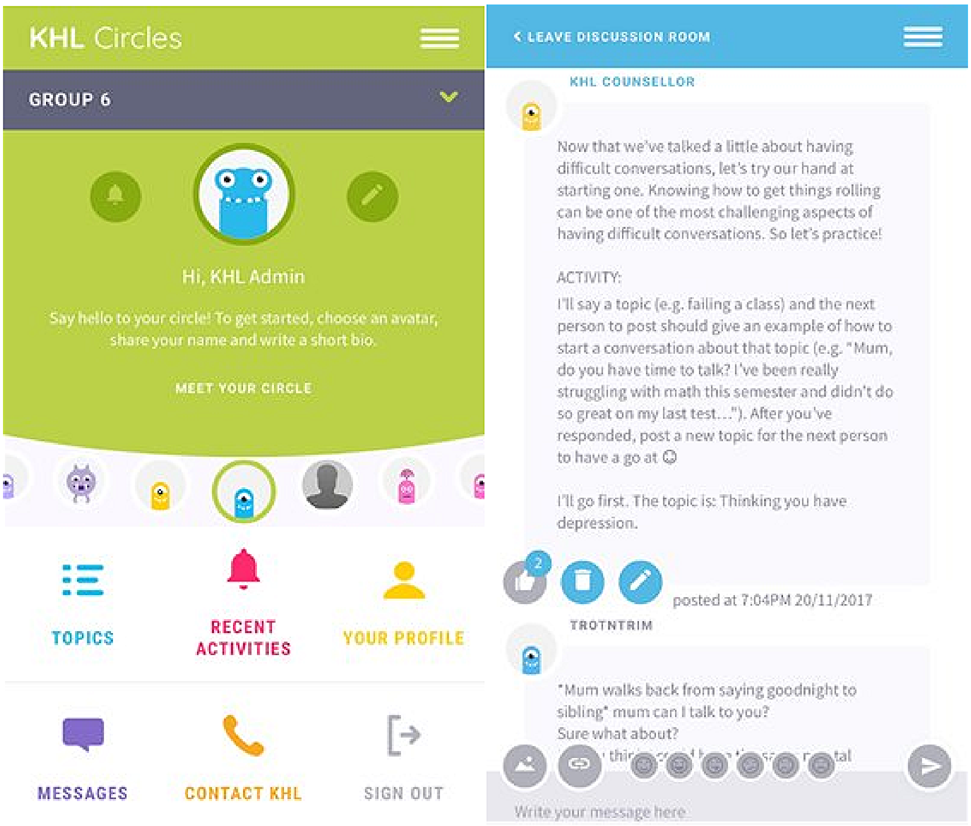
As part of the baseline survey, participants put forward their pseudonym, which was reviewed by the site administrator to ensure that it did not reveal their identity. In the days leading up to week 1, the site administrator assigned participants to their Circles and emailed them unique log-in details. Participants were asked to log in to the site prior to the week 1 commencement date to complete their profiles (ie, gender, hobbies, and likes) and to choose a profile picture from a suite of *alien* images (see Figure 1 for images of some of the alien characters for user choice). On the first day of week 1, a KHL counselor posted a welcome message explaining to participants how the Circle would be run and asked them to test out the posting features of the site (ie, posting text, pictures, and videos, and *liking* or commenting on posts of other users, similar to well-known Facebook functions; see Figure 1). Participants were also provided with some ground rules (eg, respecting others, no offensive material, and keeping their identity private) and were asked to expand on this list with their own expectations of their Circles.

The main menu bar of the site presented six tools:

1. Topics: the default view, which showed a list of the all discussion posts and threads posted to date, with the most recent at the top of the page.
2. Recent activities: allowed participants to quickly access topics they had contributed to.
3. Your profile: participants could update their profile information here.
4. Messages: participants could send and receive a private message to or from a Kids Helpline counselor but not to or from other participants.
5. Contact KHL: a link to the Kids Helpline phone and Web-chat counseling service.
6. Sign out.

For each Circle, Kids Helpline Counselors posted three new *topics* each week—every Monday, Wednesday, and Friday—consisting of age-appropriate psychoeducational material about family discord, including conversational text, images, and videos; topics also consisted of a reflection and discussion activity to encourage engagement and interaction between participants on ways of addressing various issues within this subject. Each week focused on one of eight modules: (1) Introduction; (2) Family relationships; (3) Emotions; (4) Mental health and resilience; (5) Help-seeking and social support; (6) Family communication and negotiation skills; (7) Conflict resolution, self-care, and relapse prevention; and (8) Summary and close. Participants could also start their own *topics* or contribute to an ongoing *Song of the Day* topic.

Figure 1. Kids Helpline Circles (KHL Circles) mobile phone interface design.



Say hello to your circle! To get started, choose an avatar, share your name and write a short bio.

Now that we've talked a little about having difficult conversations, let's try our hand at starting one. Knowing how to get things rolling can be one of the most challenging aspects of having difficult conversations. So let's practice!

ACTIVITY:

I'll say a topic (e.g. failing a class) and the next person to post should give an example of how to start a conversation about that topic (e.g. "Mum, do you have time to talk? I've been really struggling with math this semester and didn't do so great on my last test..."). After you've responded, post a new topic for the next person to have a go at ☺

I'll go first. The topic is: Thinking you have depression.

posted at 7:04PM 20/11/2017

Mum walks back from saying goodnight to sibling mum can I talk to you?
Sure what about?

Safety Protocols

The safety protocol of KHL Circles is based upon the existing safety protocols of the Kids Helpline phone and Web counseling service, which includes policies for mandatory reporting. Monitoring of KHL Circles by Kids Helpline counselors was done 24/7 and was combined with having access to contact details via particpants' Kids Helpline files; this allowed any potential risks to the safety or mental health of participants to be addressed proactively by contacting the participant directly via email or via the private messaging function of KHL Circles, encouraging them to contact the Kids Helpline phone counseling service.

KHL Circles was hosted on Kids Helpline's private server, using a URL secured with HTTP over Secure Socket Layer (SSL); HTTP Secure (HTTPS) conformed to industry best practice as defined by the Open Web Application Security Project [13]. Privacy and online safety were managed in accordance with recommendations by the eSafety Commissioner of the Australian Government [14], with participants required to accept the terms of use of KHL Circles, which included clauses regarding their privacy, online bullying or harassment, and the use of offensive comments. Participants were informed that failure to comply with guidelines may result in temporary or permanent removal from the service. In accordance with international standards for the legal age of having a social media account, only those 13 years of age and over were permitted into the study. Moreover, in accordance with The University of Sydney HREC and the ANZCTR, those aged 13-15 years needed to provide personal assent, while those 16 years of age and over needed to provide personal consent. All participants under the age of 18 years were informed that they had the option to gain parental consent for the study.

Measures

The following psychometric tests were included as part of each survey (ie, the baseline survey; *check-in* surveys at weeks 2, 4, and 6; and the final survey at week 8): (1) the Multidimensional Scale of Perceived Social Support [15], (2) the Centre for Epidemiological Studies—Depression Scale for Children [16], (3) the Revised Children's Manifest Anxiety Scale [17], and (4) the Rosenberg Self-Esteem Scale [18].

The baseline survey asked participants what they hoped to gain from KHL Circles (open response). Each check-in survey and the final survey asked participants whether they felt that KHL Circles had helped them feel supported in coping with their problems (yes/no) and, if so, what made them want to return to communicate with their Circle (open response). The final survey also asked participants to indicate how helpful they found KHL Circles (4-point scale), if they would return to KHL Circles for any future issues (yes/no), and what sorts of issues they would be comfortable discussing in KHL Circles (from a list of nine options or specify *other*). Participants were also asked to indicate the most helpful and least helpful aspects of KHL Circles (from a list of four options for each or specify *other*) and what they considered to be the most important features of a social media peer-support site (from a list of eight options or specify *other*). Each survey concluded with the opportunity for participants to provide any other comments or feedback (open response).

Safety was assessed using the following a priori indicators: (1) any instances of adverse events, (2) any instances of breaching guidelines of use, and (3) qualitative feedback from participants.

Results

Participants

As recorded in the baseline survey, most participants were female (86/105, 81.9%) and aged between 13 and 15 years (43/105, 41.0%). A total of 105 participants responded to the baseline survey; however, over the course of the study, the number of participants who completed the *check-in* surveys and the final survey (week 8) reduced significantly (see Table 2).

Table 2. Participant demographics and response count.

Questionnaire	Participants (N=105), n (%)
Baseline survey	105 (100)
Week 2 survey	48 (45.7)
Week 4 survey	12 (11.4)
Week 6 survey	13 (12.4)
Final survey (week 8)	8 (7.6)

Qualitative Data Analysis

A simple content analysis of responses to the qualitative questions was conducted. Each response was read and assigned an open code that summarized the key idea in their initial response [19,20]. For example, “to see if some other people are in my situation so I don’t feel like my problems only apply to me and my family” was assigned an open code of *Relate with others*. Similar codes were grouped together under axial codes, which were given a descriptive heading. For example, *Relate with others* was grouped with *Not to feel alone* under *Connect with others*. Similar axial codes were then grouped together under main categories and provided with a descriptive title. For example, *Connect with others* was grouped with *Receive support* under the category *Engage with others for support*. KA reviewed all coding and BR provided a second review: each was a research associate covered under HREC approval for the study analysis. Disagreements were resolved by consensus [21].

As part of the baseline survey, participants were asked, “What do you hope to gain from joining Kids Help Line Circles?” Content analysis of the 105 participant responses to this question produced six categories: (1) *Engage with others for support* (76/105, 72.4%; eg, “I hope to gain support through meeting people going through similar experiences and not feeling as alone”); (2) *Receive information* (26/105, 24.8%; eg, “An insight into how others deal with similar circumstances”); (3) *Positive self-outcome* (22/105, 21.0%; eg, “Something that can make me feel happy and worthy of myself”); (4) *Provide support* (11/105, 10.5%; eg, “I hope to gain a better mindset and help others that are in trouble”); (5) *Miscellaneous* (3/105, 2.9%; eg, “I hope that it’s worth joining”); and (6) *Unsure* (8/105, 7.6%).

As part of the *check-in* surveys, participants were asked, “Do you feel that being a member of the KHL Social Network 'Circles' has helped you feel supported in coping with your problems?” to which 41 out of 68 (60%) responses were *yes*. Participants were further asked, “If being part of Kids Helpline Circles has helped you, what makes you want to return to talk to people when you feel like it?” Content analysis of 22 participants’ open responses revealed four categories: (1) *Sense of community* (15/22, 68%); eg, “I feel like others understand what I am going through, and that I am not alone in my feelings and struggles”); (2) *Safe environment* (6/22, 27%; eg, “Knowing that it’s a safe environment to help others and to get help”); (3) *Helpful environment* (5/22, 23%); eg, “All the people I have talked to is [sic] really nice and I feel like we all really make an effort to help and support each other in any way we can”); and (4) *Miscellaneous* (2/22, 2%; eg, “I don't use it much but I will try to more”).

The final survey also asked participants, “Do you feel that being a member of the KHL Social Network 'Circles' has helped you feel supported in coping with your problems?” to which there were 5 responses, 3 (60%) of which were *yes*. Only one participant provided a response to the follow-up open-response question “If being part of Kids Helpline Circles has helped you, what makes you want to return to talk to people when you feel like it?” so qualitative analysis was not possible.

User Experience

As part of the final survey, participants were asked questions about their experiences using KHL Circles. Of the 8 participants who responded to the final survey, 5 (63%) provided responses to the user experience questions. The topics participants felt most comfortable discussing were peer relationships (3/5, 60%), family relationships (3/5, 60%), depression (3,/5 60%), and anxiety (3/5, 60%). Other responses included well-being, motivation, sexuality, romantic relationships, gender and identity, and image. When asked, “What did you find the most helpful aspect of KHL Circles?” responses included “connecting with people who understood my concerns” and “learning a lot about the topic discussed.” The only unhelpful aspect identified was “focusing on just the topic” (ie, family discord). When asked about what they thought the most important features of a social media peer-support service were, the most common response was *emojis* (4/5, 80%), followed by *games* (3/5, 60%), *anonymity* (3/5, 60%), *mobile phone app integration* (3/5, 60%) and *easy navigation* (3/5, 60%).

Weekly Summary Reports by Counselor Facilitators

In addition to the questionnaires completed by participants, the counselor facilitators submitted weekly summaries to report on participant activity and user experiences. In each Circle, activity was highest in week 1, with 207 posts or comments and 532 *likes* in total across all groups. Activity generally started to drop off by week 2 (170 posts or comments and 326 *likes*), with the biggest drop during week 3 (73 posts or comments and 128 *likes*). Engagement typically continued to reduce over the remaining weeks, reaching a low of 11 posts or comments and 69 *likes* in week 8. Counselors reported a pattern where many participants were logging on and participating earlier in the week but not returning during the remainder of the week.

The most frequent comments made about the experience using the platform were about the navigation challenges. These included clunky scrolling mechanics, inability to resize images, manual linking of images and videos, and inability to archive posts for better flow. Frequent mention was also made about the need to include an automated time stamp to orient users about when posts were made.

Simple technical issues raised by participants involved issues uploading images and videos and the changing of passwords, which were guided or corrected by the counselors directly. Issues that needed immediate attention included counselors not being able to see groups due to log-in or log-out errors and an inability to directly message participants via Elgg, unless participants had directly messaged them first. One participant also suggested to counselors that mobile app notifications were needed, which was a function that was unfortunately not available within the Elgg platform.

Psychometric Tests Analysis

An intention of this exploratory study was to conduct repeated-measures quantitative analyses of the psychometric tests administered to participants; however, due to the drop-off in response rates between the baseline survey (105/105, 100%) and final survey (8/105, 7.6%), data quality was too low to conduct meaningful analysis.

Discussion

Principal Findings

This exploratory, mixed-methods, PAR study aimed to assess the user experience and potential benefits of a purpose-built social networking platform, KHL Circles, for online group counseling of young people experiencing family discord. Results showed that the main benefit participants hoped to gain from KHL Circles prior to joining was engaging with others with similar lived experiences. This was the most common theme identified in relation to engaging with others for support. Other themes identified included gaining new information and positive self-outcomes. While low response numbers precluded any significant findings from the psychometric measures used in the study, the majority of participants reported that the overall experience of being a member of KHL Circles helped them in being supported in coping with their problems with family discord. Of those who reported that the service did not help them, it was found that comorbid problems not specific to family discord may have been a factor (eg, school bullying, romantic relationship problems, and specific mental health concerns). While the response rate to the final survey was very low, the majority of those who did remain engaged through the full 8 weeks reported they would continue to use the purpose-built social network if it was made available, which qualitative responses indicated was largely due to obtaining a sense of community about a specific issue they all shared.

As reported by the counselor facilitators of KHL Circles, the least helpful aspect of KHL Circles was reported to be the Elgg platform itself, given that it was not easy to navigate or find threaded responses for counselor engagement with each group. Many users reported that the platform would have been more engaging if it was like existing, popular social networks that they were familiar with (eg, Facebook) and provided a better quality of standard tools (eg, emojis, games, and better mobile phone operability).

Limitations

While providing proof of concept for the KHL Circle model, results from this study are limited by low retention rates across the 8-week cycle of each group. User experience feedback should, therefore, be interpreted with caution as it only reflects the experiences of participants who completed the entire 8-week cycle. Completion rates of all psychometric surveys were poor beyond initial baseline collection (see Table 2), so no inferences could be drawn regarding any impact on mental health and emotional well-being. Low engagement with these surveys is not surprising given the age group studied and their primary motivation to be part of the study (ie, to connect with others the same age with lived experience of family discord). The length and clinical focus of the surveys—those not focused on family discord issues—may also have led to refusal to complete the surveys due to self-perceived lack of relevance, disinterest, or disengagement from the study. Phase 2 of KHL Circles will seek to significantly reduce the number and length of mental health surveys provided, as well as to make changes to the platform to increase engagement and activity within the groups in order to encourage higher retention across the 8-week program.

The recruitment for this study was restricted to those with mild-to-moderate levels of depression, anxiety, or stress, in order to abide by the strict ethics protocol provided for this exploratory research. As such, through careful ethical consideration of online safety of minors, this study may have inadvertently denied access to those who are in significant need of such an innovation to aid their distress around family discord and provide relatable online community support and expert counselor facilitation. Phase 2 will seek the inclusion of all young people who wish to access the KHL Circles service, given that Kids Helpline's services already attract a high level of distressed young people that would not fit the category of mild-to-moderate levels of depression and anxiety.

Of importance to note was the very high rate of female participants in this study. While not unusual to see more females than males engage in seeking help [22]—historically, yourtown Kids Helplines' client data over two decades supports this trend—ways in which to attract males to online services needs to be further explored. This could include the introduction of more *project*-oriented group counseling set around a focus activity such as gaming, for example [23].

From a technical perspective, the Elgg platform was reported by users and counselors to be too rigid to use in comparison to popular platforms such as Facebook. Given this, at the conclusion of the Phase 1 study, the researchers sourced a new platform called HumHub [24], which will undergo customization by Kids Helpline for Phase 2. It includes high-level server security features and functions requested by users (ie, emojis, better integration with linked images and videos, and notifications), with an interface like publicly available SNS's such as Facebook. Of notable importance for this research progressing into Phase 2 will be the continuous monitoring of user experience of the social network service platform in order to incorporate iterative design changes to meet the needs of both the end user (ie, client) and the counselor facilitator.

Conclusions

Social network uptake and sustained use by young people, not only for leisure but for community support or nonexpert counseling and advice-seeking, has been documented over many years [4,5,25-27]. The risk of utilizing nonexpert, nonsecure, social network support groups via such platforms as Facebook is problematic at best and dangerous at worst for the well-being and safety of young people [25,28]. Kids Helpline's innovation in developing a custom-built, social network platform focused on the two most common topics young people contact their services around: family discord and mental well-being. Phase 1 is the first phase of a series of PAR studies to refine such a resource to address typical youth issues. Thus, the findings from this study support proof of concept and user interest for its evolution as a service delivery model. The potential significance of the proposed research is the provision of greater access to online support for clients of Kids Helpline and other online mental health services globally; lack of access is highly problematic, given that young people often do not know how to access mental health services as first-time users, find the services on offer costly and invasive to their needs, or simply do not trust what is available, whether it is online or offline [3-5,9,11,22,25,27,29].

As determined by Ridout and Campbell's [6] systematic review, this research is the first of its kind in determining an innovative online model for cost-effective provision of short-to-long-term psychosocial support, with potential for ongoing group counseling support of Australian youth with mental illness. The applied research approach between academic experts, clinical expertise, and a not-for-profit group—yourtown Kids Helpline—demonstrates clearly the recommendations of utilizing a partnership model in innovating and developing mental health services for hard-to-reach populations (eg, youth) [29]. This research has moved on to Phase 2, where data collection began in 2018 and will continue through 2020, during which the implementation of the revised platform will be evaluated with the inclusion of a larger and more diverse user group, inclusive of young people experiencing greater-than-moderate levels of distress.

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Conflicts of Interest

None declared.

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Abbreviations

ANZCTR: Australian New Zealand Clinical Trials Registry
FGX: Future Generation Investment Fund
HREC: Human Research Ethics Committee
HTTPS: HTTP Secure
KHL Circles: Kids Helpline Circles
PAR: participatory action research
SNS: social networking site
SSL: Secure Socket Layer

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Original Paper

Compliance and Retention With the Experience Sampling Method Over the Continuum of Severe Mental Disorders: Meta-Analysis and Recommendations

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Abstract

Background: Despite the growing interest in the experience sampling method (ESM) as a data collection tool for mental health research, the absence of methodological guidelines related to its use has resulted in a large heterogeneity of designs. Concomitantly, the potential effects of the design on the response behavior of the participants remain largely unknown.

Objective: The objective of this meta-analysis was to investigate the associations between various sample and design characteristics and the compliance and retention rates of studies using ESM in mental health research.

Methods: ESM studies investigating major depressive disorder, bipolar disorder, and psychotic disorder were considered for inclusion. Besides the compliance and retention rates, a number of sample and design characteristics of the selected studies were collected to assess their potential relationships with the compliance and retention rates. Multilevel random/mixed effects models were used for the analyses.

Results: Compliance and retention rates were lower for studies with a higher proportion of male participants (*P*<.001) and individuals with a psychotic disorder (*P*<.001). Compliance was positively associated with the use of a fixed sampling scheme (*P*=.02), higher incentives (*P*=.03), higher time intervals between successive evaluations (*P*=.02), and fewer evaluations per day (*P*=.008), while no significant associations were observed with regard to the mean age of the sample, the study duration, or other design characteristics.

Conclusions: The findings demonstrate that ESM studies can be carried out in mental health research, but the quality of the data collection depends upon a number of factors related to the design of ESM studies and the samples under study that need to be considered when designing such protocols.

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KEYWORDS

experience sampling; ecological momentary assessment; compliance; retention; severe mental disorders

Introduction

Background

The experience sampling method (ESM) [1] or ecological momentary assessment (EMA) [2] can be used interchangeably to refer to an assessment method that involves the collection of repeated and momentary self-evaluations in the context of an individual’s daily life. Compared with conventional clinical tools that are typically administered once and in a lab/clinical setting, this methodology improves ecological validity, limits potential artifacts because of retrospective recall [3-6], can capture the within-person fluctuations of psychological states and behaviors [7-9], and allows for a more fine-grained examination of contextual factors [10-12]. As such, ESM is of particular interest in clinical psychology where patients are affected by memory problems [3,4], unstable affective states [5,6], and by a heightened sensitivity to contextual factors [17-19]. ESM has, therefore, been extensively used in this field of research over the past 30 years [7,8], particularly in populations with depressive disorders [7,9] and psychosis [8,10].

Although ESM presents several advantages over conventional clinical assessment tools, the very nature of this method, requiring multiple self-evaluations over time in daily life, also introduces some challenges. One major challenge is to achieve high compliance and retention rates. The compliance rate can be defined as the ratio of the number of self-evaluations that participants actually completed over the theoretical maximum number of self-evaluations allowed by the protocol (0%-100% when expressed as a percentage), whereas the retention rate refers to the proportion (or percentage) of participants included in the final analyses (eg, a subject withdrawing their participation from a study, for example, because the data collection procedure is experienced to be too burdensome, would be excluded). These two rates are often inherently linked in ESM research, as participants providing an insufficient number of responses are conventionally excluded from the analyses [11], which in turn influences the retention rate.

In the framework of ESM, compliance and retention rates are often reported to describe the quantity of data collected and to provide an indication of the quality of the data collection procedures. ESM studies are naturalistic investigations, inevitably leading to missing data. When people are engaging in certain sport, leisure, or work activities, driving in their car, or taking a nap, they will not be able to fill out the ESM questionnaire (either because they do not hear the notification of the data collection device or because responding would be inconvenient, unsafe, or inappropriate to do in a given situation). Compliance rates close to 100% are therefore unlikely. Yet, ideally, one wants to reach the highest compliance possible, as this alleviates concerns about selective reporting at moments that are most convenient for the study participants (which could lead to bias). At the same time, we also need a sufficient number of data points to investigate, for example, variability over time, and to estimate stable associations between variables measured using this method. It is, therefore, important to identify how characteristics of both the ESM design and the samples under investigation influence compliance and retention. Using this information, we might be able to identify designs that are more acceptable to a given group of study participants.

To our knowledge, whether design and sample characteristics influence retention has not been the focus of prior research, but several studies have examined this question with respect to compliance. Compliance tends to decrease over the duration of the ESM follow-up [12], during the early mornings [26-28], the evenings [13], in the middle of the week [14], outside home [15], when questionnaires encompass more items [16], when successive self-evaluations are separated by longer periods [15], and in the absence of incentives [16]. In addition, even if not directly targeting compliance, Stone et al [17] found that the number of daily self-evaluations correlated significantly with an increased perception of burdensomeness, which may indirectly impact compliance. In other words, compliance may be tightly related to methodological aspects that researchers could adjust to increase the amount of data collected and to enhance the acceptability of ESM for study participants.

The ESM literature displays a rather heterogeneous methodological landscape. Designs vary from 2 [18] to 50 evaluations per day [19], occurring at fixed [20], semirandom [21], or random time intervals [22], for 1 [23] to 150 days [24], using paper-and-pencil [25] or electronic devices [26], Likert scales [27], or visual analogue scales [28], and with questionnaires varying in length from 2 [29] to 100 items [30]. In addition, Janssens et al [31] argued that the methodological choices in designing ESM research are often guided more by practical considerations (contextual constraints, statistical requirements, and replication of existing protocols) rather than based on theory or evidence. Thus, whereas these decisions may have considerable influence on the quality of the data collection, there is currently a lack of empirical evidence to guide researchers when designing their ESM protocols.

The compliance rate in ESM studies may also be influenced by the individual characteristics of the study samples. Indeed, compliance appears to drop in relation to the ratio of male participants [14,32], in substance users [14], alcohol users [15], and in younger samples [16], but also in individuals with higher levels of negative affect [15], or in those with a psychotic disorder [32], putting clinical samples at particular risk for exhibiting low compliance levels.

Therefore, both design- and participant-related factors may influence compliance. Fortunately, compliance is typically reported within the ESM literature, making this information highly accessible for a meta-analysis over a large sample of studies. To date, two studies have addressed this question through a meta-analysis. Morren et al [16] demonstrated the effect of several design- (ie, length of ESM questionnaires, use of an alarm, and use of an incentive) and participant-related (ie, age and gender of the sample) characteristics on the compliance rate in ESM studies. Conversely, Jones et al [33] did not observe any effect of design characteristics (ie, frequency of evaluations, duration of the study, and device) or of clinical status (ie, substance use) on compliance. However, these reviews focused on patients with chronic pain and substance users, respectively, which limits the comparability of their findings and, importantly, the generalizability to other clinical samples. Finally, the potential influence of design and sample characteristics on the retention rate in ESM research remains unexplored.

Objective

This meta-analysis, therefore, aims to fill this gap and examines compliance and retention in ESM studies focusing on severe mental disorders, investigating the effect of a large set of design- and participant-related factors with the aim to provide, if achievable, empirically-based guidelines that could support researchers' choices in designing ESM protocols.

Methods

Protocol Registration

This study was based on the PRISMA-P (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols) guidelines [34]. The protocol has been registered in the

International Prospective Register of Systematic Reviews database (PROSPERO 2017: CRD42017060322) and is described in more detail elsewhere [35].

Data Sources and Literature Search

A systematic literature search was performed until February 2017 without publication time limit in PubMed and Web of Science (ie, Web of Science Core Collection). The search strategy was designed to include relevant terms for identifying studies using momentary assessment methods (eg, "experience sampling method" and "ecological momentary assessment") and terms related to the clinical diagnosis of the participants under study (eg, "psychotic disorder", "major depressive disorder", and "bipolar disorder"). The search strategy used either Medical Subject Heading or keyword headings. A concept plan was built with the identified keywords and descriptors to run the search (see Multimedia Appendix 1).

Inclusion and Exclusion Criteria

Studies using ESM/EMA designs in adults with a psychotic disorder, major depressive disorder, bipolar disorder, or at high risk for these disorders, and samples of the general population including individuals with or at high risk for these disorders have been included in this review to cover a broader range of the continuum of mood and psychotic disorders. Observational and randomized controlled studies have been included. Case studies, case reports, protocols, descriptions of study designs, systematic reviews, and studies published in a language other than English have not been considered. When available within the included studies, data from nonpsychopathological/healthy control groups have also been considered to serve as a reference group. Studies with only a single daily assessment have been excluded as this form of time sampling is qualitatively distinct from the repeated momentary assessments within a day that defines ESM research. To determine the eligibility of the original studies, two researchers (HV and AR) independently conducted the screening of the studies in the title/abstract and full-text phases based on the inclusion and exclusion criteria. Screening results were compared with identify any discrepancies. In case of a disagreement, a third researcher (IM-G) was consulted and the discrepancy was resolved through group consensus.

Data Extraction

When available, data were extracted for the following items: (1) general study characteristics (ie, authors, title, year, and study design); (2) sample characteristics (ie, number of participants included in the study/analysis, mean age, gender composition, clinical status, ethnicity, educational status, employment status, marital status, cohabiting status, and medication use); (3) design characteristics (ie, number of momentary assessments per day, number of assessment days, number of assessment periods as continuous or intermittent assessment, delay between assessment periods, sampling method [fixed, semirandom, or random sampling], time intervals between the assessments within a day, time intervals between the first and the last assessment within a day, time of the start and the end of the assessments within a day, number of items in the questionnaire, approximate mean duration of the questionnaire, type of scales used in the questionnaire, type of method used to perform the assessment, type of incentive, and amount of the incentive); and (4) the compliance rate (proportion of self-evaluations completed by the participants compared with the theoretical maximal number of self-evaluations allowed by the design) and the retention rate (proportion of individuals included in the final analysis out of the number of individuals included at baseline). For studies that included multiple groups (eg, a psychotic disorder group and a healthy control group), sample/design characteristics and the compliance and retention rates were coded at the group level. Studies that fulfilled the inclusion criteria were examined for overlapping samples (Multimedia Appendix 1). When needed, the corresponding authors of the original studies were contacted for further information. Data from the included studies have been extracted and stored in a customized spreadsheet structured according to the items mentioned above, which is provided as part of the Multimedia Appendix 1.

Risk of Bias

According to the PRISMA guidelines, risk of bias should be assessed for each study (eg, lack of blinding, lack of randomization). However, the current review did not investigate randomized controlled trials and neither compliance nor retention rates were primary outcomes within the sample of studies included in the meta-analysis. Additionally, there is to date no standardized risk of bias assessment guideline for ambulatory studies. The evaluation of the risk of bias was therefore not performed (although we did examine the data for potential publication bias; see further below).

Statistical Analysis

For compliance, there is, in principle, a proportion of completed self-evaluations per participant (eg, 0.80 for the first subject, 0.65 for the second subject, and so on), but this information is never reported. Instead, we analyzed the mean proportions (equation [a], Figure 1), where p_{ij} denotes the proportion of completed evaluations for the jth participant in the ith group and n_i the group size). We expected either p_i to be reported directly (either in terms of a proportion or percentage) or the total number of self-evaluations collected, which is easily converted to p_i (equation [b], Figure 1), where x_i denotes the total number of self-evaluations collected and m_i the theoretical maximal number of self-evaluations per subject as allowed by the design). The sampling variance of p_i was computed following equation (c) (equation [c], Figure 1), where SD_i is the SD of the compliance rates of the n_i subjects in the ith group. As SD_i was not available for approximately half of the groups, we imputed missing SD_i values based on the expected quadratic relationship between p_i and SD_i (ie, SD_i must be 0 for p_i equal to 0 and 1 and will peak around p_i=0.5). For this, we first meta-analyzed the available log-transformed SD_i values [36] using a mixed effects meta-regression model with p_i and p_i^2 as predictors and then imputed missing SD_i values based on the fitted values from this model (Multimedia Appendix 1).

Figure 1. Equations.

$$\text{(a)}\ \bar{p}_i = \left(\Sigma_{j=1}^{n_i} p_{ij}\right) / n_i$$

$$\text{(b)}\ \bar{p}_i = x_i / (n_i \times m_i)$$

$$\text{(c)}\ Var[\bar{p}_i] = SD_i^2 / n_i$$

$$\text{(d)}\ y_i = \text{arcsin}\left(\sqrt{p_i}\right)$$

$$\text{(e)}\ Var[y_i] = 1/(4 \times n_i)$$

For the analysis of the retention rates, the reported/calculated proportions (of individuals included in the final analysis compared with the number of individuals included at baseline) were first transformed using the (variance-stabilizing) arcsine transformation before the analysis (equation [d], Figure 1), where p_i is the proportion of individuals in the *i*th group that were retained for the final analysis [37]. This allowed the inclusion of groups with perfect (ie, 100%) retention rates (which occurred in about a quarter of the groups) without the need to make use of continuity corrections. The sampling variance of the transformed proportions was computed following equation (e), Figure 1.

As a study may include multiple groups, we used a multilevel random/mixed effects model [38] with random effects for studies and groups within studies for the analysis of both outcomes. The overall mean compliance and retention rates, averaged over groups and studies, were estimated using intercept-only models. The influence of the various sample and design characteristics on the outcomes was examined by including such characteristics as predictors in the models. Group type (6 levels: healthy control, general population, high risk, major depressive disorder, bipolar disorder, and psychotic disorder), ESM sampling scheme (3 levels: fixed, semirandom, and random), data collection method (7 levels: paper-and-pencil, personal digital assistant [PDA], Web-based, call, SMS, voicemail, and mixed), and scale type (3 levels: Likert scale, visual analogue scale, and mixed) were included as factors in the models. All other design characteristics (eg, duration of the ESM follow-up and frequency of the daily evaluations) and sample characteristics (eg, mean age of the sample) were included as continuous predictors in the models. Each of the design and sample characteristics was examined separately. All models were fitted using restricted maximum likelihood estimation, using the R metafor package [39] for the analyses. For the intercept-only models, we report the estimated mean rates (as percentages and after back transformation of the mean arcsine rate for retention) with corresponding 95% CIs. For the meta-regression models, we report the model coefficients, corresponding standard errors, tests and 95% CIs of the individual coefficients, and, for models containing factors, the Q_M test of the factor as a whole. For each meta-regression model, we also report pseudo-R^2-type values [40] for the between-study and between-group variance accounted for by the moderator included in the model.

Heterogeneity was assessed using the Q-test [41] and based on the estimates of the between-study and between-group heterogeneity variance components (with 95% profile likelihood confidence intervals). The presence of outliers or influential studies was determined based on using Cook distance [42] and by examining the distribution of the standardized residuals and the predicted random effects at the group and study levels. Funnel plots and meta-regression models using sample size as predictor were used to examine the data for funnel plot asymmetry.

Results

After screening based on title and abstract, a total of 220 studies were considered for inclusion (Figure 2). Of these, 141 were excluded for reasons as outlined in Figure 2. Finally, 79 studies fulfilled all inclusion criteria (Multimedia Appendix 1). Table 1 shows the characteristics of the studies included in the meta-analysis.

Figure 2. Flow chart of study inclusion protocol.

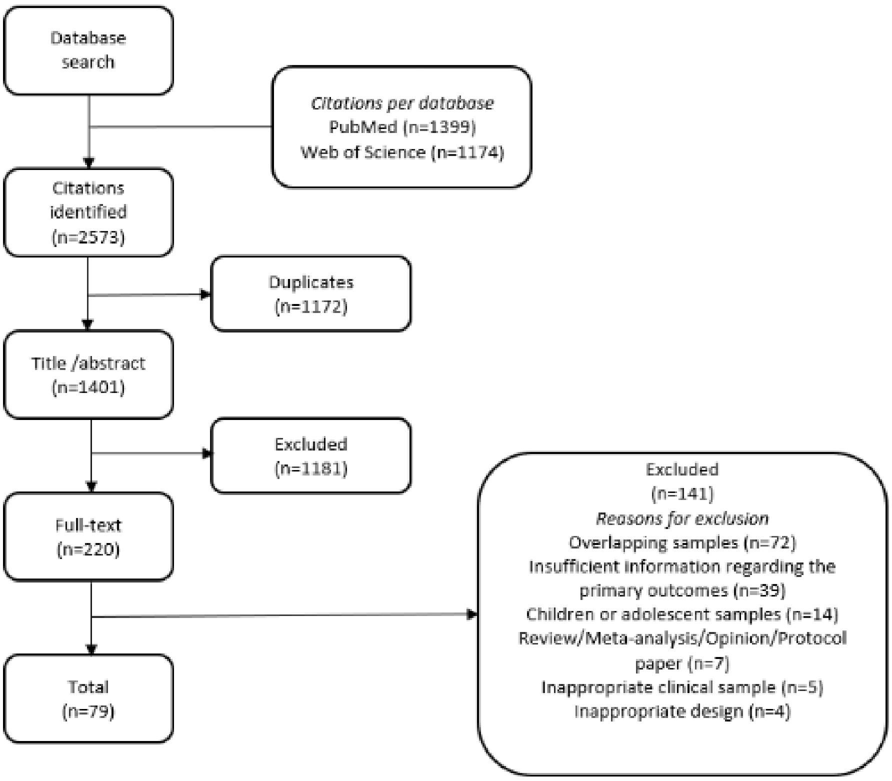


Table 1. Descriptive statistics of the sample of studies (N=79).

Characteristics	Study level, n (%)	Group level, n (%)
General characteristics		
Year of publication		
<2000	4 (5)	N/A[a]
2000-2004	4 (5)	N/A
2005-2009	10 (13)	N/A
2010-2014	41 (52)	N/A
≥2015	20 (25)	N/A
Sample size		
0-49	24 (30)	80 (61)
50-99	26 (33)	32 (24)
100-149	14 (18)	9 (7)
150-199	6 (8)	4 (3)
≥200	9 (11)	7 (5)
Number of groups per study		
1	42 (53)	N/A
2	26 (33)	N/A
3	7 (9)	N/A
4	3 (4)	N/A
5	1 (1)	N/A
Sample characteristics		
Age (years)		
18-29	29 (37)	39 (30)
30-39	23 (29)	45 (34)
40-49	15 (19)	27 (21)
≥50	3 (4)	5 (4)
Unavailable	9 (11)	16 (12)
Gender (% female)		
<25	4 (5)	11 (8)
25-49	18 (23)	28 (21)
50-74	34 (43)	57 (43)
≥75	17 (22)	26 (20)
Unavailable	6 (8)	10 (8)
Clinical status		
Healthy controls	N/A	33 (25)
General population	N/A	19 (14)
High risk for a severe mental disorder	N/A	10 (8)
Major depressive disorder	N/A	30 (23)
Bipolar disorder	N/A	9 (7)
Psychotic disorder	N/A	31 (24)
Design characteristics		
Number of days		
1-5	12 (15)	20 (15)

Characteristics	Study level, n (%)	Group level, n (%)
6-10	54 (68)	94 (71)
>10	13 (17)	18 (14)
Number of evaluations/day		
2-3	11 (14)	17 (13)
4-5	23 (29)	33 (25)
6-7	6 (8)	11 (8)
8-9	9 (11)	13 (10)
10	27 (34)	54 (41)
>10	2 (3)	3 (2)
Unavailable	1 (1)	1 (1)
Sampling scheme		
Fixed	14 (18)	23 (17)
Semirandom	32 (41)	55 (42)
Random	31 (39)	51 (39)
Unavailable	2 (3)	3 (2)
Number of items		
<20	36 (46)	58 (44)
20-39	24 (30)	36 (27)
40-59	8 (10)	15 (11)
≥60	1 (1)	4 (3)
Unavailable	10 (13)	19 (14)
Scale type		
Likert scale	46 (58)	80 (61)
Visual analogue scale	8 (10)	11 (8)
Mixed	23 (29)	38 (29)
Unavailable	2 (3)	3 (2)
Data collection method		
Paper	27 (34)	50 (38)
Personal digital assistant	42 (53)	66 (50)
Other	11 (14)	16 (12)
Compliance rate (%)		
50-59	3 (4)	7 (5)
60-69	8 (10)	12 (9)
70-79	24 (30)	39 (30)
80-89	21 (27)	35 (27)
≥90	9 (11)	16 (12)
Unavailable	14 (18)	23 (17)
Retention rate (%)		
50-59	1 (1)	2 (1)
60-69	4 (5)	6 (4)
70-79	10 (13)	13 (10)
80-89	11 (14)	19 (14)
≥90	46 (58)	76 (58)

Characteristics	Study level, n (%)	Group level, n (%)
Unavailable	7 (9)	16 (12)

[a] N/A: not applicable.

Descriptive Information

The final sample of studies comprised 8013 individuals from 132 different groups (with 1-5 groups per study). The mean age of the individuals was 31.7 years (SD 10.3, range of the mean age of the groups=18-71.9), and 62.79% (5032/8013) of the participants were female (SD 23.1, range of the percentage of females in the groups=6.7%-100%). Overall, 1282 (1282/8013, 16.00%) were individuals without a diagnosis of psychiatric illness, 3456 (3456/8013, 43.13%) were recruited from the general population, 1423 (1432/8013, 17.76%) were diagnosed with a psychotic disorder, 1326 (1326/8013, 16.55%) were diagnosed with major depressive disorder, 266 (266/8013, 3.32%) were diagnosed with bipolar disorder, and 260 (260/8013, 3.24%) were diagnosed with a high risk for one of the mental disorders under study.

From a design perspective, ESM studies included in the meta-analysis involved a mean of 6.9 evaluations per day (SD 3.0, range 2-14) for 11.2 days (SD 19.0, range 1-150) for a total mean number of 60.2 evaluations per study (SD 45.0, range 8-300). Successive evaluations within a day were separated by an average of 131.2 min (SD 92.8, range 45-720) and participants were required to fill in evaluations during a mean total time window of 13.5 h per day (SD 2.2, range 3-17). The sampling scheme was random in 39.2%, semirandom in 40.5%, and fixed in 17.7% of the studies. On average, 22.5 items per questionnaire were collected by the ESM studies (SD 18.6, range 2-135). As compensation, the mean value of the incentives for the completion of the ESM studies was €63.6 (SD 69, range 0-350).

Other variables such as ethnicity, education level, marital status, or other design parameters (eg, continuous or intermittent assessment, approximate mean duration of the questionnaire, type of incentive, and strategies taken by the researchers to maintain/increase retention and compliance) may be relevant for the association with compliance and retention, but were reported inconsistently or by too few studies to be taken into account.

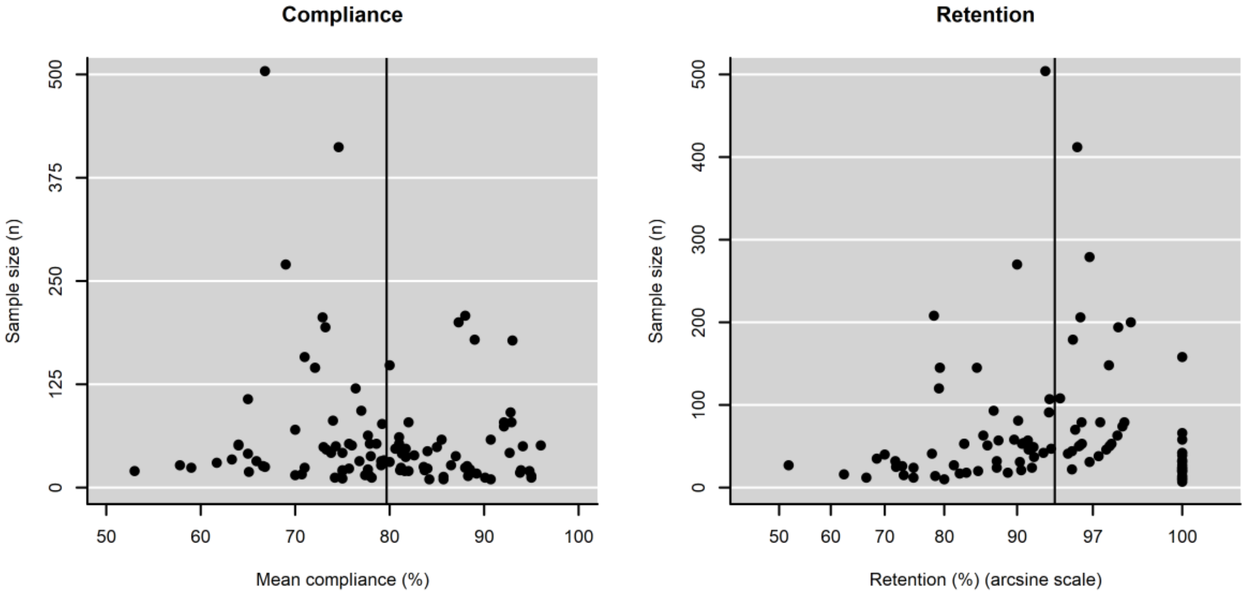
Meta-Analyses of the Compliance and Retention Rates

Mean compliance was reported in 65 (65/79, 82%) of the studies, whereas retention rate was reported in 73 (73/79, 92%) of the studies, and 58 (58/79, 73%) of the studies reported both compliance and retention rates. All studies included in the analysis reported at least one of these main outcomes. At the group level, compliance rates were available for 109 (109/132, 82.6%), and retention rates were available for 116 (109/132, 87.9%) of the groups (see Multimedia Appendix 1 for forest plots). On the basis of the multilevel models, the estimated average compliance was 78.7% (95% CI 76.2 to 81.2), and the estimated average retention was 93.1% (95% CI 90.8 to 95.1). However, 2 studies with very low compliance rates [43,44] and 3 studies with very low retention rates [44-46] were found to be overly influential based on their Cook distances (larger than the median Cook distance plus 2.5 times the interquartile range) and were excluded from further analyses (Multimedia Appendix 1). On the basis of the reduced dataset, the estimated average compliance and retention increased slightly to 79.7% (95% CI 77.5-81.8) and 94% (95% CI 92.0-95.7), respectively.

The underlying true effects were heterogeneous, showing $Q_{104}=3398.31$, $P<.001$, and $Q_{111}=666.94$, $P<.001$, for compliance and retention, respectively. For compliance, the estimates of the between-study and between-group variance components were 50.9 (95% CI 22.4-89.4) and 33.3 (95% CI 19.7-58.2), respectively. Hence, a larger part of the total amount of heterogeneity in the underlying true outcomes was because of differences between studies (60%) as opposed to differences between groups (40%). The same pattern held for retention, with estimated between-study and between-group variance components of 0.015 (95% CI 0.006-0.028; 57% of total amount of heterogeneity) and 0.011 (95% CI 0.005-0.022; 43% of total amount of heterogeneity), respectively.

Visual inspection of the funnel plots did not reveal any marked asymmetry (Figure 3). Moreover, the regression test for funnel plot asymmetry was not significant for either outcome (P=.24 and P=.84, respectively).

Figure 3. Funnel plots for compliance and retention.



Meta-Regression Analyses of the Sample Characteristics

The results of the meta-regression analyses of the sample characteristics are shown in Table 2. For some continuous predictors, the distribution of the predictor included some extremely large or low values. In such cases, we restricted the analysis to a range that excluded such extreme values. Scatterplots of the unrestricted and the restricted data (where applicable) are provided as part of Multimedia Appendix 1.

The analyses revealed significant relationships between some of the characteristics of the participants and the mean compliance and retention rates. Specifically, the proportion of women in ESM studies was found to be a significant predictor of both compliance (*P*<.001) and retention (*P*=.006), with estimated compliance and retention levels increasing by 18.1% and 11.9% points, respectively, when comparing a sample constituted exclusively of female participants with a sample composed exclusively of male participants. Second, the clinical status of the participants was also found to be a significant predictor of compliance and retention (*P*<.001). In particular, mean compliance and retention rates of samples of individuals without a psychiatric condition were estimated to be 10.8% and 9.5% points, respectively, higher when compared with samples of individuals with a psychotic disorder. Contrary to our expectations based on previous research, the mean age of the samples did not exhibit a significant relationship with compliance (*P*=.08) nor retention (*P*=.35).

Table 2. Results of the meta-regression analyses of the sample characteristics.

Sample characteristics	k	Estimate	SE	*P* value	95% CI	Q_M test (*df*)	R² (%)	
							Study	Group
Compliance								
Age	98					—[a]	34	0
Intercept		85.65	3.44		78.91-92.39			
Beta		−0.18	0.1	.08	−0.38 to 0.02			
Gender (% female)	99					—	0	44
Intercept		68.41	2.51		63.49-73.33			
Beta		0.18	0.04	<.001	0.11-0.25			
Clinical status	105					41.48 (5)	0	54
Intercept (HC[b])		82.61	1.53		79.61-85.6			
Beta (GP[c])		−1.55	2.6	.55	−6.64 to 3.54			
Beta (HR[d])		−1.67	2.36	.48	−6.30 to 2.96			
Beta (MDD[e])		−0.77	1.8	.67	−4.31 to 2.76			
Beta (BD[f])		0.57	2.44	.82	−4.21 to 5.36			
Beta (PD[g])		−10.77	1.75	<.001	−14.2 to −7.34			
Retention								
Age	102					—	0	42
Intercept		1.382	0.067		1.250-1.514			
Beta		−0.00	0.002	.35	−0.006-0.002			
Gender (% female)	107					—	12	0
Intercept		1.183	0.055		1.075-1.290			
Beta		0.002	0.001	<.01	0.001-0.004			
Clinical status	112					26.27 (5)	0	41
Intercept (HC)		1.405	0.031	—	1.344-1.466			
Beta (GP)		−0.081	0.047	.09	−0.173 to 0.011			
Beta (HR)		−0.123	0.064	.06	−0.249 to 0.004			
Beta (MDD)		−0.035	0.041	.39	−0.114 to 0.045			
Beta (BD)		−0.098	0.064	.13	−0.224 to 0.028			
Beta (PD)		−0.192	0.039	<.001	−0.268 to −0.116			

[a] Not applicable.

[b] HC: healthy control.

[c] GP: general population.

[d] HR: high risk for a severe mental disorder.

[e] MDD: major depressive disorder.

[f] BD: bipolar disorder.

[g] PD: psychotic disorder.

Meta-Regression Analyses of the Design Characteristics

The results of the meta-regression analyses of the design characteristics are shown in Table 3. The analyses revealed significant relationships between some of the design characteristics and compliance but not with retention. First, the number of evaluations per day was found to be a significant predictor of compliance (*P*=.008). To illustrate, mean compliance is estimated to fall by 8% points when comparing a follow-up involving 2 evaluations per day with a follow-up involving 10 evaluations per day (Figure 4).

Second, the duration of the time interval between successive evaluations within a day was also found to be a significant predictor of compliance (*P*=.02), with an estimated decrease in mean compliance by 10.8% points when comparing time intervals of 240 min with time intervals of 60 min. Third, relying on fixed sampling is predicted to yield a mean compliance that is 6.7% points higher (*P*=.02) compared with more conventional semirandom sampling (which did not differ from random sampling, *P*=.78). Fourth, the use of Web-based or mixed data collection method (ie, using different devices or platforms) was found to be a significant predictor of compliance (*P*=.03) compared with the use of PDAs, with an estimated decrease in mean compliance by 14% points and 16.5% points, respectively. Finally, the value of the incentives was found to significantly predict compliance (*P*=.02), with an estimated increase of 8.8% points in mean compliance when comparing the use of €20 incentives with the use of €200 incentives.

Table 3. Results of the meta-regression analyses of the design characteristics.

Design characteristics	k	Estimate	SE	*P* value	95% CI	Q_M test (*df*)	R² (%)	
							Study	Group
Compliance								
Evaluations	104					—[a]	19	0
Intercept		86.23	2.75		80.84-91.61			
Beta		−0.99	0.38	<.01	−1.73 to −0.25			
Days	103					—	1	0
Intercept		78.69	1.86		75.04-82.34			
Beta		0.14	0.18	.43	−0.21 to 0.49			
Hours/day	76					—	36	0
Intercept		74.8	10.41		54.39-95.21			
Beta		0.28	0.76	.71	−1.21 to 1.78			
Duration between evaluations	71					—	51	0
Intercept		71.43	3.4		64.76-78.10			
Beta		0.06	0.02	.02	0.01-0.11			
Items	83					—	0	0
Intercept		81.96	2.39		77.27-86.65			
Beta		−0.15	0.1	.14	−0.34 to 0.05			
Sampling scheme	103					6.78	22	0
Intercept (semirandom)		78.5	1.64		75.27-81.72			
Beta (random)		−0.63	2.29	.78	−5.13 to 3.86			
Beta (fixed)		6.7	2.95	.02	0.90-12.50			
Data collection method	105					14.98	27	0
Intercept (PDA[b])		81.14	1.38		78.45-83.84			
Beta (paper-pencil)		−2.90	2.24	.20	−7.29 to 1.49			
Beta (calls)		6.89	4.75	.15	−2.43 to 16.20			
Beta (SMS)		−0.91	6.06	.88	−12.79 to 10.97			
Beta (voicemail)		−12.64	8.19	.12	−28.69 to 3.41			
Beta (Web-based)		−13.99	6.49	.03	−26.70 to −1.27			
Beta (mixed)		−16.5	7.79	.03	−31.77 to −1.23			
Scale type	102					0.28[c]	7	0
Intercept (LS[d])		79.03	1.45		76.19-81.87			
Beta (VAS[e])		−0.84	3.45	.81	−7.60 to 5.93			
Beta (mixed)		0.98	2.48	.69	−3.87 to 5.83			
Incentives	43					—	23	0
Intercept		75.36	2.23		70.99-79.73			
Beta		0.04	0.02	.02	0.01-0.09			
Retention								
Evaluations	111						0	1
Intercept		1.275	0.053		1.171-1.379			
Beta		0.007	0.007	.34	−0.007 to 0.020			

Design characteristics	k	Estimate	SE	*P* value	95% CI	Q_M test (*df*)	R^2 (%)	
							Study	Group
Days	109					—	0	0
Intercept		1.329	0.036		1.259-1.399			
Beta		−0.000	0.004	.96	0.007-0.007			
Hours/day	87					—		
Intercept		1.358	0.186		0.994-1.722			
Beta		−0.001	0.014	.92	−0.028 to 0.025			
Duration between evaluations	86					—	2	17
Intercept		1.36	0.06		1.243-1.478			
Beta		−0.000	0	.71	−0.001 to 0.001			
Items	92					—	0	2
Intercept		1.274	0.044		1.188-1.360			
Beta		0.002	0.002	.35	−0.00 to 0.01			
Sampling scheme	111					0.17[c]	0	0
Intercept (semirandom)		1.322	0.031		1.263-1.382			
Beta (random)		−0.007	0.045	.88	−0.095 to 0.082			
Beta (fixed)		0.018	0.058	.76	−0.095 to 0.131			
Data collection method	112					7.22[c]	7	0
Intercept (PDA)		1.342	0.026		1.291-1.393			
Beta (paper-pencil)		−0.039	0.043	.36	−0.124 to 0.046			
Beta (calls)		−0.123	0.114	.28	−0.346 to 0.101			
Beta (SMS)		0.082	0.121	.50	−0.155 to 0.318			
Beta (Web-based)		−0.153	0.089	.09	−0.328 to 0.022			
Beta (mixed)		0.229	0.164	.16	−0.093 to 0.550			
Scale type	111					1.55[c]	0	0
Intercept (LS)		1.3	0.026		1.248-1.352			
Beta (VAS)		0.062	0.07	.37	−0.074 to 0.198			
Beta (mixed)		0.047	0.045	.30	−0.042 to 0.135			
Incentives	52					—	0	19
Intercept		1.272	0.041		1.193-1.352			
Beta		0	0	.62	−0.001 to 0.001			

[a] Data not applicable.

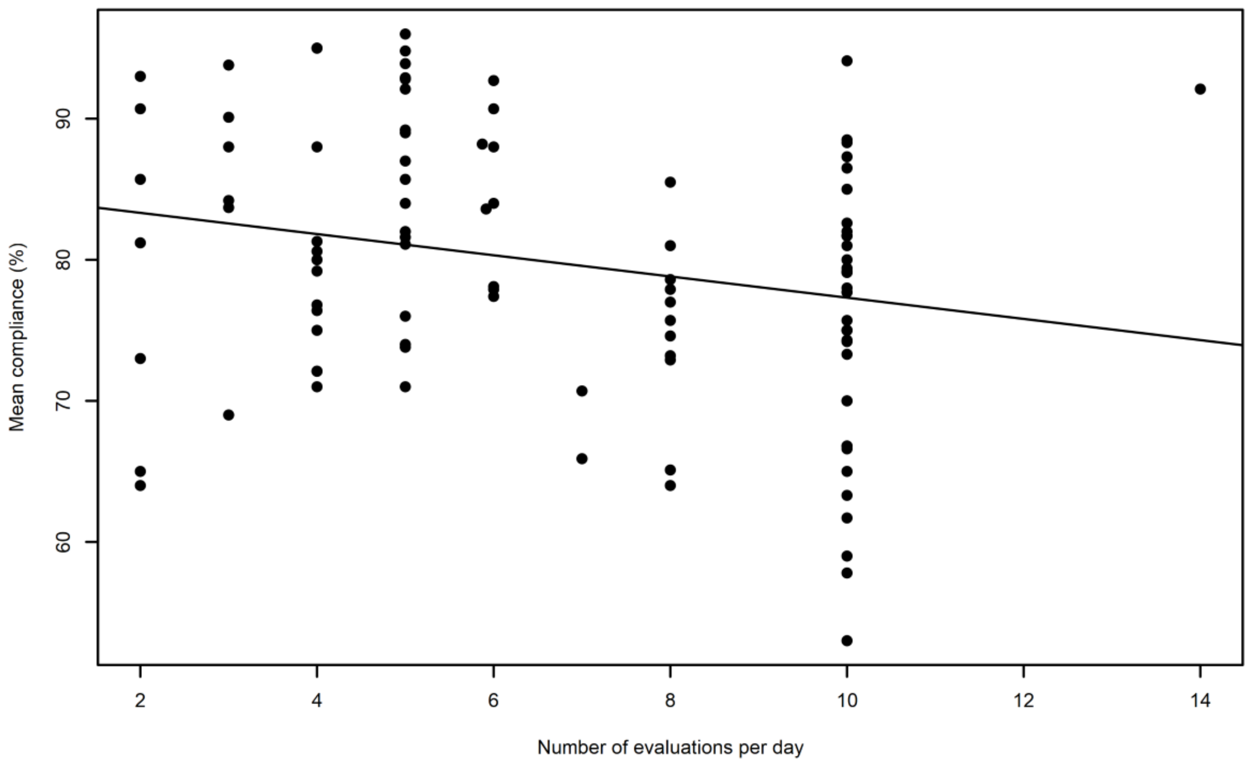
[b] PDA: personal digital assistant.

[c] Not significant.

[d] LS: Likert scale.

[e] VAS: visual analogue scale.

Figure 4. Graphical representation of the relationship between the compliance of experience sampling method studies and the frequency of daily self-evaluations.



Discussion

The aim of the present meta-analysis was to investigate compliance and retention rates in ESM studies including subjects across the spectrum of severe mental disorders and to examine how these outcomes are related to various person characteristics and design aspects. First, we found relatively high mean levels of compliance (ie, 78.7%) and retention (ie, 93.1%) across the included ESM studies. This is in line with previous findings in individuals with chronic pain [16] and substance users [33], supporting the feasibility and acceptability of ESM in mental health research. Second, we were also able to identify several sample and design characteristics that appear to be related to both the compliance and retention rate in ESM studies.

Influence of the Sample Characteristics

Both the gender composition and the clinical status of the groups were found to predict the degree of compliance and retention in ESM studies. First, the proportion of male participants within a sample was negatively associated with compliance, supporting similar findings in adolescents [15] and adult samples [14,32,47]. Second, as reported previously in the literature [32,48], individuals with a psychotic disorder exhibited significantly lower compliance and retention rates compared with the other groups. In contrast, we did not find differences in the mean compliance and retention rates in samples at risk for a psychiatric condition and in individuals with mood disorders compared with healthy control or general population samples. This result is not in line with previous findings suggesting that greater negative affect in adolescents [15] and higher depressive symptoms in young adults [47] predicts lower compliance with ESM. The lower compliance in individuals with a psychotic disorder may be because of the inclusion of more severely ill people (eg, during acute phases of psychosis) or because of the presence of more severe cognitive impairments in individuals with a psychotic disorder compared with a major depressive [49] or bipolar disorder [50]. Finally, contrary to previous studies [16,32], we did not observe a significant association between the mean age of the samples and compliance. This could be because of a difference in the nature of the sample, with Morren et al review [16] focusing specifically on chronic pain patients, or to a difference in the nature of the study design, with Rintala et al [32] relying exclusively on paper-and-pencil assessment schemes. Thus, while younger samples were found to be less compliant when ESM assessments were conducted using a paper-and-pencil approach, the emergence of electronic devices in ESM research together with the current mobile phone use habits in young individuals [51] may have facilitated and increased the feasibility of ESM studies in younger samples.

In sum, ESM studies in individuals with a psychotic disorder or in samples with a higher proportion of male participants are at risk for lower compliance and retention rates. To increase compliance and retention, researchers could engage in procedures that aim to maintain the compliance of the participants as described in the review of Morren et al [16], such as sending reminders, providing a more extensive briefing, or contacting the participants regularly by phone to increase motivation. However, Jones et al [33] did not find any difference in compliance between studies mentioning a preliminary training of the participants for ESM and the ones not mentioning it.

These methods may thus not be sufficient to improve compliance. Therefore, the potentially higher loss of data should also be taken into account in the sample size calculation preceding any ESM study investigating individuals with these characteristics.

Influence of the Design Characteristics

We also found a number of design characteristics that were associated with the compliance and retention rates. First, the number of evaluations per day was associated with compliance levels in the ESM studies. On average, for each additional evaluation per day, mean compliance is predicted to fall by approximately 1% point. However, a lower compliance rate with a higher number of evaluations may still result in more data points. For example, according to our results, an ESM study involving 8 evaluations per day would result in an estimated mean of 6.18 completed evaluations/day, whereas a sampling frequency of 7 evaluations per day would result in only 5.48 evaluations/day. This result does not corroborate the findings of previous single studies investigating samples with different characteristics [17,33], which could be explained by the potential lack of statistical power inherent in single studies. In addition, the severity of the psychiatric disorders under study in the current meta-analysis compared with the aforementioned conditions might play a role in this discrepancy of results. For instance, individuals with severe mental disorders might be more reactive to the repetition of self-evaluations through the requirement of larger cognitive efforts to self-evaluate or the experience of a greater affective reactivity to the follow-up compared with individuals with milder conditions.

Second, the current meta-analysis found no significant association between the number of data collection days and the compliance and retention rates. This result corroborates the absence of an effect of study duration on compliance observed in substance users [33]. This finding is also in line with an ESM study in patients with schizophrenia [52], which reported that missing data were not associated with the number of assessment days in the study. These findings are particularly worth emphasizing when considering the current common practice in ESM research in severe mental disorders. Indeed, in the current review, most studies relied on relatively intensive (ie, median number of evaluations per day, =7.5 evaluations) and short (ie, median duration of ESM studies, =7 days) assessment schemes. Given the current findings, together with the observation of a beneficial effect of longer intervals between successive evaluations on mean compliance, it may be worthwhile for researchers and practitioners to favor longer protocols with less intensive assessment frequencies to maximize compliance to ESM while collecting the same amount of data. Some statistical approaches (eg, time-lagged analyses or network analyses) [53] could, however, require a sufficient number of evaluations at the day level.

Third, our analyses revealed an association between the ESM sampling strategy and the compliance and retention rate, with fixed sampling schemes resulting on average in higher compliance and retention rates. Although this seems to favor fixed over random sampling schemes to improve the quantity of the data, the choice is not so simple. For instance, Husky et al [54] used a fixed sampling scheme and reported that participants were more likely to be alone over the duration of the ESM study, an observation that “may reflect the choice of participants to be in a quiet environment or to otherwise isolate themselves when completing electronic interviews.” In other words, a fixed sampling scheme allows participants to plan their daily tasks in accordance with the scheduled assessment times, which may increase compliance rates but potentially at the cost of lower ecological validity and increased bias. A random assessment scheme would avoid this problem, but, as argued by Piasecki et al [55], random time sampling may be perceived as more burdensome by study participants, thus potentially leading to lower compliance because of the respondents not knowing when the next assessment will occur. As such, if both sampling schemes present respective advantages, the current meta-analysis cannot clearly establish the optimal choice regarding this design characteristic. Therefore, this choice should be based on the requirements of the scientific question under study.

Fourth, we found a positive association between the value of the incentives and the compliance rates in ESM studies, similar to what was reported by Morren et al [16] in chronic pain patients. In contrast, Jones et al [33] did not find any effect of tying the amount of the incentives to the compliance rates (eg, providing an incentive per filled out report). However, it is worth noting that we did not consider the administration mode of the incentives, nor the value of the incentives per evaluation, but only the total value of the incentives provided to the participants at the end of the study.

Finally, no significant differences in compliance or retention rates were found between studies using a PDA compared with paper-and-pencil diaries. A similar result was recently reported in a meta-analysis of ESM studies in substance users [33]. In addition, the number of items within the ESM questionnaire was not significantly associated with compliance or retention, which contradicts previous research that found a lower number of items to be associated with higher compliance rates [16]. One reason for this discrepancy may be the lack of transparency about the actual number of items used in an ESM questionnaire. As argued by Morren et al [16], most studies only report the items that they have included in the analyses and hence may fail to report the actual number of items used in the entire questionnaire. This lack of transparency necessarily undermines the reliability of the analyses.

In fact, this point underscores a more general lack of clarity in the description of the methods used in ESM research, an issue previously underlined by Morren et al [16] and Jones et al [33]. In our sample, 73% of the studies reported both compliance and retention rates, which is definitely higher than the proportion observed in the review by Morren et al, where only 25% of the studies reported both these indexes [16]. However, it is necessary to point out that (1) this relatively high proportion of studies reporting compliance and retention rates in the current review is likely to be an overestimation as our inclusion criteria required at least 1 of these indexes to be reported and; (2) if mean compliance was reported in 82% of the studies, the corresponding variance was only reported in 50% of the studies.

We, therefore, argue that ESM studies should clearly disclose all aspects of the protocol while systematically providing the standard statistical indexes (ie, mean and variance of the compliance rate and the retention rate) to allow an assessment of the quality of the data collection procedures.

Recommendations

Overall, this systematic review and meta-analysis demonstrate that both the characteristics of the samples under study and the design of ESM studies may influence compliance and retention rates in ESM research. On the basis of these findings, we propose the following recommendations:

1. There is evidence that compliance and retention rates depend on the characteristics of the individuals under investigation. Samples of individuals with psychosis and a higher number of male participants appear to have a higher risk of lower compliance and retention. The potentially higher loss of data should be taken into account in the sample size calculation preceding any ESM study investigating individuals with these characteristics.
2. The evidence also suggests that the degree of compliance depends on various design choices in ESM studies.
   - A higher number of evaluations per day and smaller time intervals between successive evaluations are associated with lower compliance, whereas this is not the case for the number of days in an ESM study. Therefore, it may be worthwhile to decrease the number of evaluations while increasing the number of days, as such obtaining a similar number of data points while maximizing compliance.
   - The total amount of the incentive was associated with better compliance. Therefore, increasing the amount of the incentive may have a beneficial effect on the compliance of the participants with an ESM study.
3. The relative lack of transparency in reporting ESM protocols is likely to undermine the replicability of ESM studies and the assessment of their feasibility in severe mental disorders.
   - We recommend disclosing clearly all aspects of the procedures used in a given ESM study, regardless of their relevance for a given study, including but not limited to the actual number of ESM items participants answered, the amount of time between a signal and the answer of a participant that experimenters used to define compliance with a momentary evaluation, and any exclusion reasons, especially if experimenters exclude participants based on a predefined minimal mean compliance level.
   - We advise to report both the compliance mean level and the related SD, and the retention rate. When possible, this information should be provided at the group level.

Limitations

This is the first review to systematically investigate predictors of compliance and retention rates in ESM research in severe mental disorders. However, despite its strengths, this review is not without limitations. First, the inconsistent report of essential information on the design of the ESM studies is likely to have introduced statistical errors in the estimation of the associations.

Second, compliance and retention rates are differently operationalized across studies in the literature. For compliance, evaluations are considered unanswered if the participants responded after 15 min following the trigger in some studies [11], whereas others used shorter time windows [56]. Concomitantly, subjects may only be retained for the analysis if they exceed a certain minimal compliance threshold [11], a threshold that also varies across studies. Thus, as the calculation of both these central indexes is not standardized in current practice in ESM research, the results might also reflect the heterogeneity of the experimenters’ methodological decisions.

Finally, it would have been of interest to examine to what degree potential participants are willing to participate in a study using ESM as a data collection method in the first place (and whether this is associated with certain participant or design characteristics). A brief search of the literature revealed considerable heterogeneity in reported *acceptance rates* across studies investigating clinical populations, varying from 38% in a group of patients with acute psychotic symptoms [57] to 96% in patients with schizophrenia [52], and from 67% to 97% in patient groups with an affective disorder [58,59]. Unfortunately, this type of information is not regularly reported in the literature and, if so, in even less standardized ways than compliance and retention rates. We were therefore unable to investigate this outcome in a systematic manner as part of this meta-analysis.

Conclusions

This meta-analysis constitutes a first step toward the optimization of ESM research. Compliance and retention were associated with the gender and clinical status of the participants. Compliance, but not retention, was also associated with a number of design characteristics. In particular, compliance was lower with higher sampling frequencies but not with the duration of ESM studies, a finding that stands in contrast with current practices in ESM research. This review also demonstrates that ESM studies can be carried out in mental health research, but the quality of the data collection may depend upon a number of factors related to the design of the studies and samples under investigation that need to be considered when designing such protocols.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Supplementary material.

[DOCX File , 2074 KB - jmir_v21i12e14475_app1.docx]

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Abbreviations

BD: bipolar disorder
EMA: ecological momentary assessment
ESM: experience sampling method
GP: general population
HC: healthy control
HR: high risk for a severe mental disorder
LS: Likert scale
MDD: major depressive disorder
PD: psychotic disorder
PDA: personal digital assistant
PRISMA-P: Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols
VAS: visual analogue scale

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Original Paper

Detecting Lifestyle Risk Factors for Chronic Kidney Disease With Comorbidities: Association Rule Mining Analysis of Web-Based Survey Data

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Abstract

Background: The rise in the number of patients with chronic kidney disease (CKD) and consequent end-stage renal disease necessitating renal replacement therapy has placed a significant strain on health care. The rate of progression of CKD is influenced by both modifiable and unmodifiable risk factors. Identification of modifiable risk factors, such as lifestyle choices, is vital in informing strategies toward renoprotection. Modification of unhealthy lifestyle choices lessens the risk of CKD progression and associated comorbidities, although the lifestyle risk factors and modification strategies may vary with different comorbidities (eg, diabetes, hypertension). However, there are limited studies on suitable lifestyle interventions for CKD patients with comorbidities.

Objective: The objectives of our study are to (1) identify the lifestyle risk factors for CKD with common comorbid chronic conditions using a US nationwide survey in combination with literature mining, and (2) demonstrate the potential effectiveness of association rule mining (ARM) analysis for the aforementioned task, which can be generalized for similar tasks associated with noncommunicable diseases (NCDs).

Methods: We applied ARM to identify lifestyle risk factors for CKD progression with comorbidities (cardiovascular disease, chronic pulmonary disease, rheumatoid arthritis, diabetes, and cancer) using questionnaire data for 450,000 participants collected from the Behavioral Risk Factor Surveillance System (BRFSS) 2017. The BRFSS is a Web-based resource, which includes demographic information, chronic health conditions, fruit and vegetable consumption, and sugar- or salt-related behavior. To enrich the BRFSS questionnaire, the Semantic MEDLINE Database was also mined to identify lifestyle risk factors.

Results: The results suggest that lifestyle modification for CKD varies among different comorbidities. For example, the lifestyle modification of CKD with cardiovascular disease needs to focus on increasing aerobic capacity by improving muscle strength or functional ability. For CKD patients with chronic pulmonary disease or rheumatoid arthritis, lifestyle modification should be high dietary fiber intake and participation in moderate-intensity exercise. Meanwhile, the management of CKD patients with diabetes focuses on exercise and weight loss predominantly.

Conclusions: We have demonstrated the use of ARM to identify lifestyle risk factors for CKD with common comorbid chronic conditions using data from BRFSS 2017. Our methods can be generalized to advance chronic disease management with more focused and optimized lifestyle modification of NCDs.

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KEYWORDS

chronic kidney disease; association rule mining; Behavioral Risk Factor Surveillance System; noncommunicable diseases

Introduction

Chronic kidney disease (CKD) is a progressive disease associated with high rates of mortality, morbidity, and disability [1,2]. Renal replacement therapies have been performed on approximately 8 million adults in the United States, with significant economic burdens [3]. The rate of progression of CKD from one major stage to another varies based on both unmodifiable (eg, age, race/ethnicity, family history) and modifiable (eg, hypertension, dyslipidemia, cigarette smoking, overweight/obesity, physical inactivity, dietary patterns) risk factors. Modifiable lifestyle risk factors account for 24% of the excess risk of CKD [4]. Observational and nonrandomized prospective studies have suggested that patients who modify their unhealthy lifestyles have fewer hospitalizations, are more likely to adhere to established CKD treatment goals (anemia or mineral and bone disease), and may have improved rates of survival [5-7]. Therefore, recognition of those lifestyle risk factors is vital in informing strategies to achieve renoprotection.

Lifestyle modification for CKD patients involves long-term habit changes, requires considerable effort from patients, and may take years to be effective. Evidence does exist that supports the value of lifestyle intervention for treating hypertension or diabetes and preventing cardiovascular events, but studies on suitable lifestyle interventions for patients with CKD are sparse. In addition, lifestyle risk factors for CKD with different comorbidities may vary. For example, lifestyle interventions for CKD with mineral and bone disorder include adequate calcium and vitamin D consumption, exercise, and fall prevention. The lifestyle risk factors for CKD with diabetes include unhealthy diet, sedentary lifestyle, and obesity. The lifestyle risk factors and modification strategies for CKD suggested by different guidelines may also vary [8-10], which poses a major challenge for clinical practice and research.

With the advance of digital health care strategies, a large amount of data can be leveraged for identifying lifestyle risk factors. Popular approaches for identifying lifestyle risk factors include epidemiological or statistical approaches with an implicit assumption that risk factors are linearly associated with a disease. However, it oversimplifies complex relationships between risk factors and diseases.

In this paper, we explore the use of a popular data mining technique, association rule mining (ARM), to determine more nuanced relationships between lifestyle risk factors and CKD with comorbidities. ARM is commonly used for performing unsupervised exploratory data analysis over a wide range of research and commercial domains, including biology and bioinformatics (eg, biological sequence analysis, analysis of gene expression data) [11-13]. Rules produced by ARM are able to summarize the impact of several factors in combination in a nonhierarchical fashion.

Methods

Materials

Behavioral Risk Factor Surveillance System

We conducted an ARM analysis using the 2017 Behavioral Risk Factor Surveillance System (BRFSS), which was published in July 2018 [14]. The BRFSS is an annual health-related telephone survey conducted by the Centers for Disease Control and Prevention that is designed to measure the health-related risk behaviors, chronic health conditions, and use of preventive services of adult residents (≥18 years) of the United States (including all 50 states, the District of Columbia, Guam, and Puerto Rico). More than 400,000 adults are interviewed each year, making it the largest telephone-based survey in the world and enabling it to be a powerful tool for health promotion activities. The BRFSS system consists of 29 modules and 358 variables that collect information about health status, healthy days or health-related quality of life, health care access, exercise, inadequate sleep, chronic health conditions, oral health, tobacco and e-cigarette use, alcohol consumption, immunization status, falls, seat belt use, drinking and driving, breast and cervical cancer screening, prostate cancer screening, colorectal cancer screening, and HIV/AIDS [15]. The validity of BRFSS variables for indexing chronic disease conditions has been previously demonstrated [15,16]. The BRFSS 2017 contains a total of 450,016 responses and 17,547 CKD cases.

Semantic MEDLINE Database

The Semantic MEDLINE Database (SemMedDB) [17] is a repository of semantic predications (subject-predicate-object triples) extracted from the titles and abstracts of all PubMed citations, which is widely used to conduct literature-based knowledge discovery in the biomedical domain [18-21]. The predications are extracted by SemRep [22], which is a semantic interpreter developed by the National Library of Medicine. Specifically, the semantic predications consist of UMLS (Unified Medical Language System) metathesaurus concepts as arguments (eg, subject and object) and a semantic relationship (eg, “treat”) from an extended version of the UMLS Semantic Network as a predicate. There are currently more than 83 million semantic predications in this database in the June 30, 2017, version of this database. Although SemMedDB provides structured predications, further inference work is needed to filter out noisy data and discover new knowledge. In this study, we treated the SemMedDB as a knowledge resource and extracted a subgraph that contains all triples related to CKD for enriching the survey data.

Charlson Comorbidity Index

We evaluated the noncommunicable diseases (NCDs) of each participant by using the classification of Charlson Comorbidity Index (CCI) [23], consisting of 17 comorbidities, developed and validated as a measure of 1-year mortality risk and burden of disease. In addition to CKD, we investigated five NCDs:

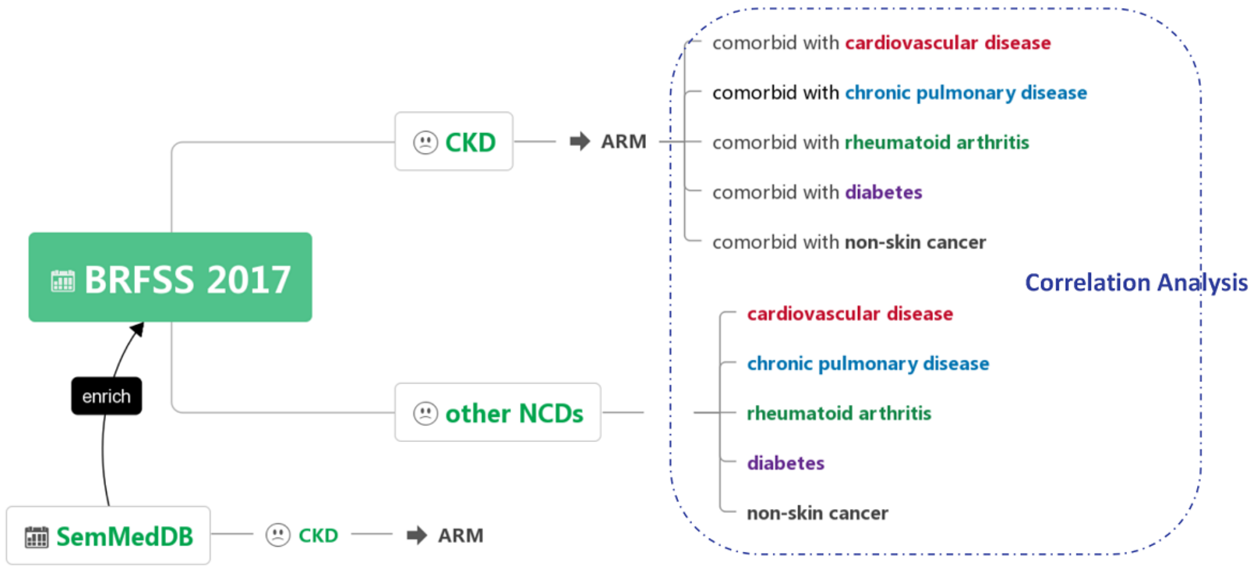
cardiovascular disease, chronic pulmonary disease, rheumatoid arthritis, diabetes, and non-skin cancer.

Institutional review board approval was not necessary for this study due to the nature of the study (secondary analysis of an anonymized dataset).

Methodology Overview

We applied ARM for the CKD population using the 2017 BRFSS data to generate rules for detecting lifestyle risk factors for CKD progression, including demographic information, lifestyle behaviors, clinical symptoms, and chronic disease conditions. Correlation analysis was performed to assess differences in lifestyle risk factors in the status of comorbidity-related CKD. To enrich the BRFSS data, SemMedDB was mined to identify lifestyle risk factors for CKD presented in publications. The workflow is shown in Figure 1. The arules package (version v1.6-4) for R (version 3.5.2) was used for ARM analysis.

Figure 1. Workflow of this study. ARM: association rule mining; BRFSS: Behavioral Risk Factor Surveillance System; CKD: chronic kidney disease; NCD: noncommunicable disease; SemMedDB: Semantic MEDLINE Database.



BRFSS Input Data Preparation

We first selected 58 variables (involving 18 modules) related to behaviors from the BRFSS 2017 data by utilizing domain expert knowledge (from two nephrologists: S Peng and X Liu), with a focus on the presence of a condition or behavior rather than the questions about obvious feelings (as shown in Multimedia Appendix 1). If the given condition of interest was present in the patient, it was marked as 1, otherwise 0 or NA. For example, completion of the flu vaccine series was defined by a participant answering “yes” to the question: “During the past 12 months, have you had either a flu shot or a flu vaccine that was sprayed in your nose?” (possible answers were “yes,” “no,” “don’t know/not sure,” and “refused”). Only those who answered “yes” were annotated as 1 and included in the analysis. Records with responses of “no,” “unknown,” or “refused” were annotated as 0; those with missing data were completely excluded from the analysis to minimize underestimation. For each patient, we extracted all variables that were marked as 1 and prepared the input.

Association Rule Mining of the Chronic Kidney Disease Cohort in BRFSS

We then applied the Apriori algorithm [24] on the input data for 58 variables among 17,547 CKD patients. Apriori is a popular algorithm for mining association rules that is divided into two steps: (1) finding frequent itemsets and (2) constructing rules from frequent itemsets. An association rule is an implication between disjoint itemsets: m ⇒ n. The left-hand side of the rule is the antecedent and the right-hand side the consequent. An itemset containing *k* items is called a *k-itemset*. If *T* is a transaction, *m* is an itemset, and $m \subseteq T$, then T contains m. The support of the rule m ⇒ n is the fraction of transactions that contain both m and n (equation 1 in Figure 2). A frequent itemset is one whose support is at least some threshold, always denoted as *minSup*.

The rule m ⇒ n with confidence (equation 2 in Figure 2) means that the fraction of transactions in *T* containing *m* that also contain *n* is confidence. It measures how often items in *m* appear in transactions that contain *n*. Confidence can also be referred to as the strength of the rule. The threshold of confidence is always denoted as *minConf*.

Lift (equation 3 in Figure 2) is an index that indicates the relative magnitude of the probability of observing *m* under the condition of *n*, compared with the overall probability of observing *m*. When lif*t* = 1, the two occurrences, m ⇒ n, are independent of each other. When the lift value is greater than 1, the two occurrences are dependent on one another; the higher the value, the greater the relevance of the interaction.

Figure 2. Equations.

(1)	$support(m) = \frac{\#\text{ of unique transaction with risk factor } m}{\#\text{ of transaction}}$ $support(n) = \frac{\#\text{ of unique transaction with risk factor } n}{\#\text{ of transaction}}$ $support(mn) = \frac{\#\text{ of unique transaction with risk factors } m \text{ \& } n}{\#\text{ of transaction}}$
(2)	$confidence(m \Rightarrow n) = \frac{\text{support (mn)}}{\text{support (m)}}$
(3)	$lift(m \Rightarrow n) = \frac{\text{support (mn)}}{\text{support (m)} * \text{support (n)}}$

We used the following heuristic for generating the final association rules to be analyzed. We first selected itemsets with support value larger than the average of support values of all itemsets and lift value greater than 1. We then kept itemsets with lift value larger than the average lift values of those selected itemsets as our final association rules. We focused our analysis of the association rules of five NCDs as determined by the CCI: cardiovascular disease, chronic pulmonary disease, rheumatoid arthritis, diabetes, and non-skin cancer.

Correlation Analysis of Comorbidities and Risk Factors

To assess differences of lifestyle risk factors in the status of comorbidity-related CKD, correlation analysis was performed. We retrieved five subcohorts of NCDs (cardiovascular disease, chronic pulmonary disease, rheumatoid arthritis, diabetes, non-skin cancer) from the CKD cohort and evaluated the contribution and correlation of lifestyle risk factors.

Literature Enrichment Analysis

We mined SemMedDB for lifestyle risk factors that were not present in the BRFSS system by also using ARM. We first retrieved all relevant triplets (subject, predicate, and object) related to CKD. For example, <Diet Therapy, Treats, CKD>, <CKD, Coexists_With, Diabetes>, and <CKD, Causes, Hypertensive Disease> are some example triplets retrieved. We then selected terms from the triplets that were relevant to lifestyle behavior, symptoms, and diseases based on a list of relevant semantic types (see Multimedia Appendix 2). We filtered out 47 terms with generic meaning (eg, patients, agent, woman, child, author, disease).

We then applied the Apriori algorithm on the extracted pairwise terms to mine frequent itemsets and generate rules. Based on our previous work [25], our item matrix was very sparse, with a density of 0.00026. To mine sufficiently interesting rules, we set the minimum support and minimum confidence by making sure every rule was presented at least two times and selected itemsets with lift value greater than 1. We then kept itemsets with lift value larger than the average lift values of those selected itemsets as our final association rules. Specifically, we focused our analysis of the association rules on six specific semantic types (daily or recreational activity, food, hazardous or poisonous substance, individual behavior, mental or behavioral dysfunction, finding) to detect lifestyle risk factors present in publications that the BRFSS questionnaire does not mention.

Results

Characteristics of Patients With Chronic Kidney Disease Cohort

Overall, a total of 17,547 participants were reported have CKD in the BFRSS 2017 data; 80.09% (14,053/17,547) were white and 60.13% (10,551/17,547) were men. The mean age was 64.42 (SD 13.81) years. The characteristics of the CKD cohort are presented in Table 1.

Table 1. Characteristics of participants in the BFRSS (Behavioral Risk Factor Surveillance System) 2017 with chronic kidney disease (N=17,547).

Characteristics	Participants
Age (years), mean (SD)	64.42 (13.81)
Male, n (%)	10,551 (60.13)
Completed interview, n (%)	15,348 (87.47)
Ever served on active duty in the United States Armed Forces, n (%)	2940 (16.76)
Income categories[a], n (%)	
Less than $15,000	2608 (14.86)
$15,000 to less than $25,000	3455 (19.69)
$25,000 to less than $35,000	1792 (10.21)
$35,000 to less than $50,000	1955 (11.14)
$50,000 or more	4734 (26.98)
Education level, n (%)	
Did not graduate middle school	1933 (11.02)
Did not graduate high school	5213 (29.71)
Attended college or technical school	5151 (29.36)
Graduated from college or technical school	5181 (29.53)
Marital status, n (%)	
Married	7904 (45.04)
Divorced	3047 (17.36)
Widowed	3821 (21.78)
Separated	494 (2.82)
Never married	1801 (10.26)
A member of an unmarried couple	374 (2.13)
Race, n (%)	
White	14,053 (80.09)
Black or African American	1763 (10.05)
American Indian or Alaskan Native	535 (3.05)
Asian	261 (1.49)
Native Hawaiian or other Pacific Islander	159 (0.91)
Other race	351 (2.00)
No preferred race	50 (0.28)
Comorbidity, n (%)	
CHD[b] or myocardial infarction	4828 (28.12)
Stroke	15,204 (86.65)
COPD[c], emphysema, or chronic bronchitis	3763 (21.45)
Asthma	2888 (16.46)
Rheumatoid arthritis	10,798 (61.98)
Diabetes	6642 (37.85)
Cancer	3974 (22.65)

[a] The rest of the people refused to answer this question.

[b] CHD: coronary heart disease.

[c] COPD: chronic obstructive pulmonary disease.

Association Rule Mining of the Chronic Kidney Disease Cohort in BRFSS

For heuristics, we set a lower bound of 0.1 for support and computed the average for all selected support values. As a result, we set the average support (0.150) as a threshold and selected 12,141 frequent itemsets. Among the 12,141 frequent itemsets, we then picked the average lift 1.094 as the threshold to finalize 7677 association rules. Figure 3 shows the curve between ranked associations and interestingness metrics (support and lift). The threshold was also marked on the curve.

Among the 7677 association rules, we retrieved subsets that related to five adverse conditions included in NCDs from CCI, including cardiovascular disease, chronic pulmonary disease, rheumatoid arthritis, diabetes, and non-skin cancer. For each of the input conditions, we then selected the top 10 association rules with the highest lift score regardless of whether the disease appeared on the left or right side.

From the top rules of each comorbidity, we determined that (1) CKD patients with comorbidity of cardiovascular disease have symptoms of high blood pressure, high cholesterol, asthma, function limitation, and lower aerobic and strengthening level; (2) CKD patients with a comorbidity of chronic pulmonary disease tend to have clinical manifestations of being overweight, hypertension, unhealthy diet (french fries or fried potatoes, less consumption of fruit and vegetables), and lower aerobic and strengthening level; (3) CKD patients with a comorbidity of rheumatoid arthritis are associated with hypertension, overweight, asthma, difficulty walking/doing errands alone, and less leisure-time physical activities; (4) CKD patients with a comorbidity of diabetes have a variety of clinical manifestations, including hypertension, high cholesterol, overweight, less leisure-time physical activities, and lower aerobic and strengthening level; and (5) CKD patients with non-skin cancer are associated with age (older than 65 years), asthma, less muscle strengthening, and lower aerobic level.

Examples of the top rules with the highest lift scores are shown in Table 2 (see Multimedia Appendix 3 for details on the results of the top 10 rules for subsets).

Figure 3. Support and lift value selection.

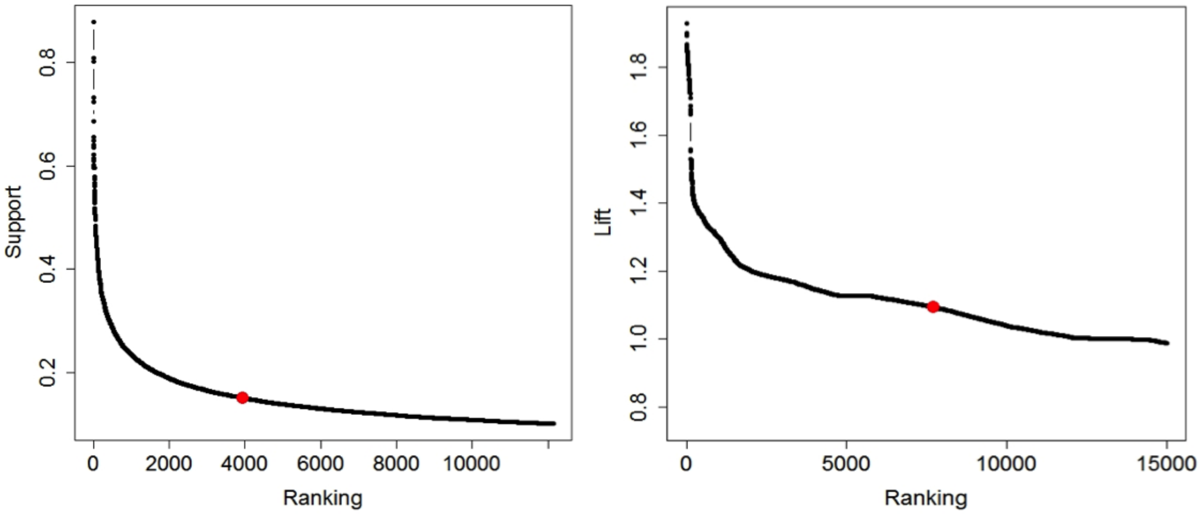


Table 2. Examples of the top rule for subsets.

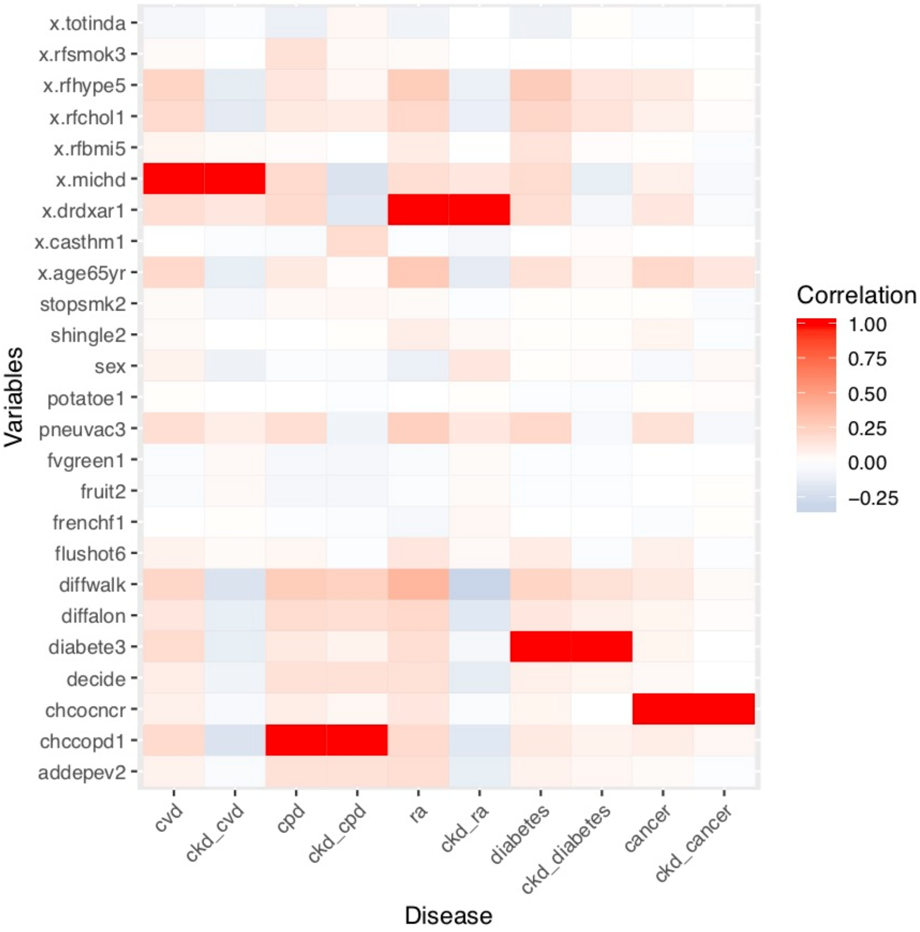
Comorbidities	Keywords[a]	Top rule	Lift	Count
Cardiovascular disease	‘x.michd’	{diffwalk,x.casthm1,x.rfhype5,x.rfsmok3} => {x.michd}	1.43	2783
Chronic pulmonary disease	chccopd1,’ ‘x.casthm1’	{diffalon,x.casthm1,x.drdxar1,x.rfsmok3} => {diffwalk}	1.93	2643
Rheumatoid arthritis	‘x.drdxar1’	{diffalon,x.casthm1,x.drdxar1,x.rfsmok3} => {diffwalk}	1.93	2676
Diabetes	‘diabete3’	{diffwalk,x.casthm1,x.rfchol1,x.rfhype5,x.rfsmok3} => {diabete3}	1.53	2726
Cancer	‘chcocncr’	{chcocncr,x.casthm1} => {x.age65yr}	1.2	2697

[a] We used the variable code to represent each variable. The meaning of the code is shown in Multimedia Appendix 1.

Correlation Analysis of Comorbidities and Risk Factors

We conducted a correlation analysis using variables present in the top 10 rules for the five NCDs and CKD with a total of 25 variables. Figure 4 shows the heatmap of the correlation coefficient values of those variables with the five NCDs, CKD, and CKD with the comorbidities. Spearman rank correlation test was used for the analysis.

Figure 4. Heatmap for correlation analysis of comorbidities and lifestyle risk factors.



The correction analysis showed that people with NCDs including CKD have less physical activity in their leisure time and consume fewer fruits and vegetables. Hypertension, high cholesterol, age older than 65 years, male sex, difficulty walking, and difficulty concentrating had positive correlations with cardiovascular disease and rheumatoid arthritis but negative correlations with CKD comorbid conditions.

Literature Enrichment Analysis

We set the support threshold to 0.00047 and the confidence threshold to 0.0001 to ensure every rule was presented at least two times, and then expressed the results with lift value greater than 1 by descending order to finalize important association rules. Among all 1323 association rules, 140 keywords from six specific semantic types were selected as a lifestyle word list (daily or recreational activity, food, hazardous or poisonous substance, individual behavior, mental or behavioral dysfunction, finding) to detect novel rules related to lifestyle risk factors present in publications. Multimedia Appendix 4 shows the top 20 rules.

Associations found using this method indicated that iron deficiency, depressed mood, sedentary lifestyle, and malnutrition were associated with anemia, hyperparathyroidism, obesity, and atherosclerosis, respectively, which the BRFSS questionnaire does not mention (Table 3).

Table 3. Lifestyle-related top rules of SemMedDB.

Top rules	Lift	Count
{Iron deficiency} => {Anemia}	20.92	3
{Depressed mood} => {Hyperparathyroidism; Secondary}	16.24	2
{Obesity} => {Sedentary}	15.18	2
{Obesity} => {Hypercholesterolemia}	15.18	2
{Malnutrition} => {Atherosclerosis}	9.33	3

Discussion

Comparison With Other Studies and Reviews

The association rules indicated that CKD patients comorbid with cardiovascular disease are more likely to have symptoms of high blood pressure, high cholesterol, asthma, function limitation, and lower aerobic and strengthening levels.

The proper assessment of overall progressive risk in patients with CKD requires an adequate assessment of the presence and severity of other major risk factors. CKD is an independent risk factor for the development of cardiovascular disease; CKD is considered a cardiovascular disease risk equivalent [26,27]. Damaged kidneys may release too much renin, which helps to control blood pressure but increases the risk for heart attack, congestive heart failure (CHF), and stroke. CHF is responsible for up to 50% of deaths in patients with renal failure [3,28]. The signs and symptoms of heart failure include shortness of breath (dyspnea), fatigue, and weakness, consistent with our findings. The Physicians' Health Study and other observational studies suggest that increased physical activity, higher cardiorespiratory fitness, and lower sedentary time are associated with reduced incidence of CHF [29]. Evidence shows that exercise training results in improved physical performance and functioning in patients with CKD [30]. Hence, the highlight of lifestyle modification of CKD with cardiovascular disease is to increase aerobic capacity by improving muscle strength or functional ability.

Findings also point to similar risk factors for CKD with chronic pulmonary disease or rheumatoid arthritis. The relationship between rheumatoid arthritis and chronic pulmonary disease (especially for chronic obstructive pulmonary disease) was found recently, in which people with rheumatoid arthritis were at 47 percent greater risk of hospitalization for chronic obstructive pulmonary disease than those in the control group [31]. Our finding supported evidence in the CKD cohort, the mechanisms that link CKD comorbid with the two diseases are speculative at present, which might be inflammation, autoimmunity, or genetic predispositions shared between them.

The lifestyle risk factors of these two comorbidities include hypertension, overweight, unhealthy diet (french fries or fried potatoes, less consumption of fruit and vegetables), and physical inactivity. Because the items did not determine exactly when symptoms of CKD or other NCDs originated, there are two possible interpretations of the result. One possible interpretation is that participants began reducing their physical activity and intake of fruits and vegetables when they developed CKD or chronic conditions. Symptoms of chronic conditions, such as hypertension, bone pain, peripheral neuropathy, side effects from medicines and fluid retention, itch, or sleep disturbance, can all negatively affect daily physical activity level, especially for CKD patients. Fruits and vegetables are a rich source of carbohydrates, vitamins, potassium, magnesium, and dietary fiber, whereas legumes and dried beans are important vegetable proteins. However, the limitation of potassium, fructose [32,33], or dietary protein intake has been common practice to control uremia. Despite the known benefits of fruit and vegetable consumption, intake remains poor in both the general and CKD populations [34].

An alternative interpretation is that lower vegetable and fruit consumption contributes to the development or maintenance of CKD or other NCDs. This interpretation has greater plausibility because it is consistent with other epidemiological studies and existing biological knowledge. However, fruits and vegetables should not be omitted from the everyday diet; this practice may lead to nutrient deficiency and low fiber-related constipation, which contribute to further accumulation of uremic toxins. The national "2 fruits and 5 vegetables" campaign guides Australians toward healthy fruit and vegetable consumption, which is applicable to CKD [35]. Also, regular participation in moderate-intensity exercise may enhance certain aspects of immune function and exert anti-inflammatory effects. Therefore, the lifestyle modification of CKD with chronic pulmonary disease or rheumatoid arthritis should be high dietary fiber intake and participation in moderate-intensity exercise to decrease inflammation and oxidative stress.

CKD is associated with insulin resistance and, in advanced CKD, decreased insulin degradation. In the association rules for CKD with diabetes, the results pointed to hypertension, high cholesterol, overweight, less leisure-time physical activities, and lower aerobic and strengthening as lifestyle risk factors rather than an unhealthy diet. Hence, the lifestyle modification of CKD with diabetes is consistent with the prevention of type 2 diabetes (predominantly exercise and weight loss), which can successfully decrease the development of CKD with diabetes.

CKD is recognized as a disease that may complicate cancer and its therapy (eg, immunotherapy). Cancer can cause CKD either directly or indirectly through the adverse effects of therapies; conversely, CKD may be a risk factor for cancer [36,37]. We found that age older than 65 years and physical inactivity were associated with CKD with non-skin cancer. The BRFSS questionnaire does not incorporate the therapeutics of cancer; therefore, the lifestyle risk factors of CKD with cancer cannot be evaluated in our research.

Enrichment of the BRFSS Questionnaire

The BRFSS does not specifically target CKD or NCDs; therefore, many clinical manifestations were not considered, including potentially relevant items such as anorexia, nausea, vomiting, fatigue, anemia, and bone disease. To enrich the questionnaire, we used the SemMedDB to find lifestyles that related to the clinical manifestations specifically with CKD from publications. The results indicated that iron deficiency, depressed mood, sedentary lifestyle, and malnutrition are associated with anemia, hyperparathyroidism, obesity, and atherosclerosis, respectively, which the BRFSS questionnaire did not mention. CKD can affect a patient's health-related quality of life in many ways. The diagnosis alone might cause fear or anxiety. Anemia, frailty, coexisting comorbidities, and depression are also major contributory factors to quality of life in CKD. Meat and meat alternatives are the main source of protein in the CKD diet. Healthy choices include lean cuts of meat, skinless poultry, eggs, fish, seafood, and plant-based protein foods such as legumes, dried beans, nuts, and seeds. The questionnaire of the BRFSS does not contain the variables of meat or protein consumption, nor does it contain information on micronutrient deficiency.

Effectiveness of Association Rule Mining in the Noncommunicable Disease Domain

The results of the correlation analysis found that hypertension, high cholesterol, age older than 65 years, male sex, difficulty walking, and attention deficit disorder were positively correlated with cardiovascular disease and rheumatoid arthritis, but negatively correlated with corresponding CKD comorbidities (CKD with cardiovascular disease/rheumatoid arthritis). The ARM results suggest that patients with CKD older than 65 years are more likely to have signs or symptoms of hypertension, asthma, and difficulty walking, which is inconsistent with the aforementioned findings. It was caused by the differences between the two algorithms: a correlation is the relationship that exists between two or more variables in which a change in one variable causes a change in the other variable when the two variables are said to be correlated. Association rules are of the form $\{X_1, ..., X_n\} \rightarrow Y$, meaning that if you find all signs or symptoms of $X_1, ..., X_n$ in a disease it is possible to find another sign or symptom (Y). Epidemiological studies and existing domain knowledge are inconsistent with the result of correlation analysis but consistent with the results of ARM.

A wide range of disorders may develop as a consequence of the loss of renal function with CKD. These include disorders of fluid and electrolyte balance, as well as abnormalities related to hormonal or systemic dysfunction. Treatment strategies should be modified based on the needs of the individual patient. Variations and inconsistencies are inevitable in clinical practice; therefore, recognizing modifiable risk factors in medical interventions are important for providing effective chronic disease management. ARM has several applications in the medical domain, and it has been used for detecting risk factors for diabetes and cardiovascular disease [38,39]. This study illustrates how ARM approaches could be used in risk factor detection of CKD and provides the potential effectiveness of the method of ARM analysis for NCDs. ARM methods, such as Apriori, have also been used on electronic health record data to identify associations among clinical concepts. The strength of the ARM approach compared with a more conventional correlation analysis is that it has identified sizeable groups that can easily be defined and identified for intervention at a practice level in real time to allow more focused and immediate correction of bias in chronic disease management.

Limitations

This research used a large representative sample, was based on items that asked about diagnosed disease, and included a number of relevant covariates; however, there are some aspects of this study that should be noted as limitations.

First, from 17,547 CKD patients, only 15,348 completed the interview. The dataset was skewed toward the white race and male gender, which may affect the generalizability of lifestyle interventions to other races and females. Other research found similar results [40] in which lower response rates (<40%) were associated with the underrepresentation of racial/ethnic minorities (eg, Hispanics), women, and younger individuals in the BRFSS survey.

Second, CKD and cancer can influence each other either directly or indirectly through the adverse effects of therapies. Since the BRFSS questionnaire was based on self-reporting, we cannot connect enough information. The lifestyle risk factors of CKD with cancer could be confirmed in further research using direct physical examination or biochemical indexes.

Third, the semantic predications consist of UMLS metathesaurus concepts as arguments, so we cannot tell whether "sedentary lifestyle" and "depressed mood" can be treated as "leisure-time physical activity calculate variables" or "ever been told you have depressive disorder." As such, whether these differences are involved in observed associations for CKD needs to be considered in further epidemiological research. More robust observational or quasi-experimental studies would be needed to fully support the long-term impact of interventions for modifiable risk factors.

Finally, for the semantic predication triples extracted from the SemMedDB, we ignored the semantic meaning of the predicates and only kept subjects and objects as pairwise associations. However, we also found some predications with negative meanings. For example, the triples <Diet; Protein-Restricted, Neg_Treats, CKD>, <Dietary intake, Neg_Associated_With, CKD>, <End-stage renal failure, Neg_Coexists_With, CKD>, and <Ferritin level, Neg_Manifestation_Of, CKD> contain predicates with negative meaning, like not treats, have no association with, does not coexist with, or does not manifest. The reason we did not completely remove those triples is that we found inconsistency because both positive and negative relationships for the same factor may be reported. For example, according to a 2015 study conducted by Wong [41], a positive relationship between abnormal blood pressure and CKD was found in SemMedDB; however, in a 1992 study conducted by Taniguchi et al [42], a negative relationship between the same two items was detected. The SemMedDB only maintains information contained in the title and abstract; therefore, it is difficult to address inconsistencies without reading through the full text. In the future, we will count positive and negative associations for each pairwise term and assign weights for different predications for a better semantic representation.

Conclusion

This study related both lifestyle risk factors and CKD with five other comorbid chronic conditions using the largest national US survey available and provided a suggestion for BRFSS questionnaire enrichment. Various lifestyle risk factors result in the presence of different comorbid conditions for CKD patients, and different signs and symptoms may be observed. The findings illustrate how ARM approaches could be used in risk factor detection of chronic diseases to allow more focused and optimized chronic disease management.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
BRFSS 2017 code mapping index.
[DOCX File , 20 KB - jmir_v21i12e14204_app1.docx]

Multimedia Appendix 2
Selected semantic types.
[DOCX File , 15 KB - jmir_v21i12e14204_app2.docx]

Multimedia Appendix 3
Top 10 rules for subsets.
[DOCX File , 19 KB - jmir_v21i12e14204_app3.docx]

Multimedia Appendix 4
Lifestyle-related rules from SemMedDB.
[DOCX File , 15 KB - jmir_v21i12e14204_app4.docx]

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Abbreviations

ARM: association rule mining
BRFSS: Behavioral Risk Factor Surveillance System
CCI: Charlson Comorbidity Index
CHF: congestive heart failure
CKD: chronic kidney disease
NCDs: noncommunicable diseases
SemMedDB: Semantic MEDLINE Database
UMLS: Unified Medical Language System

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Original Paper

QardioArm Upper Arm Blood Pressure Monitor Against Omron M3 Upper Arm Blood Pressure Monitor in Patients With Chronic Kidney Disease: A Validation Study According to the European Society of Hypertension International Protocol Revision 2010

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Abstract

Background: Hypertension is considered as a main risk factor for chronic kidney disease development and progression. Thus, the control and evaluation of this disease with new software and devices are especially important in patients who suffer from chronic kidney disease.

Objective: This study aimed to validate the QardioArm mobile device, which is used for blood pressure (BP) self-measurement in patients who suffer from chronic kidney disease, by following the European Society of Hypertension International Protocol 2 (ESH-IP2) guidelines.

Methods: A validation study was carried out by following the ESH-IP2 guidelines. A sample of 33 patients with chronic kidney disease self-measured their BP by using the QardioArm and Omron M3 Intellisense devices. Heart rate (HR), diastolic BP, and systolic BP were measured.

Results: The QardioArm fulfilled the ESH-IP2 validation criteria in patients who suffered from chronic kidney disease.

Conclusions: Thus, this study is considered as the first validation using a wireless upper arm oscillometric device connected to an app to measure BP and HR meeting the ESH-IP2 requirements in patients who suffer from chronic kidney disease. New validation studies following the ESH-IP2 guidelines should be carried out using different BP devices in patients with specific diseases.

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KEYWORDS

blood pressure; hypertension; kidney disease; mobile apps; software validation

Introduction

Background

Increased afferent sympathetic activation may be an early event in patients who suffer from chronic kidney disease [1]. Various types of kidney damage may lead to a heightened sympathetic drive by central integrative pathways to the hypothalamus [2,3]. The ensuing efferent response may lead to an increase in renin activity, retention of sodium retention, and, eventually, vasoconstriction, which may contribute to hypertension development and propagation [4]. Hypertension may be considered as a main risk factor for chronic kidney disease development and progression. Thus, the control and evaluation of this disease with new software and devices are especially important in patients who suffer from chronic kidney disease. Patients who suffer from chronic kidney disease must strictly control their hypertension. Nevertheless, most of these patients failed to control their blood pressure (BP), showing a lower control rate compared with the general population [4-6].

Active involvement is required in patients with hypertension to get a successful management of this disease. Encouragement of home BP monitoring is considered as one of the main measures that increased patient compliance with their treatment, showing a great potential to improve hypertension control rates [7-9]. To get efficient home BP monitoring, an accurate BP measurement technique needs to be used by a validated device [7]. Standard validation protocols are considered as objective guidelines, which allow health care professionals to recommend a device to their patients [10-13].

The Association for the Advancement of Medical Instrumentation published a protocol to validate electronic and aneroid sphygmomanometers in 1987. In 1990, the protocol of the British Hypertension Society appeared as a new guideline. Afterward, both protocols were revised in 1993 [10,11]. On the basis of these experiences, the Working Group on Blood Pressure Monitoring of the European Society of Hypertension published a simplified international protocol to facilitate this assessment process in 2002 to revise, unify, and simplify the previous protocols [12]. In 2010, this last European Society of Hypertension protocol was revised (ie, European Society of Hypertension International Protocol 2 [ESH-IP2]), being more exigent than the previous protocol [13]. These protocols have been validated for the general adult population; nevertheless, their validation needs to be carried out in special populations, such as patients with chronic kidney disease [14].

Objectives

The hypothesis of this study was that QardioArm (Atten Electronics Co) would be valid for self-measurement of BP and heart rate (HR) in renal patients according to the ESH-IP2 guidelines. Hence, the purpose of this study was to validate the QardioArm for BP self-measurement in patients who suffer from chronic kidney disease, following the ESH-IP2 guidelines.

Methods

Study Design

This study was a descriptive investigation study to validate the QardioArm device for the measurement of BP and HR in patients with chronic kidney disease according to the ESH-IP2 guidelines [13]. It was performed between January 2019 and May 2019.

Ethical Information

The Institutional Research and Ethical Committee at the University of Extremadura (Badajoz, Spain), with the code 151/2019, approved this study. This study adhered to the Declaration of Helsinki [15]. Participants were fully informed about the study protocol. All participants signed their written informed consent to participate in this study.

Devices

Omron M3 Intellisense

The Omron M3 Intellisense (Omron Healthcare) was considered as the gold standard in this study. This device was validated in the general population [16] and in patients with chronic kidney disease [14] following the ESH-IP2 guidelines. This device has been validated in comparison with a mercury sphygmomanometer with a mean of −1.3 mm Hg (SD 4.3) for systolic pressure and a mean of 2.1 mm Hg (SD 4.1) for diastolic pressure in patients with chronic kidney disease [14]. In addition, at the beginning of this study, the Omron M3 was evaluated in comparison with a certified pressure device (the Omron M2) [16] in 3 BP measurements to ensure the correct functioning of the gold standard. The used Omron M3 Intellisense monitor was purchased in a local market. The Omron M3 Intellisense is an automated and oscillometric upper arm device for home BP monitoring. This device comprised a standard arm cuff, circumference ranging from 22 to 32 cm, and a large cuff, circumference ranging from 32 to 42 cm. This device used *IntelliSense* technology to acquire a comfortable controlled inflation without pressure presetting or reinflation.

QardioArm

The QardioArm was selected as the test device in this study. QardioArm is a fully automatic, noninvasive, wireless BP monitor. QardioArm comprises a BP measurement system intended to assess the diastolic BP and systolic BP and HR in the adult population [17].

This device used an inflatable cuff that was wrapped around the upper arm. Cuff circumference ranged from 22 to 37 cm.

A specific free Qardio app was downloaded from the Apple App Store or Google Play Store. A device with Bluetooth 4.0, iOS 7.0 (or later), and Android 4.4 *KitKat* (or later) was required, being compatible with iPod, iPhone, Apple Watch, iPad, and Android phones and tablets.

Furthermore, the QardioArm provided an automatic screen, including graphics, to facilitate visual data interpretation. This app is configured by issue reminders and warnings, and the measurements and progress are real time shared with other users.

Patients and Recruitment

All patients were recruited from the *Fresenius Medical Care* dialysis clinics in Plasencia (Extremadura) and signed the written informed consent.

Following the ESH-IP2 guidelines [13], 33 patients who fulfilled the selection criteria were included in this study. Inclusion criteria were women and men, aged at least 25 years, who underwent hemodialysis treatment. Of the total participants, this study included at least 10 men and 10 women, according to the requirements of the guidelines. Exclusion criteria were patients with a sustained arrhythmia or circulatory problems, which are considered as contraindicated conditions for the use of the cuff, as well as pregnant women.

Study Protocol

A total of 2 nurses with experience in BP measurement carried out all assessments. The measurement room provided an adequate temperature without any factor that could have influenced the measurements, such as noise and distractions [12,13].

Each participant self-reported birth date, sex, height, weight, and body mass index (using the Quetelet index in kg/m^2), and the arm circumference was measured to ensure the adequate cuff size.

Furthermore, participants were placed in sitting position in the measurement room, and BP measurements were assessed after a rest period (from 10 to 15 min). BP coinciding with the HR was measured on the right arm in 30 patients with chronic kidney disease, whereas BP was assessed on the left arm in 3 patients because of the presence of an arteriovenous fistula on the right arm (n=2) and right hemiplegia (n=1). A total of 9 consecutive measurements were carried out following the ESH-IP2 guidelines [12,13], alternating the 2 described devices (the Omron M3 Intellisense and the QardioArm). All measurements were recorded according to the following protocol:

- BP A—entry BP using the standard device
- BP B—device detection BP using the test instrument
- BP 1—using standard device
- BP 2—using the test instrument
- BP 3—using standard device
- BP 4—using the test instrument
- BP 5—using the standard device
- BP 6—using the test instrument
- BP 7—using the standard device

At the same time of measurement, the patients remained quiet, calm, sitting and without moving, placing the back straight, maintaining the feet over the floor in parallel position, without crossing their legs, and resting the arm over a flat surface, with the hand palm upward and the elbow in a slightly flexed position to place their fist at the height of the heart. The interval time between BP measurements varied from 30 to 60 seconds [13]. All measurements were performed in the same room.

Data Analysis

Statistical analysis was performed by using IBM SPSS Statistics, version 19 (SPSS Inc). Results were described in mean (SD).

The device accuracy following the ESH-IP2 guidelines was based on a comparison between the measurements of the reference (Omron M3) and test device (QardioArm).

For each patient, the device measurements such as BP 2, BP 4, and BP 6 were first compared with the measurements such as BP 1, BP 3, and BP 5, respectively, and also with the measurements such as BP 3, BP 5, and BP 7, respectively. Comparisons that were more favorable to the device were used.

Indeed, differences were classified separately for both diastolic BP and systolic BP, depending on whether their values were within 5, 10, or 15 mm Hg [13], and for HR, depending on whether their values were within 3, 5, or 8 beats per minute.

Results were analyzed and detailed according to the ESH-IP2 requirements to conclude if the used device passed or failed to pass the explained validation protocol. Parts 1 and 2 of the validation protocol concern the differences in number of the requested ranges for each individual measurement (99 measurements) and each individual patient (33 patients), respectively [13].

Furthermore, Bland and Altman graphs were used to illustrate the relationship between systolic BP differences (systolic BP and device-reference) and mean systolic BP (device and reference), diastolic BP differences (diastolic BP and device-reference) and mean diastolic BP (device and reference), or HR differences (HR and device-reference) and average HR (device and reference).

Results

Patients With Chronic Kidney Disease

A sample of 35 patients with chronic kidney disease were recruited to assess 33 participants who met the ESH-IP2 inclusion criteria, and 2 of them were excluded because of device failure (n=1) and arrhythmias (n=1).

The remaining sample (n=33) was screened. There were 15 females and 18 males. The characteristics of the patients, such as age, height, weight, body mass index, and arm circumference, are presented in Table 1.

Table 1. Sociodemographic characteristics of the patients.

Variables	Total group (N=33)		Male (n=18)		Female (n=15)	
	Mean (SD)	Range (minimum to maximum)	Mean (SD)	Range (minimum to maximum)	Mean (SD)	Range (minimum to maximum)
Age (years)	71.03 (11.24)	45.0-91.0	70.11 (11.11)	45.0-90.0	72.13 (11.69)	48.0-91.0
Weight (kg)	70.70 (15.68)	46.5-101.0	70.33 (13.66)	46.5-100.0	71.15 (18.31)	46.80-101.0
Height (cm)	162.30 (9.52)	141.0-180.0	166.61 (5.63)	155.0-180.0	157.13 (10.77)	141.0-174.0
Body mass index (kg/m^2)	27.02 (6.70)	18.07-43.72	25.26 (4.27)	18.07-33.48	29.14 (8.48)	18.96-43.72
Arm circumference (mm)	267.27 (31.18)	215.0-350.0	262.50 (24.15)	220.0-310.0	273.0 (38.06)	215.0-350.0

Blood Pressure Outcome Measurements

Validation findings for the QardioArm BP device following the 2010 ESH-IP2 are presented in Table 2 (Part 1), Table 3 (Part 2) and Textbox 1 (Part 3).

The measurement numbers differing from the standard device (Omron M3) of 5, 10, and 15 mm Hg or less were presented in Tables 2 and 3 and Textbox 1, for diastolic BP and systolic BP, following the ESH-IP2 [13].

Mean differences between the test device and standard device were 2.43 mm Hg (SD 4.15) for diastolic BP and 4.03 mm Hg (SD 4.42) for systolic BP.

From these analyses, of 99 measurements, 81 differences for systolic BP and 85 differences for diastolic BP showed an absolute difference within 5 mm Hg (compared with at least 65 differences for diastolic BP and 73 differences for systolic BP according to the ESH-IP2 criteria). Furthermore, 92 comparisons for systolic BP and 95 comparisons for diastolic BP showed an absolute difference within 10 mm Hg (compared with at least 81 differences for diastolic BP and 87 differences for systolic BP according to the ESH-IP2 criteria). In addition, of 99 differences, 96 for systolic BP and 95 for diastolic BP exhibited an absolute difference within 15 mm Hg (compared with at least 93 for diastolic BP and 96 for systolic BP according to the ESH-IP2 criteria). Indeed, the validation of part 1 of the device was successfully completed.

According to part 2 of the 2010 ESH-IP2 criteria, of 33 patients, 29 patients showed a minimum of 2 of 3 comparisons within a 5 mm Hg difference for systolic BP, and 30 patients showed a minimum of 2 of 3 comparisons within a 5 mm Hg difference for diastolic BP (compared with at least 24 patients for systolic BP and diastolic BP according to the ESH-IP2 criteria). Nevertheless, 2 patients showed their 3 differences outside 5 mm Hg for systolic BP, and no patients showed their 3 differences outside 5 mm Hg for diastolic BP (compared with a maximum of 3 patients for diastolic BP and systolic BP according to the ESH-IP2 criteria). Owing to these 2 described conditions, validation of part 2 of the device was successfully completed.

Therefore, part 3 of the QardioArm device validation was completed, as both parts 1 and 2 were validated for diastolic BP and systolic BP.

Table 2. Validation results of the Part 1 of the QardioArm blood pressure device according to the European Society of Hypertension International Protocol 2010.

Validation results of QardioArm—Part 1[a]	≤5 mm Hg	≤10 mm Hg	≤15 mm Hg	Grade 1	Mean (SD), mm Hg
Pass requirements[b]					
Two of	73	87	96	—[c]	—
All of	65	81	93	—	—
Achieved[d]					
Systolic blood pressure	81	92	96	Pass	4.03 (4.42)
Diastolic blood pressure	85	95	95	Pass	2.43 (4.15)

[a] Accuracy is determined by the number differences in these ranges for both individual measurements (part 1) and individual subjects (part 2). To pass, a device must achieve all the minimum pass requirements shown.

[b] Pass requirements: as required by the IP.

[c] Not applicable.

[d] Achieved: as recorded by the device.

Table 3. Validation results of the Part 2 of the QardioArm blood pressure device according to the European Society of Hypertension International Protocol 2010.

Validation results of QardioArm—Part 2[a]	2/3≤5 mm Hg	0/3≤5 mm Hg	Grade 2	Grade 3
Pass requirements[b]	≥24	≤3	—[c]	—
Achieved [d]				
Systolic blood pressure	29	2	Pass	Pass
Diastolic blood pressure	30	0	Pass	Pass

[a] Accuracy is determined by the number differences in these ranges for both individual measurements (part 1) and individual subjects (part 2). To pass, a device must achieve all the minimum pass requirements shown.

[b] Pass requirements: as required by the IP.

[c] Not applicable.

[d] Achieved: as recorded by the device.

Textbox 1. Validation results of the Part 3 of the QardioArm blood pressure device according to the European Society of Hypertension International Protocol 2010.

Validation results of QardioArm—Part 3

- Result: Pass

Heart Rate Outcome Measurements

Validation findings for the QardioArm HR device following the 2010 ESH-IP2 are presented in Table 5 (Part 1), Table 6 (Part 2) and Textbox 2 (Part 3).

Measurement numbers differing from the standard device Omron M3 of 3, 5, and 8 beats per minute or less are detailed in Tables 5 and 6 and Textbox 2 for HR. Mean differences between the test device and standard device were 1.93 beats per minute (SD 3.04).

From these analyses, of 99 differences, 85 showed an absolute difference within 3 beats per minute, 94 differences showed an absolute difference within 5 beats per minute, and 95 differences showed an absolute difference within 8 beats per minute. Thus, part 1 device validation was successfully completed for the HR.

According to the part 2 of the 2010 ESH-IP2, of 33 participants, 29 showed a minimum of 2 of 3 comparisons within 3 beats per minute difference for HR. Nevertheless, 1 participant showed 3 differences outside 3 beats per minute. As these 2 detailed conditions were validated, the part 2 device validation was successfully completed.

Therefore, part 3 of the QardioArm device validation was completed, as both parts 1 and 2 were validated for HR.

Indeed, the QardioArm device met the validation criteria of the ESH-IP2 for the diastolic BP, systolic BP, and HR for patients who suffered from chronic kidney disease.

The prior findings coincided with the Bland and Altman graphs that visually showed the differences between QardioArm device measurements and Omron M3 measurements for systolic BP (Figure 1), diastolic BP (Figure 1) and HR (Figure 1).

Table 5. Validation results of the Part 1 for the QardioArm heart rate device according to the European Society of Hypertension International Protocol 2010.

Validation results QardioArm—Part 1[a]	≤3 bpm	≤5 bpm	≤8 bpm	Grade 1	Mean (SD), bpm
Pass requirements[b]					
Two of	73	87	96	—[c]	—
All of	65	81	93	—	—
Achieved[d]					
Heart rate	85	94	95	Pass	1.93 (3.04)

[a] Accuracy is determined by the number differences in these ranges for both individual measurements (part 1) and individual subjects (part 2). To pass, a device must achieve all the minimum pass requirements shown.

[b] Pass requirements: as required by the IP.

[c] Not applicable.

[d] Achieved: as recorded by the device.

Table 6. Validation results of the Part 2 for the QardioArm heart rate device according to the European Society of Hypertension International Protocol 2010.

Validation results QardioArm—Part 2[a]	2/3≤3 bpm	0/3≤3 bpm	Grade 2	Grade 3
Pass requirements[b]	≥24	≤3	—[c]	—
Achieved[d]				
Heart rate	29	1	Pass	Pass

[a] Accuracy is determined by the number differences in these ranges for both individual measurements (part 1) and individual subjects (part 2). To pass, a device must achieve all the minimum pass requirements shown.

[b] Pass requirements: as required by the IP.

[c] Not applicable.

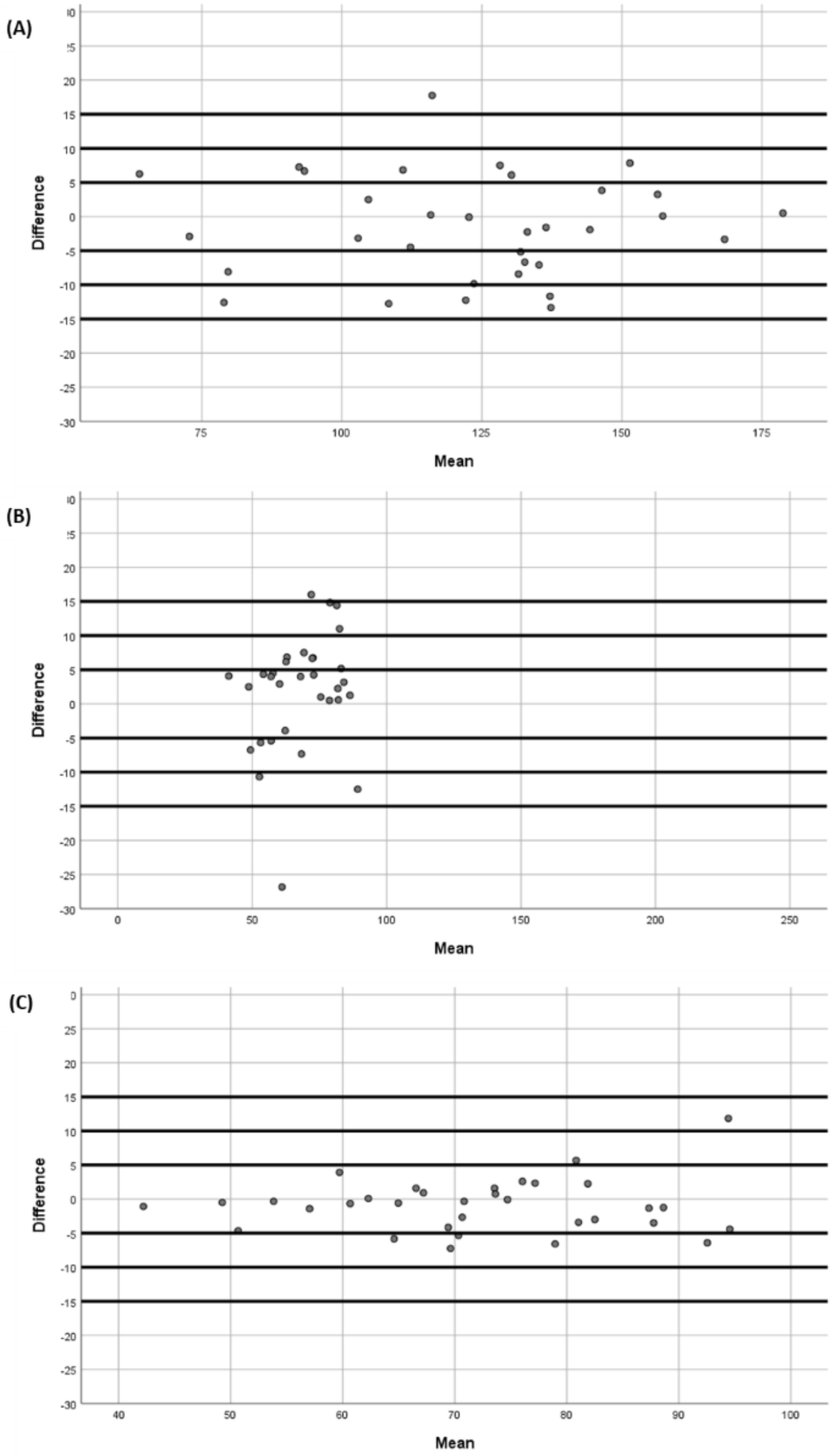
[d] Achieved: as recorded by the device.

Textbox 2. Validation results of the Part 3 for the QardioArm heart rate device according to the European Society of Hypertension International Protocol 2010.

Validation results QardioArm—Part 3

- Result: Pass

Figure 1. Plots of (A) systolic blood pressure, (B) diastolic blood pressure, and (c) heart rate differences between the QardioArm and Omron M3. Difference: systolic blood pressure (A), diastolic blood pressure (B), or heart rate (C) differences between the QardioArm and Omron M3. Mean: mean systolic (A), diastolic (B), or heart rate (C) average values of the QardioArm and Omron M3.



Discussion

Principal Findings

Globally, the use of home BP monitoring is increasing in several countries, being a useful complement to clinic measurements with significant acceptance by patients with hypertension with several advantages [7,9,18,19]. Patients who suffer from chronic kidney disease may use a validated sphygmomanometer at home because it seems to be especially cost-effective [6,7,18,20-22].

The main disadvantage of automated home sphygmomanometers is their inaccuracy, although their accuracy is progressively improving [13]. This inaccuracy is more frequent in populations with specific diseases, which may require additional validation tests [7,23]. Indeed, the European Society of Hypertension

Practice Guidelines 2010 for home BP monitoring recommended specific validation tests for patients with end-stage chronic kidney disease [9]. Arterial stiffness may influence the correspondence between readings measured by using mercury and oscillometric devices [8,24].

Nevertheless, there is a lack of research studies, which validate devices in patients with chronic kidney disease [14,24-27]. Further validation studies are necessary for patients with chronic kidney disease. Indeed, further studies should specifically investigate the validation of QardioArm in patients with chronic kidney disease with arterial stiffness as a future line of research.

This research is considered as the first study investigating the validation of a wireless upper arm oscillometric device connected to an app to measure HR and BP in chronic kidney disease patients. This validation has been carried out following the ESH-IP2 guidelines, although a validated noninvasive oscillometric upper arm device was used as a reference instead of a mercury sphygmomanometer.

QardioArm has been previously validated for the general population in the first place by our team [28] and later by other authors [29]. In addition, our team validated QardioArm in obese patients [30].

According to the results of our prior works, the number of differences included in each category according to the ESH-IP2 (5, 10, and 15 mm Hg) for systolic BP and diastolic BP was similar in the 3 validations [28-30], as parts 1 and 2 of the protocol were passed. QardioArm in the general population achieved better results in both phases of the protocol for systolic and diastolic BP, especially in part 1 (higher differences in the 3 categories) [28]. Within phase 1, the differences obtained in the systolic BP of renal patients in this study were very similar to those of the general population [28], whereas the differences obtained in the diastolic BP were more similar to the obese population [30]. Phase 2 of this study was almost identical to the 3 previous validations [28-30], with minor differences (1 or 2 individuals).

Following the ESH-IP2 guidelines, the findings of this study showed that the QardioArm device successfully passed the validation requirements for patients with chronic kidney disease [13]. Nevertheless, our findings may not be extrapolated to other specific populations with specific diseases such as elderly or diabetic patients as well as pregnant women, as these conditions have not been addressed. In addition, it should be considered that patients with advanced chronic kidney disease could present a specific chronic kidney disease type and future studies should be carried out to develop new app validations according to the specific recommendations in each kind of chronic kidney disease patients Nevertheless, arterial stiffness measurements of patients with chronic kidney disease involved in this study could be useful, although the standard validation protocols did not require these measures. Finally, consecutive sampling bias should be considered in this study, and a simple randomization sampling process could be more adequate for future studies.

Conclusions

The findings of this study are relevant because it is considered as the first validation to show that a device connected to an app to measure BP and HR met the requirements of the 2010 ESH-IP2 in the patients who suffer from chronic kidney disease.

Besides, the ESH-IP2 guidelines should stress on validating the BP devices in other specific populations by publishing explicit criteria for such a validation in these populations.

Finally, it is highly recommended to determine the accuracy of this device in other populations with specific diseases such as pregnant women, elderly people, or arrhythmic patients.

Conflicts of Interest

None declared.

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Abbreviations

BP: blood pressure
ESH-IP2: European Society of Hypertension International Protocol 2
HR: heart rate

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Original Paper

Comparative Effectiveness of a Web-Based Patient Decision Aid for Therapeutic Options for Sickle Cell Disease: Randomized Controlled Trial

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Abstract

Background: Hydroxyurea, chronic blood transfusions, and bone marrow transplantation are efficacious, disease-modifying therapies for sickle cell disease but involve complex risk-benefit trade-offs and decisional dilemma compounded by the lack of comparative studies. A patient decision aid can inform patients about their treatment options, the associated risks and benefits, help them clarify their values, and allow them to participate in medical decision making.

Objective: The objective of this study was to develop a literacy-sensitive Web-based patient decision aid based on the Ottawa decision support framework, and through a randomized clinical trial estimate the effectiveness of the patient decision aid in improving patient knowledge and their involvement in decision making.

Methods: We conducted population decisional needs assessments in a nationwide sample of patients, caregivers, community advocates, policy makers, and health care providers using qualitative interviews to identify decisional conflict, knowledge and expectations, values, support and resources, decision types, timing, stages and learning, and personal clinical characteristics. Interview transcripts were coded using QSR NVivo 10. Alpha testing of the patient decision aid prototype was done to establish usability and the accuracy of the information it conveyed, and then was followed by iterative cycles of beta testing. We conducted a randomized clinical trial of adults and of caregivers of pediatric patients to evaluate the efficacy of the patient decision aid.

Results: In a decisional needs assessment, 223 stakeholders described their preferences, helping to guide the development of the patient decision aid, which then underwent alpha testing by 30 patients and 38 health care providers and iterative cycles of beta testing by 87 stakeholders. In a randomized clinical trial, 120 participants were assigned to either the patient decision aid or standard care (SC) arm. Qualitative interviews revealed high levels of usability, acceptability, and utility of the patient decision aid in education, values clarification, and preparation for decision making. On the acceptability survey, 72% (86/120) of participants rated the patient decision aid as good or excellent. Participants on the patient decision aid arm compared to the SC arm demonstrated a statistically significant improvement in decisional self-efficacy (*P*=.05) and a reduction in the informed sub-score of decisional conflict (*P*=.003) at 3 months, with an improvement in preparation for decision making (*P*<.001) at 6 months. However, there was no improvement in terms of the change in knowledge, the total or other domain scores of decisional conflicts, or decisional self-efficacies at 6 months. The large amount of missing data from survey completion limited our ability to draw conclusions about the effectiveness of the patient decision aid. The patient decision aid met 61 of 62 benchmarks of the international patient decision aid collaboration standards for content, development process, and efficacy.

Conclusions: We have developed a patient decision aid for sickle cell disease with extensive input from stakeholders and in a randomized clinical trial demonstrated its acceptability and utility in education and decision making. We were unable to demonstrate its effectiveness in improving patient knowledge and involvement in decision making.

Trial Registration: ClinicalTrials.gov NCT03224429; https://clinicaltrials.gov/ct2/show/NCT03224429 and ClinicalTrials.gov NCT02326597; https://clinicaltrials.gov/ct2/show/NCT02326597

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KEYWORDS

decision aids; decision support; sickle cell anemia; sickle cell disease; sickle cell disorders

Introduction

Sickle cell disease (SCD) is a major public health problem in the United States, affecting an estimated 100,000 individuals [1] and associated with significant morbidity caused by pain crises, acute chest syndrome, stroke, pulmonary hypertension, leg ulcers, and irreversible organ damage [2]. SCD has substantial health care utilization, with total annual charges in the United States that exceed $1.5 billion [3,4]. Quality of life is impaired [5-12], productivity is diminished (with a 40-60% unemployment rate [13]), and there is increased risk of premature mortality, especially in patients with the genotypes HbSS or HbS/β° thalassemia [2,14-18]. SCD predominantly affects ethnic minorities, with African Americans, followed by Hispanics, being the largest affected communities [18]. Disease-modifying therapies, such as hydroxyurea (HU), chronic transfusion therapy (CTT), and bone marrow transplantation (BMT), have demonstrated efficacy in clinical trials. HU is effective at reducing complications and health care utilization in children and adults, and improves survival in adults [19-25]; however, it must be taken daily and indefinitely with regular monitoring for side effects, and its impact on long-term organ function is unknown. HU is underprescribed and when prescribed is underutilized, with 85% of SCD patients who received a HU prescription never filling it [19,23,25,26] and an average prescription refill rate of 58% [27]. Over 20% of families refuse HU, citing reasons such as fear of cancer or other side effects, concern about lack of efficacy, and unwillingness to take the medicine or make the additional visits to clinic or pharmacy [23,26]. BMT is potentially curative, but is associated with treatment-related morbidity, risk of mortality, and later effects such as infertility [28]. Only a small minority of eligible patients undergo BMT even when an HLA-identical sibling donor is available [29,30]. CTT is efficacious in primary and secondary prevention of stroke but is associated with significant risks such as allo-immunization and iron overload [31-34]. In making choices regarding HU, BMT, or CTT, patients and caregivers are most influenced by perceived efficacy and safety [35,36]. There are trade-offs between the benefits and harms between the different treatment options, such that an individual patient's preference, values, and risks of different outcomes could influence their decisions. A major contributor to decisional dilemma associated with treatments for SCD is the absence of studies to compare the benefits and harms of these treatments and guide patients in their choice of treatments. Thus, there is a need for research that helps to understand patient values and preferences to determine how to help them make informed treatment decisions in line with these values and preferences.

The Ottawa Decision Support Framework is an evidence-based, practical guideline for assisting patients in making health or social decisions [37-40]. It uses a three-step process to: (1) assess client and practitioner determinants of decisions to identify decision support needs; (2) provide decision support through counseling and decision tools; and (3) evaluate decision making. The Ottawa decisional support framework has been used to guide the development and evaluation of more than 30 patient decision aids, practitioner decision support resources, and tools to evaluate the quality and outcomes of decisions [37-40].

The overarching objective of this study was to develop a Web-based patient decision aid, drawing input from patients, their caregivers, and other stakeholders to meet the decisional needs of patients with SCD considering various treatment options, and then to test the efficacy of the patient decision aid in real life conditions. The research question was whether a Web-based decision aid that is comprehensible, acceptable, and usable, and would meet the decisional needs of those with SCD, is feasible. We hypothesized that the use of a patient decision aid would help patients and families better navigate treatment choices. Further, we proposed that a Web-based patient decision aid would help clarify patient values for themselves and for their health care providers.

Methods

Needs Assessment

We identified and recruited stakeholders connected with decision making for SCD. We included: (1) individuals with SCD aged 8-80 years old; (2) individuals who were post bone marrow transplant for SCD; (3) parents/legal guardians/caregivers (including significant others, family, and friends) of individuals with SCD (newborn to 80 years) directly involved in decision making with/for that individual; (4) parents/legal guardians/caregivers (including significant others) of individuals who were post-bone marrow transplant for SCD who were directly involved in decision making with/for that individual; (5) stakeholders involved in any aspect of SCD; (6) health care providers who were directly involved in sickle cell health care, including but not limited to physicians, nurse practitioners, physician assistants, social workers, and nurses; and (7) those able to comprehend English.

We excluded family members/individuals/caregivers not directly involved in decision making regarding SCD health care, and stakeholders who were not involved in any aspect of SCD. We recruited participants in local, regional, and national SCD meetings as well as SCD clinics. We conducted semistructured qualitative interviews of stakeholders to elicit their experience in seeking information about, and making decisions related to, SCD and to identify decisional conflict (uncertainty), knowledge and expectations, values (what is important to patients), support and resources, decision types, timing, stages and learning, and personal clinical characteristics. We also explored what values were most important to patients to inform not only the development of the patient decision aid but also future approaches to therapy. The interviews were conducted utilizing both open- and closed-ended questions. Demographic and disease complication information were also collected from each participant. Interviews lasted 30-40 minutes and were transcribed verbatim. A coding scheme to organize data into themes was developed using QSR NVivo 10 software (QSR International Pty Ltd, Chadstone, Victoria, Australia). Each code was defined and sustained throughout the analysis, and these codes were eventually developed into categories. From the coding process, we retained the categories that we believed held the most explanatory power, and then the primary categories were further analyzed. In the initial steps of analysis, we gave all data equal consideration and we focused on variation across the data rather than frequency counts of concepts. Analysis concluded when we observed the replication of concepts. Ultimately, we developed categories from consistent patterns in the data. Thematic saturation was achieved when the team believed the development of categories addressed the research question. Inter-coder agreement was achieved in three steps: (1) one team member performed the initial coding of the transcripts, and as concepts developed, they were discussed and deliberated by the entire team; (2) once coding and deliberation was completed, a second team member coded all transcripts and verified the original coding scheme (in the event of disagreement between the two coders, a third team member served as arbitrator by also coding the transcripts in question); and (3) results were discussed until the entire team came to a consensus.

Development of the Patient Decision Aid

The results of the needs assessment were used to create the storyboard for the patient decision aid, and through iterative cycles of refinement they were used in the creation of its first draft prototype. We developed the patient decision aid [41] in accordance with International Patient Decision Aids Standards (IPDAS) [42-44]. The patient decision aid was designed to describe SCD and provide information on all three treatment options, describe the positive and negative features of each option, and describe the likelihood of positive and negative outcomes. We used up-to-date scientific evidence, cited the sources in a reference and technical section, disclosed sources of funding, and disclosed any conflicts of interest. The patient decision aid was written at a Grade 5 equivalent reading level or less, and provided ways to help patients obtain additional information through means other than reading, such as audio and video. We also included patient stories to represent a range of positive and negative experiences.

Field Testing of the Patient Decision Aid

Alpha testing for clarity, comprehensibility, and usability was completed by patients, stakeholders, and clinicians. The results of the alpha testing then informed the finalization of the prototype of the Web-based patient decision aid. We conducted two iterative cycles of beta testing with patients, caregivers, stakeholders, and health care providers from around the United States.

Qualitative interviews with patients and health care providers were conducted during the beta testing of the patient decision aid to elicit stakeholder perspective on the quality, accuracy of, and satisfaction with the content and presentation of the patient decision aid, as well as suggestions on how to improve it. After the first round of beta testing, all the qualitative interviews were contemporaneously analyzed, and when thematic saturation was achieved they were used to modify the prototype patient decision aid. This was then subjected to a second iterative cycle of beta testing. We then synthesized these findings and applied them to the design of the final patient decision aid.

We included all potential subgroups (ie, adults, adolescents, parents of adolescents, and parents of young children), and we focused our efforts on recruiting the largest number of patients possible to include individuals drawn from different demographic descriptions and who were considering different treatment options. While the recommended sample size in qualitative interviews is 12-90 individuals with a median of 30 [45], we planned a larger sample size to enable us to characterize patients based on their experiences with the intervention or usual care, as well as age and role (patient versus parent), while enabling us to achieve thematic saturation [45]**.**

Benchmarking of the Patient Decision Aid

For benchmarking the final patient decision aid, we used the International Patient Decision Aids Standards self-evaluation instrument (IPDASi), a validated, interrater-reliable [46-49,50]. The IPDASi provided an internationally accepted benchmark to assess the quality of development, the process, the content, any potential biases, and the methods of field testing and evaluating a patient decision aid.

Randomized Clinical Trial of the Efficacy of the Patient Decision Aid

We further evaluated acceptability and usability of this final patient decision aid among participants in a randomized clinical trial (NCT03224429). Inclusion and exclusion criteria are listed in Textbox 1.

Textbox 1. Inclusion and exclusion criteria of the randomized clinical trial.

Inclusion criteria:

- Individuals with sickle cell disease (SCD) aged 8-80 years old

OR

- Parent/legal guardian of patients (age<18 years) with SCD who are directly involved in decision making regarding SCD health care treatment

OR

- Health care provider directly involved in care of individuals with SCD, including child of parent/legal guardian enrolled in study
- Patients/parents/caregivers who have made a past decision to not obtain treatment of the considered option or who have not obtained treatment of the chosen option in past 12 months
- Able to comprehend English
- Patients/parent/legal guardian who will have access to the internet from iPad, smart phone, or personal computer
- Patients <18 years may participate in Testing of Decision Aid, Cohort B, if they have participated in the Qualitative Needs Assessment first

Exclusion criteria:

- Family members/individuals/caregivers not directly involved in decision making regarding SCD health care
- Patient/parent/legal guardian who has already decided to begin and has started the treatment option
- Parent/legal guardian of child who is participating in Cohort B of this study
- Child <18 years of age of parent/legal guardian who is participating in Cohort A of this study and randomized to the control arm and not the decision aid arm
- Spouse, significant other, or other family member involved in decision making for child <18 years if parent/legal guardian of child already enrolled into this study.

Participants considering disease-modifying therapies for SCD were randomized to receive either the patient decision aid or standard care (SC) arms prior to deciding. Cohort A consisted of three subgroups: (1) parents or legal guardians of children aged <18 years old; (2) individuals with SCD who were between 18-28 years old; and (3) individuals with SCD who were >28 years old. Within each of these groups, we identified what particular treatment decision participants were considering (HU/BMT/CTT), and then assigned them to the HU, BMT, or CTT strata according to the intervention that they were contemplating. Cohort A subgroup participants were randomized to patient decision aid versus SC. SC was defined as usual care with a current health care provider in usual practice without the use of a patient decision aid. We collected demographic information from adults with SCD, or caregivers of pediatric patients, that included age, gender, race, education, marital status, and employment.

Participants in the patient decision aid arm completed surveys at randomization and were provided access to the patient decision aid with a unique access ID and password for the purpose of this study. Participants were scheduled for their second research visit to coincide with the completion of discussions with the health care provider/team regarding treatment options. Participants were asked to complete the study surveys via a paper version or online within 2 weeks of the office/clinic visit. Self-reported information regarding themselves or the patient they cared for was updated relative to SCD management and complications, since Consent/Visit 1 Participants received a monthly follow-up via telephone or email to verify their ability to access and navigate the website. Soon after, and within 4 months following their discussion with their health care provider, participants were scheduled for their final research visit. Participants were asked to complete the study surveys as either a paper or online version within 2 weeks of this office/clinic visit.

After completion of the final study visits and surveys and data collection on the patient decision aid arm, participants in the SC arm were offered password-protected access to the patient decision aid website. Participants were given 4 weeks to review this site, at which time they were asked to complete a series of questionnaires either electronically or via a paper version.

Adolescent patients aged 10-18 years old were assigned to cohort B and were offered the ability to view the patient decision aid without randomization. The purpose of cohort B was to test the quality and comprehension of information and the impact on daily life relating to management of SCD in patients <18 years of age.

Outcomes Studied in the Clinical Trial

Overview

We used the measurement tools developed to operationalize the variables in the Ottawa decisional framework to study several patient centered outcomes.

Acceptability of the Patient Decision Aid

Acceptability of the patient decision aid was tested using the Acceptability of Education Survey (8 multiple choice questions, 2 short answer questions), [48] a validated measure of the comprehensibility of components of a patient decision aid, as well as its length, pace, amount of information, balance in presentation of information about options, and overall suitability for decision making [49-52].

Patient Knowledge and Understanding of Treatment Risks and Benefits

The impact on patient knowledge was tested by using a knowledge questionnaire. Since knowledge is different from understanding, we designed questions that tested understanding (specifically health literacy).

Patient Attitudes Towards Decision Making

The desirability or personal importance a participant assigns to the risks and benefits of a treatment option was determined by administering a Values survey (14 multiple choice questions, six fill in the blank questions) [48,52-54]. The measures of the Decision/Choice Predisposition scale (one multiple choice questions and four fill in the blank questions) [55] were used to determine if the participant was leaning towards, or had a propensity to select, an option. The Stage of Decision Making refers to the individual's readiness to engage in decision making, progress in making a choice, and receptivity to considering or reconsidering an option. For the Stage of Decision Making survey (10 multiple choice questions) [56], participants indicated their stage of decision making with responses ranging from "I haven't thought about the decision" to "I have made my decision and am unlikely to change my mind". Decision support is most likely to be useful in individuals who are in active contemplation or are willing to consider or reconsider an option. The tool is not scored but it is used to screen out patients or to study the covariation in decisional conflict or interventions.

Impact on Decision Making

The impact of the patient decision aid on the decision-making process and on the treatment decision includes the preparation for decision making, the specific decision made, satisfaction with the decision-making process, and satisfaction with the decision. We used the Preparation for Decision Making scale (10 multiple choice items) [57] to assess a patient's perception of how useful a patient decision aid or other decision support intervention is in preparing the respondent to communicate with their practitioner at a consultation focused on making a health decision. It is not specific or temporally-related to a particular visit to the doctor and as such was well suited to this study.

Psychological Impact of the Patient Decision Aid on Decision Making

This was assessed by the decisional regret scale [58], which measures distress or remorse after a health care decision, the Decision Self-Efficacy Scale (11 multiple choice questions) [59], which measures self-confidence or belief in one's ability to make decisions and includes participating in shared decision making, and the Decisional Conflict Scale (16 multiple choice questions) [60], which measures the uncertainty in choosing options and the modifiable factors contributing to this uncertainty.

Patient and Caregiver Perspectives Elicited by Qualitative Research Methods

Qualitative interviews were conducted at baseline for all cohorts, with a focus on how people prefer to learn about SCD, the information content (ie, what physicians and other health care personnel share with patients and caregivers), and medical decision making. Participants were asked about their questions for their health care providers and what they would like to learn about SCD. Qualitative interviews were then conducted within 4 weeks of visit 3 to evaluate the extent to which the method of educational tool (standard practice or patient decision aid) helped the participant to recognize that a decision needed to be made regarding treatment of SCD, to understand the values that affected the decision, and understand if and how these values were addressed with the health care provider in making the health care decision. Qualitative interviews of pediatric patients were conducted after they had accessed the patient decision aid in order to assess their involvement in decision making, their preferences regarding Web-based educational content, and their views about the quality and acceptability of the patient decision aid.

Analytic Methods

We assumed that 30% of patients or parents participate in decision making with standard care, and that the rate of patient or parent participation would double with the intervention. Based on a 90% power and a 0.05 significance level, we required 110 patients, 55 in each group, for comparing 2 binomial proportions. To account for attrition we recruited 120 patients, 60 in each treatment group and 20 in each age group. Reasons for missing data were considered in the analysis. We also assessed the plausibility of the assumptions associated with the approach.

Systematic efforts were instituted to maximize follow-up. A calendar was maintained for the timing for subject procedures, and participants were contacted by telephone and email for reminders and scheduling. If a subject did not respond after five contact attempts, the subject was considered to be lost to follow up. We assumed that the data were missing at random and conducted simple imputation to calculate total scores and subscores. We then compared changes in these scores between the patient decision aid and SC control groups. We did not use model-based methods such as multiple imputation, as the purpose of this study was not to estimate a model but to evaluate the assigned intervention based on survey results over time. We then imputed the missing responses with the mean. We realize that imputing the mean preserves the mean of the observed data and these estimates remain unbiased, but we also realized that imputation with the means results in underestimation of the SE and introduces a source of bias.

Results

Decisional Needs Assessment

A total of 223 individuals, including adult patients, caregivers of pediatric patients, health care providers and other stakeholders, participated in qualitative interviews regarding decisional needs assessment about decision making for treatments for sickle cell disease (Table 1).

The participants had a higher level of academic achievement, with 86% reporting having had some college education. Thus, their views may or may not be representative of the sickle cell community at large. It should be noted that participants had predominantly been enrolled in local, regional and national conferences about SCD and so may have been more active about their own care. We included qualitative interviews conducted on entry into the randomized clinical trial in this analysis because patients had not been exposed to the patient decision aid yet.

Table 1. Subject flow and baseline demographics for the decisional needs assessment.

Demographic	Adult patient (n=63)	Caregiver (n=61)	Stakeholder (n=42)	Health care provider (n=56)
Age (years), median (range)	27 (18-66)	39 (16-71)	—[a]	—
Gender (female), n (%)	50 (79)	47 (77)	24 (57)	28 (50)
Race (African-American), n (%)	60 (96)	56 (92)	24 (57)	—
Ethnicity (non-Hispanic), n (%)	62 (98)	60 (98)	41 (98)	—
Education (some college or greater), n (%)	54 (86)	40 (65)	42 (100)	—
Employment (part or full time), n (%)	38 (60)	38 (63)	—	—
Married, n (%)	8 (12)	19 (31)	—	—

[a] Not applicable.

Qualitative analysis yielded the following major themes in the various aspects of decision making: how people prefer to learn about SCD, their thoughts about the content, and how they used this information for medical decision making. They discussed the content of the information shared by physicians and other health care personnel with patients and caregivers regarding what they would like to learn about SCD and what outcomes were important to them. While patients and caregivers relied on their conversations with their physicians for making decisions regarding treatment, they also shared several perspectives on how they would like to receive information that would help them participate in decision making (Textbox 2).

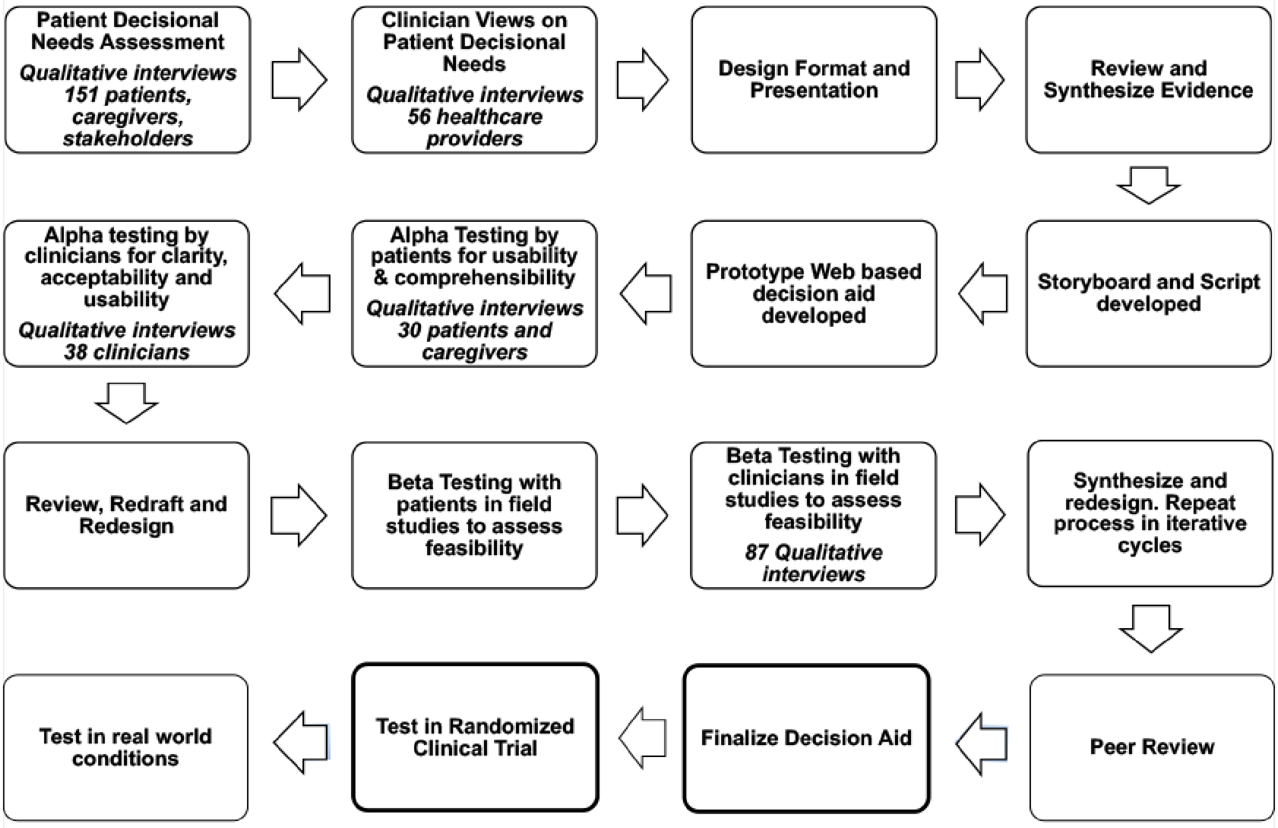
Textbox 2. Stakeholder preferences regarding Web-based educational resources to aid in decision making regarding treatment options.

- High quality, unbiased, evidence-based information to guide decision making
- Interactive design with easily comprehensible, customizable content presented in a visually pleasing, user-friendly format with limited text and attractive graphics
- Hear directly from individuals like themselves regarding their experiences with treatments and treatment decisions
- Patient video testimonials on the participants covered
- Accurate and unbiased information about pros, cons, and outcomes of each treatment option

In accordance with the stakeholder preferences, we designed the presentation format, synthesized evidence generated, created a script and storyboard, and drafted a Web-based prototype of the patient decision aid. The iterative process utilized for the development and testing of the patient decision aid using the Ottawa decisional framework is outlined in Figure 1. The following key elements were included in the design of the patient decision aid:

- Each line of text was designed to read at ≤5th grade level and tested using the Smog Readability Formula. Where necessary, definitions of words were provided.
- Minimizing of text and maximizing the use of graphics.
- High quality information which was subjected to extensive peer review by national SCD experts.
- Links to peer-reviewed references and credible sources of information.
- Information was divided into sections (sickle cell care, treatment options, values clarification, communication with physicians, etc).
- Content was displayed in accordion format to eliminate clutter and allow users to customize specificity and detail as desired.
- Ability to personalize content in the context of personal health information and a personalized folder with saved content, graphics, and videos.
- Values clarification exercises, with side by side comparison of treatment options based on values or combination of values.
- Ability to save information and values clarification exercises in preparation for discussions with their physician.

Figure 1. The iterative process for the development and testing of the patient decision aid using the Ottawa decisional framework.



Field Testing

Alpha testing for clarity, comprehensibility, and usability was completed with 30 patients/stakeholders and 36 clinicians. The results of alpha testing helped with the finalization of the prototype Web-based patient decision aid. We then conducted two iterative cycles of beta testing with 87 patients, caregivers, stakeholders, and health care providers from around the US. The qualitative interviews conducted as a part of the beta testing were also subjected to rigorous qualitative analyses.

The following themes emerged in the qualitative analyses of patient and health care provider interview transcripts from beta testing of the patient decision aid:

- A high level of satisfaction with the accuracy and quality of the content and presentation.
- Acceptability of the patient decision aid for ease of use, comprehensibility, and use of graphics.
- High perceived utility of the values clarification exercises.
- Satisfaction with the large number of video testimonials from patients and stakeholders sharing their personal narrative about medical decisions making regarding disease modifying therapy for SCD.

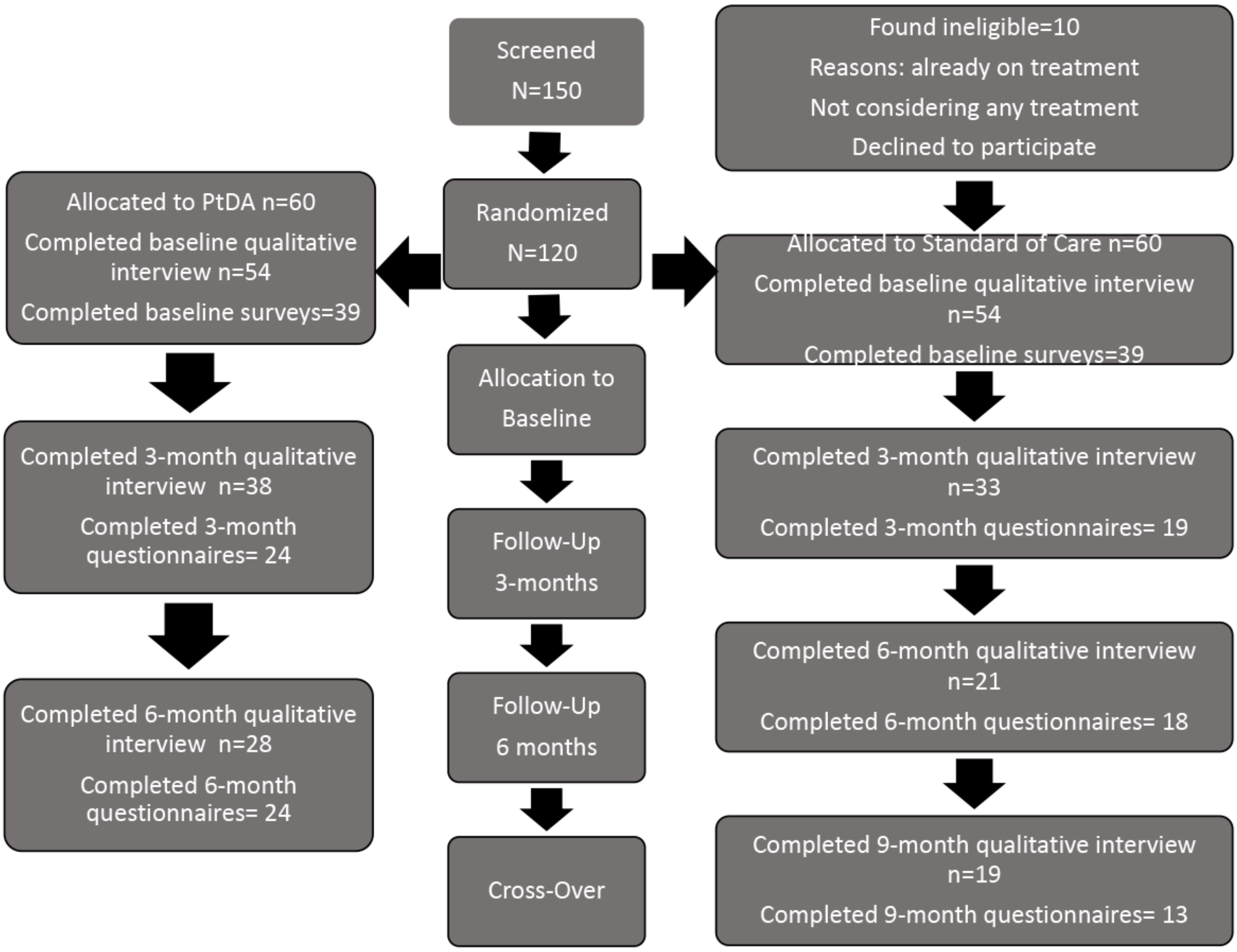
Benchmarking the Patient Decision Aid

We evaluated the quality of the development process, content, potential biases, and the methods of field testing and evaluating a patient decision aid using the 12 domains from the 2006 IPDASi checklist. The patient decision aid met 61/62 standards (see Multimedia Appendix 1). However, since we were unable to provide stories of patients who had an adverse outcome after BMT in the patient decision aid, it did not meet all requirements.

Randomized Clinical Trial

We randomized 120 participants to a clinical trial of the patient decision aid to determine its impact on knowledge and decisional conflict, preparedness, and regret. Participants were assigned to HU, BMT, and CTT strata according to the intervention that they were contemplating (BMT 73, HU 29, CTT 18). Participants randomized to the patient decision aid underwent interviews and completed surveys at study assignment, then again three months later after having a chance to review the instrument, and then again after six months when they were likely to have made their therapeutic decisions. Participants assigned to the control arm provided the same measures at baseline and at three and six months. After six months, they were given access to the patient decision aid and were interviewed and completed surveys at seven months. Of all the participants in the trial, 76% (91/120) were female with a median age of 34 years (mean 35.5), 75% (90/120) were African American, 8% (11/120) were Hispanic, 80% (96/120) had some college education, 53% (64/120) were employed, and 26% (31/120) were married (Figure 2 and Table 2). Over the different stages of the study, 76 patients were lost to follow up. Of those patients lost to follow up, 72% (55/76) were female with a median age of 31.5 years (mean 33), 75% (57/76) were African American, 8% (6/76) were Hispanic, 72% (55/76) had some college education, 56% (43/76) were employed, and 21% (16/76) were married. Of the 120 patients enrolled, 16% (19/120) did not complete any study procedures and were lost to follow up despite our *a priori* defined methods to retain contact. Completion rates for different surveys, overall and at different timepoints, ranged from 43-68%. In a univariate analysis the age, gender, race, ethnicity, educational level, employment status, and marital status did not statistically significantly predict loss to follow-up (Table 2).

Figure 2. Consort diagram describing the recruitment in the randomized clinical trial. PtDA: patient decision aid.



Of 120 patients enrolled in the study, completion rate of interviews varied between qualitative interviews and survey instruments and at different stages of the study. Qualitative interviews and surveys were completed by 101 and 78 patients at baseline, 71 and 48 patients at 3 months, 49 and 42 patients at 6 months, and 18 and 13 subjects at 9 months. These data suggest at least in this study the burden of completion of qualitative interviews may have been less than the completion of surveys and that participants seemed to lose interest in the study over time.

Table 2. Subject flow and self-identified demographics of all participants versus those who were lost to follow up.

Demographic	Lost to follow up (n=76)	Total participants (N=120)	*P* value
Age (years), median	31.5	34	.21
Gender (female), n (%)	55 (72)	91 (76)	.45
Race (African-American), n (%)	57 (75)	90 (75)	.99
Ethnicity (non-Hispanic), n (%)	69 (91)	109 (91)	.99
Education (some college or greater), n (%)	55 (72)	96 (80)	.19
Employment (part or full time), n (%)	43 (56)	64 (53)	.68
Married, n (%)	16 (21)	31 (26)	.42

Acceptability Survey

Overall, 144 out of a maximum possible 300 individual surveys (response rate 48%) were completed on the acceptability of the patient decision aid information on SCD treatment options pertinent to BMT, CTT, or HU at different timepoints. A range of 58-85% (median 72%) of participants rated the information as good or excellent on various sections of the patient decision aid. Detailed descriptions of the response to each individual section is described in Table 3. In completing acceptability surveys, 106 participants also provided additional narrative comments. Participants said the website was informative, helpful, easy to understand, provided a lot of new information in one place, and was very helpful in making decisions.

Participants appreciated being able to save information, to clarify values, and to view video testimonials.

Table 3. Results of the acceptability survey.

Criterion	Median (% ranking as good or excellent)
Comprehensibility of different information sections (1=Poor, 2=Fair, 3=Good, 4=Excellent)	
Impact of sickle cell	3 (84)
Risk factors	3 (72)
Research	3 (57)
Treatment options	3 (69)
Evidence supporting self-care	3 (68)
HU[a]/BMT[b]/CTT[c]	3 (68)
Evidence about HU/BMT/CTT	3 (64)
Stories about others	3 (58)
Amount of time learning took: (1=too much, 2=too little, 3=just right)	3 (72)
The amount of information was: (1=Poor, 2=Fair, 3=Good, 4=Excellent)	3 (72)
Found the information: (1=slanted towards self-care, 2=slanted towards interventions, 3=balanced)	3 (62)
Information was useful when making decision regarding HU/BMT/CTT (1=Yes, 2=No)	1 (87)
Ways to calculate risk factors (1=Easy, 2=Difficult)	1 (68)
Health history worksheet made the decision: (1=Easy, 2=difficult)	1 (81)
Portfolio worksheet made your discussion with the physician more: (1=Easy, 2=Difficult)	1 (81)
Did it provide information to help someone decide on whether to accept HU/BMT/CTT (1=Yes, 2=No)	1 (76)

[a] HU: hydroxyurea.

[b] BMT: bone marrow transplantation.

[c] CTT: chronic transfusion therapy.

Values Survey

Patients/caregivers also completed validated values questionnaires [52] at multiple timepoints throughout the study, for a total of 172 out of a possible 420 completed surveys (43% completion rate). Intriguingly, at each timepoint in all subgroups, the median score for the values questionnaire (Table 4) was 11, the highest possible score. In the patient decision aid group, at the final research visit (visit three, at the six-month time point), 41/60 participants (68% completion rate) who completed the values survey all gave the highest possible score for the values queried, indicating that these values were their most important considerations for making decisions. At the final research visit, 33 participants also gave additional narrative comments following completion of the values questionnaire, with freedom from pain, not having to take medications, and improved quality of life among the most important considerations in considering a treatment. Being well informed about complications of a treatment and not being worse off because of complications were also major sources of caution.

Table 4. Values considered important by patients and caregivers regarding treatments.

Value	Median[a] (25th, 75th percentile)
How important is it for you to know the complications of SCD[b]?	11 (11, 11)
How important is the benefit of reducing SCD-related complications?	11 (10, 11)
How important is the possibility of living longer due to a treatment?	11 (10, 11)
How important is risk of hair loss from hydroxyurea?	11 (7, 11)
How important is risk of darkening of nails due to hydroxyurea?	11 (7, 11)
How important is risk of cancer due to hydroxyurea?	11 (9, 11)
How important is the need for recurrent blood draws on treatment?	11 (8, 11)
How important is possibility of reducing stroke risk due to transfusion?	11 (10, 11)
How important is risk of transfusion reaction?	11 (10, 11)
How important is risk of infection due to transfusions?	11 (10, 11)
How important is risk of iron overload due to transfusion?	11 (10, 11)
How important is possibility of cure by BMT[c]?	11 (10, 11)
How important is risk of graft failure from BMT?	11 (10, 11)
How important is risk of graft versus host disease from BMT?	11 (10, 11)
How important is risk of infertility following BMT?	11 (5, 11)
How important is risk of death following BMT?	11 (11, 11)

[a] Evaluated on an 11-point Likert scale.

[b] SCD: sickle cell disease.

[c] BMT: bone marrow transplantation.

Knowledge Survey

Participants completed a knowledge survey about SCD and treatment options, first at baseline and then at different time points (Table 5). Differences in the proportion of correct answers in the patient decision aid and in the SC control arm at all time points did not reach statistical significance. The study was powered based on differences detected in the group, since attempting to detect differences in impact on individual decisions in each group would have required an unrealistically large sample size. Patients were nonrandomly assigned to BMT, HU, or CTT subgroups based on the decision they were considering. Surprisingly, most of the participants indicated that they were considering the BMT option. Subgroup analysis was underpowered and not realistic given the low rate of compliance with survey completion, with further attrition over time. Thus, the small numbers and asymmetric distribution limited the numbers available for meaningful subgroup analysis. In addition, participants were given access to the entire patient decision aid containing information on all the treatment options, which could have resulted in them simultaneously considering more than one of the options available to them. We therefore believed that it was difficult to clearly separate the impact of the patient decision aid on different decisions, so we combined the three cohorts for comparison between the patient decision aid and SC control arms. Since there was no statistically significant difference in the knowledge scores between the patient decision aid and SC groups at any time point, we did not carry out analyses of comparison of difference in change in scores from baseline.

Table 5. Percentage of correct answers for knowledge questionnaire.

Time-point	Patient decision aid, N (Mean)	Standard care control, N (Mean)	*P* value
Baseline	39 (49.83)	38 (49.87)	.97
3 months	23 (52.90)	19 (52.90)	.12
6 months	22 (55.54)	17 (46.49)	.12
9 months (cross-over)	—[a]	12 (51.18)	—

[a] Not applicable.

Choice Predisposition Survey

A total of 170 choice predisposition scale surveys (40.5% response rate) were completed by participants at different time points to indicate which treatment they were leaning towards. There was no statistically significant change in the predisposition scale following the use of the patient decision aid. The median scale score was 52 at baseline and 72 at 6 months (*P*=.57). Of 30 participants who completed the choice predisposition survey at six months, 7 indicated an inclination towards making a decision (23%). A total of 109 participants gave narrative comments on their choice predisposition survey. The major reasons for not making a choice for a treatment were: (1) a desire to think more about the decision; (2) not being convinced that the benefits outweighed the risks; (3) not being convinced that their disease was severe enough; and (4) not being convinced that the treatment would benefit them in particular. Those choosing a treatment did so: (1) to have a better quality of life; (2) to be free of pain; and (3) because they were confident they were making an informed decision.

Stages of Decision Making

We scored stages of decision making on a six-point Likert scale ranging from, “I haven’t thought about the decision,” to “I have made my decision and am unlikely to change my mind.” The tool is not typically scored but is used to screen out patients or to study the covariation in decisional conflict or interventions. Differences in the median stages of decision making at baseline and at three and six months in the two arms were not statistically significant.

Preparedness for Decision Making Survey

Individual subscales on a five-point Likert scale (ranging from not at all to a great deal) are summed and converted into a composite score, with a higher score indicating a greater preparedness for decision making. There were 74 participants (37 patient decision aid, 37 SC) with baseline data, 42 participants (23 patient decision aid, 19 SC) with three-month data, and 39 participants (22 patient decision aid, 17 SC) with six-month data. Of these, 38 had both three-month and baseline data, and 32 had both six-month and baseline data. Of the 10 survey questions, five had missing data. Four of those questions had only one missing value; one question had two. Again, we performed single mean imputation. There were no differences observed after three months among our 38 participants, but an overall difference at six months. At six months, the patient decision aid participants had a significantly higher change in preparedness for their decision-making score (*P*<.001) than the SC participants.

The mean diference of change in the preparedness for the decision making survey was not statistically significant at 3 months (*P*=0.16), but was statistically significant at 6 months (*P*<.001)

Decisional Regret Survey

The 7 participants who made a treatment decision regarding HU and the 4 patients who made a treatment decision regarding CTT in the course of the study completed the decisional regret scale [58]. No patient in the subgroup considering a decision regarding BMT completed a decisional regret survey. All individuals indicated a low level of regret following the HU or CTT decision, with scores ranging from 20-25 on a 100-point scale, but the number of individuals who made a decision was not large enough for any formal statistical analysis. Follow-up qualitative interviews after the completion of the study with the 46 participants in the patient decision aid group and the 16 participants in the SC group who crossed over to the patient decision aid group at the end of the study indicated that participants were able to carefully consider pros and cons, clarify their own values, and felt empowered to make a decision about a therapeutic option.

Decision Self-Efficacy Survey

Regarding the decision self-efficacy survey, there were 78 participants (39 patient decision aid, 39 SC) with baseline data, 42 participants with three-month data, and 42 participants (23 patient decision aid, 18 SC) with six-month data. Of these, 36 had both three-month and baseline data and 35 had both six-month and baseline data. Of the 11 survey questions, 4 had missing data. Three of those questions had only one missing value; one question had two. Again, we performed single mean imputation for partially completed surveys. There was a statistically significant difference in the change in the decisional self-efficacy score (*P*=.05) observed after three months among our 36 participants. However, the difference in the change in decisional self-efficacy scores from baseline among the 35 participants with baseline and six-month data was not statistically significant, though the patient decision aid participants had a greater change in self-efficacy score (*P*=.06) than the SC patients.

Decisional Conflict Survey

During the randomized clinical trial, 172 decisional conflict scales were completed. Decisional conflict scale responses were scored for the total score, uncertainty subscore, informed subscore, values clarity subscore, support subscore, and effective decision subscore. The decisional conflict scale consists of 16 items in 5 response categories and is scored on a 0-100 scale.

There were 41 participants that completed both the baseline and the three-month surveys. Analyses were conducted with two-tailed *t* tests (alpha=.05) as hypotheses were based on inequality rather than specifying the direction of the inequality. A total of 9 participants had some missing data, with only one participant having missed more than one question. We do not believe that certain treatment preference subgroups were more likely to have missing values, as 7 were interested in BMT and 2 in HU (*P*>.99 by Fisher’s exact test). Similarly, 4/9 participants were randomly assigned to the patient decision aid group and 5/9 to the SC group. Certain questions did not seem to be more likely to be missing than others, as the number of missing questions ranged from 0-3 for each of the 16 questions. However, we confirmed the results of the *t* test with a nonparametric method that didn’t utilize SE. Table 6 depicts the total scores and subscale scores difference over time, with the mean difference representing the baseline scores minus the 3-month scores. The *P* value refers to the difference in the mean differences from baseline. We tested whether the average change in scores equaled zero, and in all cases, inference from the nonparametric Wilcoxon test matched the results of the *t* test (Table 6). Average difference and *P* value are shown in Table 6. Based on these analyses, the patient decision aid group had a significantly greater decrease in the informed subscore of decisional conflict when comparing the three-month datae to the baseline data. Of the 79 patients with baseline data and 42 patients with six-month data, there were 36 participants with results from both time points. The six-month versus baseline results are depicted in Table 7. There was no difference in total decision conflict score or subscale scores when comparing the six-month survey with baseline data. This lack of difference remained when we compared patients by random assignment.

Table 6. Comparison of change in decision conflict scale from baseline at the 3-month time point for the patient decision aid group versus the SC group.

Parameters	Mean difference, patient decision aid	Mean difference, SC[a]	*P* value
Subscales			
Uncertainty	5.21	1.32	.38
Informed	–14.65	1.75	.003
Values clarity	–4.17	–4.39	.97
Support	1.14	–7.02	.15
Effective decision	1.69	–3.46	.35
Total score	–1.91	–2.43	.81

[a] SC: standard care.

Table 7. Comparison of change in decisional conflict scale from baseline at the 6-month time-point according to randomization to Patient decision aid versus SC.

Parameters	Mean difference, patient decision aid	Mean difference, SC[a]	*P* value
Subscales			
Uncertainty	10.1	–1.2	.34
Informed	–2.4	–6.9	.72
Values clarity	–2.4	–4.2	.89
Support	5.2	–6.0	.40
Effective decision	6.8	–1.7	.48
Total score	3.7	–3.8	.52

[a] SC: standard care.

Qualitative Interviews After Use of the Patient Decision Aid in the Randomized Clinical Trial

Another set of qualitative interviews was conducted within three months of the initial education about/use of the patient decision aid. These qualitative interviews provide substantial insight into the user experience of the patient decision aid and as such are reported here in some detail. The following were the major themes that emerged from these interviews. Users of the patient decision aid:

- Overwhelmingly endorsed and appreciated the patient decision aid and found it to be very educational for decision making;
- Reported that the information was concise and presented well;
- Particularly noted that good information was provided on risks and benefits;
- Noted that doctors did not elaborate as much as patients wanted them to on the risks of treatment (especially HU) and that the patient decision aid was a useful supplementary source of information;
- Thought that the testimonials were very important and had an impact on decision making, helping users see patients who had experience with the treatment;
- Felt that the identification of risks, benefits, family needs, and what is important through questions and information provided in the steps (values clarification) helped them to decide whether to pursue the treatment;
- Felt that information on the website empowered users to talk to doctors because it helped to identify information patients/parents should ask about and gave them a place to start when bringing up a treatment with the doctor;
- Particularly felt that they did not receive information about BMT as a treatment option from their health care providers and that information was provided in the patient decision aid. Patients/parents reported that when they brought up BMT they were sometimes told they did not qualify or the doctor would not recommend that treatment without sending them to a specialist;
- Felt that not all patients/parents brought up treatments to the doctors but went about trying to find information on their own. These methods of learning included the internet, talking to others, and conferences. When patients/parents talked with doctors about a treatment they felt that the doctors did not always give enough information regarding risks and benefits and that the information did not include patient experiences, which was deemed to be very important.

Qualitative Interviews of Pediatric Patients (Cohort B) After Using the Patient Decision Aid

We enrolled 16 adolescents in cohort B, which was open to adolescents under the age of 18, and they were nonrandomly assigned to the patient decision aid arm. Participants completed a baseline decisional needs qualitative interview and were then given the opportunity to view the patient decision aid. During follow-up, the patients completed an interview about their experience with viewing the patient decision aid and they were also offered an opportunity to take the self-efficacy scale, but none did. Qualitative analysis was performed on the transcripts of the 29 interviews (16 at baseline, 6 at 3 months, and 7 at 6 months). The following themes emerged from the baseline interviews: (1) patients reported being aware of information about self-management and supportive medical treatments; (2) they reported being involved along with their parent in the medical decision-making process; (3) they reported an eagerness to learn from high quality sources on the internet; (4) they mainly accessed the internet over the telephone; and (5) they indicated a desire to see information that was in graphic form rather than as text. In follow-up interviews, patients reported that they found the patient decision aid to be easy to use, easy to read and understand, and that it helped them speak with their physicians.

Analysis of Online Usage of the Patient Decision Aid

We analyzed patterns of use for the patient decision aid with the online Google Analytics tool from the opening of the website to the general public following the completion of the clinical trial on October 1, 2016. From then to March 17, 2019 there have been 38,787 page views by 4587 users from 103 countries, with the United States being responsible for 55.73% of the sessions. The contents of the site were accessed in US English by 3281 users (71.39%). The bounce rate (ie, the proportion of single page sessions of zero second duration with no interaction) was 52%. The average session lasted 7.27 minutes and covered 4.72 pages. The 2017 content marketing benchmark report analyzed Google analytics data from 181 websites from 2015-2016 in order to establish industry benchmarks across a wide swath of web analytics metrics [61]. Compared with the industry benchmarks for bounce rate (53-67%), session duration (1:47-3:38 minutes), and pages viewed per session (1-2 pages), the patient decision aid performed very well. While the site has been accessed in 43 states and 92 metro areas in the United States, more than 70% of the sessions have occurred in 10 states. The site was accessed using a mobile device in 1/3 of the sessions and 77% of the users were in the 18-54 years old age group. The patient decision aid's Facebook page, which is meant to promote the site, has received over 100 likes.

Discussion

Primary Findings

In this paper, we reported the development, completion, and testing of the first ever patient patient decision aid for SCD [41], which was created with the extensive engagement of patients, their caregivers, health care providers, community advocates, and policy makers. Using a theory-based, iterative process based on the Ottawa decision support framework and large-scale community engagement, we obtained substantial input from these stakeholders on the conception, design, development, alpha and beta testing, finalization, and peer review of the patient decision aid. Stakeholder input also yielded insights into how patients and caregivers navigate decision making for SCD [62,63].

Overall, both the qualitative interviews of participants obtained during the beta testing phase and during the randomized clinical trial) and the surveys of acceptability indicated a strong endorsement from patients and caregivers regarding the utility and ease of use of the patient decision aid. Traffic to the website, the proportion of visitors who left immediately, the proportion of new visitors, the amount of time spent by the average visitor, and the average number of pages visited per session all met and compared favorably with the industry standards for Web-based education [64-66]. The patient decision aid met all but one of 62 benchmarks for patient decision aids established by the IPDAS collaboration. Specifically, the patient decision aid did not include patient stories of those with an adverse outcome after BMT because no caregiver of a patient who had an adverse outcome of BMT came forward to share their story. In the patient decision aid arm, compared to the SC arm, there were statistically significant differences in improvement in decisional self-efficacy, a reduction in the informed subscore of the decisional conflict at three months, and improvement in preparedness for decision making at six months. In addition, there were no statistically significant differences in change in knowledge or preparedness for decision making at three months, or other domains of decisional conflict or change in self efficacy at six months. However, these results must also be viewed against the overall high dropout rate in survey completion in the randomized controlled trial. We were unable to draw conclusions about the decision quality (ie, whether or not people made decisions congruent with their values) for two reasons, one of which was that the median score that participants assigned to each value queried was the highest possible score, suggesting that this study identified the most important values that patients and caregivers considered when making decisions. However, the remarkable homogeneity of the scores that this population assigned to each of these values made it impossible to study any value-based differences. Second, very few individuals completed the decision regret scale, and most of those who completed it were in the SC arm. Overall, the findings of this study suggest that the patient decision aid provided high-quality information and enabled patients and their caregivers to work with their physicians to make treatment decisions based on their own values and preferences.

Prior studies indicated that, as compared with usual care, the patient decision aid can better improve people's knowledge regarding therapeutic options and reduce their decisional conflict related to feeling uninformed and unclear about their personal values [67]. However, in this study we did not find any significant differences or improvement in knowledge, instead observing reduced decisional conflict, improved preparation, and improved self-efficacy for decision making. These observations are in keeping with the findings of systematic reviews of the utility of patient patient decision aids, which suggest that while a patient decision aid may improve knowledge, reduce decisional conflict, and stimulate patients to be more active in decision making, they have little effect on satisfaction and a variable effect on decisions [37-40].

Stakeholders representing the SCD community, a population dealing with a serious chronic illness and disproportionate socioeconomic disadvantage, indicated a strong preference for a Web-based educational resource and demonstrated the acceptability and usability of such an instrument. The patient decision aid provides detailed values clarification exercises in the section, “What is important for me.” This section allows users to clarify their own values by directly rating the importance of each attribute of a decision after they have viewed the information. Users can compare treatment options by placing predefined values as prioritized by them and then comparing pros and cons of each of the options side by side. While there are at least 98 different values clarification methods, there is a paucity of data on the optimal design of values clarification methods to be used [68,69]. The most promising design feature identified is explicitly showing people the implications of their values by, for example, displaying the extent to which each of their decision options aligns with what matters to them [68,69]. We have now included this as well as several other values clarification methods. Of note, during the qualitative interviews of participants, they overwhelmingly endorsed the perceived utility of the values clarification exercises. This study thus demonstrates the potential for use of a patient decision aid by other racial and minority ethnic groups dealing with chronic illness.

Our tests of efficacy were inconclusive, so more research is needed to determine how patients and caregivers use the patient decision aid in decision making and how the patient decision aid can be used in supporting SCD treatment decisions. While a patient decision aid is a decision support tool, patient and caregiver participation in shared decision making may be related to patient, physician, and decision characteristics, as well as socioeconomic and demographic factors [63,70]. This study did not involve an intervention aimed at influencing physician behavior regarding involving patients in decision making. It is possible that this may have limited the impact of the use of the patient decision aid on patient/caregiver involvement in decision making. Further studies are therefore required to determine how physician involvement in incorporating a patient decision aid in discussions with patients may contribute to shared decision making in real world settings. Crosby et al have described the use of patient decision aids for HU in SCD patients that included coaching by clinicians [71]. Further study is needed to develop and test coaching methods for use of the patient decision aid to determine if they will improve both its utilization and utility.

HU, CBT, and BMT have disparate therapeutic intents and side effects, and they may be offered at different stages of disease progression according to evidence-based guidelines rather than simultaneously. We nonrandomly assigned subjects to the study arm based on the decision they were considering, without attempting to verify whether the patient was eligible, the treatment was recommended or was being actively considered.

The study population was split in each arm into groups of 20, representative of each age group and the treatment option they were looking to decide on. As such, the numbers were too small to study the impact of the patient decision aid in each age group for each type of decision. Instead, we had to undertake pooled analyses of these types of decisions. We were intrigued by the fact that most patients wanted to learn about BMT, which was unanticipated because until now only a small number of patients have undergone this treatment. This choice may be reflective of several factors including increasing interest in, or the lack of information about, BMT. It may also be reflective of the fact that information about HU is generally available through other sources, but that there is a general lack of information about BMT. Since the pros and cons and intent of each treatment is different, future studies may consider examining the efficacy of a patient decision aid for individual age ranges and individual decision types.

A major limitation of this study is the large amount of missing survey completion data in the randomized control trial. This introduces a source of bias and limits our ability to draw statistically valid conclusions. The likely causes of missing data in the study are the burden of surveys to be completed, geographic dispersion of participants around the country, and the fact that investigators had no direct contact or ongoing therapeutic relationship with participants. This underscores the inherent difficulty in conducting studies with national enrollment through direct contact with patients in the absence of an ongoing therapeutic relationship with the investigators. We chose to recruit patients primarily in national conferences to access a large, nationally representative population who would provide their candid opinion about the decision-making process without concerns about offending a health care provider. However, this approach limited our ability to follow up with patients during routine clinical encounters. Participants in the study had unusually high levels of academic achievement, with 80% reporting at least some college education. Further, the majority were attending national or regional sickle cell conferences. It is thus possible that the participants were unusually active regarding their care and may not be representative of the SCD population at large. We anticipate that in studies basing their recruitment in sickle cell clinics, we are more likely to have access to the entire range of activity of the general sickle cell population. The evaluation measures used in this study are those that are included in the Ottawa decision framework. However, it is possible that health literacy may have contributed to the burden of completion of surveys, as there was a long interval between first access to the patient decision aid and the offering of surveys for completion. Future trials may also consider limiting subject burden of survey completion and planning a short interval between an intervention and assessment to be better able to test various aspects of efficacy of the patient patient decision aid in patients with SCD.

Conclusions

We created a patient decision aid for patients with SCD with engagement and input from consumers, patients, caregivers, physicians, and other stakeholders in the conception, design, development, alpha and beta testing, finalization, peer review, and implementation of this resource. The development stage and qualitative interviews among trial participants demonstrated a high degree of acceptability of the patient decision aid among users. While there were statistically significant improvements in decisional conflict and preparation for decision making, because of the large amount of missing data in the completion of follow-up surveys we cannot draw conclusions about the effectiveness of the patient decision aid in improving patient involvement in decision making, and in decision-making quality.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Completed IPDAS checklist Indicating Compliance of sickleoptions.org with IPDAS standards.
[PDF File (Adobe PDF File), 297 KB - jmir_v21i12e14462_app1.pdf]

Multimedia Appendix 2
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 3145 KB - jmir_v21i12e14462_app2.pdf]

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Abbreviations

BMT: bone marrow transplantation
CTT: chronic transfusion therapy
HU: hydroxyurea
IPDAS: International Patient Decision Aids Standards
IPDASi: International Patient Decision Aids Standards self-evaluation instrument
SC: standard care
SCD: sickle cell disease

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Original Paper

Searching the Internet for Infertility Information: A Survey of Patient Needs and Preferences

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Abstract

Background: Given the complexity of infertility diagnoses and treatments and the convenience of the internet for finding health-related information, people undergoing infertility treatments often use Web-based resources to obtain infertility information and support. However, little is known about the types of information and support resources infertility patients search for on the internet and whether these resources meet their needs.

Objective: The aims of this study were to (1) examine what individual factors, namely, demographic characteristics and distress, are associated with searching the internet for different types of infertility-related information and support resources and (2) determine whether Web-based resources meet the needs of patients.

Methods: Men and women seeking infertility care responded to a survey assessing use of Web-based resources for accessing infertility-related information and support. The survey further assessed satisfaction with Web-based resources as well as perceived stress and depressive symptomatology.

Results: A total of 567 participants, including 254 men and 313 women, completed the survey. Most participants (490/558, 87.8%) had searched the internet for infertility information and support. Searchers were more likely to be women (*P*<.001), highly educated (*P*=.04), long-term patients (*P*=.03), and more distressed (*P*=.04). Causes of infertility, treatment options, and scientific literature about infertility were the three most frequently searched topics, whereas ways to discuss treatment with family and friends as well as surrogacy and ways to find peer support were the three least searched topics. Of those who searched the internet, 70.9% (346/488) indicated that their needs were met by Web-based information, whereas 29.1% (142/488) said that their needs were not met. Having unmet needs was related to greater levels of perceived stress (*P*=.005) and depressive symptomatology (*P*=.03).

Conclusions: This study provides evidence for the important role of the internet in accessing infertility information and support and for the ability of Web-based resources to meet patients' needs. However, although distressed patients reported particularly high rates of searching, their needs were not always met, suggesting that they may benefit from alternative sources of information and support or guidance from health care providers when searching the internet.

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KEYWORDS

infertility; internet; consumer health information; patient satisfaction; stress, psychological

Introduction

Background

The widespread access to internet technologies (eg, computers and mobile phones) has facilitated the delivery and acquisition of health information and support. Approximately 70% of North American adults use the internet as a source of health information [1,2], with higher rates among people with health concerns as well as those who rate their health as poor [3,4]. Web-based resources offer a number of advantages over print and face-to-face resources; these include ready availability, instantaneous access to frequently updated sources of information, anonymity, and contact with people with similar difficulties. Furthermore, the internet may offer an opportunity to increase access to health resources by overcoming geographic and socioeconomic barriers that can sometimes prevent underserved populations, such as infertile men and linguistic minorities, from obtaining information and support. Accordingly, people with infertility concerns may seek out information and emotional support using the internet.

Infertility, defined as the inability to achieve clinical pregnancy following 12 months of regular unprotected intercourse [5], has an estimated Canadian prevalence between 11.5% and 16% [6]. Infertility is a chronic health condition that is associated with feelings of stigma, loss of control, and *a rollercoaster of emotions* [7,8]. To gain familiarity with the medical language used in the diagnosis and treatment of infertility and to better cope with the potential stigma and psychological distress, people with infertility concerns are likely to search the internet to find infertility-related information and social support [9-11]. Accordingly, a systematic review revealed that patients with infertility tend to go on the internet to meet their informational needs, find emotional and psychological support, and find assistance for medical decision making [12]. After accessing Web-based sources of information, infertile women have been shown to feel better informed and better able to make infertility-related decisions [10]. Previous research has also demonstrated how the internet may be a useful tool to provide educational and emotional support to those living with a stigmatized health condition [13]. The use of online support groups has been associated with a number of advantages including increased patient empowerment [14,15], normalization of patients' experiences [16,17], and reduced social isolation [18]. These benefits suggest that online discussion about emotions and personal experiences [17,19] may be helpful for improving patients' psychosocial experience of infertility.

Notwithstanding the potential benefits of online communication, evidence suggests that the use of the internet poses risks of misinformation and increased emotional strains to infertility patients [12,20]. Examples of emotional consequences include feelings of sadness and distress after reading both negative and positive stories relating to others' treatment outcomes, obsessive use of online communities, and misunderstandings among group members [21]. Furthermore, using the internet to access health information involves challenges such as difficulty locating or accessing the information, judging the quality and comprehensiveness of sources, and understanding technical terms [22,23]. Studies investigating the quality of Web-based infertility-related information suggest that available websites generally do not meet standards for readability, quality, and suitability [24,25]. Varying levels of electronic health (eHealth) literacy, which is the ability to search, find, understand, and appraise health information found on the internet [26], can exacerbate the difficulties to access resources for one's needs.

However, few studies have investigated whether the information and support resources available on the internet in fact meet patients' needs and expectations [12]. Moreover, one study found that only half of their sample of women with infertility issues who used an online expert forum to discuss infertility were satisfied with the responses received [27]. Although this study highlights the potential of Web-based resources to meet users' needs, previous research is limited in studying online communities who may not represent the diverse infertility patient population. Research has also primarily focused on the experiences of infertile women, whereas less emphasis has been given to the needs and experiences of men. More research is needed to gauge the impact of Web-based resources other than forums on the needs of diverse infertility patients, especially men who tend to be underrepresented in infertility care and research [28,29] and whose needs for information and support may be different from those of women.

Individual characteristics such as gender may be related to the tendency to search for Web-based infertility-related information. Gender differences in help–seeking [30,31] and health information–seeking behaviors [32] extend to searches for health information on the internet. Specifically, past studies indicate that women engage in more Web-based health information seeking [33-35], indicating that infertile women may be particularly likely to search the internet for infertility information and support. Furthermore, in addition to enduring the physical burden of infertility, women more often report infertility-related emotional distress [36]. Perhaps, for this reason, infertile women generally seek more social support [37]. Research shows that women are generally more active in online communities compared with men [21,38], although there is some evidence that men also benefit from interacting online [39-41].

Other individual characteristics found to be associated with the use of Web-based health resources include white non-Hispanic ethnicity, higher educational attainment, higher income, and frequent internet use in general [42,43]. Language and health literacy difficulties can reduce accessibility to Web-based health information and support, thereby making it challenging for immigrants [44] and people with less education [45] to access the appropriate resources for their needs. In addition, greater psychological distress may encourage more Web-based health information seeking and the use of more online sources of support [46,47]. Similarly, individual characteristics are likely to influence whether Web-based health information meets people's needs. Specifically, nonwhite ethnicity and lower income have been shown to be related to greater perceived helpfulness of infertility-related Web-based resources [10], emphasizing the need to explore differences in how people use and perceive Web-based health resources in a diverse group of individuals with infertility concerns.

Given the omnipresence of the internet in the lives of infertility patients, efforts should be made to better understand patients' online experiences. This study addressed an important gap in the literature by investigating how both men and women seeking infertility care use the internet and whether they are satisfied with what they find. By understanding the online experiences of patients from diverse sociodemographic backgrounds, we may be better able to characterize the types of information and support resources that people need and analyze whether the internet is useful in meeting those needs. Such information is necessary to guide the development of future Web-based resources that are tailored to the needs of infertility patients.

Study Objectives

The first objective of this study was to examine whether people seeking infertility care searched the internet for infertility-related information and support resources and to explore whether demographic and psychological factors were associated with searching. Specifically, gender, immigration status, education, treatment duration, perceived stress, and depressive symptomatology were examined in relation to searching the internet. The second objective was to describe the infertility-related topics that people endorsed searching for and to explore the relationships between types of searches and participant characteristics. Finally, this study aimed to inquire whether Web-based resources met people's informational and support needs and to examine which participant characteristics were associated with satisfaction with Web-based resources.

Methods

Procedure and Participants

A self-report survey was distributed to men and women seeking infertility care services to investigate their needs and preferences regarding information and support about infertility issues. Recruitment was conducted from July to December 2015 in four fertility and urology clinics in the Montreal and Toronto areas. Participants were recruited in both private and hospital-based fertility clinics to ensure a sociodemographically diverse sample. Participants were eligible to participate if they were (1) seeking care at a fertility clinic, (2) at least 18 years old, (3) able to read and answer questions in French or English, and (4) able to access the internet. Of the 808 patients approached, almost all (795/807, 98.4%) were eligible. Only 6.2% (49/710) patients refused because of lack of interest, time constraints, and personal stress level or because they were unprepared to discuss infertility experiences. Those who agreed to participate in the study (n=746) accessed the Web-based survey on a tablet while sitting in clinicians' waiting rooms, or through an emailed link that directed them to a secured website where they could complete the survey at a later time. Consent was implied if the participant accessed the link. Following completion of the study, participants received a Can $10 gift card. A total of 88.3% (659/746) of people who agreed to participate completed the survey. This study focused specifically on the experiences of men and women undergoing infertility treatment as a dyadic unit and thus reported data from participants in heterosexual relationships only (n=567). Respondents who were single (n=23), nonheterosexual (n=28), or who did not indicate their relationship type (n=89) were excluded from this analysis because their small number did not allow to appropriately investigate their distinct needs and experiences.

The study protocol was approved by the research ethics boards of all the institutions where recruitment took place.

Materials

Patient Survey

The patient survey (Multimedia Appendix 1) was developed by the corresponding author in collaboration with coinvestigators and community stakeholders including reproductive health specialists and infertility patients. The survey was pilot tested to ensure the clarity and relevance of the items, the appropriate order of the questions, and the length of time required to complete the questionnaire. Feedback from stakeholders guided the final version of the questionnaire. The survey was sent via email; data were then anonymized by removing all personal information in the final dataset. The survey consisted of questions addressing patients' experiences and opinions toward different sources of information and support as well as questions regarding fertility history and psychological and sociodemographic characteristics (eg, income and ethnicity). The survey assessed the use of Web-based resources for accessing infertility-related information and support. This section of the survey included three questions: (1) *Have you searched online for information about infertility?* to which participants answered yes or no; (2) *Did you look online for the following...?* (eg, scientific literature about infertility, diagnostic tests, and how to find peer support or mentor), where respondents selected all types of information and support resources that applied to them; and (3) *In general, did the information you found online meet your needs?* to which participants answered yes or no.

For the purpose of analysis, individual items listed in question 2 were grouped into four conceptual categories: *diagnostic information* (diagnostic tests, interpreting results of diagnostic tests, my diagnosis, scientific literature about infertility, and causes of infertility), *treatment information* (treatment options, success rates of treatment, medications used in treatment, side effects of treatment, adoption/foster parenting, using donor sperm or eggs, and surrogacy), information about *services and providers* (clinics where treatment is offered, my physician or medical team, coverage by provincial health care plans, coverage by private health care plans, and how to get a second opinion), and *connections with others* (others' experiences with infertility, how to discuss treatment with family/friends, and how to find peer support/mentor). The categories were created by summing the number of specific items that heuristically fell in that category.

Depressive Symptomatology

The 2-item Patient Health Questionnaire [48] was used to assess the level of depressive symptoms patients had experienced in the previous 2 weeks. Each item is rated on a 4-point Likert-type scale ranging from 0 (not at all) to 3 (nearly every day). The score for each item is summed to obtain a total score between 0 and 6, with higher scores indicating more severe depressive symptomatology. A score of ≥2 warrants further clinical investigation for depression. The scale was shown to be comparable with its longer version (9-item Patient Health Questionnaire) and other depression scales in terms of reliability (Cronbach alpha=.83) and criterion and construct validity [48,49].

Perceived Stress

Perceived stress was evaluated using the 4-item Perceived Stress Scale [50]. Each item asks participants to rate the extent to which they experience life events as stressful and whether they feel able to overcome difficult events on a Likert-type scale ranging from 0 (never) to 4 (very often). Total scores vary between 0 and 16, with higher scores corresponding to greater perceived stress. The 4-item Perceived Stress Scale is normally distributed [51] and has demonstrated satisfactory reliability (Cronbach alpha=.77) and strong criterion validity [50,51].

Data Analysis

Descriptive statistics were used to describe sample characteristics, including sex, age, annual household income, education, immigrant status, treatment duration, and causes of infertility. Descriptive statistics were also used to determine how many participants searched the internet for information and support resources and how many reported that this information met their needs. Bivariate analyses including Chi-squares and *t* test statistics were then performed to examine differences between those who did and did not search the internet (ie, searchers and nonsearchers) and those who reported that their information needs were or were not met. Furthermore, correlations, *t* tests, and analysis of variance were used to explore the relationship between individual characteristics and searching for each of the four information categories. Post hoc Hochberg GT2 tests were used to further investigate difference between groups. Variables that were significantly related to searching the internet were included in the regression analyses, which were used to examine the relationship between participant characteristics and having searched for specific categories of infertility health information. Participants were classified into two groups according to treatment duration: those who spent ≤6 months undergoing infertility treatments and those who had been in treatment for >6 months. Treatment duration was dichotomized to determine whether there are differences in the Web-based queries of novice and experienced infertility patients.

Sample Characteristics

Sample characteristics are presented in Table 1. In the sample of heterosexual couples, nine people did not answer the question about searching the internet; hence, the final sample consisted of 558 participants, including 249 men and 309 women. The mean age was 36.53 (SD 5.5) years and ranged from 22 to 62 years. Approximately half of the sample was born in Canada and had an income below Can $80,000/year. In terms of education, 8.6% (47/548) of participants had completed high school, 25.9% (142/548) obtained a "Collège d'enseignement général et professionnel" diploma (CEGEP, ie, preuniversity and professional training) or technical degree, and 65.5% (359/548) obtained a university degree or more, revealing an overall well-educated group of participants. About one-third of participants reported male factor infertility, whereas another third reported female factor infertility. A small number (44/558, 7.9%) of participants reported diagnoses involving both male and female factors, 17.7% (99/558) of cases were left unexplained, and 5.4% (30/558) of couples had not received diagnostic testing.

Table 1. Patients' demographic characteristics (n=558).

Characteristics	Values, n (%)
Gender	
Male	249 (44.6)
Female	309 (55.4)
Annual household income (Canadian dollars)	
<$80,000	258 (47.7)
≥$80,000	283 (52.3)
Education (highest level achieved)	
High school degree or less	47 (8.6)
Collège d'enseignement général et professionnel/technical college degree	142 (25.9)
University degree or more	359 (65.5)
Cause of infertility	
Male factor only	180 (32.3)
Female factor only	194 (34.8)
Male and female factors	44 (7.9)
Unexplained	99 (17.7)
No diagnostic testing	30 (5.4)
Treatment duration (months)	
≤6	218 (39.4)
>6	335 (60.6)
Born in Canada	288 (52.4)

Results

Do Participants Search the Internet?

A majority (490/558, 87.8%) of participants searched the internet for health information about infertility, whereas 12.2% (68/558) of participants did not. On average, those who used Web-based resources endorsed searching for 11 of 20 (SD 3.92) infertility-related topics. Significantly more women (290/309, 93.9%) searched compared with men (200/249, 80.3%; χ^2_1=23.6; P<.001). Searching the internet was prevalent at all education levels, although those with more education were more likely to search (χ^2_2=6.5; P=.04); specifically, 89.4% (321/359) of participants with a university degree or more and 88.0% (125/142) of participants with some CEGEP or university degree searched the internet, whereas slightly fewer participants with a high school degree or less (36/47, 76.65%) searched the internet. Participants with longer treatment duration (303/335, 90.4%) were more likely than new patients (184/218, 84.4%) to have searched for Web-based infertility information (χ^2_1=4.6; P=.03). Perceived stress was associated with searching, with searchers (mean 5.95, SD 2.88) reporting significantly higher levels of perceived stress compared with nonsearchers (mean 5.16, SD 3.02; t_{555}=–2.11; P=.04). Similarly, searchers (mean 1.36, SD 1.40) reported significantly more depressive symptomatology compared with nonsearchers (mean 0.99, SD 1.39; t_{552}=–2.09; P=.04).

What Do Participants Search for?

Descriptive Analysis by Search Category

Out of the 490 participants who searched the internet, all (490/490, 100%) endorsed searching for *diagnostic information*. In addition, nearly all participants endorsed searching for at least one item in the categories *treatment information* (443/490, 90.4%) and *services and providers* (440/490, 89.8%). Approximately two-third of participants (317/490, 64.7%) searched for topics within the category *connections with others*. Table 2 presents a comparison of searching frequencies between men and women for each specific topic of information and support subsumed under the four conceptual categories: *diagnostic information*, *treatment information*, information about *services and providers*, and *connections with others*. Gender and other participant characteristics were examined in relation to search categories.

Table 2. Comparison of topics searched by men (n=200) and women (n=290) who reported using the internet to access infertility-related information and support resources.

Types of infertility information	Women, n (%)	Men, n (%)	Chi-square (*df*)	*P* value
Diagnostic information				
Scientific literature about infertility	255 (88.2)	158 (79.0)	7.7 (1)	.006
Causes of infertility	271 (94.1)	182 (91.0)	1.7 (1)	.19
Diagnostic tests	225 (78.1)	135 (67.8)	6.5 (1)	.01
Interpreting results of diagnostic tests	185 (64.5)	199 (59.8)	1.1 (1)	.30
My diagnosis	223 (77.2)	145 (72.9)	1.2 (1)	.28
Treatment information				
Treatment options	252 (87.5)	169 (84.5)	0.9 (1)	.34
Medications used in treatment	230 (79.9)	140 (71.1)	5.0 (1)	.03
Success rates of treatment	242 (83.7)	166 (84.7)	0.1 (1)	.78
Side effects of treatment	225 (77.9)	143 (72.2)	2.0 (1)	.16
Using donor sperm or eggs	61 (21.3)	41 (20.9)	0.01 (1)	.91
Surrogacy	29 (10.1)	27 (13.9)	1.6 (1)	.21
Adoption/foster parenting	89 (31.1)	52 (26.7)	1.1 (1)	.29
Information about services and providers				
My physician or medical team	200 (69.4)	99 (49.5)	19.8 (1)	<.001
Clinics where treatment is offered	203 (70.7)	109 (55.6)	11.6 (1)	.001
How to get a second opinion	69 (24.1)	51 (26.0)	0.2 (1)	.64
Provincial health care coverage	170 (59.6)	116 (59.2)	0.01 (1)	.92
Private health care coverage	148 (51.9)	87 (44.6)	2.5 (1)	.12
Connections with others				
How to find peer support/mentor	31 (10.9)	20 (10.2)	0.1 (1)	.81
Others' experiences with infertility	199 (69.8)	102 (52.0)	15.7 (1)	<.001
How to discuss my treatment with family or friends	44 (15.4)	21 (10.7)	2.2 (1)	.14
Other	4 (1.3)	2 (0.8)	31.9 (1)	.67

Diagnostic Information

Seeking *diagnostic information* was significantly associated with gender (t_{479}=–2.32; *P*=.02), such that women (mean 6.43, SD 1.90) searched for more *diagnostic information* compared with men (mean 6.00, SD 2.12). It was further associated with treatment duration ($t_{330.511}$=–3.49; *P*=.001), indicating that those who have been in treatment for longer (mean 6.52, SD 1.81) sought more *diagnostic information* than people new to treatment (mean 5.84, SD 2.20). In this category, causes of infertility, scientific literature, and information about diagnosis and diagnostic tests were among the most searched topics for both men and women, although women searched significantly more for scientific literature (255/289, 88.2% vs 158/200, 79.0%) and diagnostic tests (225/288, 78.1% vs 135/199, 67.8%) compared with men (Table 2).

Treatment Information

Searching for *treatment information* was significantly related to treatment duration (t_{475}=–4.19; *P*<.001) only, meaning that people with longer treatment duration (mean 1.90, SD 1.21) searched for more topics related to *treatment information* than people with shorter treatment duration (mean 1.44, SD 1.05). Within the *treatment information* category, treatment options and treatment success rates were among the most searched topics for both men and women, whereas surrogacy and adoption were less commonly searched (Table 2). In addition, more women (230/288, 79.9%) searched for medications used in treatment as compared with men (140/197, 71.1%).

Services and Providers

Searching for *services and providers* was associated with gender (t_{478}=3.52; *P*<.001), with women (mean 2.52, SD 1.25) endorsing searching for more items than men (mean 0.73, SD 0.84). In addition, there was a significant difference between levels of education for searching for that category (F_{2471}=6.25; *P*=.002). Post hoc Hochberg GT2 tests indicated that those with CEGEP/technical-level (mean 2.40, SD 1.34) and university-level (mean 2.41, SD 1.29) education searched for significantly (*P*=.004 and *P*=.002, respectively) more topics than people with a high school degree or less (mean 1.60, SD 1.24). Searches of people with a CEGEP/technical degree did not differ from those of people with a university degree (P>.99). Compared with men, women were significantly more likely to search for information on their physician and medical team (200/288, 69.4% vs 99/200, 49.5%) and for clinics where infertility treatment is offered (203/287, 70.7% vs 109/196, 55.6%; Table 2).

Connections With Others

Finally, searching for topics related to *connections with others* was positively correlated with perceived stress (r=0.11; P=.01) and depressive symptomatology (r=0.12; P=.01). It was also associated with gender ($t_{396.356}$=–3.10; P=.002), such that women (mean 0.96, SD 0.78) endorsed more topics in that category compared with men (mean 0.73, SD 0.84). In addition, searching for *connections with others* was related to treatment duration (t_{474}=–3.44; P=.001), suggesting that those with longer treatment duration (mean 0.97, SD 0.82) searched for more *connections with others* than those with shorter treatment duration (mean 0.71, SD 0.77). There was a significant difference between levels of education (F_{2470}=3.19; P=.04). Post hoc Hochberg GT2 tests revealed that those with CEGEP/technical degrees (mean 0.60, SD 0.74) searched significantly more (P=.04) for *connections with others* than those with high school diplomas or less (mean 0.98, SD 0.90). However, there was no difference in searching between high school and university (P=.20) nor between CEGEP/technical and university (P=.38). Others' experiences with infertility was the most endorsed item in this category, sought by significantly more women (199/285, 69.8%) than men (102/196, 52.0%), whereas the two remaining items about how to find peer support and how to discuss infertility with family and friends were searched less frequently (Table 2).

Regressions

Regression analysis was used to investigate the unique contribution of the variables that were significantly associated with searching for each of the different categories (Table 3). As only one variable was significantly associated with searching for *treatment information*, no regression analysis was performed for that category. The multiple regression predicting searching for *diagnostic information* was significant (F_{3467}=7.31; P<.001) and explained 4.5% of the variance. More education and longer treatment duration were shown to be significant predictors of seeking *diagnostic information*, whereas gender was not. As for searching for *services and providers*, the significant model (F_{2471}=8.61; P<.001) demonstrated that both being a woman and being more educated were significant predictors of searching for this category, accounting for 3.5% of the variance. As depression and perceived stress were highly correlated with each other (Pearson r=0.63; P<.001), we tested two separate models predicting the search for *connections with others*. The first model (F_{3469}=8.12; P<.001; R^2=0.049) showed that being a woman, having a longer treatment duration, and feeling depressed were significant predictors of looking on the internet for resources regarding connections with others. The second model (F_{3471}=8.06; P<.001; R^2=0.049) also indicated that gender and treatment duration were significant determinants but perceived stress was not.

Table 3. Regression analysis summary for participant characteristics associated with searching for diagnostic information, services and providers, and connections with others.

Variables	Unstandardized beta	SE for unstandardized beta	Standardized beta	t value (df)	P value
Diagnostic information					
Gender	.35	.18	.09	1.88 (467)	.06
Education	.34	.15	.11	2.36 (467)	.02
Treatment duration	.60	.19	.15	3.23 (467)	.001
Services and providers					
Gender	.39	.12	.15	3.26 (471)	.001
Education	.23	.10	.11	2.43 (471)	.02
Connections with others - model 1					
Gender	.20	.08	.12	2.61 (469)	.01
Treatment duration	.24	.08	.14	3.12 (469)	.002
Depression	.05	.03	.09	2.00 (469)	.05
Connections with others - model 2					
Gender	.20	.08	.12	2.63 (471)	.01
Treatment duration	.24	.08	.14	3.12 (471)	.002
Perceived stress	.02	.01	.08	1.77 (471)	.08

Meeting the Needs of Patients

Of those who searched on the internet, 70.9% (346/488) indicated that their needs were met and 29.1% (142/488) indicated that their needs were not met by Web-based information. Table 4 represents the proportions of participants who searched for specific topics of information depending on whether their needs were or were not met. Participants who reported having their needs met by Web-based resources were more likely to search for information about the following topics: their diagnosis, treatment options, success rates of treatment, provincial health care coverage, how to find peer support/mentor, and how to discuss treatment with family or friends. With respect to the broader categories, those with met needs (mean 6.42, SD 1.94) reported searching for more items in the *diagnostic information* category compared with those with unmet needs (mean 5.85, SD 2.11; t_{478}=–2.87; *P*=.004); there was no difference between groups for the three other categories.

Table 4. Comparison of topics searched by participants reporting met (n=346) and unmet (n=142) needs.

Types of infertility information	Met needs, n (%)	Unmet needs, n (%)	Chi-square (*df*)	*P* value
Diagnostic information				
Scientific literature about infertility	296 (85.5)	117 (82.4)	0.8 (1)	.38
Causes of infertility	323 (93.4)	129 (91.5)	0.5 (1)	.47
Diagnostic tests	263 (76.2)	96 (68.1)	3.4 (1)	.06
Interpreting results of diagnostic tests	223 (64.8)	80 (56.7)	2.8 (1)	.10
My diagnosis	271 (78.6)	96 (67.6)	6.5 (1)	.01
Treatment information				
Treatment options	307 (88.7)	113 (80.1)	6.2 (1)	.01
Medications used in treatment	266 (77.3)	103 (73.6)	0.8 (1)	.38
Success rates of treatment	300 (87.7)	108 (76.1)	10.3 (1)	.001
Side effects of treatment	268 (77.9)	99 (69.7)	3.6 (1)	.06
Using donor sperm or eggs	75 (21.9)	27 (19.4)	0.4 (1)	.54
Surrogacy	37 (10.9)	19 (13.7)	0.7 (1)	.39
Adoption/foster parenting	94 (27.6)	47 (33.8)	1.9 (1)	.17
Information about services and providers				
My physician or medical team	213 (61.6)	85 (60.3)	0.1 (1)	.79
Clinics where treatment is offered	222 (64.9)	90 (64.3)	0.02 (1)	.9
How to get a second opinion	89 (26.0)	31 (22.3)	0.7 (1)	.39
Provincial health care coverage	215 (62.9)	71 (51.1)	5.7 (1)	.02
Private health care coverage	172 (50.4)	63 (45.3)	1.0 (1)	.31
Connections with others				
How to find peer support/mentor	43 (12.6)	8 (5.8)	4.8 (1)	.03
Others' experiences with infertility	212 (62.2)	89 (64.0)	0.1 (1)	.7
How to discuss my treatment with family or friends	53 (15.5)	12 (8.6)	4.0 (1)	.046
Other	3 (0.9)	3 (2.1)	48.0 (1)	.09

Only the psychological distress variables were found to be significantly related to having unmet needs for information. Participants whose needs were unmet (mean 6.51, SD 2.89) reported greater perceived stress than participants whose needs were met (mean 5.72, SD 2.85; t_{485}=2.80; *P*=.005). Similarly, people with unmet needs (mean 1.58, SD 1.53) reported significantly more depressive symptomatology compared with those with met needs (mean 1.28, SD 1.35; t_{482}=2.18; *P*=.03). Gender, education level, and treatment duration were unrelated to having met or unmet needs.

Discussion

Principal Findings

To determine whether there is a need to tailor Web-based health resources to support infertility patients, this study sought to identify the kind of information users were seeking and whether existing resources met their needs. Survey results revealed a nearly ubiquitous search for Web-based information about infertility diagnosis, treatment, services, and providers, and many respondents also sought online emotional support and access to others. Web-based resources were generally perceived to meet the searchers' needs, and there was little evidence of a digital divide, in that there were no differences in search patterns by income or immigrant status. However, certain factors were associated with distinct search patterns and satisfaction with

Web-based resources; these included gender, infertility treatment duration, and psychological distress.

Although men and women searched for similar types of information, women were more likely to search the internet for scientific literature, their physician or medical team, diagnostic tests, medications used in treatment, clinics where treatment is offered, and for others' experiences with infertility, demonstrating women's greater interest in gathering both practical and experiential information about infertility. This finding is in line with research showing that women engage in more Web-based health information seeking than men [35] and that they are more active in online support groups [37]. Women also tend to assume primary responsibility for gathering information about infertility [10]. As most treatment procedures are centered on women's bodies regardless of the cause of infertility, it makes sense that women take a greater interest in searching for information such as medications used in treatment. Men, on the other hand, often feel excluded from the infertility treatment experience [52]. Furthermore, a recent review of Canadian infertility websites revealed that only 20% of fertility clinic websites included information about male infertility [25], indicating that Web-based resources may be more targeted to women. This study did not identify any specific topic searched more by men compared with women. Given that the current findings indicate that some men are in fact searching for infertility information on the internet, and other research suggests that men also benefit from experiential information found on online forums [39], further investigation of the specific interests of male infertility patients is warranted.

Treatment duration was associated to more searching for information about diagnosis and treatment, suggesting that participants who had spent more time in treatment may have been looking for alternatives because of treatment failures. In addition, those with longer treatment duration sought more connections with others, which may indicate a greater need for emotional support following a prolonged treatment process. Seeking online social support may benefit infertility patients by providing a medium for normalizing and validating infertility-specific problems and reducing social isolation during this difficult time.

This study addressed an important gap in the literature regarding the ability of Web-based resources to meet infertility patients' needs [12], given the variability of Web-based infertility-related resources in terms of quality, readability, and suitability [24,25]. In this study, the majority of participants found Web-based resources useful in meeting their informational and support needs. As infertility patient populations tend to be fairly well educated, they may have the eHealth literacy and searching skills necessary to find and access the infertility resources that correspond to their needs. Indeed, the results of this study indicated that less well-educated patients were less likely to search the internet, though there was no difference by education in reporting that the resources met their needs. Alternative sources of information such as written materials (ie, pamphlets) and in-person discussions may be preferred by patients with lower levels of education. Further investigation of the relationship between level of education and searching the internet is needed to understand the nature of this correlation.

Although people with higher levels of psychological distress were more likely to search for Web-based sources of information, they more often reported unmet needs for information and support. Psychological distress was the only factor that distinguished the almost one-third of participants who reported that Web-based information and support resources did not meet their needs. It is well established that infertility can be a source of psychological distress for both men and women [36]. It may be that greater perceived stress and depression triggers patients to rely more on the internet to access informational and emotional support resources. In support of this, previous research has identified a number of psychological factors associated with increased online health seeking behaviors including health anxiety [46], neuroticism [53], dissatisfaction with care [54], and perceptions of poor health [3]. Our results also show that distressed participants sought more social support resources than those without distress. This suggests that people experiencing infertility-related stress and depression have an increased desire to connect with people who understand their situation compared with those who are less distressed and that Web-based resources may facilitate those connections.

Despite the fact that they searched more for Web-based resources about infertility, our findings indicate that the likelihood of unmet needs increased with greater stress and depressive symptoms. It is possible that Web-based resources are not tailored to the needs of those with high levels of infertility-related distress. Future research should investigate the types of resources that people with high levels of infertility-related distress want and work with them to develop those resources. On the other hand, it may also be that the internet caused distress in certain cases or that distressed people viewed things more negatively [55]. For example, Malik and Coulson [20] found that participating in online support groups can expose users to stories about negative experiences with infertility, pregnancy news, and inaccurate information, which may be upsetting to infertility patients. In other cases, people may not succeed in finding or accessing the information and support resources that they are looking for on the internet, thereby feeling more distressed than before the search. Research shows that patients who have difficulty understanding or filtering available Web-based information are likely to experience information overload, which has been associated with poorer psychological well-being [56]. In contrast, participants with better mental health may have been more likely to report met needs because they were not looking for information regarding mental health and how to cope with infertility. However, this study did not explicitly ask participants why internet resources did or did not meet their needs nor whether the resources included an information category regarding mental health and coping. Future studies should inquire directly about the reasons why certain infertility patients are dissatisfied with the information and support resources available on the internet and why other patients feel that the internet appropriately meets their needs. This is an important step for tailoring Web-based resources to better meet the needs of those with infertility concerns. It is also possible that other sources of information and support, such as health care professionals, counselors, and in-person peer support groups, may be better suited to meet the needs of people in distress. A recent study found that the perceived stress of women participating in online support groups for infertility was unrelated to the supportive elements gained from those groups [57], suggesting that other forms of support may be required to relieve their stress.

Strengths and Limitations

One of the strengths of this study is the recruitment of participants from fertility clinics rather than through online infertility forums. This allowed for greater generalizability of the results as it does not restrict the sample to only those who use online communities, thereby assessing how a diverse sample of infertility patients use different Web-based health resources and allowing the investigation of the characteristics of those who do not search the internet. In addition, this study inquired about a comprehensive list of topics that infertility patients are likely to look for. Furthermore, this study extended the literature by having a sample that included not only women but also an almost equal number of men. Including men in fertility research is important, as men also go through the challenges involved in infertility diagnosis and treatment as well as experience infertility-related distress [58]. Although more women than men reported that they had searched for Web-based infertility resources, most men still used the internet to seek infertility information and support.

Notwithstanding several study strengths, limitations must be noted. First, the participants of this study included only people seeking infertility care; therefore, this sample may not be representative of people with infertility who are not seeking medical treatment. Furthermore, the recruitment procedure involved a self-selection process, which may introduce bias among study participants as those individuals who volunteered to take our Web-based survey may be more comfortable using the internet. Although a large majority (81.15%) of people in the United States have access to the internet according to a recent survey, internet access remains associated with sociodemographic factors such as age lower than 35 years, non-Hispanic white ethnicity, higher education, higher income, and urban residency [59]. It should be noted that in this study, all those who were approached to solicit their participation met the inclusion criterion of having internet access. In addition, these analyses included heterosexual couples only. Future studies should explore the online experiences and satisfaction of a more diverse sample of people with infertility concerns by including single and nonheterosexual individuals. This would allow infertility researchers and care providers to better understand the distinct needs and concerns of single individuals and same-sex couples who are increasingly using assisted reproduction techniques to fulfill their family plans. For example, it would be important to understand the extent to which Web-based resources meet the needs for social connection in these groups as well as information regarding such topics as donor gametes and surrogacy.

Although it was found that participants with met needs searched significantly more for medical information about diagnosis and treatments as well as for proactive social support resources, this study did not identify any type of Web-based infertility information and support that was searched more by those with unmet needs. Although our list of items was comprehensive, it is possible that these participants searched for types of resources that were not included in the response options. It is also possible that other participant characteristics, such as low health literacy [60], may have made it less likely that participants would find the right information for their needs or be satisfied with the information found.

Finally, data analysis was primarily performed using correlational statistics, which, although suitable to identify statistical relationships between variables, does not allow detection of the directionality of relationships or to make causal interpretations. Thus, we cannot draw conclusions about whether distress caused participants to have unmet needs or whether having unmet needs caused distress.

Implications for Future Research

Longitudinal research is needed to examine the direction of the relationship between experiencing psychological distress, searching the internet, and having needs met or unmet by the internet. In addition, qualitative interviews or questionnaires could be used to determine why infertility patients believe Web-based information did or did not meet their needs. This information may help to inform the development of Web-based resources with appropriate information and support tools that correspond to the needs of infertility patients and of those not in treatment but who require information and support in the process of trying to conceive. The vastness, inconsistency, and variable quality of Web-based resources may act as a barrier for obtaining infertility information and support. Future research should explore whether individualization and tailoring of Web-based resources can improve the perceived met needs and well-being of infertility patients, especially those who experience distress. Emergent evidence suggests that the development of patient-centered psychoeducational eHealth interventions may provide an opportunity to empower people with infertility problems and to address their needs for information and support [61-65]. However, the eHealth literature could benefit from more research to assess the feasibility and usability of these interventions as well as the informational and emotional advantages and the cost-effectiveness of these potential solutions [66].

Conclusions

Both men and women undergoing infertility treatment used the internet to seek a broad range of information and support resources related to infertility. Most of them reported that Web-based resources met their needs. Distressed patients reported particularly high rates of searching, but their needs were not always met. Further research is needed to understand why distressed patients do not find Web-based resources helpful in meeting their needs and whether alternative ways of providing information and support may be better suited for these people. This study reveals that most infertility patients are well able to find Web-based resources that meet their needs. However, certain infertility patients may benefit from discussions with their health care providers regarding the use of the internet for obtaining information and support; providers may be able to help them navigate through the large number of infertility-related resources by suggesting trustworthy and suitable websites.

Authors' Contributions

The first author, FB, performed the analyses, interpretation of the results, and write up of the manuscript. SR, SAM, and PHG were involved in the revision of this manuscript. PC, KL, HH, NM, SO, and TT were involved in study recruitment and revision of this manuscript. PZ supervised the project and manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1
The patient survey.
[PDF File (Adobe PDF File), 116 KB - jmir_v21i12e15132_app1.pdf]

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Abbreviations

CEGEP: Collège d’enseignement général et professionnel
eHealth: electronic health

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Original Paper

Exploring the Characteristics and Preferences for Online Support Groups: Mixed Method Study

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Abstract

Background: Osteoarthritis (OA) is a chronic, disabling, and prevalent disorder. As there is no cure for OA, long-term self-management is paramount. Support groups (SGs) can facilitate self-management among people living with OA. Understanding preferences in design and features of SGs, including online SGs (OSGs), among people with OA can inform future development of SG interventions for this condition.

Objective: The objective of this study was to investigate health care– and health information–seeking behavior, digital literacy, and preferences for the design of SGs in people with OA. The study also explored the perceived barriers and enablers to being involved in OSGs.

Methods: An online survey study was conducted with a mixed method design (quantitative and qualitative). Individuals aged ≥45 years with knee, hip, or back pain for ≥3 months were recruited from an extant patient database of the Institute of Bone and Joint Research via email invitations. Quantitative elements of the survey included questions about sociodemographic background; health care– and health information–seeking behavior; digital literacy; and previous participation in, and preferences for, SGs and OSGs. Respondents were classified into 2 groups (Yes-SG and No-SG) based on previous participation or interest in an SG. Group differences were assessed with Chi-square tests (significance level set at 5%). Responses to free-text questions relating to preferences regarding OSG engagement were analyzed qualitatively using an inductive thematic analysis.

Results: A total of 415 people with OA completed the survey (300/415, 72.3% females; 252/415, 61.0% lived in a major city). The Yes-SG group included 307 (307/415, 73.9%) participants. Between the Yes-SG and No-SG groups, there were no differences in sociodemographic characteristics, health care– and health information–seeking behavior, and digital literacy. An online format was preferred by 126/259 (48.7%) of the Yes-SG group. Trained peer facilitators were preferred, and trustworthiness of advice and information were highly prioritized by the respondents. Qualitative analysis for OSG participation revealed 5 main themes.

Lack of time and motivation were the main barriers identified. The main enablers were related to accessibility, enjoyment of the experience, and the content of the discussed information.

Conclusions: These findings highlight the preferences in design features and content of SGs and OSGs and may assist in the further development of such groups.

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KEYWORDS

osteoarthritis; self-help groups; self-management; surveys and questionnaires

Introduction

Osteoarthritis (OA) is a highly prevalent chronic condition [1] and can have a significant negative impact on both the individual and society. OA is one of the leading causes of functional limitation in older adults [1] and is associated with considerable direct and indirect health care costs [2,3]. These costs are predicted to rise substantially over the coming decades [2]. Accessible, high-quality strategies that support people to self-manage OA successfully are urgently needed.

The international chronic condition self-management support (CCSMS) framework describes principles to guide the implementation of strategies to support self-management [4]. These principles recommend that strategies should be as follows: (1) informed by evidence and the needs of the users, (2) person-centered, (3) easily accessible, (4) offering choice and autonomy, (5) aligned with treatment options that are available, and (6) emphasizing maximum benefits while minimizing harms [4]. Self-management support strategies offered to people with knee and hip OA, as well as back pain, typically involve therapeutic exercise programs, general physical activity promotion, and weight loss programs for those who are overweight [5,6]. These OA self-management support strategies aim to reduce pain and improve physical function and the quality of life. Previous research into painful musculoskeletal disorders has shown that self-management support strategies that provide social support and networks may also lead to improved pain and self-efficacy and increase physical function [7-9]. Social support provided in groups promotes a sense of belonging and active interaction [10,11], something that is important for both the individual and the group—the individual must continue to participate to receive all of their benefits, and the group relies on the aggregate knowledge where a larger community is likely to know more about a problem than a smaller one [12]. Therefore, the addition of social support and networks could potentially improve the outcomes of people living with knee, hip, and back OA.

A medium through which people with OA can potentially access social support and networks is support groups (SGs). SGs aim to provide avenues for people with a disease or condition to share information, provide empathy, and promote positive health behaviors. Given the availability of the internet in most households in the Western countries [13,14] and the data showing an increase in online health service usage [14], online SGs (OSGs) may be an inexpensive and convenient way for people to participate in SGs. The number of OSGs has increased in recent years, particularly as adjuncts to traditional care [15]. The nature of such groups varies widely. A systematic review of SGs across all health conditions [16] reported that about half were found to include only peer-to-peer engagement, whereas the other half included peer-to-peer engagement as part of a multifactorial intervention. The latter may be moderated by health professionals or administrators [17]. How people engage in OSGs varies. Broadly, participants might be readers or posters. Among the posters, participants may be initiators, responders, authorities, discussants, supporters, and more. Many participant styles are unique to the health condition [18]. Retrospective studies suggest that the benefits obtained from participation may be influenced by how an individual chooses to participate, but direct associations are yet to be made [12,19]. Reducing depressive symptoms and improving social support are the most commonly proposed mechanisms by which the OSGs were thought to afford health benefits [18,20]. Other outcomes of interest include general well-being, empowerment, anxiety, quality of life, health care utilization, or specific behavior changes (eg, weight loss) [21-24].

If SGs and OSGs are to be employed as strategies of self-management support, the principles of the CCSMS framework should be considered [4]. However, currently, the first guiding principle for self-management support strategies (ie, informed by evidence and the needs of the users) cannot be met as there is a paucity of evidence to inform the design and implementation of effective OSGs, particularly, in relation to people with OA. No previous studies have investigated the needs and preferences of people with OA regarding the design features and content of OSGs. There is no evidence outlining whether people are willing to engage with such groups and reasons why or why not. We are also uninformed regarding the demographic profile of those who are willing to engage with SGs, compared with those who are not. This study surveyed people with OA to determine the needs of potential SG and OSG users by investigating the health care– and health information–seeking behavior, digital literacy, and preferences for the design of SGs. The specific study aims were as follows: (1) compare sociodemographic characteristics, health care– and health information–seeking behavior, and digital literacy between those who are currently using or interested in joining and those who are not using or not interested in joining SGs; (2) evaluate preferences for content, delivery method, and types of engagement in relation to SGs; and (3) explore the perceived barriers and enablers to being involved in OSGs.

Methods

Study Design and Setting

An online survey study was conducted with a mixed method design conforming with the checklist for reporting result of internet electronic surveys (Multimedia Appendix 1). Potentially eligible participants were identified from the patient database of the Institute of Bone and Joint Research (University of Sydney). An email invitation to participate, including a link to the survey, was sent to people who had consented to be contacted for future research opportunities. Ethics approval was obtained from the Human Research Ethics Committee (HREC) of the University of Sydney (HREC #2017/957). Online informed consent was provided before the survey could be accessed by clicking a required checkbox.

Participants

People aged ≥45 years who had previously received a clinical diagnosis of OA for any joint [25] were invited to participate. The survey commenced with 2 screening questions: (1) “Are you over 45 years of age?” and (2) “Do you have knee, hip, or back pain lasting more than 3 months?” Respondents who answered *no* to either question were excluded from the survey. People with comorbidities (eg, diabetes and heart disease) were also eligible; however, questions pertaining to SGs were specific to musculoskeletal conditions.

Sample Size

A generic sample size calculation was used to determine the minimum sample size needed for generalizable results, given the exploratory aims of the study. Considering the estimated population size of people living with OA (primarily affecting the hands, spine, knees, and hips) in Australia is over 2 million [26], an acceptable margin of error of 5%, and accepted confidence level of 95%, the minimum sample size required was 385.

Procedure

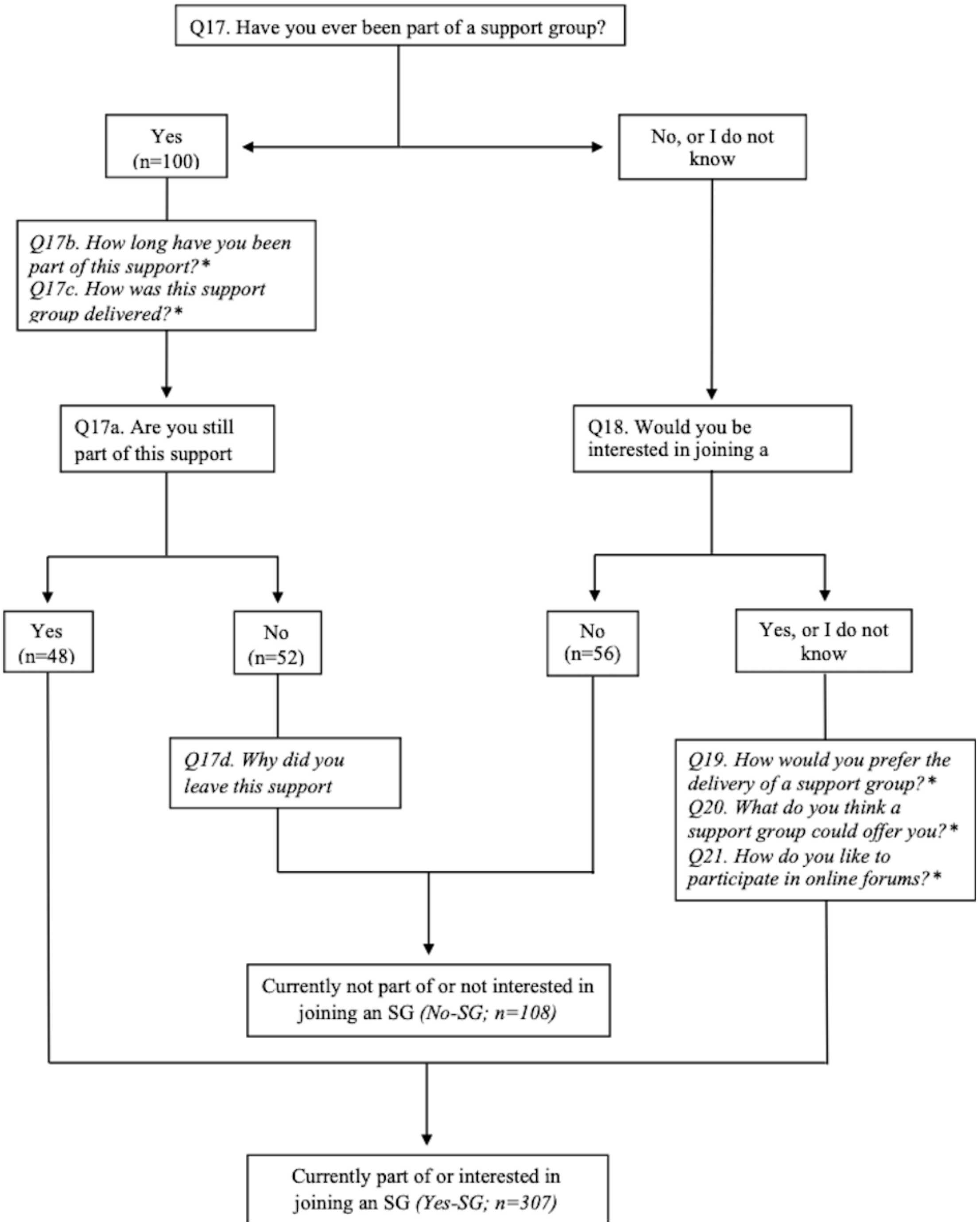
Data collection occurred between March and September 2018. The survey was administered through the Research Electronic Data Capture (REDCap) survey software (version 9.3.6, Vanderbilt University) and comprised closed, open, and multiple-choice questions (Multimedia Appendix 2). The quantitative information (closed and multiple-choice questions) was collected across 4 blocks of questions: (1) sociodemographic characteristics, (2) health care– and health information–seeking behavior, (3) use of technology (digital literacy), and (4) participation and preferences of SGs. The specific musculoskeletal condition (ie, hip OA, knee OA or back pain) was not identified. The type and wording of each question was composed by the research team. Face validity was ascertained by asking a sample of patient representatives (N=5) to view and provide feedback on each question in blocks 2 to 4. The order of questions was not randomized. Rather, the survey followed a predetermined logic where contingent questions were included/skipped based on participants’ previous responses. Qualitative data were collected with 3 open questions exploring possible barriers and enablers to OSG engagement: “What would make it difficult for you to use an OSG?” (Q36), “What would make it easier for you to use an OSG?” (Q37), and “Is there anything else you would like to say about using OSGs?” (Q38). Recruitment and data collection were conducted concurrently.

Analysis

Quantitative Analysis

All data were exported from REDCap into Microsoft Excel, and quantitative data were processed using the Statistical Package for the Social Science (version 13.0, IBM). All nominal or categorical variables were described with absolute frequency and percentages, and ordinal data were described with median and interquartile range. Respondents were categorized in 2 groups based on their response to the question “Have you ever been a part of an SG?” (Q17), followed by the question “Are you still a part of this SG?” (Q17a). If the answer on the former (Q17) was *no*, this was followed by the question: “Would you be interested in joining an SG?” (Q18). The *Yes-SG* group were respondents that were either currently part of an SG (*Yes* to Q17 and Q17a) or interested in joining one (*No* to Q17 followed by *Yes* to Q18). The *No-SG* group were respondents that were neither currently part of an SG nor interested in joining one (*No* to Q17a and Q18; Figure 1). Group differences were assessed with Chi-square (categorical data) and Mann-Whitney U (ordinal data) tests. The significance level was set at 5%.

Figure 1. Flowchart of questions for classifying respondents into Yes-SG and No-SG. Logic questions included in the survey that were not used for classification are specified with an asterisk. Q: question; SG: support group.



Qualitative Analysis

Data from all respondents (Yes-SG and No-SG groups) were considered in the qualitative analysis. To explore perspectives on the barriers and enablers to involvement in an OSG, inductive thematic analysis was conducted with the free-text responses following principles outlined by Braun and Clarke [27]. First, 3 health researchers familiarized themselves with the entire qualitative dataset by reading, rereading, and noting preliminary codes related to the study objective (JS, JE, and MP) [27]. Codes were then grouped into provisional themes using Microsoft Excel by a researcher (MP). Coding anomalies and provisional themes were then discussed, and themes were refined until a final theming structure was agreed upon (JS, MP, KM, and TE). A theme was considered a final theme if it captured perspectives of multiple responders and was grounded in the data. All relevant criteria of the consolidated criteria for reporting qualitative research checklist were addressed to ensure qualitative rigor [28].

Results

Respondents

A total of 695 respondents accessed the survey. Of these, 39 did not meet the inclusion criteria, and 235 did not complete the survey. In total, 415 respondents with OA completed the survey and were included in the analysis. The Yes-SG group comprised those who were either currently part of an SG (n=48) or interested in joining one (n=259). The No-SG group comprised those who were neither currently part of an SG (n=52) nor interested in joining one (n=56; Figure 1).

Quantitative Results

Sociodemographic Characteristics and Health Care– and Health Information–Seeking Behavior

Sociodemographic characteristics and health care– and health information–seeking behavior of respondents are described in Table 1. The majority of respondents were female (300/415, 72.3%) and lived in a major city (252/415, 61.0%). Employment status revealed that 189 out of 415 respondents were retired (189/415, 45.8%), 165 were working (165/415, 40.0%), 31 were on a pension (other than age pension; 31/415, 7.5%), and 28 were not working (eg, unemployed or caring for another person; 28/415, 6.8%). Technology and media (eg, internet searches, social media, newspaper, or television) were used for health information seeking by the majority of respondents (367/415, 88.4%). Sociodemographic characteristics and current health care– or health information–seeking behavior were not significantly different between Yes-SG and No-SG respondents.

Table 1. Sociodemographic characteristics and health care– and health information–seeking behavior of the survey respondents.

Sociodemographic characteristics and health information–seeking behavior	All respondents (N=415)	Yes-SG[a] (N=307)	No-SG[b] (N=108)	*P* value
Sex (female), Q[c]3, n (%)	300 (72.3)	225 (73.3)	75 (69.4)	.44
Accessibility/Remoteness Index of Australia code[d] (Q3), n (%)				.62
Major city	252 (61.0)	184 (60.3)	68 (63.0)	
Inner regional	110 (26.6)	88 (28.9)	22 (20.4)	
Outer regional	42 (10.2)	30 (9.8)	12 (11.1)	
Remote	9 (2.2)	3 (1.0)	6 (5.6)	
State of residence (Q3), n (%)				.02
Australian Capital Territory	19 (4.6)	16 (5.2)	3 (2.8)	
New South Wales	289 (69.6)	214 (69.7)	75 (69.4)	
Queensland	28 (6.7)	22 (7.2)	6 (5.6)	
South Australia	6 (1.4)	3 (1.0)	3 (2.8)	
Tasmania	9 (2.2)	6 (2.0)	3 (2.8)	
Victoria	54 (13.0)	40 (13.0)	14 (13.0)	
Western Australia	10 (2.4)	6 (2.0)	4 (3.7)	
Employment (Q5), n (%)				.09
Retired	189 (45.8)	145 (47.5)	44 (40.7)	
Working	165 (40.0)	115 (37.7)	50 (46.3)	
Pension	31 (7.5)	27 (8.9)	4 (3.7)	
Not working (eg, unemployed or caring for another person)	28 (6.8)	18 (5.9)	10 (9.3)	
Financial status (Q6), n (%)				.65
Careful	179 (43.1)	132 (43.0)	47 (43.5)	
Able to manage	32 (7.7)	21 (6.8)	11 (10.2)	
Straining	133 (32.0)	99 (32.2)	34 (31.5)	
Comfortable	71 (17.1)	55 (17.9)	16 (14.8)	
Education (Q7), n (%)				.90
Year 11 or below	67 (16.2)	46 (15.0)	21 (19.4)	
Year 12	28 (6.8)	22 (7.2)	6 (5.6)	
Certificate 3 or 4	57 (13.8)	41 (13.4)	16 (14.8)	
Diploma/advanced diploma	92 (22.2)	69 (22.5)	23 (21.3)	
Undergraduate	79 (19.1)	60 (19.6)	19 (17.6)	
Postgraduate	91 (22.0)	68 (22.2)	23 (21.3)	
Limitation of daily activities (0-100), Q8, median (IQR)	52 (31-66)	52 (31-66)	51 (32.5-65)	.92
Seeking professional health care (Q9), n (%)				.57
I do not currently	100 (24.1)	75 (24.4)	25 (23.1)	
Once a year	36 (8.7)	23 (7.5)	13 (12.0)	
Once every 6 months	50 (12.0)	39 (12.7)	11 (10.2)	
Once every 3 months	85 (20.5)	63 (20.5)	22 (20.4)	
Once monthly	108 (26.0)	83 (27.0)	25 (23.1)	
Once weekly	36 (8.7)	24 (7.8)	12 (11.1)	
Use of technology for health information seeking (Q11), n (%)				.38
Yes	367 (88.4)	274 (89.3)	93 (86.1)	

Sociodemographic characteristics and health information–seeking behavior	All respondents (N=415)	Yes-SG[a] (N=307)	No-SG[b] (N=108)	*P* value
No	48 (11.6)	33 (10.7)	15 (13.9)	
Types of technology used (ranked in top 3 for Q12), n (%)				—[e]
Website endorsed by advocacy group	228 (62.1)	177 (64.6)	51 (54.8)	
Google or internet search	172 (46.9)	132 (48.2)	40 (43.0)	
Health app	143 (39.0)	111 (40.5)	32 (34.4)	
Wikipedia	117 (31.9)	97 (35.4)	20 (21.5)	
Newspaper/magazine	87 (23.7)	58 (21.2)	29 (31.2)	
Free flyers	81 (22.1)	50 (18.3)	31 (33.3)	
Internet forums	70 (19.1)	49 (17.9)	21 (22.6)	
Podcasts	69 (18.8)	50 (18.3)	19 (20.4)	
Television/radio	68 (18.5)	48 (17.5)	20 (21.5)	
Social media	66 (18.0)	50 (18.3)	16 (17.2)	

[a] Using or wishing to join a support group.

[b] Not using and not interested in joining or using a support group.

[c] Q: question.

[d] Australian International Standard Recording Code national agency.

[e] Not applicable.

Digital Literacy

Digital literacy characteristics, including the type of electronic device, frequency of internet use, and self-reported ability to use the internet, were not statistically different (*P*<.05) between Yes-SG and No-SG groups. Respondents reported that they used all types of devices (mobiles, tablets, laptops, and desktop computers). The majority of respondents (334/415, 80.5%) indicated accessing the internet every day, and 351 out of 415 respondents rated themselves as having good or excellent ability to use the internet (85.4%; Multimedia Appendix 3).

Participation and Preferences of Support Groups

For those who reported having been part of an SG (N=100), 32 had been part of it for <6 months, 28 between 6 months and 2 years, and 40 for >2 years. The majority participated in an SG delivered in person (54/100, 54.0%) or Web-based through social media (eg, Facebook; 41/100, 41.0%). Remaining respondents (3/100, 3%) participated over the phone and Web-based through a specialist website. For those who were not currently part of an SG (N=52), only 29 informed the reasons for leaving it. The main reported reason was “Not enough time to participate” (18/29, 62.1%), followed by “I did not find the information relevant to me” (6/29, 20.7%) and “I did not agree with the information on the SG” (3/29, 10.3%).

Regarding the level of importance of the different types of information that could be provided, Yes-SG respondents most frequently reported information pertaining to having *research results explained in language that was understandable*, *potential new treatments*, and *pain management advice* as being (extremely/very) important (302/307, 98.4%; 297/307, 96.7%; 288/307, 93.8%; respectively). However, *diet advice* and a discussion on *media programs of interest* were selected least often (Figures 2 and 3). For the types of services that could be available through SGs, respondents selected having *treatment programs available in my area* and *access to health professionals* as (extremely/very) important (293/307, 95.4%; and 264/307, 86.0%; respectively), whereas having *social meetups* was selected least often (111/307, 36.2%).

Among all respondents, 369 out of 415 (88.9%) thought they would (strongly) benefit from an OSG, 260 out of 415 (62.7%) thought receiving support from peers is (extremely) important, and 243 out of 415 (58.6%) were (extremely) motivated to use an OSG. Within the Yes-SG group, 126 out of 259 respondents (48.7%) indicated that they would prefer to access an SG online (eg, online format), 67 (25.9%) through a face-to-face meeting, 58 (22.4%) via email, and 8 (2.9%) via phone (Multimedia Appendix 2). Of those preferring OSG (N=126), 31.7% (40/126) would mainly participate in an OSG by *commenting, discussing, or debating topics*, and 31.7% (40/126) indicated they would prefer to *only read articles*. Remaining responses included *asking questions* (20/126, 15.9%), *sharing articles from the OSG with non-OSG members* (16/126, 12.7%), and *having direct contact with a moderator* (4/126, 3.2%). Respondents within the Yes-SG group indicated a high level of trust (average level of trust 73.4/100 points) in advice provided by a health professional. Interestingly, trust in information provided by a trained peer facilitator with the same condition was equally high (71.7/100 points).

Figure 2. Preferences on information distribution for Yes–support group.

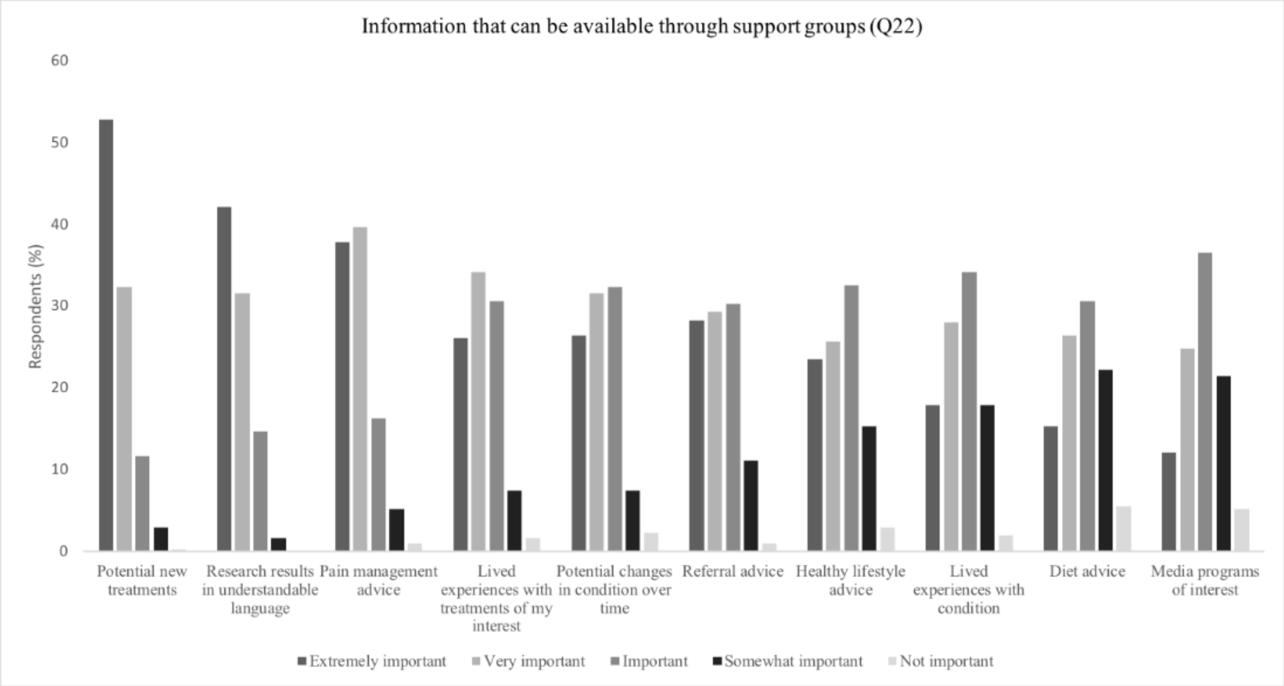
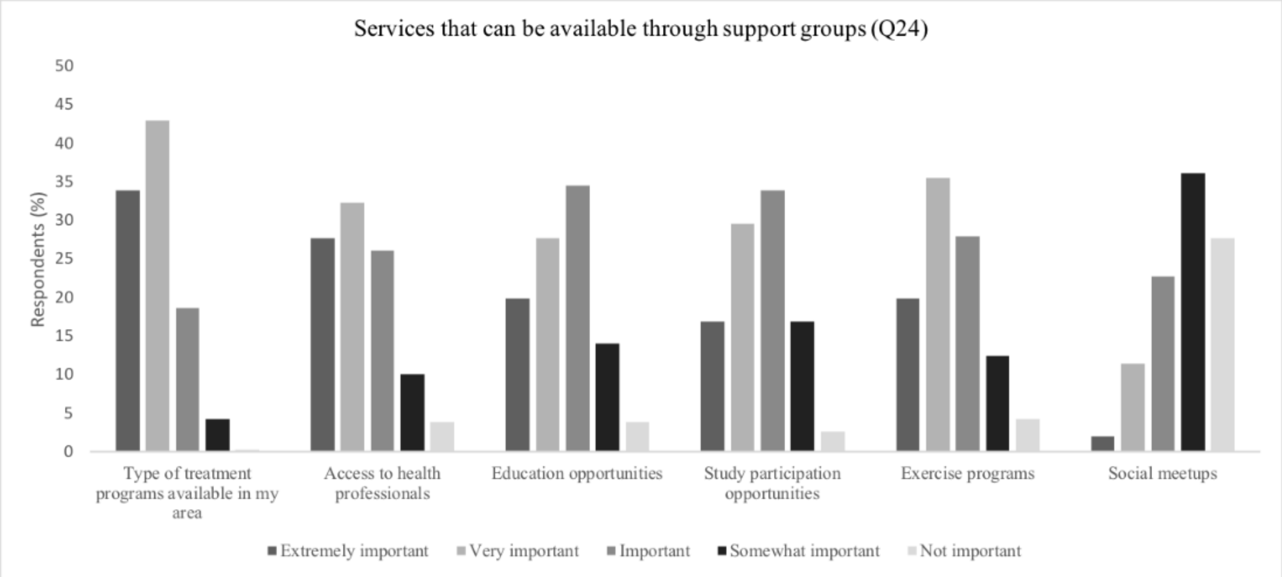


Figure 3. Preferences on service distribution for Yes–support group.



Qualitative Results

Thematic analysis of the qualitative responses identified 5 key themes related to barriers and enablers to OSG use: (1) ease of access, (2) enjoyment of experience, (3) information quality, (4) time, and (5) motivation. An overview of themes and subthemes is provided in Multimedia Appendix 4. Respondents are distinguished by numbers where quotes are used.

Theme 1: Ease of Access

Analysis identified that *ease of access* was a key concern for respondents when considering using an OSG for OA. Some respondents noted various technological factors that would help them access the OSG. These factors included making sure that the OSG was accessible to people of all abilities. Respondents identified accessibility features such as larger fonts, subtitles, clear sound and visuals, voice-activated programs, and the ability to save and print content. Many respondents emphasized a preference for an intuitive design, including making the OSG easy to use with minimal passwords, clear step-by-step instructions, technical support, and compatibility across browsers. For example, there were suggestions for *a well-structured webpage that is easy to search* (Participant 1) and *an OSG that is quick and easy to use* (Participant 2). Respondents also said it would be helpful if the OSG could be accessed across different devices, such as computers, laptops, and mobile phones. Variable internet availability and reliability as well as variable levels of digital skills were also frequently mentioned as important access considerations for OSGs.

Theme 2: Enjoyment of Experience

The *enjoyment of experience* of participating in an OSG was also identified as an important theme for respondents. Physical comfort (eg, pain, fatigue, and poor concentration ability) and personality/mood were raised as concerns by some respondents because of the potential effect of these factors on their ability to interact with an OSG. Respondents mentioned the need to encourage empathy and positivity among members of an OSG for OA and to avoid negativity and pessimism. For example, Participant 4 said:

> *[OSGs] can be very supportive but sometimes they seem to attract people who have had negative experiences with treatment, health professionals, etc. So, you need to be careful of some comments and information.* [Participant 4]

The impersonal nature of online contact was mentioned by many respondents, and having access to personalized features within the OSG, such as familiar people, face-to-face opportunities, and a contactable person for phone and/or online support, was requested. For example, Participant 5 said:

> *[The OSG] loses the personal touch. Like talking to a computer!! You wouldn't know if your problem is being addressed or if it’s generalized.* [Participant 5]

Theme 3: Quality of Information

Quality of information is considered an important aspect of an OSG. Respondents discussed that the content of an OSG should include relevant, novel, and dynamic information on a range of different topics that are tailored to the individual needs. For example, Participant 6 said:

> *Maybe specific weekly topics and activities—that would keep me more motivated.* [Participant 6]

In addition, respondents said that it was essential that the information provided in the OSG is trustworthy and facilitators are qualified. Participant 7 stated:

> *[I] would not like the sessions [within the OSG] to be just chat sessions. I believe they should be chaired by a medical specialist in the OA field.* [Participant 7]

Overall, respondents highlighted that information should be trustworthy and distributed in a clear and concise language that avoids jargon.

Theme 4: Time

The concept of *time* was mentioned by most respondents. Some respondents made assumptions that OSGs are held at set times, and in this case, they expressed concerns about the need for planning and organizing. For example, Participant 8 mentioned:

> *[I would prefer] a specific day and time allocated on a fortnightly or monthly basis.* [Participant 8]

Similarly, flexibility with regard to the amount of time to engage and the time of day seemed important to respondents. The ability to return to information at a later time or print was also suggested:

> *Just being able to access at any time the information.* [Participant 9]

Most respondents highlighted that having limited time available per day might act as a barrier to their engagement with an OSG.

Theme 5: Motivation

Respondents reported different views on *motivation*. Some respondents reported that they were highly motivated to try an OSG:

> *I am in full support of this venture, especially as I live in a regional town with minimal services and access to information comes mainly from the Internet.* [Participant 10]

Some reported they might require more motivation before becoming involved in an OSG:

> *I'm a bit skeptical, but would give it a try.* [Participant 11]

Others reported they lack motivation:

> *I don’t really like online anything.* [Participant 12]

Respondents suggested that reminders and notifications via SMS and/or email may facilitate engagement. Also, knowledge of the potential benefits of OSGs could help motivate patients to be involved.

Discussion

Principal Findings

This study used a mixed method design to explore health care– and health information–seeking behavior, digital literacy, preferences, and barriers for the design of SGs for people living with OA. Of the 415 survey participants, 307 (74.0%) were either currently using or wishing to join an SG, and the majority identified *online* as their preferred mode of delivery rather than via email, phone, or face-to-face. For those who were currently part of an SG, the 2 main methods of delivery were in person and Web-based (eg, social media). Most participants reported that they were currently using the internet on a range of devices to access health information. The majority felt that they would benefit from the participation in an SG and indicated trustworthy and qualified health professionals and peer leaders as preferred facilitators of SGs. Furthermore, up-to-date quality information (eg, new treatments, latest research results, and pain management advice) in lay language was deemed important. Qualitative analysis revealed a lack of time and motivation as the main barriers for OSG participation. Although from a small number of respondents, the reported reasons for leaving an SG sustain these qualitative findings. Respondents suggest that factors including information about benefits and reminders could facilitate engagement. The main enablers were related to accessibility, enjoyment of the experience, and quality (novel and trustworthy) of the information.

Strengths and Limitations

Strengths and limitations of this study need to be considered. Strengths included the size of the respondent group (well powered to provide generalizable data) and the high response rate after distribution of the survey. However, it is important to note the limitations to the generalizability of this study that are highly contextual. As participants represent a sample of convenience, the results may not represent the views of all people with hip, knee, or back OA. Results may also not be applicable across countries, particularly, where cultural and social conditions differ considerably from the Australian context. As recruitment was undertaken via an institutional patient database, there is also the possibility that our cohort is more comfortable with, and capable of engaging with, technology. In addition, respondents were also likely to be active seekers of health information, have English language competency, and have higher health literacy. As such, participants may not represent vulnerable groups, including people who need additional support for such health engagement and those with culturally and linguistically diverse background. A limitation of the survey is that it may not reflect all types of (online) health information resources. As such, the results should be interpreted relative to the conducted survey. This study had a high representation of people who are either currently using or interested in joining an SG (Yes-SG) and may underrepresent people who do not use SGs. Furthermore, it is possible that respondents who were not currently part of an SG (part of the No-SG group) were still interested in joining another SG, but this information was not collected. The authors acknowledge potential differences in health care– and health information–seeking behavior, digital literacy, and preferences within the Yes-SG group, for example, differences between people who are currently using and those who are interested in joining an SG. Although the majority of the Yes-SG group comprised people interested in joining an SG (259/307, 84.4%), further research is required to understand if there are differences in preferences (eg, specialist website, social media, or in person) between people who are willing to use OA SGs and those who are already in such groups. The quantitative analysis examined differences between Yes-SG and No-SG for survey questions regarding SGs including OSGs, whereas the qualitative analysis included data of all respondents but only related to OSG questions. This needs to be considered when interpreting the results. Data used for the qualitative analysis of this study were obtained through 3 open-ended survey questions. This approach potentially limits the ability to conduct an in-depth exploration of individuals' attitudes and beliefs regarding OSGs, which may be possible with interviews. However, it does enable anonymous responses, which may be advantageous by reducing the risk of a Hawthorn effect bias.

Comparison With Previous Studies

Previous research reports that people with higher income and education levels [29,30], those living with a chronic health condition [10], and those who are more proactive in seeking health information [31] are more likely to engage in OSGs. Similarly, our survey respondents were relatively well educated; however, they also were confident using technology to seek health information, and the majority of the Yes-SG group preferred OSGs. Respondents also emphasized that it would be helpful if the OSG could be accessed across different devices (computers, laptops, and mobile phones) or as an app. However, the qualitative analysis revealed that respondents had variable levels of digital skills and indicated a preference for intuitive, simple designs with clear step-by-step instructions including technical support. This finding is in line with recommendations from previous studies that state OSGs should aim to employ simple navigation design, visually appealing sites, compatibility across multiple devices, and accessible and printable content to ensure people with all levels of computer experience can participate [32,33].

Respondents in our study rated advice on pain management, new treatment options, and provision of research results in a consumer-friendly language as extremely important when they were asked to rate different types of information that could be available via SGs. Similarly, the qualitative analysis revealed the importance of having access to relevant, novel information on a range of topics tailored to individuals in an OSG. Dynamic information is preferred in clear and concise language that avoids jargon. Previous research has indicated that accurate and up-to-date information can promote active participation, allow people to make informed choices [34], and give them greater control over their own health care decisions [35,36]. Therefore, we recommend future OSGs integrate up-to-date relevant information that is simple to follow. This is potentially implementable through the use of subject headings, keywords, or moderator-driven explanations of complex topics.

The majority of respondents who were currently using or interested in joining SGs reported that they were likely to trust advice from either a health professional or a trained peer facilitator. However, qualitative analysis highlighted that some respondents felt the opposite. Specifically, respondents stressed the importance of attaining trustworthy information from online facilitators in OSGs. Previous research examining enablers and barriers to using SGs in patients with arthritis, breast cancer, or fibromyalgia found that older participants (compared with younger ones) did not favor OSGs because of a lack of trust in the internet [37]. Our participants were all aged >45 years and might have held similar perceptions regarding distrust of information from the internet. Trust in the OSGs might be facilitated by several strategies, such as embedding the group within trusted host sites (eg, consumer advocate organizations), use of a health professional or trained peer moderator or maintaining a minimum number of group membership to permit diversity of opinion. It is currently unknown whether a strategy is more effective than another at increasing consumer trust.

Conclusions

From this study, we suggest that the use of SGs could be facilitated by the inclusion of digital options such as email, social media, and health websites to enhance engagement. Our findings also suggest that efforts need to be made to ensure the online platform is intuitive and accessible. Information to help people make decisions about which treatments to seek are desired by users of OSG. Other important features of an OSG for hip/knee OA or back pain include having an expert health professional or trained peer facilitator to moderate the OSG, providing information that is free of jargon, and incorporating reminders to facilitate engagement. Members also need to feel confident about the security of their personal information, the trustworthiness of the information and advice, and the credibility of the experts providing input to the group. Finally, a moderator or facilitator’s role should include efforts to maintain interest, so the membership continues to be motivated to engage.

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Conflicts of Interest

DJH provides consulting advice to Merck Serono, TLCBio, Pfizer, and Lilly.

Multimedia Appendix 1
Checklist for Reporting Result of Internet E-surveys (CHERRIES).
[DOCX File , 17 KB - jmir_v21i12e15987_app1.docx]

Multimedia Appendix 2
Survey questions.
[DOCX File , 19 KB - jmir_v21i12e15987_app2.docx]

Multimedia Appendix 3
Table S1. Digital literacy characteristics of survey respondents.
[DOCX File , 15 KB - jmir_v21i12e15987_app3.docx]

Multimedia Appendix 4
Table S2. Themes and subthemes derived from the qualitative analysis.
[DOCX File , 14 KB - jmir_v21i12e15987_app4.docx]

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Abbreviations

CCSMS: Chronic Condition Self-Management Support
HREC: Human Research Ethics Committee
NHMRC: National Health and Medical Research Council
OA: osteoarthritis
OSG: online support group
REDCap: Research Electronic Data Capture
SG: support group

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Original Paper

Investigating How Bowel Cancer Survivors Discuss Exercise and Physical Activity Within Web-Based Discussion Forums: Qualitative Analysis

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Abstract

Background: Online cancer support group discussions enable patients to share their illness experience with others. The sharing of technical and emotional support information and the ability to ask for advice are some of the primary discussions shared online. People with bowel cancer can also use these forums to support each other by sharing information based on personal experiences. This type of support provides newly diagnosed patients with advice about several topics, including exercise from those who have been there. Information gathered from online discussion boards may complement the advice received by health professionals.

Objective: This study aimed to explore the nature of information related to exercise and physical activity exchanged online for cancer survivors.

Methods: A public open access bowel cancer discussion board was searched for threads containing information related to physical activity or exercise. Keywords such as *exercise*, *physical activity*, *moving*, *walking*, *lifting*, *weights training*, and *resistance* were used to search for threads (online conversations) related to exercise or physical activity. Only threads initiated by bowel cancer patients or survivors were included. From more than 6000 posts, the inclusion criteria yielded 75 threads for analysis. Inductive thematic analysis was conducted across all included threads.

Results: Analysis yielded 3 main themes: *level of exercise competence*, *beneficial dimensions of exercise*, and *faith in the knowledge*. *Level of exercise competence* illustrated the varying definitions of exercise that members of the forum discussed in the forum. *Beneficial dimensions of exercise* revealed that forum members shared both the spiritual benefits associated with exercise as well as the physical benefits or goodness that they feel exercise or physical activity provides them. *Faith in the knowledge* of exercise demonstrated that forum members were aware of the general benefits of exercise but felt disappointed that it did not keep the cancer at bay. However, members also had faith that exercise would keep them healthy after diagnosis and treatment.

Conclusions: The analysis revealed that people with bowel cancer discuss exercise and physical activity online and that they view exercise as having a mostly positive influence on their cancer journey. However, personal definitions of exercise became a source of conflict within the group. People with bowel cancer seeking information about exercise may benefit from participating in online support groups as it appears that there are many similar others willing to share their personal experiences with exercise. In addition, health care professionals responsible for caring for people with bowel cancer may use these findings to discuss exercise with their patients while being mindful of how they may view exercise.

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KEYWORDS

exercise; physical activity; cancer; qualitative research; patient portals; internet

Introduction

Background

Many patients with chronic disease increasingly utilize online health support groups, with the Pew Research Center reporting that 20% (N=2253) of internet users living with a chronic disease participated in some form of online discussion forum [1]. Specifically, people diagnosed with cancer use the internet to search for disease-related information, for supportive communication, for practical tips on daily living with cancer [2-4], to find out more about their disease as well as other general health issues [5], and to search for information regarding diagnosis and treatments [6].

The value of advice received from online cancer support group members appears to be different from the value of advice received from health care professionals. In some cases, the information sought in online cancer support discussion boards may complement the advice received from the health professionals [7]. However, the influences of other cancer patients' experiences discussed in online forums were found to be greater than the influences of advice given by doctors [8]. Such a view is consistent with the findings of Gill and Whisnat [9] who reported that people with ovarian cancer commonly used online forums to discuss whether the health information received from their health care professionals was honest and accurate. The members used online forums when their trust in the health care professional was low, such as in the case where the participant was not satisfied with the health care professional's suggestion to wait before initiating treatment. They also shared information about diet, activities related to daily life, and treatment side effects [9]. It is, therefore, suggested that online cancer forums provide a platform for people to discuss and advise each other on issues related specifically to their cancer, especially when they do not feel that they are getting the required information and support from their health care professionals.

Analyses of online discussion forums reported that forums served as an opportunity for members to communicate their experiences with similar others when they may have not been able to speak to others directly [10-12]. This included the ability to discuss intimate bodily symptoms [13]. Men with prostate cancer reported being able to discuss their uncomfortable and challenging experiences, such as urinary and bowel function and continence, with other members of the group [14].

Courneya and Friedenreich [15] noted that 40 out of 130 (31%) cancer survivors maintained and 21 out of 130 (16%) returned to physical activity following treatment completion. Furthermore, it was suggested that many have searched the internet and online groups for information about exercise specific to their form of cancer and treatment [16]. This implies that people with cancer are seeking exercise information, support, and advice from online cancer support groups. However, relatively little research has examined how individuals with bowel cancer may interact and benefit from online communities, despite bowel cancer being the third most diagnosed cancer internationally [17]. Despite the frequency of its diagnosis and relatively high survival rates, bowel cancer commands considerably less public—and scholarly—attention in contrast to the other 2 leading cancers, breast and prostate cancers [18].

Objectives

Research advocates physical activity and exercise for people with bowel cancer [19-21], yet little is known about bowel cancer patients' experience with physical activity, which makes it challenging for health care professionals to provide effective physical activity counseling to this population. This study applies a qualitative analysis of messages exchanged online to explore how bowel cancer online forum members define exercise in addition to describing their previous experiences with exercise. The aim of this study was to provide insights from the bowel cancer patients' perspective that can allow health care professionals to better counsel and support their patients with respect to their exercise and physical activity needs.

Methods

Selection of Online Discussion Group

To illustrate the views of people with bowel cancer about exercise, a qualitative inductive thematic analysis (ITA) of online asynchronous archived discussions on a bowel cancer discussion board was conducted. A complete search of online bowel cancer discussion groups was conducted using the Google search engine using the keywords *bowel cancer*, *online forum*, and *online support group*. The forum chosen for analysis is one of the largest online cancer forums [22] and is available internationally. International availability meant a greater potential of reaching a wider demographic. Another reason for choosing this forum was that it clearly specifies that any information posted on the discussion boards is open to public view.

An asynchronous discussion board was chosen because this type of communication enables individuals to connect with other members at a time and place convenient to them [23]. In addition, posting on an asynchronous discussion board allows all members to potentially read and respond to a message thread, even though it may have been originally posted many days or weeks previously. Furthermore, participants may search message threads using keywords to locate and read information relevant to their current information needs, with these individuals being the primary users of discussion boards [24].

The discussion boards are open to people currently being treated for bowel cancer; survivors of bowel cancer; and caregivers, significant others, and other family members of people with cancer. The research question sought to answer how people with bowel cancer discuss exercise; therefore, threads initiated by patients and survivors of bowel cancer only were included in the analyses. Threads that did not explicitly include information about the initial post's connection to bowel cancer were not included in the analysis. Inclusion criteria required that forum posts (1) must be initiated explicitly by a person currently or formally diagnosed as having bowel cancer and (2) must include a discussion related to physical activity or exercise.

Ethical Considerations

This research was approved by the lead university's ethics committee.

Traditional research ethics dictate that researchers must take the necessary precautions to ensure the privacy and confidentiality of data as well as collection of informed consent of all participants [25]. It is argued that information posted in a public discussion group is a public act and, therefore, is available for public consumption, which requires no more than the usual precautions [26]. Eysenbach and Wyatt [27] report that a *passive analysis* of online data collection does not mandate informed consent. A *passive analysis* occurs when the researcher strictly observes the interaction and communication of a public online space. This research did not actively engage with members of the online community, meaning that the processes involved in the study could be classified as a *passive analysis* of the data.

Data Collection

At the time of data collection, the discussion board consisted of 280,356 posts. Keywords such as *exercise*, *physical activity*, *moving*, *walking*, *lifting*, *weightstraining*, and *resistance* were used to search for threads related to exercise or physical activity. Threads identified were then opened, and the posts were read. *Search by Keyword* identified keyword search terms within posts. *Search by Title* identified keyword search terms in the title of the threads.

Each thread contained its own unique title named by the member who initiated the thread. This title was used as an indicator by other members to identify the contents of the thread. Each thread was briefly read online to establish that it met the inclusion criteria. Once all threads had been reviewed, they were organized chronologically based on the date of the initial post of the thread. The lead researcher (AO) read through all threads and posts several times to familiarize herself with the general context of the posts, the online community, and the interactions within the online community. Threads were dated from March 4, 2003, with the earliest thread related to physical activity or exercise, to July 11, 2014, when data collection ceased. Date restrictions on threads were not warranted because knowledge of the benefits was available as of 1999 when Courneya [28] published one of the first studies investigating the benefits of exercise for people diagnosed with cancers other than breast cancer.

Discussion threads initiated by significant others, caregivers, or others were excluded. A thorough search of the online discussion board yielded 139 threads, with 37 threads identified by a title search and an additional 102 threads by a keyword search.

Data Analysis

An ITA was conducted following the recommendations of Braun and Clarke [29]. ITA is a systematic approach that identifies commonalities laterally across the dataset and assists with outlining an understanding of what those commonalities indicate.

Analytic Approach

Highlighting phrases and statements within the text referring to exercise and physical activity achieved the first step of analysis. Initial notes were then made from the phrases and statements. Initial notes from the data extracts were then grouped based on similarities into initial codes. The initial codes were then analyzed and grouped together to create provisional themes. Provisional themes were created from similar initial codes, opposing initial codes, and linearly across a theme to create levels of a particular theme.

Regular meetings were held between the lead author and coder and an experienced qualitative researcher (SS), where potential provisional themes were discussed based on the initial codes to ensure a thorough analysis of the extracts. The lead coder also completed self-reflections to identify possible biases and address personal thoughts and actions during the analytical process. Following the recommendations of Braun and Clarke [29], the provisional themes were then checked to ensure that they were representative of the dataset and the general narrative of the analysis. Initial notes and initial codes were developed across 96 threads with 331 unique contributors, where data saturation was deemed to have occurred as reading further posts did not yield any new significant themes [30].

Results

A total of 3 themes, *level of exercise competence*, *beneficial dimensions of exercise*, and *faith in the knowledge of the benefits of exercise* were identified within the online forum that illustrated the role and presence of exercise for people with bowel cancer.

Theme 1: Level of Exercise Competence

Level of exercise competence indicated that members of the forum held different ideas of what defined exercise, what exercise provided a health benefit, and what was an appropriate amount of exercise. One post in the forum said:

> *People can have work that requires difficult physical labor for decades and still have their health deteriorate as they age, because they haven't been doing the right kinds of exercise. I watched my mother's health go in two years, despite her active life and very healthy eating habits—she gardened and did yard work, and walked, but she never ran, or cycled, or swam.* [Participant 80]

This member believed that there were the *right kinds* of exercise such as running, cycling, or swimming that preserved health, when in fact gardening, yard work, and walking can improve health outcomes [31,32]. Some members had a jaded view on what type of physical activity could help recovery and held the belief that because it was not the *right kinds* of exercise, there would be no benefits. This belief encouraged feelings of helplessness of other members because it pushed the view that running, cycling, or swimming were the only beneficial forms of exercise and physical activity for people with bowel cancer.

The description of what does, or does not, constitute as exercise was commonly discussed among members of the group. One forum member wrote:

> *I am trying to find "the perfect" diet and exercise plan so I can help my body beat this and recover.* [Participant 141]

This suggested that this participant was feeling stressed with the idea of constructing *the perfect* survivorship plan, a feeling intensified by posts that discussed the right kinds of exercise. This pressure may have discouraged this participant from beginning any activity because the plan might have been viewed by others as suboptimal or even flawed because it did not meet the other's standards of what constituted appropriate exercise.

This view of what constituted appropriate exercise was not held consistently across the group. For example, one member wrote:

> *I try to swim and do exercises 5 times a week, can't run or anything else but it all helps.* [Participant 269]

This member indicated that they participated in some form of structured exercise but also believed that any little bit counted even if participation in other forms of structured exercise was limited. Another member wrote:

> *We try to have Friday night date night at a local restaurant and we walked there. Hey, it's something!* [Participant 105]

This member accepted that although there was no engagement in any vigorous form of exercise or physical activity, something was achieved, which was felt to be better than nothing.

Theme 2: Beneficial Dimensions of Exercise

This theme illustrated that bowel cancer patients discussed exercise as having many benefits. One member wrote:

> *Another thing that is SO emphasized by every doctor I've seen or any medical article I've read is exercise. I'm not as good about it as I should be, but when I do walk on a regular basis, I feel better, both physically and mentally.* [Participant 105]

This member demonstrates to other members of the forum how exercise, specifically regular walking, has provided them with benefits. To corroborate the benefits of exercise they experience, they have included hearing about the benefits of exercise from additional sources, namely, doctors and medical articles. Another member wrote:

> *I too am and was a fitness freak (running/walking/weights/yoga daily) and almost went insane after my surgery not being able to do as much...but, I am now back to almost my normal routine and it makes a HUGE difference in how I am feeling both mentally and physically.* [Participant 13]

This member illustrated to the group how being fit and engaging in various fitness activities has provided them with general mental and physical benefits. Furthermore, this member highlights the magnitude of these benefits.

One subtheme, called spiritual benefits of exercise, was expressed by using phrases that illustrated a heightened sense of unworldliness. In their own way, bowel cancer survivors were embracing the spirituality and peace that exercise offered them and shared these experiences with other members of the group. For example, one member stated:

> *The walking will calm the universe.* [Participant 255]

Members of the forum also discussed that physical activity has the ability to provide inner strength and tranquility. For example, 1 contributor wrote:

> *I always moved as much as I could, and the pleasant fatigue and peace that I gained from the daily exercise helped me sleep and feel good about my day.* [Participant 76]

This member illustrates how exercise provided serenity that translated into changing their daily mood. This commentary highlights the psychological importance of exercise and physical activity.

Another subtheme, physical benefits of exercise, indicated the benefits exercise had on technical aspects of cancer and was expressed by this member who said:

> *We also exercise most every day and participate in yoga several times a week. I really believe that all this has helped me manage side effects, reduce tiredness, rebound to feeling "normal" again, etc.* [Participant 208]

This member shared with others that exercise was helping with cancer treatments. The owner of the post expressed the value exercise had for them during their treatment because it was helping to decrease the feelings of fatigue and allowing feelings of normalcy. Here, this member was having a better response to the disease and the treatments because of exercise. Other members shared the exercise benefits they received in a more general sense:

> *I was encouraged to walk a lot after the surgery, and I did—I think this helped my recovery.* [Participant 22]

This post demonstrated that forum members had positive experiences with exercise in relation to bowel cancer and were sharing these experiences with other members of the group.

The final subtheme, medical benefits, illustrated that some members of the forum talked about exercise as a form of complementary medicine or the medical benefits and acknowledged that:

> *While it may feel that your wife is ratting on you, I think that she is aware that walking is the best medicine for you. I imagine your surgeon told you that too.* [Participant 144]

Here, this member related exercise to a form of medicine or treatment for bowel cancer. A different member shared the same view and wrote:

> *I view my exercise and my diet and meditation as an extension of my treatment.* [Participant 255]

Members posted about exercise in medical terms by using words such as *medicine*, *treatment*, *holistic*, and *vital*. The members were using these terms to describe the value exercise had during and following treatment. The use of the medical terms suggested that these members value exercise and physical activity as therapeutically important to their recovery and had adopted a more active lifestyle as part of their medical treatment in the same way as one undergoes chemotherapy or radiotherapy as a form of therapy.

One member of the forum illustrated how they viewed exercise as a part of their medical journey. This member stated:

> *It may be hard to believe when you're lying in pain but the walking and other exercise are so good (not to mention vital) to your recovery.* [Participant 144]

This member states the indispensable importance of exercise in recovery and survivorship. This member explains that being physically active is the best thing one can do. From the analysis of the threads, it is uncertain whether or not members of the forum discussed exercise in medical terms because of the influence of the interaction they had with their health care professional. However, as some members of the forum were encouraged to participate in physical activities by their health care professional, it is possible that when they shared this information with the forum, they adopted terminology used by their health care professional. This may have resulted in other members relaying that advice to others.

Theme 3: Faith in the Knowledge of the Benefits of Exercise

This theme describes some members' disappointment in their belief that exercise would have kept them cancer free, but at the same time, speaks about the faith they have in the ability of exercise to help the recovery process. A member felt particularly let down and voiced skepticism about published research based on their experiences. This member writes:

> *Thank you for an interesting item, I have to admit I look at these studies with a jaded eye now. I was exercising (brisk walking or swimming, strength training and yoga) regularly for years (20 or more) and eating my nine servings of veggies/fruit per day. My co-workers would make fun of me. I ate very little red meat (Once a month or less). Yet I still came done with stage 4 rectal CA.* [Participant 48]

This member expressed feelings of defeat, which may have had negative implications for whether this person would continue to have an active lifestyle after treatment and may have influenced any future discussions about activities with either other members or health care professionals. This member had negative feelings toward exercise. Some other members of the forum expressed similar sentiments. Other members wrote:

> *I too was very active, walking 5 miles each morning, eating healthy—all the things I thought would keep me healthy—luck of the draw I guess.* [Participant 7]

A different forum member wrote:

> *It's funny though, you take care of yourself, try and eat right most of your life, work out physically and cardio, maintain your weight throughout your life and blamn, 2006 cancer and 2010 could be looking at a pace maker in my retirement years. Then you have people that are overweight, obese, don't watch what they eat, don't exercise, smoke, drink etc., and blamn, never a health issue. Scratch head and go figure :) :) :) :) LOL!!!!!!!!!* [Participant 83]

However, other members of the forum did not appear to adopt these negative feelings about why being physically active had not prevented them from being diagnosed with bowel cancer. Some members of the forum shared that they too exercised before diagnosis, but they did not blame exercise for not keeping them cancer free. One member wrote:

> *I have exercised most of my life before (not much during) and after cancer. Even if it didn't help stop the beast, which I do believe it does, I would still do it.* [Participant 103]

This member chose to have a positive outlook and had accepted that sometimes bad things happen, but this did not change their attitude about exercise. Another member wrote:

> *My doctor told me there would be a 95% chance that the cancer would return. I asked him what I could do to prevent reoccurrence. He told me exercise. That was no problem for me as I have always exercised.* [Participant 239]

This member appeared to have taken things as a matter of fact. It would seem that diagnosis had been accepted, treatment had been completed and now this member was working on surviving. According to their doctor, exercise was the way to survive. This member may not know that exercise had been reported to reduce the risk of bowel cancer and, therefore, did not express feelings of defeat, or this member did know, but had chosen to move forward in survivorship without dwelling on what had already happened regarding the cancer diagnosis.

Discussion

Principal Findings

An ITA of an online asynchronous bowel cancer discussion board identified several ways in which exercise and physical activity are present in the lives of people diagnosed with bowel cancer. Furthermore, this analysis identified ways in which they viewed exercise and physical activity and how they communicated their views on this topic with each other.

Limitations

Some limitations of this study exist, with the first being that the keywords related to other forms of exercise including tai chi, yoga, or Pilates were not explicitly searched. However, the search terms that were used did identify threads in which physical activities including yoga, tai chi, and Pilates were discussed among the forum members. Furthermore, the evidence surrounding the benefits of activities such as yoga for people with bowel cancer is mostly inconclusive. A randomized control trial reported that yoga did not have a significant effect on the quality of life of people with bowel cancer [33]. The second limitation is the potential cultural difference between those on the online forum. It has been reported that Puerto Rican breast cancer survivors preferred to not use the internet for seeking information on physical activity [16]. Similarly, African Americans and Latinos aged 50 years and above were more likely to search the internet for bowel cancer information compared with whites aged 50 years and above who utilized the internet to search for general health information [34]. Third, not all bowel cancer discussion forums will serve the same purpose. An evaluation of a different online bowel support community reported that threads were initiated by asking questions as a way to initiate conversations [11]. Although this was similar to the online support community analyzed here, there were several posts wherein members would introduce themselves to the group along with information about who they were, what their diagnosis was, and any therapies they were currently using or thinking about using. Therefore, the themes discussed in this research may only be applicable to this online support community. Although a limitation, these themes are apparent in the threads and speak about the ways some bowel cancer patients discussed exercise and physical activity among themselves in the online medium. They can, therefore, still inform health care professionals about the way exercise is discussed among some bowel cancer patients and can help inform future physical activity counseling practices and survivorship guidelines.

Turner et al [10] reported that members who spent more time reading posts on online communities had limited traditional face-to-face partner support. It could be speculated that more time spent reading would coincide with more posts. However, this was not the case, with Turner et al [10] finding no significant interaction between depth of face-to-face support or depth of online support and posting frequency. The nature of this analysis was to review discussions of exercise and/or physical activity; therefore, particularly passionate members of the group may have increased the likelihood of introducing user frequency bias simply by being more communicative than other members about the topic. This, however, speaks about the passion some bowel cancer survivors have in relation to exercise and physical activity and the important role exercise played in their survivorship plan.

Comparison With Previous Work

This analysis indicated that exercise and physical activity had many different meanings to members of this forum. This was identified by the *level of exercise competence* theme. While discussing exercise, which had no clear and uniform meaning across all forum members but quite narrow definitions for some individuals, the lack of nonverbal cues and tone of voice within the online environment meant that there were numerous instances of negative emotions and animosity between members of the forum. The scope of what exercise is and is not to individuals with bowel cancer was an important finding of this research. First, because it clarified for researchers that more research remains to be done to further educate bowel cancer patients on what constitutes exercise and physical activity. Furthermore, the difference in understanding the definition appears to influence their exercise and physical activity habits, which may have implications on how health care professionals gather information from and educate their patients during discussions related to cancer survivorship. As lack of time was indicated as the primary barrier to discussing exercise with cancer patients [35], developing an efficient way to gain a mutual understanding of the definition of exercise with each patient may be important to the efficiency of care.

The varied opinions of the members on what activities were considered exercise had implications for whether or not other members engaged in physical activity or contemplated engaging. Understanding that all forms of physical activity no matter how brief or low intensity are likely to have some benefits for insufficiently active cancer survivors and that some activity is better than none would encourage the discouraged to participate at some level. This has the potential to lead to greater health benefits from future involvement in longer-duration and/or higher-intensity physical activities. However, it should also be noted that there is the potential for harm in sourcing exercise advice and information from peers or those not trained in prescribing exercise. For example, it is possible that underactive or deconditioned members of the online forum may be at risk of a musculoskeletal or cardiovascular event if they begin exercise programs beyond their capabilities. At present, the negative outcomes of peer advice on exercise have not been explored; therefore, it is not possible to draw any definitive conclusions on the relative potential of benefit versus harm from seeking peer or online advice.

Exercise provided different benefits to those who chose to participate in exercise, and this information was shared among the members of the online forum. The *beneficial dimensions of exercise* theme identified that members of the forum categorized these benefits as spiritual, physical, and medical benefits. Similarly, women diagnosed with gynecological cancer used exercise as part of their spiritual practice [36]. However, because of the quantitative nature of Lopez et al's study [36], the significance of exercise in relation to life meaning was not explored. From the analysis of the online forum data in this study, it can be speculated that exercise provided these bowel cancer patients with a feeling of purpose. Members of this forum discussed the ability of exercise to reconnect them with life and feelings of calmness experienced following exercise. People diagnosed with bowel cancer who participated in preoperative exercise reported that exercise gave them a sense of purpose and that this assisted with their ability to perform their usual activities [37]. Members of this online forum wrote about similar relationships in their posts to each other about the spiritual benefits of exercise.

The members of the forum also discussed the physical benefits of exercise. Similar findings have been reported elsewhere. For example, a qualitative inquiry into the exercise experiences and preferences of bowel cancer survivors, who completed a 12-week individualized exercise intervention, reported significant improvements in strength, aerobic fitness, and endurance [38]. The reported physical benefits of the 12-week exercise intervention were similar to the benefits members discussed in this online discussion forum. This is an expected finding based on the documented results, which suggested that exercise and physical activity have many positive physical benefits for people diagnosed with bowel cancer. The findings of this study, therefore, add to the existing evidence with respect to how the benefits obtained by people with bowel cancer may reflect how they define and view exercise as a part of their cancer survivorship.

One unique finding of this analysis was the language members of the forum used when discussing exercise in terms of medical benefits. The forum members used terms generally reserved for standard cancer care. It was referred to as an *extension of treatment* or *different side of treatment* and was understood by this online bowel cancer community as not universally accepted by the medical community as standard or usual care. This information adds to the understanding of the role of exercise in cancer care and survivorship from the patients' perspectives. It is possible that health care professionals hold similar views based on discussions the bowel cancer community had about the role of their health care professional in discussing exercise with them. However, more exploration is needed. The benefits of exercise reported by the patients in the online discussion forum were influenced to some extent by the patients' varied definitions of exercise, but unified by the variety of benefits experienced by physically active members of the forum.

This analysis recognized that exercise was an important component in the lives of many people diagnosed with bowel cancer. This was expressed within the third theme, f*aith in the knowledge of the benefits of exercise.* Forum members shared their negative and positive experiences and feelings toward exercise with each other in the online discussion board. This theme explained that people diagnosed with bowel cancer have a complicated relationship with exercise, with several members expressing their anger toward the inability of physical activity and exercise to keep them disease free, whereas others shared their belief that exercise would help them in their recovery. Shaha and Cox [39] reported that people receiving a bowel cancer diagnosis experienced fear and anxiety, which led them to question their choices, goals, and attitudes toward life. This level of anxiety was similar to what was demonstrated in the third theme in this study because members of the forum questioned their attitudes and beliefs about the goal they had set for themselves to live a healthy life through exercise and physical activity. To them, bowel cancer challenged this goal by way of threatening their identity. However, these feelings were not uniform for all members. This other group of bowel cancer survivors chose not to question their beliefs about exercise and continue exercising through the illness experience. In this way, the role of exercise transformed from reducing disease risk to improving the illness experience. These members trusted exercise to help them move forward. Such divergence of patients' perceptions around the role of exercise and physical activity in reducing the risk of developing bowel cancer and improving their life post cancer diagnosis further supports the importance of health care professionals understanding their patients' perceptions on exercise if they wish their patients to optimize their cancer survivorship.

To summarize, this study adds to the body of knowledge surrounding the ways in which bowel cancer patients discuss exercise and physical activity with their peers using a qualitative analysis of their discussions in an online forum. This study draws attention to the value bowel cancer patients place on exercise in their cancer journey as well as the way they are sharing that information with others. This study is novel in the examination of language in the online context in connection with bowel cancer patients' discussions of exercise and physical activity. The results of this study can be used to inform health care professionals about how their patients view exercise and physical activity and where they are sourcing information related to this topic. Furthermore, such information can augment behavior change interventions relative to exercise and bowel cancer.

Conclusions

In conclusion, the analysis of the public online asynchronous discussion board revealed that many members associated exercise with positive feelings and were aware of and enjoying the benefits of exercise in their recovery and survivorship. It was also apparent that other members were perturbed by the discussions and the meaning of exercise for them, with such discussions being perceived as negative and threatening.

The results also highlight some key features about the ways bowel cancer survivors and patients discuss exercise among themselves and the perceived role exercise has in recovery. For example, exercise played a large role in the recovery of many of the forum members. This was demonstrated in their posts about the many benefits they received from being physically active during their journey in addition to the faith they expressed in exercise helping them live better.

The themes identified within this analysis provide important insights into how people with bowel cancer experience exercise in relation to disease and the important role of exercise in survivorship. This information is important to clinical discussions about the role that exercise may play in bowel cancer survivorship and how the patients' perceptions and previously held beliefs may influence their future exercise and physical activity behavior. Such insight may also influence future exercise and physical activity intervention research in terms of communication styles and techniques of physical activity counseling.

Authors' Contributions

AO and SS contributed to the data analysis. AO, SS, and JK contributed to the writing and editing of the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

ITA: inductive thematic analysis

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Review

Digital Alerting and Outcomes in Patients With Sepsis: Systematic Review and Meta-Analysis

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Abstract

Background: The diagnosis and management of sepsis remain a global health care challenge. Digital technologies have the potential to improve sepsis care.

Objective: The aim of this paper was to systematically review the evidence on the impact of digital alerting systems on sepsis related outcomes.

Methods: The following databases were searched for studies published from April 1964 to February 12, 2019, with no language restriction: EMBASE, MEDLINE, HMIC, PsycINFO, and Cochrane. All full-text reports of studies identified as potentially eligible after title and abstract reviews were obtained for further review. The search was limited to adult inpatients. Relevant articles were hand searched for other studies. Only studies with clear pre- and postalerting phases were included. Primary outcomes were hospital length of stay (LOS) and intensive care LOS, whereas secondary outcomes were time to antibiotics and mortality. Studies based solely on intensive care, case reports, narrative reviews, editorials, and commentaries were excluded. All other trial designs were included. A qualitative assessment and meta-analysis were performed.

Results: This review identified 72 full-text articles. From these, 16 studies met the inclusion criteria and were included in the final analysis. Of these, 8 studies reviewed hospital LOS, 12 reviewed mortality outcomes, 5 studies explored time to antibiotics, and 5 studies investigated intensive care unit (ICU) LOS. Both quantitative and qualitative assessments of the studies were performed. There was evidence of a significant benefit of digital alerting in hospital LOS, which reduced by 1.31 days (P=.014), and ICU LOS, which reduced by 0.766 days (P=.007). There was no significant association between digital alerts and mortality (mean decrease 11.4%; P=.77) or time to antibiotics (mean decrease 126 min; P=.13).

Conclusions: This review highlights that digital alerts can considerably reduce hospital and ICU stay for patients with sepsis. Further studies including randomized controlled trials are necessary to confirm these findings and identify the choice of alerting system according to the patient status and pathological cohort.

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KEYWORDS

diagnosis; electronic health records, sepsis; medical order entry systems, outcome assessment (health care)

Introduction

Sepsis Challenges

Sepsis is a major health concern causing significant mortality worldwide [1,2]. Although used to describe a variety of clinical conditions, the most recent recommendations suggest that sepsis should be defined as a "life threatening organ dysfunction caused by a dysregulated host response to infection" [3]. In the United States, the average annual age adjusted incidence is 300-1000 cases per 100,000 people [4]. The mortality from this condition is as high as one in four patients [1,2,5,6]. In addition, it poses a significant financial burden on health care systems. The annual total costs of sepsis in the United States was US $20 billion in 2011 [7]. Additionally, there are numerous indirect costs that may significantly impact patients' quality of life. For example, the older population may have severe long-term health problems after sepsis, including both cognitive dysfunction and functional disability [8].

Early Detection of Sepsis

Recognizing sepsis early and initiating timely treatment results in improved patient outcomes and significant cost reduction [9,10]. The International Surviving Sepsis Campaign recommends early identification of patients with sepsis and immediate treatment such as antibiotics within 1 hour of suspecting sepsis and septic shock [11]. A retrospective multicenter study found for every hour's delay in the treatment of patients with septic shock, the risk of death increases by 7.6% [12]. Delays in identification of sepsis are often attributable to a lack of diagnostic tools, gradual disease progression, and no gold standard for diagnosis [13]. Interventions such as regular monitoring of vital signs and elevated lactate levels aid early recognition [14]. However, despite these measures, patients are still being diagnosed late. Although track and trigger scoring systems such as the National Early Warning Score have standardized the documentation of vital signs and enabled earlier recognition to a degree, they are still subject to inaccuracies in recordings because of their subjective nature and intermittent monitoring [15]. Alternate strategies in sepsis detection are therefore urgently required to improve outcomes.

Digital Technology in Sepsis

Digital technology holds significant promise in enabling early sepsis recognition. Coupled with the rapid expansion of electronic health records (EHRs) worldwide, it is now possible to provide health care staff with real-time information on laboratory tests, imaging, and physiological vital signs at the bedside. This is particularly relevant in sepsis because of the traditional reliance on risk scoring systems used to define sepsis. These include the Systemic Inflammatory Response Syndrome (SIRS) and Sequential Organ Failure Assessment (SOFA) score [16,17]. Although usually calculated through paper-based observational charts alongside separate interfaces to retrieve blood test results, both have the potential to be automated using EHRs to reduce error and enhance digital alerting. There is now increased literature in this field that can support new clinical decisions in sepsis management. The aim of our paper was to offer an up-to-date systematic review of digital alerting systems on patient sepsis outcomes.

Methods

Data Sources and Searches

We applied the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement for this review [18]. Our search on February 12, 2019, included the following databases: EMBASE, MEDLINE, HMIC, PsycInfo, and Cochrane (April 1964 to February 12, 2019) without language restriction. The search was limited to articles reporting the use of electronic alerts in adult medical inpatients with sepsis who were not initially in intensive care. The search terms included digital technology and sepsis (for complete search strategy, see the Multimedia Appendix 1 search strategy). There were supplemental references that were manually gathered through reference lists.

Outcome Measures

Our primary outcome was hospital and intensive care unit (ICU) length of stay (LOS) for patients with sepsis. Secondary outcome measures included sepsis-associated mortality and the time to antibiotics.

Study Selection

Studies were eligible for inclusion if patients had sepsis with a clear reporting of the diagnostic criteria. In addition, studies were only eligible for inclusion if the outcomes could be compared pre- and postintroduction of digital alerts for sepsis. Studies where the clear outcome measures of interest were not stated were not included. The outcomes of interest were mortality, time to antibiotics, and ICU LOS, and hospital LOS. Studies only required one outcome of interest to be eligible for inclusion. There was no fixed number of patients required in each treatment group nor a fixed duration of follow-up.

Data Extraction and Quality Assessment

All included study characteristics and outcome measures were extracted by one investigator and verified by another. All full-text reports of studies identified as potentially eligible after title and abstract review were obtained for further review. All empirical research into digital sepsis alerting in adults and outcome measures were included. Information on the study location, type of hospital, type of alert, and whom the alert was directed at were all extracted using a set standardized form. Studies were only included if a comparative study of pre- and postalerting groups was performed and the number of patients in each group was clearly stated. Studies solely based on intensive care were excluded, as extra levels of care and treatments offered to these patients would affect the sepsis outcome measures. Additionally, case reports, narrative reviews, editorials, and commentaries were excluded. After full text review, if a study was excluded, the reasons were noted and disagreements were resolved by a third reviewer. A PRISMA flow diagram was used to map studies included, studies excluded, and the reasons for their inclusion/exclusion (Multimedia Appendix 2).

Data Synthesis and Analysis

A qualitative assessment of all studies was performed. For the primary outcome of hospital LOS, a weighted mean difference was calculated. A weighted mean difference was also used in ICU LOS. For the secondary outcome measure of mortality, we used percentage change between the pre- and postalerting groups. To ensure a standard way to compare the studies, all times to antibiotics were converted into minutes and number of days used for ICU/hospital LOS. For the meta-analysis, outcomes were analyzed by calculating the difference in means between studies or the ratio of means within each study. We substituted the median for the mean in studies where only the median was reported. We employed an inverse-variance approach with a random effects model using the DerSimonian and Laird methodology for both continuous and categorical variables. This was accomplished using Stata 13 (StataCorp, College Station, Texas). The I^2 statistic was used to estimate the degree of heterogeneity between studies.

Risk-of-Bias Assessment

The Newcastle-Ottawa scale (NOS) was used to score the included papers on the basis of the quality [19]. The range of scores was from 0 to 9. Studies with a score of ≥7 were rated as *higher-quality* studies, whereas those with scores ≤ 7 were rated as *lower-quality* studies.

Results

Search Results

The literature search identified 3861 references (appendix). One article was found through hand searching. After screening, 72 full-text reviews were reviewed, including one translated from Spanish. A total of 16 studies met the inclusion criteria and were included in the final analysis. A description of the studies including the sepsis intervention, alert type, and criteria used to define sepsis can be found in Multimedia Appendix 3. All studies that defined sepsis alerts and the pre- and postalerting stages are presented in Multimedia Appendix 4.

Characteristics of Studies and Digital Alerting Used

All studies investigated digital sepsis alerts (Multimedia Appendix 3). Several studies additionally used a rapid response team in combination with the digital sepsis alert in the alerting group [20-22]. An electronic order set was used by four studies in the alerting group [21,23-25].

The studies were predominantly single-center studies; however, one study that was multicenter study across three hospital sites [26]. Most studies were based in the United States; however, one study was from the Kingdom of Saudi Arabia [20] and one was from Spain [27]. Most studies were based in large hospital settings; six studies were based in academic centers [20,22,23,28-30], and three centers were level 1 trauma centers [21,29,31]. Within the hospital setting, only one study had a hospital-wide sepsis alert [21], and eight had alerts solely in the emergency department (ED) [20,23,27,29-33]. In addition, five studies included only medical wards [24,26,28,34,35], and two studies included both on medical and surgical wards [22,25]. All the studies were pre- and postimplementation studies.

The type of electronic alerts used in the studies varied. Most studies used digital alerts generated through EHRs on desktop-based computers [20-23,27,29-35]. Two studies involved alerting via a mobile device [24,25] and two studies used text paging [26,28]. One study predominantly used alerting through EHRs but used additional text paging at the discretion of the ED attending [23]. This is shown in Multimedia Appendix 3. Most of the digital alerts in the study were aimed at the nursing staff [20,22-25,28,32]. Although one study was aimed solely at clinicians [31], two studies had alerts sent to both clinicians and the rapid response team [21,26]. In addition, in four studies, it was unknown whom the digital alerts were sent to [27,29,33,35].

The sepsis-alerting criteria varied among studies; many studies used a variation of the SIRS criteria [20-24,26,29,34]. SIRS is defined as a temperature >38°C or <36°C, heart rate >90 beats/min, respiratory rate >20 breaths/min or arterial CO_2 lower than 32 mm Hg, and white blood cell count >12,000/mm^3 or <4000/mm^3 [16]. Only one study used two or more SIRS criteria alone [34]. Some used two or more SIRS criteria with a suspicion of infection [21,23,31]. Hayden et al used two or more SIRS criteria with a suspicion of infection but had two subgroups of patients: one with a systolic blood pressure (SBP) of <90 mm Hg and one with an SBP >90 mm Hg. A combination of two or more SIRS criteria with evidence of end-organ dysfunction was also used as a criterion to alert [20,26,30]. Narayanan et al reported two types of sepsis alerts: one alert if two or more SIRS criteria were used and another if severe sepsis/septic shock criteria (ie, two or more SIRS criteria + end-organ dysfunction OR fluid nonresponsive hypotension) [30]. One study used the combination of two or more SIRS criteria and anion gap acidosis [22]. Crum et al used a combination of two or more SIRS criteria; infectious ED diagnosis or symptom diagnosis and antibiotic administration in the ED; and acute organ dysfunction (lactate level ≥4.0 mmol/L and persistent hypotension within 6 hours of triage or vasopressor use) [29]. Austrian et al had two types of alerts: one with two or more SIRS criteria and another with an SBP <90 mm Hg or lactate level ≥ 4 mg/dL. Not all studies used SIRS; Pulia et al [33] used a fever plus any abnormal vital sign, whereas Sawyer et al [28] and Ferreras et al [27] used an algorithm consisting of laboratory values and hemodynamic parameters. The study by Mathews et al [35] was an abstract only and no details were found on the alerting criteria used.

All studies included had clear outcome measures with a defined sepsis alert and pre- and postalerting stage (Multimedia Appendix 4). Some studies reviewed several outcome measures of interest. All studies were non-ICU based and either alerted in the ED or the hospital wards. In total, 8 studies reviewed the hospital LOS, 5 studies reviewed the ICU LOS, 11 reviewed the mortality outcomes, and 5 studies reviewed the time to antibiotics. Several studies have tried to adjust for potential confounders. Guirgis et al [21] performed multivariate adjusted comparisons, whereas Westra [25] used techniques such as propensity scoring and bootstrapping to adjust for confounders [25]. Each outcome measure is reviewed below in further detail.

Hospital Length of Stay

Hospital LOS was included in eight studies [20,21,23,25,26,28,32,34]. In total, there were 3948 patients in the prealerting group and 4872 patients in the postalerting group across these eight studies. The results highlight a significant reduction in hospital LOS by 1.311 days in the postalerting group (95% CI –2.362 to –0.261; *P*=.014). The proportional decrease in hospital LOS was the study with the biggest impact on LOS, which was Arabi et al [20]. The strong treatment effect seen may be partly explained by the addition of a rapid response team; however, the rapid response team was also used in the study by Guirgis et al [21] and the effect on LOS was not as remarkable.

Intensive Care Unit Length of Stay

For ICU LOS (when patients were escalated from the ward setting), five studies were included [20,21,23,26,32] (Multimedia Appendix 4). In total, 3627 patients were included in the prealerting group and 4475 were included in the postalerting group. The weighted mean difference for all studies showed a significant reduction in ICU LOS by 0.766 days for the alerting group versus the prealerting group (95% CI –1.324 to 0.209; *P*=.007). The biggest impacting study was the one by Arabi et al [20]. This may have been explained by the addition of a rapid response team; however, the rapid response team was also used in the study by Guirgis et al [21] and the effect on LOS was not as remarkable.

Mortality

For mortality, 11 studies were included [20,24,27,28,31,32,34,35]. In total, there were 5868 patients in the prealerting group and 6629 in the postalerting group. There was no significant reduction between digital alerts and mortality (mean decrease 11.4%; 95% CI –0.873 to 0.646; *P*=.77).

Time to Antibiotics

For time to antibiotics, five studies were included [20,23,29,33] (Multimedia Appendix 4). In total, there were 991 patients in the prealerting group and 1473 in the postalerting group. On the basis of three studies with available data, the weighted mean difference in time to antibiotics from the prealerting to the alerting group showed no significant reduction (126 min) in time to antibiotics (95% CI -291.113 to 39.015; *P*=.13).

Diagnostic Accuracy

The diagnostic accuracy of the digital sepsis alerts is shown in Multimedia Appendix 5. Of all the abovementioned studies included in the review, only five studies attempted to address the diagnostic accuracy [24,32]. There was high heterogeneity in the accuracy of alerting in these studies. The specificity of digital alerting in sepsis remained high, with four studies reporting specificities of 81.92% (78.73-84.8 range) [24], 97% [26], 82.0% [25], and 94.56% (93.64-95.32 range) [27]. Although the specificity remained high, the sensitivity showed high heterogeneity: 95.16% (89.77-98.20) [24], 95.2% [25], 87% (81.93-91.66) [27], 80.4% [32], and 16% [26]. The sensitivities and specificities were not given in any other studies. In total, three studies had high negative predictive values of digital alerting and sepsis ranging from 94% [26] to 98.88% (97.58-99.59) [24] and 99.11% (98.69-99.4) [27]. The positive predictive value was much lower at 14.6% [32], 26% [26], 50.21% (43.64-56.78) [24], and 51.64% (46.15-57.11) [27].

Risk of Bias Assessment

All included studies were assessed for the quality of their methodology. All studies had a nonrandomized design methodology, and the NOS was used (Multimedia Appendix 6). Of all studies included, only six were of *higher* quality. Many had poor comparability due to a lack of randomization.

Discussion

Patients with sepsis have high morbidity, mortality, and associated treatment costs [1,7,36].

This review found that digital alerting in sepsis is associated with significant reductions in hospital LOS by 1.311 days (*P*=.014) and ICU LOS by 0.766 days (*P*=.007). Both mortality and time to antibiotics showed no significant differences between the prealerting and postalerting groups.

Reduced hospital LOS and ICU LOS are likely due to earlier diagnosis, improved time to treatments such as antibiotics, earlier fluid replacement, minimized inflammatory cytokines, and cytokine stress. A previous systematic review on the diagnostic accuracy and effectiveness of digital alerts found no improvements in clinical outcomes when digital alerts in sepsis were employed [37]. However, since its publication, there has been a growth in the number of empirical studies on digital alerting and sepsis outcomes, as more hospitals worldwide are transferring to EHRs and digital solutions. All studies identified in this review are recent and after 2010, reflecting the entry of new technology in this field.

This review also identified a wide variation in the diagnosis of sepsis and multiple measures used for this purpose. Many of the studies included in the review have used the SIRS definition of sepsis or a modification of it. This is perhaps because it is the most practical in a clinical setting with readily available vital sign data and laboratory tests. Although SIRS was routinely used as a definition of sepsis, the Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis 3) declared that the use of two or more SIRS criteria in identifying sepsis was not specific enough [3]. The SIRS criteria may be met without infective disease processes, such as trauma [38]. The variation in diagnostic criteria may explain the lack of literature meta-analysis in digital sepsis alerts to date. The ideal alerting criteria required for sepsis in combination with guidance on the latest definitions must be reviewed in further large-scale randomized studies. The ideal sepsis alerts must correctly identify patients with sepsis and exclude those without sepsis. Alerting with low positive predictive value is likely to contribute to alert fatigue, and it is suggested that more sophisticated algorithms may be required to correctly identify patients with sepsis [32]. A recent retrospective comparison of scoring systems found the National Early Warning Score to be more accurate in detecting sepsis as compared with other scoring systems including SIRS [39]. Furthermore, multicenter studies are required to review these findings. In addition to the alert itself, the way the alert is delivered must be reviewed. There is no one best method in the literature to the type of alert to be used and who it needs to be sent to. A combination of EHR, text paging, and mobile alerts have been used in the studies included in this review.

Of all the studies included in the review, only five studies attempted to address diagnostic accuracy [24,32]. There was high heterogeneity in the accuracy of the alerting in these studies. Far more research is required in large studies to elucidate diagnostic accuracy in digital alerting. Although digital alerting in sepsis is beneficial, it is likely that the alerts be used in combination with an application of other resources such as staff education, direct communication for patients with sepsis, and rapid response teams. In one study, 5 months of training in addition to the sepsis alert helped contribute to a reduction in sepsis mortality [24].

Despite the significance of some of the clinical outcomes assessed, our study has limitations due to the variability of methodologies and study types, and most studies scored low on quality. Most of the studies are observational in design, thus creating a high risk of bias. There was a high heterogeneity between the studies, and there were very limited data on the diagnostic accuracy of many of the included results. Furthermore, the pre- and postalerting study design may be prone to selection bias due to variations in the patient population and changes in ways of providing care at hospitals over time. A further limitation of the studies is that the size of the postalerting cohort is larger than that of the prealerting cohort, despite the fact that many of the included studies followed postimplementation cohorts for a shorter period of time than the preimplementation cohort. Although all studies used electronic digital alerting, some studies additionally used a rapid response team and electronic order sets. This may have led to a confounding bias in outcomes.

There are several studies published recently with different study designs to help address some of these concerns. The first is a retrospective cohort study with patients exposed or not exposed to the electronic ICU telemedicine sepsis management in the ED [40]. This is a novel form of alerting using telemedicine. In this study, the exposed cohort had a quicker time to antibiotics than the unexposed cohort (122.3 [SD 83.3] min versus 163.4 [SD 204.4] min; *P*=.04] [40]. However, the hospital LOS and mortality were similar between both cohorts.

Another study design is the use of a prospective quality improvement study [41]. The alerting system was customized to local practice with regularly incorporated feedback through the plan-do-study-act (PDSA) cycles [41]. In this study, a machine learning algorithm was implemented with continuous incorporation of feedback, creating a system tailor made to the hospital workflow [41]. After several PDSA cycles, the machine learning algorithm sepsis mortality reduced by 60.24% with a hospital LOS reduction of 9.55% [41]. The alerting in this study was very different from that in other studies because of the machine learning approach [41]. Although it was not included in the original meta-analysis, the analysis was redone to include this study, and there was no difference in either the hospital LOS (proportional decrease: 11.3%; 95% CI –0.189 to 0.038; *P*=.003) or mortality (mean decrease: 11.4%; 95% CI –0.844 to 0.616; *P*=.76).

Further research should also seek to answer several other important questions such as the optimal type of sepsis alert, which team members should be alerted, and at what frequency should they be alerted. A recent observational cohort study reviewing successive improvements over a 10-year period found that reviewed sepsis alerts were sent to a telephonist and alerts were sent to a nurse's mobile phone [42]. They found that time to antibiotics was reduced to 1 hour (55 min to 1 hour 30 min) when the alert was sent to the telephonist and to 45 min (30 min to 1 hour) when the alert was sent directly to the nurse's mobile phone (*P*=.02) [42].

Further large-scale multicenter prospective randomized controlled trials (RCTs) with a single standardized sepsis alert are required. An RCT would help exclude confounding biases, although implementation maybe challenging. Overall, two recent RCTs have been published; however, both studies had insufficient sample sizes, with insufficient power to detect differences between the prealerting and postalerting groups [43,44]. The results of both RCTs were also contradictory. One RCT on sepsis alerting through EHRs found no significant difference in outcome measures after alerting [43]. However, at least 66% of patients were on antibiotics at the time of the alert, and this high baseline compliance may have led to a lower marginal return on improved detection through alerting and partly explain these findings [43]. The other RCT on the use of machine learning–based sepsis prediction systems supported similar findings to this review with a reduction in hospital LOS by 2.7 days and a mortality reduction of 58% [44].

The cumulative effect of an additional rapid response team, staff education, and electronic order sets alongside digital alerting must also be evaluated. Further studies should also be performed in different clinical health systems, as the value of alerting is likely to depend on baseline performance of health systems. This would aid generalizability and widespread implementation. Importantly, the diagnostic accuracy for the digital alerting in most studies included is unknown and needs to be clearly defined in future work to ascertain the validity of findings. Finally, the cost-effectiveness of digital sepsis alerts also needs further evaluation if we are to justify its use in the current fiscal climate.

Automated digital alerts can improve sepsis-related outcomes. This review highlights a significant reduction in hospital LOS by 1.311 days and ICU LOS by 0.766 days. The emergence of digital technologies has the capacity to transform the rapid identification of patient physiological deterioration and, in turn, revolutionize patient care through alerts and novel treatment innovations (such as *smart wards)*. Higher-quality evidence through larger, better-designed randomized studies is needed to guide the application of digital alerting in patients at risk of sepsis.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Search strategy.
[DOCX File , 14 KB - jmir_v21i12e15166_app1.docx]

Multimedia Appendix 2
Preferred Reporting Items for Systematic Reviews and Meta-analyses flow diagram.
[DOCX File , 38 KB - jmir_v21i12e15166_app2.docx]

Multimedia Appendix 3
Characterization of studies and digital alerts used.
[DOCX File , 23 KB - jmir_v21i12e15166_app3.docx]

Multimedia Appendix 4
All studies reviewing outcome measures.
[DOCX File , 21 KB - jmir_v21i12e15166_app4.docx]

Multimedia Appendix 5
Diagnostic accuracy.
[DOCX File , 20 KB - jmir_v21i12e15166_app5.docx]

Multimedia Appendix 6
Risk of bias of a nonrandomized prospective comparative cohort comparing pre and postalerting based on the Newcastle-Ottawa Scale.
[DOCX File , 15 KB - jmir_v21i12e15166_app6.docx]

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Abbreviations

BRC: Biomedical Research Centre
ED: emergency department
EHR: electronic health record
ICU: intensive care unit
LOS: length of stay
NOS: Newcastle-Ottawa scale
NIHR: National Institute for Health Research
PDSA: plan-do-study-act
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-analyses
PSTRC: Patient Safety Translational Research Centre
RCT: randomized controlled trial
SBP: systolic blood pressure
SOFA: sequential organ failure assessment
SIRS: systemic inflammatory response syndrome

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Original Paper

Attitudes Toward Health Care Virtual Communities of Practice: Survey Among Health Care Workers

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Abstract

Background: Virtual communities of practice (VCoPs) have been shown to be an effective means for knowledge and research uptake, but little is known about why health care workers choose to use them. The elaboration likelihood model (ELM) is a theoretical model of persuasion that distinguishes between different routes of information processing that influence attitude formation and change. To date, no research has investigated the antecedents to these processing routes for VCoPs within a health care setting. In understanding these determinants, VCoPs can be appropriately designed to increase their chances of use and value among health care professionals.

Objective: Our aim is to explore how motivation and ability affect attitudes toward using VCoPs for those working in health care.

Methods: Data were collected from 86 health care workers using an online survey at two Canadian health care conferences. Participants were shown a mock VCoP and asked about their perceptions of the online platform and related technologies. The survey instrument was developed based on previously validated scales to measure participants' ability and motivation toward using a VCoP. Attitudes were assessed both at the beginning and end of the study; intention to use the platform was assessed at the end.

Results: Ability (expertise with CoPs and VCoPs) was found to directly affect intention to use the system ($P<.001$ and $P=.009$, respectively) as was motivation ($P<.001$). Argument quality had the greatest effect on formed attitudes toward VCoPs, regardless of the user's level of experience (lower expertise: $P=.04$; higher expertise: $P=.003$). Those with higher levels of CoPs expertise were also influenced by peripheral cues of source credibility ($P=.005$ for attitude formation and intention to use the system) and connectedness ($P=.04$ for attitude formation; $P=.008$ for intention to use the system), whereas those with lower levels of CoP expertise were not ($P>.05$). A significant correlation between formed attitude and intention to use the VCoPs system was found for those with higher levels of expertise ($P<.001$).

Conclusions: This research found that both user ability and motivation play an important and positive role in the attitude toward and adoption of health care VCoPs. Unlike previous ELM research, evidence-based arguments were found to be an effective messaging tactic for improving attitudes toward VCoPs for health care professionals with both high and low levels of expertise. Understanding these factors that influence the attitudes of VCoPs can provide insight into how to best design and position such systems to encourage their effective use among health care professionals.

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KEYWORDS

virtual community of practice; eHealth; digital health; knowledge translation; implementation science; elaboration likelihood model; technology adoption

Introduction

Motivation and Background

Health care in Canada remains fragmented regarding access and delivery. As a result, there is a growing push to enhance integration across sectors, locations, and providers to improve patient experience [1]. This includes greater recognition of the need to improve information sharing and enhanced communication to meet these needs [1]. One way to achieve these goals is through communities of practice (CoPs), which are increasingly used in health care as a means of advancing knowledge use and creation through collaborative learning [2,3]. A CoP is defined as "a group of people who share a concern, a set of problems, or a passion about a topic, and who deepen their knowledge and expertise in this area by interacting on an ongoing basis" [4].

A CoP becomes a virtual community of practice (VCoP) when its members use information and communication technologies (ICTs) as their primary means for collaboration and communication. Although VCoPs do not exclude face-to-face meetings, ICT help to overcome geographic and organizational barriers, thereby increasing the efficiency of information sharing [5]. In a health care context, VCoPs allow their members to access information relevant to their practice on an as-needed basis [6], facilitate problem solving through active debate and integration of differing perspectives [7], and enable health care providers to efficiently stay up-to-date on the increasing medical evidence base and share newly acquired information with their peers [8]. However, it is important to note that relevant content is necessary to maintain engagement among VCoP members, which can quickly become outdated due to the rapidly changing evidence base and policies present in health care [7]. Additionally, many VCoP members prefer to observe and not participate, whereas some clinicians prefer to communicate only with members of their own specialty, thus limiting the potential to advance interprofessional knowledge [7,9]. Overall, research has demonstrated the effectiveness of these VCoPs for health care quality improvement, but little is known about how and why users choose to adopt technology to support CoPs [9-11]. Further, technology adoption in health care is subject to unique factors and influences [12]. To ensure the successful implementation of such a technology, it is important to understand the factors influencing the decision to use it.

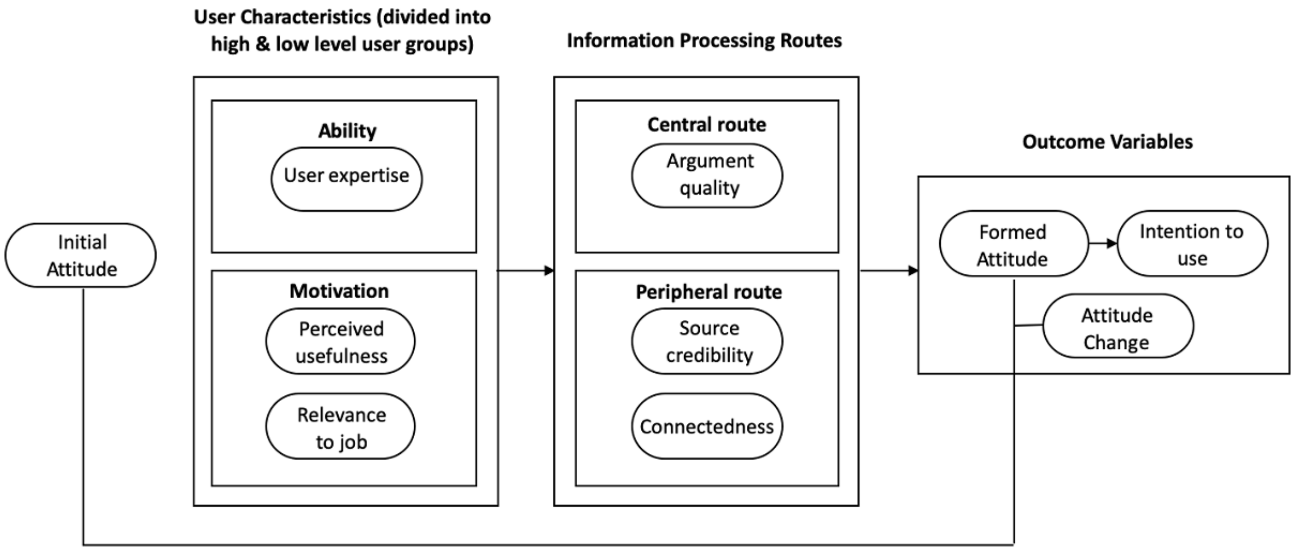
Theoretical Framework

Understanding the process by which intentions to use a platform such as a VCoP are formed is necessary, and the elaboration likelihood model (ELM) [13] provides a promising conceptual framework through which to study this. The ELM [13] is a model of persuasion that posits that users process given information (or "elaborate") based on their level of motivation and ability related to the issue at hand, leading to attitude formation and change. When information processing leads to a change in attitude, this is referred to as *persuasion* [14]. Widely validated as a framework in psychology and marketing (eg, [15]), the ELM is considered the foremost influential model used to study attitude formation and change [16].

Persuasion theories are based on the assumption that individuals process the same messages with varying levels of effort [17]. The ELM is a dual-process model that posits two routes of information processing that differ based on extent (more versus less) of processing [18]: (1) the central route, where users are highly motivated or able and are influenced by argument quality, and (2) the peripheral route, where users are not as highly motivated or able and are influenced by more superficial factors, such as the likability of the endorser, source credibility, and message medium. Attitudes formed through the latter process tend to be less stable over time [19].

The ELM was used to guide this study. This model suggests that a person's characteristics of motivation and ability determine the route through which they process information and form attitudes, leading to their intention to use the system [20]. As such, antecedents to VCoP processing routes have been divided into two broad categories: (1) ability (operationalized through four types of user experience or expertise) and (2) motivation to use the technology (operationalized through the constructs of relevance to job and perceived usefulness). The ELM also suggests that differing levels of ability and motivation may influence information processing and outcome variables, such as attitude formation and change as well as intention to use. Thus, we further investigated these antecedents by separating them into high and low levels for each user characteristic. Our research model built off of the ELM framework is shown in Figure 1.

Figure 1. Research model to investigate attitudes and intention to use health care virtual community of practice.



Ability (User Expertise)

Expertise can refer to domain expertise (ie, understanding of health care) or system expertise (ie, ability to use a VCoP system in general). The focus of this paper is on system expertise because the VCoP target users are health care workers who possess health care domain expertise. According to Bhattacherjee and Sanford [18], system experts are more inclined to critically appraise messaging to inform system attitudes and acceptance. They are more aware of the possibility of bias and inaccuracy in messaging, whereas users with lower levels of expertise tend to rely more on peripheral cues, rather than embedded message arguments, to form their opinions [18]. Thus, user expertise influences the extent of elaboration because it affects an individual's ability to process information relating to the system [20,21].

Motivation

Perceived Usefulness

Perceived usefulness is a function of productivity, performance, effectiveness, and overall usefulness of an object [18,22]. When there is a match between the user's needs and what the source offers, the user's motivation to process the message increases because it is deemed to be useful. Highly motivated users are more likely to elaborate on what the source is saying [23] and are more likely to distinguish between strong and weak arguments [19]. Strong arguments for these highly motivated individuals increase positive attitudes, whereas weak arguments result in a decrease in positive attitudes [19]. Those that perceive low usefulness will not expend the same effort on message elaboration as those that perceive high usefulness. In the context of health care, the perceived usefulness of technology has been shown to impact clinicians' motivation to accept and use the technology [24].

Relevance to Job

Job relevance is defined by Bhattacherjee and Sanford [18] as the system's relevance to the user's work. To clarify the intended application of this term, our study used "relevance to job" to minimize confusion. Systems perceived to be highly relevant to one's work tend to be subject to greater elaboration and scrutiny of related messaging. Users that perceive systems to have high relevance to their job are less likely to pay attention to peripheral cues, whereas those that perceive low relevance to job will not be motivated to dedicate effort to thoughtful processing and will rely on other, peripheral cues to shape their attitudes toward a system [18].

We examine how these antecedents affect attitudes toward, and intention to use, a VCoP system through the mediating routes of persuasion. Descriptions of the constructs used to represent these routes of persuasion are presented subsequently.

Central Route of Persuasion (Argument Quality)

Quality arguments are those viewed as informative, helpful, valuable, and persuasive [18,21]. As documented in the extant literature [18,21,25], argument quality is used to represent the central route to persuasion. ELM considers argument quality to be the determining factor for whether information is influential when in a state of high elaboration [21]; argument quality has a greater impact on attitudes for those in a state of high elaboration than in low elaboration [26].

Our study presented high-quality arguments as six positively framed arguments (as listed in Table A1 in Multimedia Appendix 1), which Angst and Agarwal [14] have defined as those that contain both credible content and beneficial outcomes. Applied to a VCoP context, an example of such an argument could be:

> *Virtual communities of practice (VCoPs) have been shown to facilitate development of an innovative patient-focused integration of medical, social, and supportive services by health-care organizations, while allowing health-care providers to use their energy and time more efficiently and provide care that is collaborative and cost-effective.* [6]

The quality of the argument is found to be more persuasive under conditions of high relevance compared with low relevance [19]. When issues are perceived to be of high relevance, if arguments are strong, then increasing the number of arguments increases persuasion [19]. However, if the quality of the argument is weak, this reduces their persuasive effect [19]. In contrast, when issues are perceived to be of low relevance, more messages (regardless of their quality) serve as a peripheral cue signaling worthiness of the message and positively affect persuasion [19,26].

Peripheral Route of Persuasion

Source Credibility

This construct refers to the perceived credibility of the message source but does not consider the message content itself [21,27]. Source credibility assesses the source's knowledgeability, expertise, trustworthiness, and credibility [18,21]. It is considered a peripheral cue because source credibility is expected to be more important for those who are not experts [21]. For such individuals, the presence of source credibility could increase the favorability of an argument, and could even bias how the quality of the argument is perceived [21,28]. In a health care context, source credibility may be exhibited through a colleague's opinion, a viewpoint from an opinion leader in the domain, or the organization affiliated with the product or system.

Connectedness

As a design element, connectedness is defined as the extent to which website visitors are able to express their views, benefit from the community of visitors to the website, and share a common bond with website visitors [25]. It is considered a peripheral cue because it does not pertain to the message content itself. Although classified and validated as a peripheral cue in a traditional information systems context [25], connectedness has not been investigated as a peripheral cue in a VCoP context. User satisfaction and knowledge self-efficacy (feeling knowledgeable and capable of helping others) have been shown to positively affect continued participation in VCoPs [29]; therefore, it is important that community members feel that their opinions matter and that they have influence on the group. Within CoPs, connection to other members and the value derived from them sustain the community's activities [4]. Within a broader online context, a sense of connectedness with other participants or consumers has been shown to positively impact trust [30,31], willingness to return, and become loyal to the site [32-34]. These are necessary considerations for the continued usage of VCoPs.

Research Question

Virtual CoPs are known to benefit health care workers [6,7,35-37]. However, the factors influencing their adoption of the technology to support them are not well understood [8,36]. Although past research has shown that the ELM's central and peripheral routes influence attitude formation and change, and ultimately the intention to use an information system, our research seeks to gain insight into the potential antecedents of these two routes of processing among health care workers for VCoPs. To date, no research has investigated these precursors in this context. By understanding what influences these two persuasion routes, we can better understand how to design and position a virtual CoP for health care workers to encourage their use.

Thus, using ELM as a guiding framework, this research seeks to investigate the following question: For those working in health care, how does motivation and ability affect attitudes toward using VCoPs?

Methods

Sample and Procedure

Participants in this study were adults older than 18 years working in the health care system (either as a clinician, administrator, researcher, or nonclinical staff). This study aimed to determine how motivation and ability affect an individual's attitudes toward health care technology adoption (specifically VCoPs); therefore, it was necessary that the participants worked in health care.

Surveys were administered at two large health care conferences that took place in Toronto during October 2016. The conferences were one day apart and had a total of approximately 3000 attendees who were predominantly health care providers, administrators, and academics. A confidence interval of 90% with a 10% margin of error was used to calculate a minimum sample size of 67 [38].

Data were collected using online surveys conducted on laptops at the conferences. Postcards (providing a link to the survey) also were handed out at the conferences for those who wished to complete the survey following the conference. There was no compensation for participation.

After an initial screening question to ensure that the participant worked in health care, each participant's consent was obtained via a detailed consent form. They were then asked a series of questions regarding their knowledge of VCoPs and related technologies, and they were asked to evaluate a mock website interface of the home page and two subpages of a proposed virtual CoP. These mock-ups were used to provide participants with a sense of what a VCoP would look like and allow for visualization of our central and peripheral cues of investigation (argument quality, source credibility, and connectedness). Participants were then asked questions about their perceptions of the VCoP, which included argument quality (the strength of an informational message's arguments), source credibility (the expertise of people providing endorsements), connectedness, and their attitude toward and intention to use such a system.

Instrument

The survey contained 25 closed-ended questions, 3 open-ended questions, and 5 demographic questions. On average, it took participants approximately 15 minutes to complete the survey. To ensure content validity, measurement scales were selected from existing literature where they had been prevalidated. Some of the questions were slightly adapted to reflect the context of this study; all items were assessed using 7-point Likert scales for their respective questions. The full measurement instrument can be found in Multimedia Appendix 1. Based on previous research [18], the concept of ability was operationalized as user expertise across four areas (expertise with social networks, electronic medical records [EMRs], CoPs, and VCoPs). Motivation was represented through the constructs of relevance to job and perceived usefulness [18]. The two routes of persuasion are represented through argument quality (central route) and source credibility and connectedness (peripheral route) and were measured in alignment with extant ELM research [14,18,25]. Attitudes were assessed both at the beginning (initial attitude) and end (formed attitude) of the study to enable the examination of attitude change [14,18,39]. Finally, the intention to use such a platform was measured using a one-item scale (as per [18,39]).

The three open-ended questions probed further into understanding health care workers' perceptions of VCoPs ("What would encourage you to use a VCoP?"; "What barriers would prevent you from using a VCoP?"; and "What helped you form your attitude toward the VCoP?"). Answers to these open-ended questions helped to provide insights to our interpretation of the closed-ended survey results. The demographic questions (age, gender, job title, sector, and education) were used to ensure our sample was representative of the broader health care worker population and to examine potential effects on the primary constructs of interest.

Analysis Strategy

To examine the proposed research model, the following steps were conducted: (1) the direct effects of user characteristics (ability and motivation) were examined on outcome variables (formed attitude, attitude change, and intention to use); (2) user characteristic constructs were divided into high- and low-level groups (ie, high and low levels of ability or expertise as well as motivation) and these groups were examined for their effects on outcome variables; and (3) based on the findings from step 2, high- and low-level groups of user characteristics were examined across information processing routes (central and peripheral) for their effects on the outcome variables.

Spearman rho correlations were used to test relationships between variables in the research model. The decision to use a nonparametric test was made because the outcomes of interest were found to violate the assumption of normality when using Shapiro-Wilk normality. This research introduced a new health care context to apply the ELM to investigate attitude formation toward VCoP; therefore, correlation was deemed an appropriate test for examining what, if any, potential relationships existed between the antecedents, persuasion routes, and outcomes.

The antecedent constructs for ability (user expertise) and motivation (relevance to job and perceived usefulness) were divided into higher (≥5 on a 7-point scale) and lower (≤3 on a 7-point scale) user groups. Answers of 4 (on a 7-point scale) were not included in this analysis to create a distinct separation of user groups for the analysis and to increase the rigorousness of the analysis.

Data were analyzed using JGR version 1.7-16 statistical software, which is an open-source graphical user interface for R. The total number of participants for the online survey was 88, from which two respondents were removed for insufficient responses to questions. This exceeded our minimum sample size requirement of 67.

Results

Participant Characteristics

Full demographic information of the participants is provided in Table 1. The mean age of participants was 39.98 (SD 10.84) years**,** reflective of the average age (ie, 43) of the health care workforce [40]. Females made up 70% (58/86) of the sample. According to the Canadian Institute for Health Information, 80% of Canadian health care workers are female [40].

Table 1. Characteristics of the participants who completed the online survey (N=86).

Characteristic	Participants
Age (years; N=76), mean (SD)	39.98 (10.84)
Gender (N=83), n (%)	
Female	58 (70)
Male	25 (30)
Primary job title, n (%)	
Physician	5 (6)
Nurse	8 (9)
Allied health professional	3 (4)
Administrator	26 (30)
Nonclinical staff	9 (10)
Researcher	3 (4)
Student	3 (4)
Other	27 (31)
Unknown[a]	2 (2)
Primary sector, n (%)	
Academia	3 (4)
Association	1 (1)
Community mental health and addictions	2 (2)
Government	20 (23)
Home and community care	6 (7)
Hospital	23 (27)
Industry	2 (2)
Long-term care	9 (10)
Primary care	7 (8)
Other	11 (13)
Unknown[a]	2 (2)
Education, n (%)	
Some high school or less	0 (0)
Completed high school or GED	0 (0)
Some college	0 (0)
College diploma	3 (4)
Undergrad or bachelor’s degree	27 (31)
Master’s degree	39 (45)
Beyond master’s	10 (12)
Other[b]	5 (6)
Unknown[a]	2 (2)

[a] Unknown: participant did not provide answer.

[b] Other: PhD (n=2); current master’s student (n=1); postgraduate master’s certificate (n=1); MD, CCFP, FCF (n=1).

Scale Validation

With the exception of user expertise and intention to use, all constructs in this research are reflective in nature. They were each measured by multiple survey questions (items) in which these items were expected to correlate with one another and share a common theme. User expertise probed into self-reported experience with technologies and forums relevant to this investigation and was not necessarily expected to correlate. Intention to use was measured using a single item adapted from Bhattacherjee and Sanford [18]. To measure the internal consistency of the reflective constructs in our survey instrument, Cronbach alphas were assessed, which all met the recommended threshold of 0.70 [41]. Multimedia Appendix 2 provides details of our scale validation.

Key Findings

Table 2 provides the results of the first step of our analysis in which the direct effects of user characteristics (ability and motivation) were examined on outcome variables (attitude change, formed attitude, and intention to use). Both motivation constructs of perceived usefulness and relevance to job were significantly correlated with formed attitude and intention to use (*P*<.001). Unlike the user expertise construct, there were no significant correlations with motivational constructs and attitude change.

Table 2. Direct influence of user characteristic antecedents on outcomes (N=86).

Characteristic	Attitude change		Formed attitude		Intention to use	
	Spearman rho	*P* value	Spearman rho	*P* value	Spearman rho	*P* value
User expertise						
Online social networks	−0.104	.34	0.112	.30	0.164	.13
Electronic medical records	−0.060	.58	−0.004	.97	0.076	.49
Communities of practice (CoPs)	−0.215	.047	0.165	.13	0.362	.001
Virtual communities of practice (VCoPs)	−0.222	.04	0.068	.53	0.279	.009
Perceived usefulness	0.022	.84	0.349	.001	0.512	.001
Relevance to job	0.000	.99	0.385	.001	0.428	.001

The second step of our analysis separated both ability and motivation user characteristics into higher- and lower-level groups (higher group: >4 on 7-point Likert scale; lower group: <4 on 7-point Likert scale) to examine for their effects on outcome variables. For the motivation user characteristics (relevance to job and perceived usefulness constructs), the vast majority of participants fell into the higher category. Similarly, most participants fell into the higher category for their familiarity with online social networks and EMRs. Thus, meaningful comparisons across high and low levels of these motivation constructs and the first two experience items were not possible. However, CoPs and VCoPs expertise did reveal differences between low- and high-expertise groups. Higher expertise users for both CoPs and VCoPs exhibited greater intention to use a health care VCoP than those with lower expertise ($F_{1,56}$=7.800, *P*=.007; $F_{1,67}$=6.199, *P*=.02, respectively). When examining high and low group differences for attitude change, expertise with CoPs stood out in terms of its significance ($F_{1,54}$=5.006, *P*=.03) between higher- and lower-level experience groups (n=45 and n=30, respectively).

The third step of our analysis involved delving more deeply into the significant results of the previous step by examining high- and low-level groups of user characteristics (specifically, CoPs expertise) across information processing routes (central and peripheral) for their effects on outcome variables. As shown in Table 3, central route cues (operationalized as argument quality) were the most important persuasion route for both those with higher and lower levels of expertise. Those with higher levels of CoPs expertise were also influenced by peripheral cues of source credibility (*P*=.005 for formed attitude and intention to use the system) and connectedness (*P*=.04 for formed attitude; *P*=.008 for intention to use the system), whereas those with lower levels of CoPs expertise were not (*P*>.05).

Table 3. Impact of persuasion routes on outcomes by expertise level (N=75).

Expertise level	Argument quality		Source credibility		Connectedness		Formed attitude	
	Spearman rho	*P* value	Spearman rho	*P* value	Spearman rho	*P* value	Spearman rho	*P* value
Lower (n=30)								
Attitude change	−0.233	.22	0.131	.49	0.214	.26	0.237	.21
Formed attitude	0.377	.04	0.109	.56	0.189	.32		
Intention to use	0.413	.02	0.118	.53	0.203	.28	0.187	.32
Higher (n=45)								
Attitude change	0.193	.20	0.193	.20	0.232	.12	0.290	.05
Formed attitude	0.433	.003	0.412	.005	0.314	.04		
Intention to use	0.440	.003	0.416	.005	0.392	.008	0.554	<.001

Discussion

Principal Results

Using the ELM framework, this research found that both ability and motivation play an important and positive role in the adoption of health care VCoPs. Health care workers that perceived the VCoP to be useful and relevant to their job (motivation constructs) had a significantly more positive attitude formation toward and intention to use the system. These motivation constructs were more strongly (positively) correlated with argument quality than they were with the peripheral cues of source credibility and connectedness.

For user expertise (ability construct), familiarity with online social networks and EMRs did not play a role in the perceptions and adoption of a VCoP; however, experience with CoPs and VCoPs both had statistically significant negative correlations with attitude change. This means that the higher the experience level, the smaller the change in attitude after experiencing our experimental VCoP. Conversely, the lower the experience level with CoPs and VCoPs, the larger the change in attitude.

Health care workers with higher CoPs and VCoPs expertise exhibited greater intention to use a health care VCoP than those with lower expertise. As expected, these higher and lower levels of expertise groups differed in their processing routes. Although the central processing route (operationalized as argument quality) was the most important persuasion route for both levels of CoPs expertise, those with higher levels of expertise were also influenced by peripheral cues of source credibility and connectedness.

Connections to Previous Work

To date, the application of ELM to the field of eHealth remains limited and has been from the patient perspective and not the provider [14]. This study was the first to apply ELM to investigate attitude formation toward VCoPs for those working in health care and quality improvement. Although connectedness has been investigated as an ELM peripheral cue for traditional information systems [25], our study is the first to include this construct when investigating VCoPs in health care. Additionally, the investigation of antecedents to the validated concepts of central and peripheral routes to persuasion for health care VCoPs is novel. Thus, when compared with extant research on health care VCoPs, this study presents a unique population (health care providers) and provides insights through new constructs of investigation in this context (ability and motivation antecedents as well as the connectedness construct).

The results of this study confirmed previous ELM work that showed the importance of central and peripheral routes of persuasion for attitude formation or change and intention to use ICTs [13,14,18,29]. The importance of argument quality as a central route to persuasion was validated [18,21,25]. Surprisingly, argument quality, traditionally found most effective in persuading those in states of high elaboration [21,26], was found to be an effective influencer on attitude formation for both those with higher and lower levels of CoP expertise (ie, both high and low elaboration states).

Another interesting and surprising result related to expertise (specifically CoP expertise) was that attitude formation of those with low levels of CoP user expertise was most influenced by central rather than peripheral routes of persuasion. Connectedness and source credibility, traditionally seen as peripheral cues [18,25], were only significantly correlated with formed attitude for those with high levels of CoP user expertise. The most important factor contributing to positive attitudes for those with low levels of CoP user expertise was the central route, operationalized as argument quality. This conflicts with extant ELM research in non-health care contexts that found peripheral cues to most influence those in states of lower elaboration. Specifically, previous work has found that users with lower levels of system expertise tend to rely more on peripheral cues, rather than embedded message arguments, to form their opinions [18].

Implications

Rolls et al [9] found that those working in health care see virtual communities as a source for relevant clinical information to inform their clinical decision making, especially given the limited communication channels, which are a known barrier to translating research into practice. The potential for such systems to improve health care quality has been demonstrated, but little is known about how and why health care workers adopt technologies to support CoPs [9-11]. This research helps us to understand the factors influencing the use of health care VCoPs, thus providing a basis for understanding how to best design and position such systems to encourage their effective use among health care workers.

Our research showed that health care user motivation (perceived usefulness and relevance to job) has a positive impact on one’s formed attitude and intention to use health care VCoPs. Although there were no significant correlations between motivational constructs and attitude change, this is not surprising given the overall high rating of these two constructs in our sample. The health care workers in our study were already highly motivated (saw VCoPs as being useful and relevant to their jobs); therefore, there were no significant differences between pre and post measures of attitude. The association of high motivation with strong attitudes and intention to use highlights the importance of these factors in determining the likelihood of the technology’s success in a health care context. The implication is that manipulation of these factors, such as through leadership and organizational support to socialize and normalize the value of CoPs and VCoPs (for relevance to job and perceived usefulness), may offer a promising approach to improve their likelihood of adoption.

For ability (specifically, experience with CoPs and VCoPs), our research showed that this factor directly affects attitude change or intention to use VCoPs. Unlike motivation constructs, there was a broad range of prior expertise with CoPs and VCoPs in our sample. As our results show, health care workers with less prior experience with such systems experience a significantly positive attitude change toward these systems through initial exposure. Thus, this initial exposure to gain familiarity with VCoPs is an important opportunity for practitioners to establish positive attitudes toward such systems among health care workers. Further, the strong correlation found between attitudes and intention to use the system for those with higher levels of expertise highlights the importance of understanding how to change attitudes, and thus intention to use, among those with lower levels of expertise.

Although experience with CoPs and VCoPs provides interesting insights in establishing positive attitudes for health care VCoPs, the other two ability items (expertise with online social networks and EMRs) did not reveal any significant correlations. One explanation for this result may be that these particular items were not as applicable to this context given their high level of experience and expertise with the health care sample. These two items could not be separated into high and low expertise levels because everyone was highly familiar with these systems. Online social networks have now become commonplace; therefore, their relevance or ability to impact attitudes for other types of systems has diminished. If everyone is highly experienced with this technology, it may no longer be an effective predictor for acceptance of another technology. Although EMRs are a more specific technology, the same could be argued for its understanding and skillfulness among health care professionals. All health care professionals in our sample were highly familiar with EMRs; therefore, it no longer proved to be a predictor for acceptance of VCoPs. The implication is that these two expertise items may no longer be relevant to today's health care professionals in examining VCoPs technology acceptance.

Although the findings about the processing routes by level of expertise run counter to ELM theory, the highly educated participants and the nature of their work are reflective of an evidence-minded study population. Given the importance of evidence for health care, these research findings are not surprising but do hold important clues for how to effectively appeal to different levels of user expertise. Rather than using source credibility and connectedness for those yet to experience the system, providing evidence of the system's effectiveness is a promising tactic to use. Once persuaded to use the system, other messaging cues, such as the credibility of the source and the interface's sense of connectedness, can be used to further entrench attitudes and strengthen the intention to use. Through the insights gained about the unique antecedents to attitude formation in health care, the design and messaging can be improved to appeal to those experienced with CoPs in their traditional offline form to translate this experience to usage of an online environment. For both those with higher and lower levels of expertise, evidence-based arguments are indeed an effective messaging tactic to improving attitudes toward VCoPs.

Given the novelty of VCoPs for quality improvement in health care in Canada, this research provides needed insight into effective messaging to increase the technology's uptake and use. The relative newness of this technology for health care means opinions are not long-held; therefore, exposure to related information determines attitudes regarding its usage. To derive the maximum benefit from existing government expenditure and investment in eHealth, it is crucial to capitalize on this period when attitudes are being formed to create positive attitude changes. Increasing the capacity for sharing of evidence-based knowledge to support its implementation requires changes to structures and processes, which VCoPs have been shown to address effectively. Thus, improving the usage and adoption of VCoPs warrants investigation of the factors influencing attitudes toward such platforms. This study has provided insight into the antecedents to attitude formation, and the differences in influential factors between those with higher and lower levels of expertise.

Limitations and Future Research Directions

It is acknowledged that the conferences at which this study's surveys were administered may have biased the sample. Given that the conference participants were already actively involved in health care quality improvement by nature of their attendance, they may already have been "converted" to such concepts as CoPs. However, as this represents the target audience for such a technology, these research findings can have greater contextual relevance.

Other potential limitations are the environment in which the surveys took place and the length of the survey. Survey booths were located in high-traffic areas, and the majority of participants completed the survey during break periods; therefore, the potential for distraction as an external influence is recognized.

Another limitation is that this investigation was conducted in a Canadian context, in which health care is predominantly public based. Thus, these results may not be immediately transferrable to countries that have different health care systems or different socioeconomic, demographic, or cultural characteristics.

This study provides an important stepping stone to understand how attitudes of health care workers are formed for virtual communities of practice. There are several opportunities for future research to help deepen our understanding and further generalize our results. First, there is an opportunity to broaden the sample across different venues and contexts of health care. Venues that target different types of health care workers may allow for some interesting comparisons across professions (for example, physicians versus nurses versus administrators). Sampling across health care systems may also reveal some insights unique to public and private systems. Second, this study focused on the preusage stage of VCoPs, seeking to understand the factors that influence attitudes toward and intention to use such systems. Although participants had an opportunity to view a system mock-up from which they based their preusage survey responses, a longitudinal investigation of actual VCoP interaction may reveal insights to encourage continued usage. Finally, there are several other antecedents that could impact persuasion routes of attitude formation and change for VCoPs. This study focused on user experience, perceived usefulness, and relevance to job as ability and motivation factors. Research in non-health care contexts has shown that privacy, social influence, argument framing, and individual characteristics (age, gender, personality) may impact attitude formation or change and intention to use such systems. Future studies can explore the potential impact of these other types of variables.

Conclusion

Although ELM's framing of the central and peripheral routes to persuasion have been shown to influence attitude formation and change, and ultimately intention to use, this research gathered insights into potential antecedents of these two routes. By understanding what influences these two routes, we can better understand how to design and position a virtual CoP for health care practitioners.

There are challenges in bringing evidence into practice in health care [42]; however, this research highlights an exciting opportunity to translate research findings through peer knowledge-sharing in a trusting, online environment. Showcasing VCoPs value to members through the interface and eventual effects on practice will be a necessary future endeavor to ensure continued usage, and warrants further investigation. Health care resources are increasingly stretched. Enabling effective collaboration through VCoPs will contribute positively to fostering a culture of health care quality improvement.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Survey instrument.
[DOCX File , 22 KB - jmir_v21i12e15176_app1.docx]

Multimedia Appendix 2
Scale validation.
[DOCX File , 16 KB - jmir_v21i12e15176_app2.docx]

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Abbreviations

CoP: community of practice
EHR: electronic health record
ELM: elaboration likelihood model
ICT: information and communications technology
VCoP: virtual community of practice

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Original Paper

Clinically Meaningful Use of Mental Health Apps and its Effects on Depression: Mixed Methods Study

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Abstract

Background: User engagement is key to the effectiveness of digital mental health interventions. Considerable research has examined the clinical outcomes of overall engagement with mental health apps (eg, frequency and duration of app use). However, few studies have examined how specific app use behaviors can drive change in outcomes. Understanding the clinical outcomes of more nuanced app use could inform the design of mental health apps that are more clinically effective to users.

Objective: This study aimed to classify user behaviors in a suite of mental health apps and examine how different types of app use are related to depression and anxiety outcomes. We also compare the clinical outcomes of specific types of app use with those of generic app use (ie, intensity and duration of app use) to understand what aspects of app use may drive symptom improvement.

Methods: We conducted a secondary analysis of system use data from an 8-week randomized trial of a suite of 13 mental health apps. We categorized app use behaviors through a mixed methods analysis combining qualitative content analysis and principal component analysis. Regression analyses were used to assess the association between app use and levels of depression and anxiety at the end of treatment.

Results: A total of 3 distinct clusters of app use behaviors were identified: learning, goal setting, and self-tracking. Each specific behavior had varied effects on outcomes. Participants who engaged in self-tracking experienced reduced depression symptoms, and those who engaged with learning and goal setting at a moderate level (ie, not too much or not too little) also had an improvement in depression. Notably, the combination of these 3 types of behaviors, what we termed “clinically meaningful use,” accounted for roughly the same amount of variance as explained by the overall intensity of app use (ie, total number of app use sessions). This suggests that our categorization of app use behaviors succeeded in capturing app use associated with better outcomes. However, anxiety outcomes were neither associated with specific behaviors nor generic app use.

Conclusions: This study presents the first granular examination of user interactions with mental health apps and their effects on mental health outcomes. It has important implications for the design of mobile health interventions that aim to achieve greater user engagement and improved clinical efficacy.

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KEYWORDS

mHealth; mobile apps; mental health; engagement

Introduction

Over the past decade, mobile phone apps have become portals for managing health. These digital tools help users monitor physical activity, plan healthy meals, and keep track of daily moods and other personal data. Given the accessibility and ubiquity of mobile phones, researchers and clinicians have increasingly leveraged mobile phone apps to deliver health interventions and enhance self-management of chronic conditions such as depression and anxiety [1-4]. Mental health apps can enhance skill building, deliver psychoeducation, and facilitate self-monitoring, thereby reducing symptoms of depression and anxiety [2,5,6]. These mobile technologies incorporate a wide array of system features and strategies that foster user engagement and promote behavior change, such as customization, reminders, self-monitoring, rewards, and peer support [3,7-10].

For mental health apps to be effective and successful, user engagement is critical. However, little consensus exists on how to define and measure engagement [11-13]. Engagement has been inconsistently viewed as a multidimensional construct, variably encompassing behavioral, emotional, and cognitive factors [14,15]. Consequently, engagement measures vary enormously, ranging from self-report questionnaires to system usage data or sensor data [16,17]. In this study, we define user engagement as a behavioral experience that involves people’s physical interaction with mobile phone apps [18]. System usage data are the most commonly used behavioral measures of engagement in mobile health (mHealth) interventions, as they can be acquired in the course of app use and require no additional effort from the user [14]. These data quantitatively capture how users physically interact with the app in terms of intensity (eg, number of app use sessions [19]), frequency (eg, number/percentage of days the app is used [20]), duration (eg, time spent on the app [21,22]), time between first and last app use [19,20]), and types (eg, passive, active, reflective, and didactic [23,24]). These measures of behavioral engagement have been found to be related to health outcomes such as psychological well-being [20,22].

However, behavioral engagement metrics have typically employed broad use metrics that measure the *quantity* of engagement. Few studies have examined more granular user interactions with specific components of mHealth interventions, which might provide insight into *how* a person is using an app in ways that are clinically meaningful [25]. For example, a user might simply open an app in response to a prompt without any deeper engagement, whereas others might engage in more meaningful activities such as inputting or reflecting on data and reading content. These different types of activities might reflect differing levels and types of engagement, resulting in various health outcomes. Identifying the types of user behaviors could provide insight into what aspects of mHealth interventions are engaging to users and what aspects may drive behavior change and symptom improvement [15,26]. This could also inform opportunities for designing more engaging and clinically effective mHealth interventions.

This study aimed to provide a categorization of the types of user behaviors in a suite of mental health apps for depression and anxiety. We then examine how the different types of app use are related to improvements in symptoms of depression and anxiety. To provide a holistic picture of app use, we also differentiate the more nuanced app use from generic app use (ie, intensity and duration of app use) and examine how these different use metrics influence outcomes. As such, this study presents the first granular classification of user interactions with mental health apps and their impact on outcomes.

Methods

Participants and Procedure

This study represents a secondary analysis of data from a randomized trial examining the efficacy of coaching and app recommendations to increase engagement with IntelliCare, a suite of mental health apps (Clinicaltrials.gov NCT02801877). Full study details have been described elsewhere [27]. In brief, participants were recruited between July 2016 and May 2017 via social and print media advertising, research registries, and commercial recruitment firms. People interested in participating completed an initial Web-based questionnaire deployed through a secure Web-based data capture system (Research Electronic Data Capture; [28]). The inclusion criteria were as follows: (1) aged 18 years or older, (2) reported elevated symptoms of depression (Patient Health Questionnaire-9 [PHQ-9] ≥10) or anxiety (generalized anxiety disorder-7 [GAD-7] ≥8), (3) resided in the United States, (4) could speak and read English, and (5) had an Android phone with data and text plans. Following baseline assessment, 301 eligible participants were randomized to 1 of the 4 treatments within a 2×2 factorial design for 8 weeks. Brief descriptions of the mobile intervention and each condition are provided below. The trial was approved by the Northwestern University Institutional Review Board before participant contact and monitored by an independent data safety monitoring board throughout the study period. All participants provided informed consent.

Treatments

IntelliCare

The IntelliCare platform consists of 12 clinical apps, each targeting a specific behavioral or psychological treatment strategy (eg, cognitive restructuring, behavioral activation, social support, and relaxation) to improve symptoms of depression and anxiety. The specific apps have been described in more detail elsewhere [2,19]. In addition, a Hub app consolidates notifications from the downloaded clinical apps and is able to recommend other apps in the suite. IntelliCare apps prioritize interactive skills training over psychoeducation and are designed for frequent, short interactions.

Coaching

Participants assigned to the coach condition received 8 weeks of coaching aimed to support engagement. Coaching was based on a low-intensity coaching model [29] that relied primarily on brief SMS text messaging (2-3 messages per week) to promote engagement. Participants assigned to the self-guided condition had no sustained contact with coaches. Participants in both conditions received an orientation call at the beginning of the trial to ensure they had appropriately installed the Hub app and understood how to use the IntelliCare platform.

Recommendations

Participants randomized to the recommendation condition received recommendations for new apps weekly through the Hub app. The recommendation system leveraged app use data from approximately 80,000 users who had downloaded the IntelliCare apps to identify apps that the individual was more likely to use based on their app use profile. Participants not assigned to the recommendation condition did not receive recommendations and were encouraged to explore the apps by themselves.

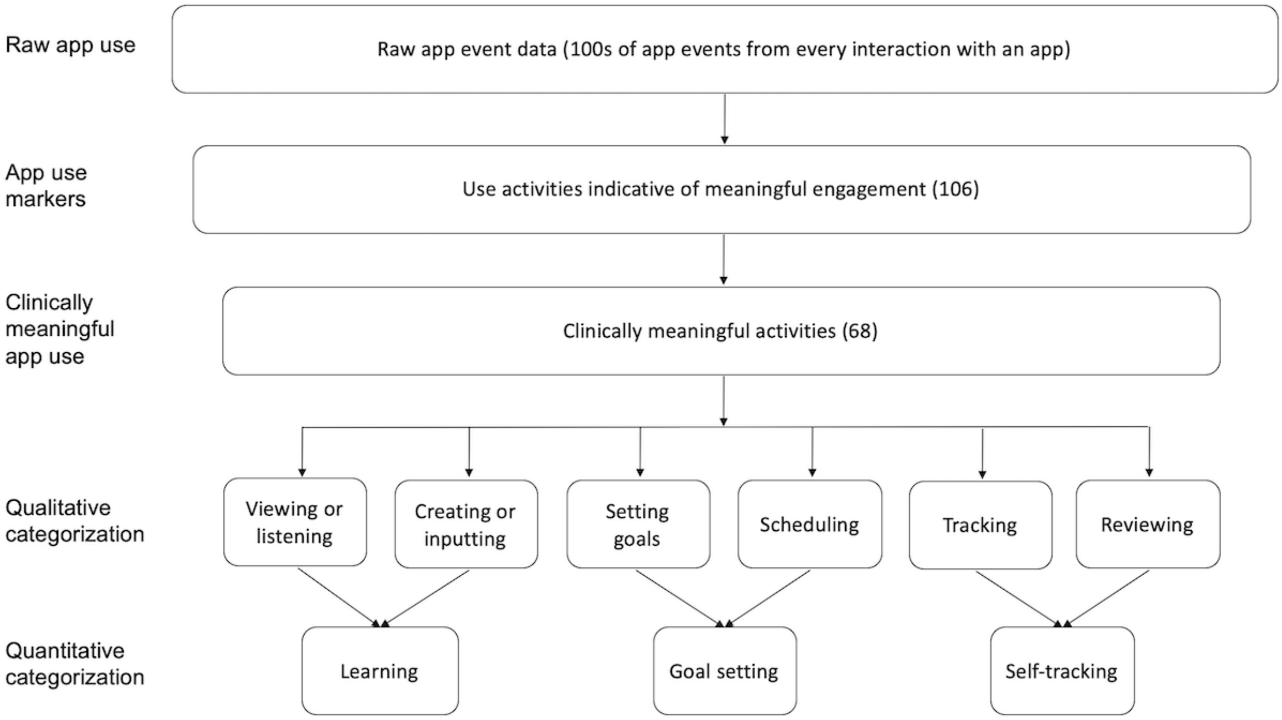
Measures

App Use Metrics

Usage logs for each app were recorded locally on the user's mobile phone, which were then obtained and analyzed to extract app use metrics. In this study, we categorized 2 types of app use: clinically meaningful app use and generic app use.

Clinically meaningful app use metrics were developed in a 2-step process. First, a group of 5 psychologists who had been involved in the design of the apps created granular app use markers from raw event data. These app use markers were each defined by a small number of app event data considered to be indicative of meaningful engagement. Examples of such markers are app event data that defined completion of a skill-building exercise, reading psychoeducational text, or logging daily activities. Second, 2 authors (AZ and JN) developed a coding scheme to categorize these app use markers, drawing on existing literature and qualitative interviews with 32 IntelliCare users. Specifically, these 2 authors first collectively coded 18.8% (20/106) of the app use markers to develop the coding scheme and then used this coding scheme to separately categorize the remaining markers. Any disagreements in categorization were sent to the third author (AK), who served as a tiebreaker, and were resolved through rigorous discussion. During this process, we removed a number of app use markers that rarely occurred (eg, texting a friend from within the app) or were not considered clinically meaningful (eg, launching the app and viewing app use tips). Through this process, we identified 67 aggregated activities considered to be clinically meaningful, which we labeled "clinically meaningful use activities." These activities were further grouped into 6 types (see Multimedia Appendix 1). The categorization procedure is presented in the bottom 4 steps of Figure 1. The 6 types of clinically meaningful activities identified were as follows:

Figure 1. Procedure for categorizing app use activities across 13 IntelliCare apps.



1. Viewing/listening: reading/watching/listening to content from the app (eg, playing an exercise video, viewing a coping card, and listening to a relaxing audio)
2. Creating/inputting: creating and editing content for the purpose of learning and cultivating a skill (eg, identifying a coping activity and creating a positive or self-affirming statement)
3. Setting goals: selecting, editing, or adding self-identified or assigned goals (eg, adding or deleting a checklist item and selecting a weekly goal)
4. Scheduling: scheduling activities or changing reminders to fit one's schedule (eg, scheduling an upcoming exercise and changing the reminder time)
5. Tracking: keeping track of one's own performance or status through checking off, rating, or logging personal activities and moods, including facts and reasons (eg, checking a

completed activity, rating a level of stress, and creating a sleep log)

6. Reviewing: reviewing one’s own content and progress (eg, reviewing past activities and lessons).

Generic app use was measured by 2 metrics: intensity of use and duration of use [22]. Intensity of use was defined as a user’s total number of app use sessions over the 8-week treatment period. An app use session was specified as a sequence of user-initiated actions or events separated by less than 5 min. Duration of use was defined as the total time an individual spent using the apps over the treatment period. It was calculated by summing the mean duration (in hours) of daily app sessions across all days in treatment.

Outcome Assessment

The primary outcomes of the study were depression and anxiety symptom severity, measured with the PHQ-9 [30] and GAD-7 [31] at baseline and end of treatment (week 8). Higher scores reflect higher levels of depression or anxiety.

Data Analysis

Principal component analysis was performed on the 6 identified types of clinically meaningful activities, standardizing by type, to explore any underlying patterns of these activity types. Medians and IQRs of app use metrics were reported. Then, the relationship between app use metrics and treatment outcomes was analyzed using linear regression analyses, adjusting for baseline PHQ-9 or GAD-7 and randomization strata. We first plotted the bivariate relations between all use metrics and end-of-treatment outcomes, which revealed nonlinear patterns. In response, we categorized each app use metric into 4 quartiles. We considered the first quartile minimal intensity of use, the second quartile low intensity of use, the third quartile moderate intensity of use, and the fourth quartile high intensity of use. Regression models were fit to examine the relationship between the quartiles of app use metrics and outcomes, using the lowest quartile as the reference group. Regression coefficients (beta) with their 95% CIs and significance levels were reported for both unadjusted and adjusted models. In addition, the R^2 values were reported for the unadjusted models to assess the magnitude of the effect. All analyses were performed using R version 3.5.1.

Ethical Standards

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

Results

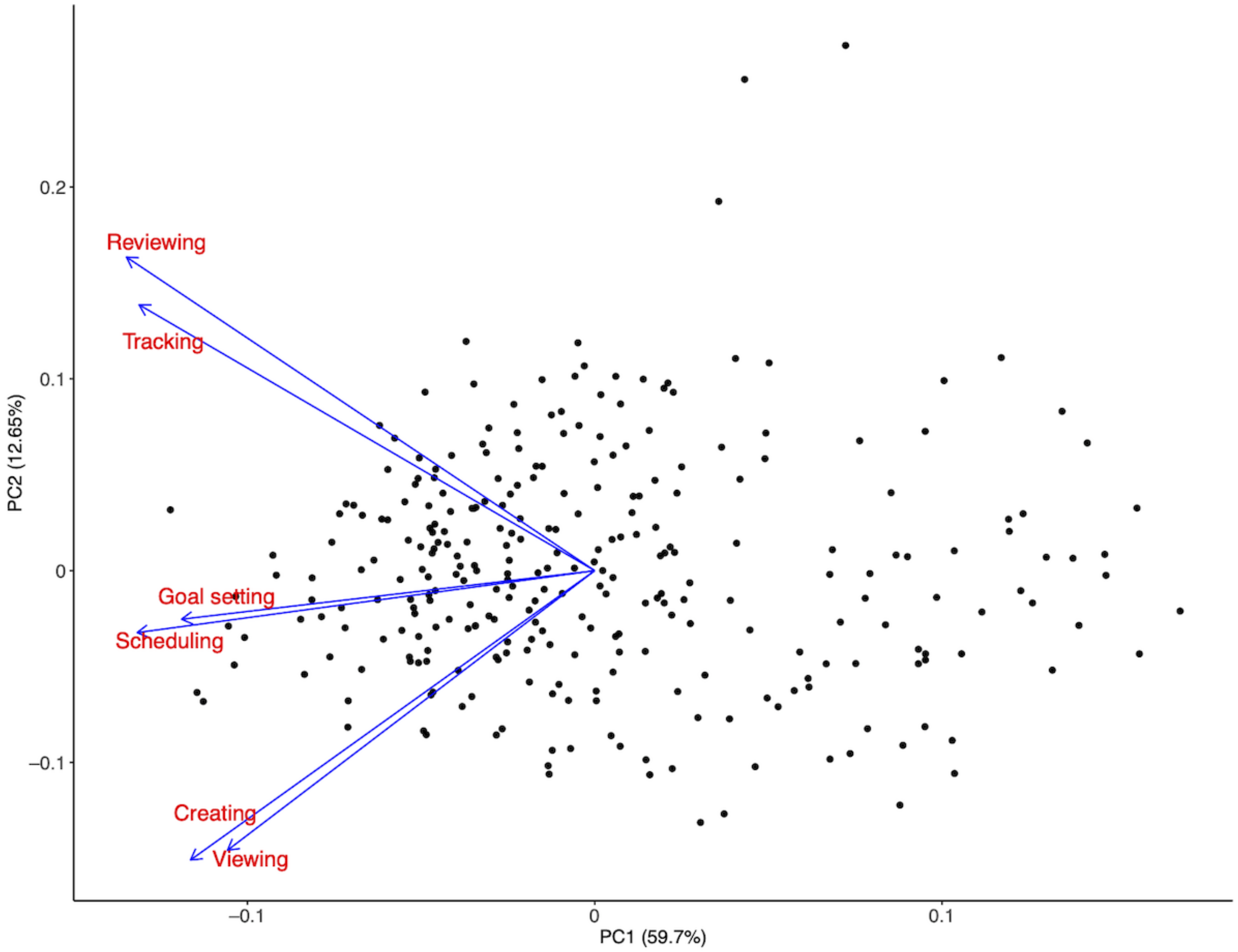
Participants

A total of 301 eligible participants were enrolled in the randomized trial. The majority of participants were female (228/301, 75.7%), and the mean age was 37 (SD 11.84) years, ranging from 18 to 69 years. Most (237/301, 78.7%) of the participants identified themselves as white, 29 (9.6%) as African American, 10 (3.3%) as Asian, and 25 (8.3%) as “other.” The mean baseline level of depression (PHQ-9) was 13.21 (SD 4.63), and the mean baseline level of anxiety (GAD-7) was 11.98 (SD 4.02). A total of 10 participants discontinued treatment and were lost to follow-up. Further details of the sample and participant flow through the study are reported in the study by Mohr et al [27].

Clinically Meaningful Use

Correlation analysis showed that the 6 identified types of clinically meaningful activities were highly correlated; accordingly, we conducted a principal component analysis to further group these activity types. The analysis identified 3 clusters of meaningful activities that could best be described as: (1) “learning,” encompassing “viewing” and “creating;” (2) “goal setting,” including “setting goals” and “scheduling;” and (3) “self-tracking,” consisting of “reviewing” and “tracking.” The first 2 principal components explained 72.4% of the variability in the data (see Figure 2). Figure 1 presents a visual illustration of the categorization of clinically meaningful activities across the apps.

Figure 2. Principal component analysis of the types of clinically meaningful activities.



Self-tracking was performed most often, with a median frequency of 152 activities (IQR 61-300). Learning was performed less often, with a median frequency of 110 activities (IQR 52-191). Goal setting was used the least, with a median frequency of 59 activities (IQR 15-141). We also examined the frequency of overall clinically meaningful app use by combining all the 67 identified clinically meaningful use activities. The median frequency of clinically meaningful app use was 400 (IQR 200-608).

Generic App Use

Over the 8-week treatment period, the median number of app use sessions was 184 (IQR 116-306), and the median duration of app use over the 8-week treatment period was 3.0 hours (IQR 1.7-5.0).

App Use and Depression Outcome

Clinically Meaningful Use

We first examined how each of the 3 clusters of clinically meaningful activities predicted individuals' level of depression at the end of treatment, compared with the lowest quartile (minimal use) of each cluster (Table 1). End of treatment PHQ-9, after controlling for treatment condition and baseline PHQ-9, was significantly related to moderate intensity of learning (beta=−2.17; *P*=.002); moderate intensity of goal setting (beta=−2.08; *P*=.007); and low, moderate, and high intensity of self-tracking (beta=−2.46; *P*=.002; beta=−1.94; *P*=.01; and beta=−1.92; *P*=.009, respectively), compared with minimal intensity use. Moreover, learning and control variables accounted for 29.2% variance of the model (adjusted R^2=0.292), goal setting and control variables accounted for 26.5% variance of the model (adjusted R^2=0.265), and self-tracking and control variables accounted for 27.4% variance of the model (adjusted R^2=0.274).

Table 1. Regression models of 3 clusters of clinically meaningful activities predicting depression outcome.

Covariate	Model 1[a]		Model 2[b]		Model 3[c]	
	Estimate (SE)	*P* value	Estimate (SE)	*P* value	Estimate (SE)	*P* value
Intercept	1.86 (0.93)	.047	1.57 (0.93)	.09	2.16 (0.91)	.02
Coached	−0.78 (0.52)	.13	−0.42 (0.56)	.46	−0.12 (0.56)	.83
Full Hub	−0.21 (0.50)	.67	−0.28 (0.51)	.59	−0.05 (0.51)	.93
PHQ9_baseline	0.54 (0.05)	<.001	0.56 (0.06)	<.001	0.55 (0.06)	<.001
Learning_minimal intensity[d]						
Learning_low intensity	0.64 (0.73)	.39	—[e]	—	—	—
Learning_moderate intensity	−2.17 (0.71)	.002	—	—	—	—
Learning_high intensity	−1.22 (0.73)	.09	—	—	—	—
Goal setting_minimal intensity[d]						
Goal setting_low intensity	—	—	−0.62 (0.76)	.41	—	—
Goal setting_moderate intensity	—	—	−2.08 (0.76)	.007	—	—
Goal setting_high intensity	—	—	−0.76 (0.76)	.32	—	—
Self-tracking_minimal intensity[d]						
Self-tracking_low intensity	—	—	—	—	−2.46 (0.78)	.002
Self-tracking_moderate intensity	—	—	—	—	−1.94 (0.76)	.01
Self-tracking_high intensity	—	—	—	—	−1.92 (0.73)	.009

[a] R^2=0.307; Adjusted R^2=0.292.

[b] R^2=0.281; Adjusted R^2=0.265.

[c] R^2=0.289; Adjusted R^2=0.274.

[d] Values of reference group.

[e] Not applicable.

In addition to examining the 3 identified clusters of clinically meaningful activities, we also explored how outcomes were related to overall clinically meaningful app use. As shown in Table 2 (model 1), after controlling for treatment condition and baseline level of depression, PHQ-9 at the end of treatment was significantly and negatively associated with low intensity of meaningful use (beta=−2.00; *P*=.007), moderate intensity of meaningful use (beta=−2.07; *P*=.006), and high intensity of meaningful use (beta=−2.05; *P*=.006), compared with minimal intensity of clinically meaningful app use. Clinically meaningful app use and the control variables accounted for 27.3% variance of the model (adjusted R^2=0.273).

Generic App Use

PHQ-9 at the end of treatment was significantly and negatively associated with low intensity of generic app use (beta=−1.44; *P*=.047), moderate intensity of generic app use (beta=−2.38; *P*=.001), and high intensity of generic app use (beta=−2.45; *P*=.001), compared with minimal intensity of generic app use (Table 2, model 2). In general, as the number of generic app use sessions increased, symptoms of depression at the end of treatment decreased. The intensity metrics and control variables accounted for 27.9% variance of the model (adjusted R^2=0.279). Only moderate duration of use was significantly associated with PHQ-9 at week 8 (beta=−1.52; *P*=.045) when compared with minimal duration of use (Table 2, model 3). The duration metrics and control variables accounted for 25.8% variance of the model (adjusted R^2=0.258).

Table 2. Regression models of total meaningful app use, generic app use, and duration of app use predicting depression outcome.

Covariate	Model 1[a]		Model 2[b]		Model 3[b]	
	Estimate (SE)	*P* value	Estimate (SE)	*P* value	Estimate (SE)	*P* value
Intercept	2.25 (0.92)	.02	2.24 (0.92)	.02	1.71 (0.93)	.07
Coached	−0.34 (0.53)	.52	−0.58 (0.51)	.26	−0.57 (0.54)	.23
Full Hub	−0.11 (0.51)	.82	0.26 (0.54)	.63	0.02 (0.53)	.98
PHQ9_baseline	0.55 (0.06)	<.001	0.55 (0.05)	<.001	0.54 (0.06)	<.001
Meaningful use_minimal intensity						
Meaningful use_low intensity	−2.00 (0.74)	.007	—[e]	—	—	—
Meaningful use_moderate intensity	−2.07 (0.74)	.006	—	—	—	—
Meaningful use_high intensity	−2.05 (0.74)	.006	—	—	—	—
Generic app use_minimal intensity[d]						
Generic app use_low intensity	—	—	−1.44 (0.72)	.047	—	—
Generic app use _moderate intensity	—	—	−2.38 (0.73)	.001	—	—
Generic app use_ high intensity	—	—	−2.45 (0.76)	.001	—	—
Generic app use_minimal duration[d]						
Generic app use_low duration	—	—	—	—	−0.32 (0.75)	.68
Generic app use_moderate duration	—	—	—	—	−1.52 (0.76)	.045
Generic app use_high duration	—	—	—	—	−1.24 (0.78)	.12

[a] R^2=0.288; Adjusted R^2=0.273.

[b] R^2=0.295; Adjusted R^2=0.279.

[c] R^2=0.274; Adjusted R^2=0.258.

[d] Values of reference group.

[e] Not applicable.

App Use and Anxiety Outcome

Anxiety (GAD-7) at the end of the treatment was neither significantly associated with the 3 clusters of clinically meaningful activities (all *P*s>.11) nor the overall clinically meaningful app use (all *P*s>.13). Therefore, no further analyses were conducted regarding the association between anxiety and additional generic app use metrics.

Discussion

Principal Findings

This study provided a categorization of user behaviors in a suite of mental health apps and investigated how different types of app use were related to improvements in depression and anxiety symptoms following an 8-week intervention. The results showed that different types of clinically meaningful activities (ie, learning, goal setting, and self-tracking) had varied effects on outcomes. Self-tracking at varied levels of intensity was related to improvement in depression symptoms, whereas only moderate intensity of learning and goal setting predicted improvement in depression symptoms. Thus, this study provides insight into how different types of app use might be conducive to improved intervention outcomes.

Drawing on a mixed methods approach, we identified 6 types of clinically meaningful activities across multiple apps, which were further grouped into 3 clusters—learning, goal setting, and self-tracking. This categorization was achieved through a combination of qualitative content analysis and quantitative statistical analysis. The results show that users engaged in self-tracking most frequently, followed by learning and goal setting. These 3 types of use activities have been well documented in mHealth and human-computer interaction (HCI) research as approaches to drive engagement and promote behavior change [8,32]. However, little is known about how these activities are related to health outcomes, as previous studies have primarily focused on the clinical outcomes of generic app use [21,33]. By shifting attention from generic app use to a more granular examination of meaningful app use, this study provides a more nuanced understanding of user engagement with mental health apps.

Notably, overall clinically meaningful app use (combination of all 67 identified clinically meaningful use activities) accounted for roughly the same amount of variance in depression severity as explained by the intensity of overall app use (ie., total number of app use sessions). Therefore, our identification of clinically meaningful app use was successful at capturing the activities associated with better mental health outcomes. This suggests that we accurately identified the clinically meaningful intervention components within this suite of apps. As such, we believe that the association between app use and outcome can be largely explained by these clinically meaningful use activities, which clustered into 3 types of activities, reinforcing the importance of self-tracking, goal setting, and psychoeducation elements within mHealth interventions for depression.

More specifically, these 3 clusters of clinically meaningful activities were associated with reductions in depression symptoms at the end of treatment. In particular, self-tracking was found to be beneficial at all levels of intensity compared with minimal intensity of use. This is in accordance with HCI research suggesting that self-tracking, or personal informatics, can lead to behavior change [34], chronic disease management [35], and self-knowledge and self-reflexivity [36,37]. Our study extends this line of research by demonstrating the clinical benefits of self-tracking in the context of mental health. It is important to note that self-tracking in our study consisted of both data collection (ie, tracking) and data reflection (ie, review), as delineated in the stage-based model of personal informatics systems [34]. This suggests that mHealth could better support users by facilitating self-tracking through the incorporation of design features that promote data collection and data reflection.

It is important to note that greater amounts of engagement did not necessarily lead to greater reductions in depression. Although self-tracking was generally beneficial, only a moderate level of engagement with learning and goal setting was associated with reduced depressive symptoms. Neither high nor low intensity of app use could predict better outcomes compared with minimal intensity of use. This result suggests that mHealth interventions might follow the Goldilocks principle—"Not too much. Not too little. Just right" [38]. Just as in many digital technologies, mental health apps do not promise that "the more engagement, the better outcomes;" rather, we argue that the benefits of app use may only be seen when the doses of various classes of intervention features "just right." Too frequent engagement with goal setting and learning may lead to fatigue, whereas too scarce engagement may lead to ineffectiveness. Thus, mental health technologies should be designed to promote use at the right amount, possibly by sending users reminders based on their app use data. An alternate explanation is that people who engage in learning and goal setting more frequently may be less responsive to treatment. That is, perhaps higher engagement in these activities is associated with a more treatment resistant course of depression, or is exhibited by individuals with more complex comorbidities, thereby indicating that the intervention components do not fit the needs of certain individuals. Thus, high engagement in these activities could be an indicator of risk of lower responsiveness to treatment and could be used to guide the implementation of alternative treatment strategies for individuals who are likely to benefit from additional support.

The overall intensity of generic app use also predicted reductions in depression symptoms. Generally, it appears that people who engaged in higher intensity of app use had lower levels of depression at the end of treatment. However, the duration of app use minimally contributed to better outcomes. This finding corresponds to prior work suggesting that people tend to use mobile apps in very short bursts of time, given their habit of using smartphones in spare moments [39,40]. Although duration of engagement plays a critical role in Web-based interventions [21], the current ways in which people interact with smartphones suggest that mHealth apps should be designed to be quick to use, have simple interactions, and support a single or limited set of related tasks [2,40]. IntelliCare aligns with these endeavors to facilitate frequent but short interactions.

However, our investigation of meaningful app use was not associated with reduced anxiety symptoms. This is consistent with the findings in the main trial, where significant reductions in anxiety symptom were not related to number of app sessions or time between first and last app use but were only associated with the number of app downloads [27]. The discrepancy in effects of app use on depression and anxiety is a novel finding and suggests that different types of use may be more effective for some psychological states and not others. We speculate that motivation may be an important factor. Users in low motivational states may require self-tracking, goal setting, and learning features in specific doses such that they receive enough to be beneficial but not so much that it overwhelms them. On the other hand, anxiety may be less sensitive to dose responses because it is a more activating condition. To understand such nuance, we need more research specifically designed to examine the relationship between clinically meaningful activities and symptoms across various disorders or symptomatology.

Overall, this study has important implications for the design of mHealth for depression, which includes the following:

- Self-tracking, goal setting, and learning are 3 components that have clinical benefits, which should be incorporated into mental health apps.
- Mental health apps could be designed according to the Goldilocks principle, incorporating the "just right" amount of intervention components and promoting use at the right amount, possibly through sending user reminders or alerts based on app use data.
- People tend to use apps in very short bursts of time, so mental health apps should be quick to use, have simple interactions, and support a single or limited set of related tasks.

However, because of the exploratory nature of the research, design considerations derived from this study focus only on app content and engagement. Within the wider context, research indicates that app design and quality assessment must also consider users' lived experience, app usability and stability, and data privacy and security [41]. For example, the critical importance of privacy and security in relation to mental health apps was highlighted in 2 recent studies, which suggest that currently available mental health apps often misuse user data [42] and that users' willingness to share personal sensing data varies depending on the type of data collected and with whom they are shared [43]. Indeed, the importance of these factors is evident within the ever-growing array of app quality measures and guidelines, including those from the American Psychiatric Association [41] and the US Food and Drug Administration [44].

Limitations

Despite its contributions and implications, this study has some limitations. First, the user activities identified in this study were not exhaustive; some activities were eliminated because of their low frequency. As a secondary analysis, this study is exploratory by nature, and future studies should continue exploring more specific types and patterns of user behaviors in using mHealth technologies and their relationships with outcomes of mental health conditions. Second, although this study demonstrated the associations of both generic and specific app use with clinical outcomes over the treatment period, it is difficult to make causal claims about the effects. The relationship between app use and symptom change is likely dynamic. For example, app use may contribute to lower subsequent symptoms, and symptom changes may in turn increase app use [45]. Experimental studies are warranted to examine how different intervention components uniquely contribute to outcomes. Third, this study only examined outcomes within the 8-week treatment period. Future research could build on this preliminary model to explore the long-term effects of different app use behaviors.

Conclusions

Engagement with digital health interventions is a long-standing problem; however, little is known about how users interact with mental health apps in clinically meaningful ways. This study employed a novel, mixed methods methodology to derive greater understanding of users' engagement with apps that cannot be seen through generic use data. Using a combination of qualitative and quantitative methods, we uncovered 3 clusters of clinically meaningful activities—learning, goal setting, and self-tracking—with each type associated with reductions in depression symptoms. However, different activities and intensities of use produced varied effects. Although only moderate intensity of learning and goal setting led to reductions in symptoms of depression, self-tracking at all levels of intensity predicted improvement in depression. Understanding the relationship between different types of user activities and clinical outcomes could inform the design of mental health apps that are more clinically effective for users.

Acknowledgments

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Conflicts of Interest

DCM has an ownership interest in Adaptive Health, Inc, which has a license from Northwestern University for IntelliCare and has accepted honoraria from Apple Inc. AKG and MJK have received consulting fees from Actualize Therapy, LLC. None of the other authors have conflicts to declare.

Multimedia Appendix 1
Codebook of the categorization of app use behaviors.
[XLSX File (Microsoft Excel File), 18 KB - jmir_v21i12e15644_app1.xlsx]

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Abbreviations

GAD-7: generalized anxiety disorder-7
HCI: human-computer interaction
mHealth: mobile health
PHQ-9: Patient Health Questionnaire-9

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Original Paper

Understanding Drivers of Resistance Toward Implementation of Web-Based Self-Management Tools in Routine Cancer Care Among Oncology Nurses: Cross-Sectional Survey Study

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Abstract

Background: Supporting patients to engage in (Web-based) self-management tools is increasingly gaining importance, but the engagement of health care professionals is lagging behind. This can partly be explained by resistance among health care professionals.

Objective: The aim of this study was to investigate drivers of resistance among oncology nurses toward Web-based self-management tools in cancer care.

Methods: Drawing from previous research, combining clinical and marketing perspectives, and several variables and instruments, we developed the Resistance to Innovation model (RTI-model). The RTI-model distinguishes between passive and active resistance, which can be enhanced or reduced by functional drivers (incompatibility, complexity, lack of value, and risk) and psychological drivers (role ambiguity, social pressure from the institute, peers, and patients). Both types of drivers can be moderated by staff-, organization-, patient-, and environment-related factors. We executed a survey covering all components of the RTI-model on a cross-sectional sample of nurses working in oncology in the Netherlands. Structural equation modeling was used to test the full model, using a hierarchical approach. In total, 2500 nurses were approached, out of which 285 (11.40%) nurses responded.

Results: The goodness of fit statistic of the uncorrected base model of the RTI-model (n=239) was acceptable (χ^2_1=9.2; Comparative Fit Index=0.95; Tucker Lewis index=0.21; Root Mean Square Error of Approximation=0.19; Standardized Root Mean Square=0.016). In line with the RTI-model, we found that both passive and active resistance among oncology nurses toward (Web-based) self-management tools were driven by both functional and psychological drivers. Passive resistance toward Web-based self-management tools was enhanced by complexity, lack of value, and role ambiguity, and it was reduced by institutional social pressure. Active resistance was enhanced by complexity, lack of value, and social pressure from peers, and it was reduced by social pressure from the institute and patients. In contrast to what we expected, incompatibility with current routines was not a significant driver of either passive or active resistance. This study further showed that these drivers of resistance were moderated by expertise (*P*=.03), managerial support (*P*=.004), and influence from external stakeholders (government; *P*=.04).

Conclusions: Both passive and active resistance in oncology nurses toward Web-based self-management tools for patients with cancer are driven by functional and psychological drivers, which may be more or less strong, depending on expertise, managerial support, and governmental influence.

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KEYWORDS

psycho-oncology; health-related quality of life; self-management; eHealth; implementation science; resistance to innovations

Introduction

In current health care, self-management is increasingly gaining importance. Self-management is defined as "those tasks that individuals undertake to deal with the medical, role, and emotional management of their health condition(s)" [1]. Despite the benefits of self-management [2,3], engagement by patients, as well as health care professionals, is still lagging behind. Self-management support in cancer care is a rather new area and not yet implemented in routine care in many countries and settings. Electronic health (eHealth) might facilitate engagement in self-management. A recent meta-review on eHealth targeting patients with cancer showed positive effects on perceived support, knowledge levels, and information competence [4]. Therefore, moving toward Web-based self-management tools as part of personal health management seems a promising avenue, but to date, the actual use of such tools is also still more an aspiration than a reality. Implementing innovations successfully, such as integrating Web-based self-management tools in clinical processes, requires institutional commitment from the management and buy-in from health care professionals and, ultimately, patients [5]. Resistance toward innovations, such as Web-based self-management, is an important phenomenon that potentially hinders a successful takeoff. In cancer care, there is an important role for oncology nurses in stimulating and supporting self-management behaviors in patients [6-9]. Understanding potential resistance regarding Web-based self-management among oncology nurses is therefore key to successfully integrating the use of Web-based self-management tools in routine cancer care.

Resistance is typically characterized by different levels of intensity. In line with previous research, we differentiate between passive and active resistance. Passive resistance represents a generic, initial attitude to resist an innovation [10], where an individual (ie, the nurse) does not adopt an innovation or postpones the decision until there is a clear reason to change routine care. Active resistance is characterized by a conscious, deliberate decision. This may go beyond the individual's decision to reject, involving public displays of disapproval and actively encouraging others to resist the innovation as well [11,12]. Nurses may "make or break" a patient's use of such tools, as patients often regard nurses as authoritative figures; in addition, they are key players in the introduction of Web-based self-management tools [6-9]. Both passive and active resistance may hamper implementation of Web-based self-management tools, but knowledge about drivers of passive and active resistance among oncology nurses is lacking. Therefore, the objective of this study was to investigate the drivers of passive and active resistance among oncology nurses toward Web-based self-management and identify possible factors that may moderate the effect of these drivers. The results of this study are highly relevant in developing future interventions that aim to improve implementation of Web-based self-management tools.

Methods

Study Design, Participants, and Recruitment

All participants in this cross-sectional survey study were registered nurses working in oncology care in Dutch health care organizations. On the basis of sample size calculations for structural equation models, the minimum sample size for the base model structure was set at 100 (anticipated effect size: 0.1; desired statistical power level: 0.95; number of latent variables: 2; number of observed variables: 8; probability level: 0.05) [13]. To investigate potential moderating effects, we aimed to include 400 participants. In line with policies regarding studies among health care professionals in the Netherlands, no informed consent, further than regular provision of information about the study, was needed.

Participants were recruited in the second half of 2016 through "V&VN Oncologie," a professional association for Dutch oncology nurses. All 2500 members were first approached through a call in the monthly email newsletter to fill out an open Web-based version of the survey (data of respondents were protected and only accessible by authorized users: the authors). Respondents filled out the same version of the survey and were presented with a limited number of questions per page. Respondents were asked to answer all questions. If there were blank answers, respondents were prompted to fill out all answers (respondents could still skip and leave an answer blank). Respondents could navigate freely between successive pages before submitting the Web-based survey. To incentivize participation, participants were offered a €10 participation fee and were able to enter a raffle to win a tablet, smartwatch, or gift card. Initial response was lower than anticipated (*n=276*, initial response rate: 11.04%); therefore, a paper version of the survey was subsequently distributed among the attendees of the yearly 2-day conference for nurses working in Dutch oncology, organized by the V&VN Oncology. This conference was attended by V&VN Oncology members who perhaps had already seen the first survey recruitment messages, as well as nonmembers who had not seen the messages yet. Another 400 hard copies of the survey were distributed at the conference, of which 81 were returned (response rate: 20.3%). In total, 357 out of 2500 nurses responded (response rate 14.28%). To prevent multiple entries from the same individual, double entries were removed on the basis of personal identifiable information entered by participants, preserving the first entry. In addition, initially, only respondents who completed the demographics section of the survey were included, leading to a study population of 285 out of 2500 potential participants (response rate: 11.40%).

Measures

For this study, the Resistance to Innovation model (RTI-model) was developed and used (Figure 1). The RTI-model draws from theory of innovation resistance, related frameworks in health care, and, especially, the field of implementation science [10,11,14-17]. The outcome to actively or passively resist an innovation can be influenced by functional and psychological drivers. Functional drivers include incompatibility with current routines [18], complexity of the innovation [19], lack of value—especially in comparison with existing alternatives [20,21]—and expected risks about performance and reliability [12,20,22]. Psychological drivers include role ambiguity, which is defined as the lack of clarity on how to incorporate and use an innovation in routine care [23], as well as social pressure [24] from patients, peers, and the organization. The effect of these drivers on resistance may be moderated by staff-, organization-, patient-, and environment-related characteristics. These included experience and expertise in supporting patients in (Web-based) self-management activities (staff related) [23], institutional orientation and support, technical support, managerial support (organization related) [24], ability of patients, as well as value for patients as perceived by nurses (patient related), dynamics of Dutch oncological care [25], and influences of external stakeholders (government and health care insurance companies; environment-related). Several staff-related control variables were included: demographics (age, type of institution, position, counselor position, and years of experience), tendency to comply [26], and organizational commitment [27]. “Perceived rate of adoption” was included as an organization-related control variable (see Figure 1).

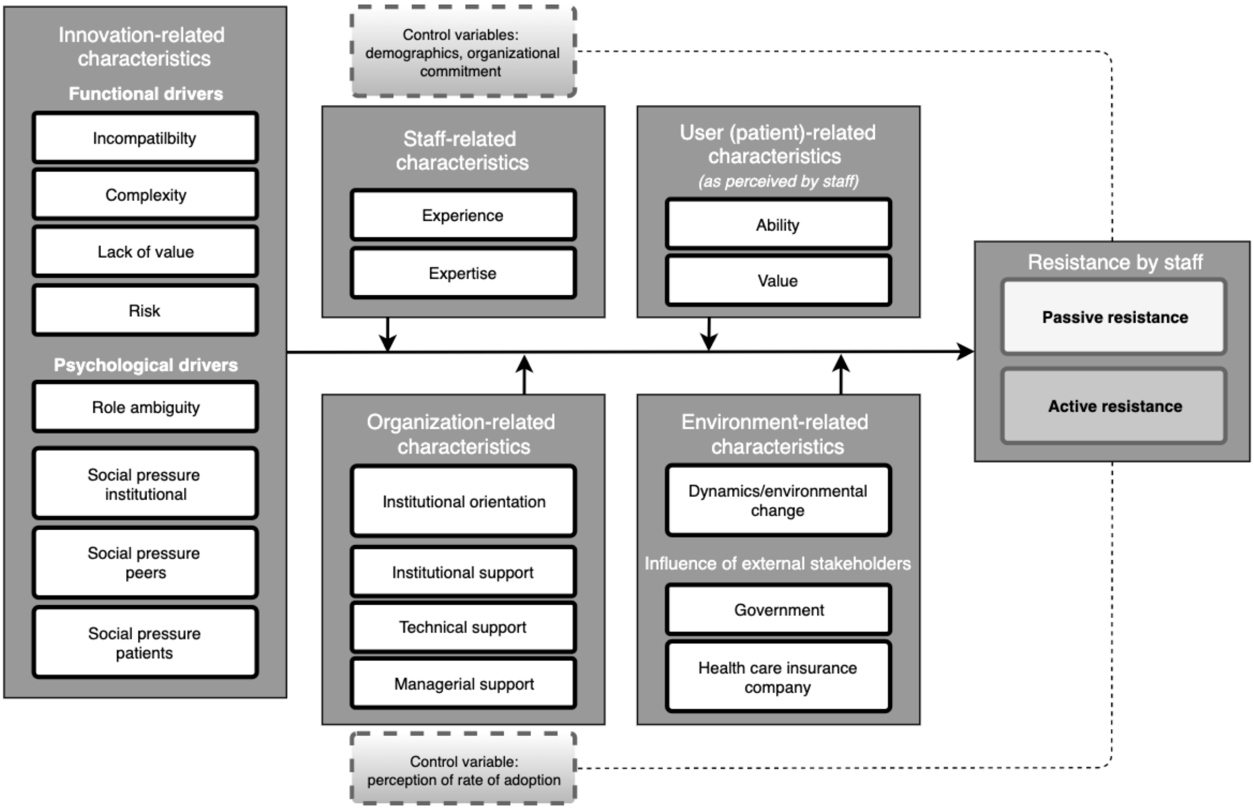


Figure 1. The Resistance to Innovation model.

To cover all components of the RTI-model (passive and active resistance, functional and psychological drivers of resistance, and moderating and control variables), a 118-item survey was composed, including 34 scales (see Multimedia Appendix 1 for an overview of all items and scales used for each variable. See Multimedia Appendix 2 for the questionnaire). On the basis of psychometric properties, some scales were excluded from further analyses (see Results section and Multimedia Appendix 1 for more information, such as factor loadings). The previously validated multi-item scales were tailored to the context of Web-based self-management and health care institutions in the Netherlands. Most original items were transformed to 5-point Likert scales, ranging from strongly disagree to strongly agree. The draft version of the survey was pretested among 9 nurses using the plus-minus method [28], combined with an interview with debriefing questions. Feedback from this pretest resulted in minor changes, such as reformulation of certain items and answer options, addition of total estimated time needed to fill out the questionnaire, and an example of the concept of self-management for clarification purposes. The electronic survey was thoroughly tested regarding usability and technical functionality by the authors, but this was not part of the pretest. Translation validation was based on consensus among the authors, partially informed by the pretest among 9 nurses.

Statistical Analyses

A 2-step approach was used to test the RTI-model and assess the fit of the final model [29]. Only complete cases at the base model were included in the analyses of the RTI-model. In the first step, a Confirmatory Factor Analysis (CFA), using Lavaan for R [30], was performed to examine the consistency of all measurement scales for variables with more than 2 items. To purify the measures, factor loadings (factor loading <0.5 and >3.0 compared with the reference factor), fit indices (Comparative Fit Index/Tucker Lewis index [CFI/TLI] ≥0.9; Root Mean Square Error of Approximation [RMSEA] <0.06; Standardized Root Mean Square [SRMR] <0.08), and consensus among the authors were used as decision rules to remove items, to split measurement scales into 2 or more new variables, or to combine separate scales into 1 new variable. These modifications based on the CFA results are reported in the Results section and led to improvements regarding reliability and validity of the set of measures, to perform the next steps in the analysis.

In the second step, structural equation modeling, using Mplus (version 7) [31], was used to test the full model via a hierarchical approach. A base model was estimated first, including all direct effects of functional and psychological drivers on the exogenous constructs' passive and active resistance. Thereafter, several control variables were added individually to the base model as direct effects on the exogenous constructs. Control variables were modeled uncorrelated with the endogenous constructs, and correlations were added one by one on the basis of modification indices >10. The control variables were "demographics" (modeled as 1 latent variable comprising age, type of institution, position, counselor position [providing psychosocial care], and years of experience), organizational commitment, and perception of rate of adoption. Following this, moderators were investigated in the base model with multi-group comparison, after dividing the moderator in 2 groups by using a median split. Finally, each moderator was added as direct effects to the base model and to each of the models that were corrected for the control variables. The moderators were modeled to be uncorrelated to the endogenous constructs and control variables, and variables were allowed to be correlated on the basis of modification indices >10 to improve the fit of the model.

Results

Sample Characteristics

In total, 285 nurses participated, of whom 239 participants filled out all questions. Most participants were female (227/239, 94.4%). Their mean age was 43 years (SD 10.8) and a majority (150/239, 62.8%) were oncology nurses by training. The median years of working experience was 6 years (IQR 2-12 years), and the majority worked on a part-time basis. All sample characteristics are presented in Table 1. Differences between nurses who completed the questionnaire and those who did not are presented in Table 2. Groups differed significantly on training (P=.01) and type of hospital (P=.02).

Table 1. Study sample characteristics.

Variables	Nurses (N=239)
Age (years), mean (SD)	43.3 (10.8)
Sex, n (%)	
Female	227 (94.4)
Male	12 (5.6)
Training, n (%)	
Nurse	25 (10.5)
Nurse specialist	64 (26.8)
Oncology nurse	150 (62.8)
Counseling, n (%)	
Yes	128 (53.6)
No	111 (46.4)
Type of hospital, n (%)	
University hospital	69 (28.9)
General teaching hospital	91 (38.1)
General hospital	54 (22.6)
Miscellaneous (home care and hospice)	25 (10.5)
New patients each year, n (%)	
0-50	37 (15.5)
51-100	83 (34.7)
>100	118 (49.4)
Missing	1 (0.4)
Years of experience current position, median (IQR)	6 (2-12)
Working hours per week, median (IQR)	32 (26-32)

Table 2. Statistics of incomplete cases compared with complete cases.

Variables	Complete cases (N=239)	Incomplete cases (N=46)	*P* value
Age (years), mean (SD)	43.3 (10.8)	44.2 (10.9)	.62
Sex, n (%)			.29
Female	227 (94.4)	41 (89.1)	
Male	12 (5.6)	4 (8.7)	
Missing	0 (0.0)	1 (2.2)	
Training, n (%)			.01
Nurse	25 (10.5)	12 (26.1)	
Nurse specialist	64 (26.8)	8 (17.4)	
Oncology nurse	150 (62.8)	26 (56.5)	
Counseling, n (%)			.26
Yes	128 (53.6)	20 (43.5)	
No	111 (46.4)	25 (54.3)	
Missing	0 (0.0)	1 (2.2)	
Type of hospital, n (%)			.02
University hospital	69 (28.9)	8 (17.4)	
General teaching hospital	91 (38.1)	15 (32.6)	
General hospital	54 (22.6)	11 (23.9)	
Miscellaneous (home care and hospice)	25 (10.5)	12 (26.1)	
Number of new patients each year, n (%)			.13
0-50	37 (15.5)	9 (19.6)	
51-100	83 (34.7)	9 (19.6)	
>100	118 (49.4)	28 (60.9)	
Missing	1 (0.4)	0 (0)	
Years of experience current position			.22
Median	6	8	
Range	0-36	0-30	
IQR	2-12	2-14	
Working hours per week			.34
Median	32	30	
Range	16-40	24-38	
IQR	26-32	25.5-32	

Measurement Model Results

Confirmatory Factor Analyses

The validity of most scales with more than 2 items was good. For 5 scales, either 1 item was removed or more items were removed: complexity (item 2; functional driver), social pressure from the institution (item 2; psychological driver), experience (item 1 and 3; staff-related moderator), perception of rate of adoption (item 1; control variable of organizational-related moderator), and rejection (item 1; active resistance). Active resistance was initially operationalized on 2 subdimensions—rejection and opposition—but based on the analysis merged into 1 overall variable capturing active resistance. A total of 2 scales were split: dynamics of the environment (item 1 and 3 and item 2 and 4; environment-related moderator) and tendency to comply (item 1 and 2; staff-related control variable). Final factor loadings for each scale are reported in Multimedia Appendix 1, and an overview of all decisions made on the basis of the CFA results.

Structural Equation Model

The goodness of fit statistic of the uncorrected base model (Figure 2) was acceptable [32]—χ^2_1=9.2; CFI=0.95; TLI=0.21; RMSEA=0.19; SRMR=0.016; Tables 3 and 4. Passive resistance was enhanced by complexity, lack of value, and role ambiguity, whereas social pressure from the institute significantly reduced passive resistance. Active resistance was enhanced by complexity, lack of value, and social pressure from peers, and this was reduced by social pressure from the institution and from patients. Of the moderators presented in Figure 1, only the significant moderators are discussed, that is, expertise, managerial support, and influence external stakeholders (government; see Tables 3 and 4 and Figure 2). Correcting the models for the control variables produced similar factor loadings and model fits results.

Figure 2. Schematic overview of the effects of functional and psychological drivers on passive and active resistance. *$P \leq .05$, **$P \leq .01$, ***$P \leq .001$.

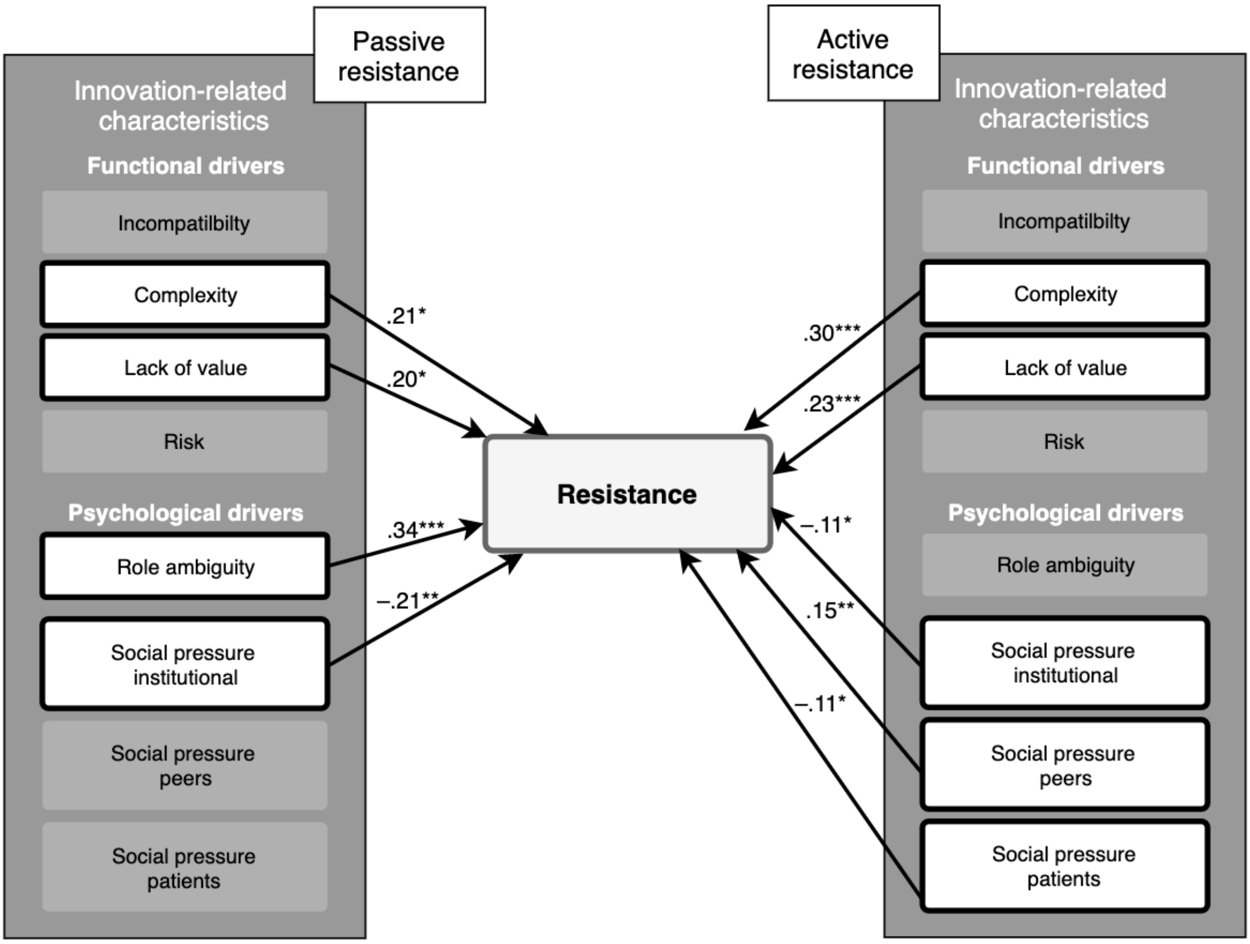


Table 3. Standardized factor loadings of functional and psychological drivers on active and passive resistance, including moderator effects: Base model (Model 1), Expertise regarding self-management as moderator (Model 2), Influence from Government as moderator (Model 3), and Managerial support as moderator (Model 4).

Driver	Model 1: Base model (N=239)	Model 2: Expertise		Model 3: Influence from government		Model 4: Managerial support	
		Low (N=110)	High (n=129)	Low (n=104)	High (n=135)	Low (n=126)	High (n=111)
Passive resistance							
Incompatibility	0.035	0.12	−0.035	0.14	−0.053	0.010	0.14
Complexity	0.21[a]	0.24	0.093	0.048	0.37[b]	0.094	0.39[b]
Lack of value	0.20[a]	0.44[c]	0.12	0.23	0.13	0.094	0.24[a]
Risk	0.15	−0.068	0.26[a]	0.064	0.25[a]	0.12	0.19
Role ambiguity	0.34[c]	0.11	0.39[b]	0.34[b]	0.34[b]	0.31[b]	0.30[b]
Social pressure: institutional	−0.21[b]	−0.32[c]	−0.12	−0.075	−0.29[b]	−0.073	−0.27[b]
Social pressure: peers	−0.033	0.006	−0.15	−0.13	0.023	−0.089	0.12
Social pressure: patients	−0.068	0.076	−0.14	−0.19	0.067	−0.098	−0.020
Active resistance							
Incompatibility	0.031	0.10	−0.001	0.010	0.022	−0.079	0.22
Complexity	0.30[c]	0.37[c]	0.22[b]	0.18	0.38[c]	0.19[b]	0.44[c]
Lack of value	0.23[c]	0.41[c]	0.14	0.12	0.26[c]	0.12	0.26[b]
Risk	0.089	−0.058	0.15[a]	0.17	0.075	0.14[a]	0.088
Role ambiguity	−0.041	−0.13	−0.022	−0.027	−0.045	0.066	−0.16
Social pressure: institutional	−0.11[a]	−0.13[a]	−0.11	0.008	−0.15[b]	−0.065	−0.21[b]
Social pressure: peers	0.15[b]	0.019	0.19[b]	0.012	0.21[c]	0.050	0.30[c]
Social pressure: patients	−0.11[a]	0.044	−0.21[b]	−0.20[a]	0.010	−0.13[a]	−0.025

[a] $P \leq .05$.

[b] $P \leq .01$.

[c] $P \leq .001$.

Table 4. Model information of the different models: Base model (Model 1), Expertise regarding self-management as moderator (Model 2), Influence from Government as moderator (Model 3), and Managerial support as moderator (Model 4).

Model information	Model 1	Model 2	Model 3	Model 4
Mode fit indices				
χ^2 (*df*)	9.2 (1)	8.4 (2)	6.2 (2)	7.2 (2)
P value	.002[a]	.02[b]	.045[b]	.03[b]
CFI[c]	0.95	0.95	0.98	0.97
TLI[d]	0.21	0.22	0.61	0.51
RMSEA[e]	0.19	0.16	0.13	0.15
SRMR[f]	0.016	0.016	0.013	0.015
Multigroup comparison: Wald (*df*=16); *P* value	—[g]	28.21; .03[b]	27.472; .04[b]	34.91; .004[a]
Residual variances				
Passive resistance	0.43	0.32[h]; 0.47[i]	0.43[h]; 0.40[i]	0.46[h]; 0.30[i]
Active resistance	0.19	0.17[h]; 0.18[i]	0.19[h]; 0.16[i]	0.16[h]; 0.19[i]

[a] *P*≤.01.

[b] *P*≤.05.

[c] CFI: Comparative Fit Index.

[d] TLI: Tucker Lewis index.

[e] RMSEA: Root Mean Square Error of Approximation.

[f] SRMR: Standardized Root Mean Square Residual.

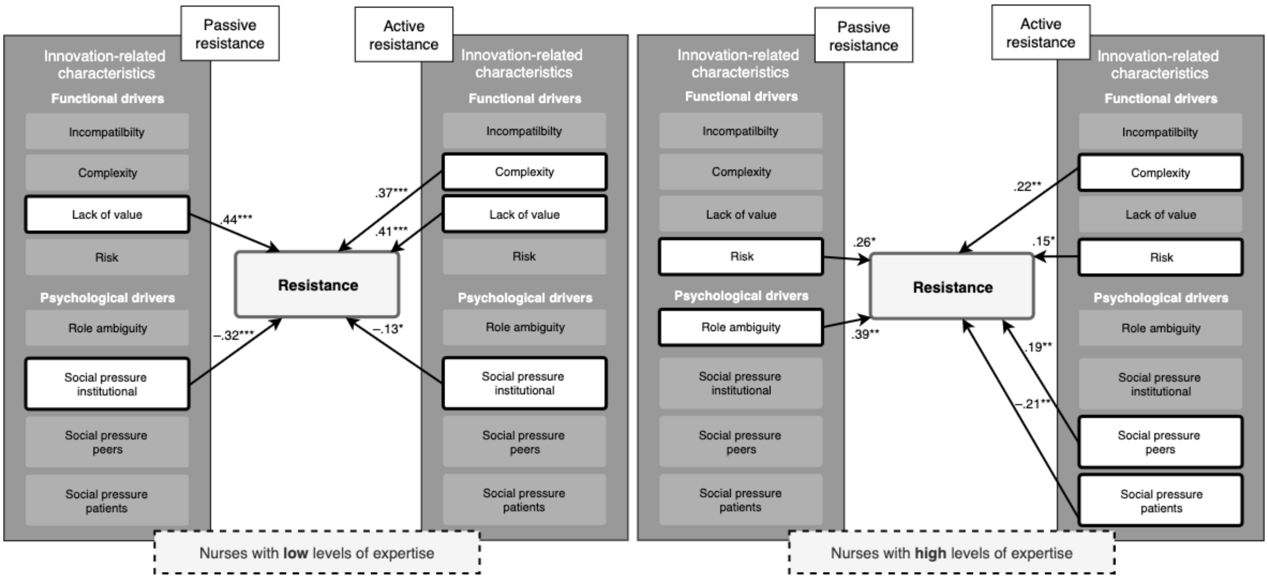
[g] Not applicable.

[h] Low subgroup.

[i] High subgroup.

With regard to possible staff-related moderators, expertise regarding self-management was found to significantly moderate the effect of functional and psychological drivers on resistance (*P*=.03, Table 4), whereas experience was not (*P*=.29). Among nurses with a low level of expertise, lack of value enhanced passive resistance, whereas institutional pressure reduced passive resistance. Complexity and lack of value enhanced active resistance, and institutional pressure reduced active resistance for this group (Figure 3). Among nurses with a high level of expertise (Figure 3), risk and role ambiguity significantly enhanced passive resistance. Complexity, risk, and social pressure from peers significantly enhanced active resistance among nurses with high levels of expertise, whereas pressure from patients reduced active resistance among these nurses.

Figure 3. Schematic overview of the moderating effect of expertise among nurses with low (left) and high (right) levels of expertise regarding self-management. *P≤.05, **P≤.01, ***P≤.001.



Perceived influence of external stakeholders (government; environmental moderator) also had a significant moderating effect (*P*=.04). Among nurses who perceived lower levels of influence from the government (Figure 4), role ambiguity significantly enhanced passive resistance, and social pressure from patients significantly reduced active resistance. Among nurses who perceived high levels of influence from the government (Figure 4), complexity, risk, and role ambiguity enhanced passive resistance, whereas social pressure from the institute significantly reduced passive resistance. Among these nurses who perceived high levels of governmental influence, complexity, lack of value, and social pressure from peers significantly enhanced active resistance. Social pressure from the institute significantly reduced active resistance (Figure 4).

Another significant moderating effect was found for managerial support (*P*=.004; organizational moderator). Among nurses who perceived lower levels of managerial support (Figure 5), role ambiguity significantly enhanced passive resistance; complexity and risk significantly enhanced active resistance, whereas social pressure from patients significantly reduced active resistance. Among nurses who perceived a high level of managerial support (Figure 5), complexity, lack of value, and role ambiguity were significant drivers of passive resistance, whereas institutional social pressure significantly reduced passive resistance. For this group, complexity, lack of value, and social pressure from peers enhanced active resistance, whereas institutional social pressure significantly reduced active resistance (Figure 5).

Figure 4. Schematic overview of the moderating effect of perceived influence of external stakeholders (government) among nurses with low (left) and high (right) levels of perceived influence of external stakeholders (government). *$P≤.05$, **$P≤.01$, ***$P≤.001$.

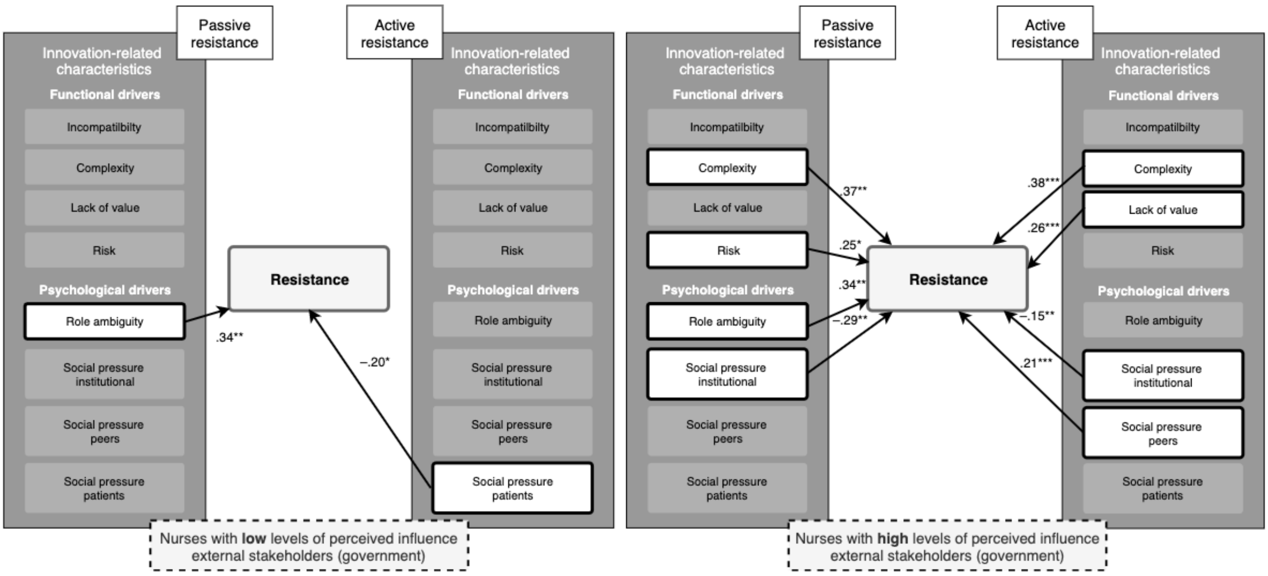
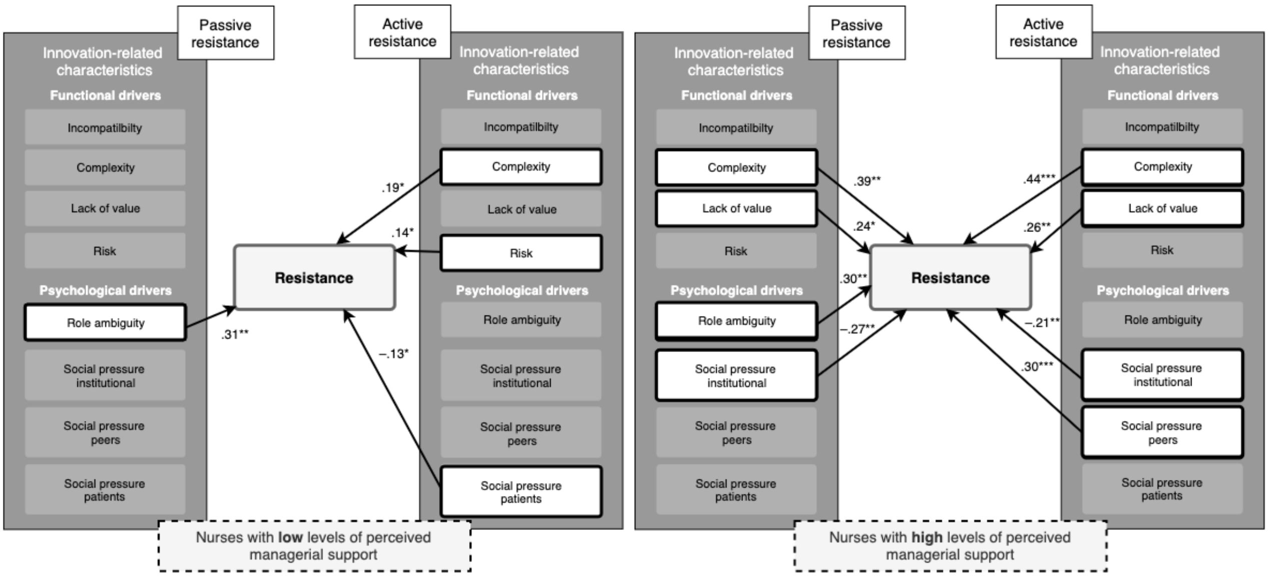


Figure 5. Schematic overview of the moderating effects of managerial support on the effect of functional and psychological drivers on passive and active resistance among nurses with low (left) and high (right) levels of managerial support. *$P≤.05$, **$P≤.01$, ***$P≤.001$.



Discussion

Principal Findings

This study showed that among oncology nurses, passive resistance toward Web-based self-management tools was enhanced by complexity, lack of value, and role ambiguity, and it was reduced by institutional social pressure. Active resistance was enhanced by complexity, lack of value, and social pressure from peers, and it was reduced by social pressure from the institute and patients. In contrast to what we expected, incompatibility with current routines was not a significant driver of either passive or active resistance. This study further showed that these drivers of resistance were moderated by expertise, managerial support, and influence from external stakeholders (government).

Perceived complexity of working with Web-based self-management tools was an important driver of both passive and active resistance among nurses, which is consistent with the view that complexity (related to "ease of use") is a key factor when evaluating innovations or technology [33,34]. Manufacturers of innovations should therefore pay extra attention to make sure the end user understands the advantage of using the innovation. If the advantages of a service can be clearly conveyed, health care providers are more likely to try it [23] and experience the (lack of) complexity themselves.

Lack of value was a significant driver of both passive and active resistance in this study. When nurses view an innovation to be of little added value to their current way of working or when they already use existing tools, this leads to higher resistance. This effect was also observed in a study among general practitioners (GPs) on referring patients to self-management programs, where a negative evaluation by GPs of advantages offered by such programs created a barrier toward implementation [35]. Another study investigating nurses' evaluations of new technologies also recognized "advantages offered" versus "the lack thereof" as the most commonly mentioned driver for both enhancing and impeding implementation [36]. However, even when providers recognize the value of an innovation, it can still potentially lead to resistance. A study on the implementation of patient-reported outcome measures (PROMs) reported that providers still voiced concerns, even when they acknowledged the value of those PROMs [37]. In this study, the lack of value was especially important as a driver of passive and active resistance among nurses with a low level of expertise but not among those with a high level of expertise. Nurses with low levels of expertise are likely to have less knowledge about such tools; therefore, they perhaps have difficulty assessing the value of the tool, resulting in a more conservative evaluation that tends to be more toward the negative side. Addressing lack of value can be challenging, but improving the performance of the tool, as well as positioning it differently, might reduce resistance caused by this driver.

Risk was found to enhance passive and active resistance, but it did so only among nurses with a high level of expertise. Uncertainty about the reliability and satisfaction of use with an innovation can lead to postponement of adoption until the adopting user can learn more about it [12]. In addition, when an innovation is perceived as a major change in the way of working, this is associated with higher levels of perceived risk [38,39]. Nurses with a high level of expertise might consider themselves able and qualified and therefore justified to vocalize their opinions and express their resistance when risk reaches a certain threshold. Risk can potentially be addressed through endorsements and testimonials, as well as facilitation of trialing the tool [12].

Role ambiguity was a significant driver of passive (but not active) resistance, especially in nurses with a high level of expertise. This finding may be similar to what we found for the risk driver: because of their abilities, they are more likely to recognize the problematic nature of role ambiguity and consequently express their concerns about the implementation of such an innovation. A study among customers in their evaluation of a new self-service system found that even a positive evaluation could be trumped by role ambiguity, which may lead to the customer not trying the service [23]. This phenomenon was also observed among nurses, where ambiguous role clarity was linked to low research utilization in evidence-based practice [40]. A recent study looking into self-management support among nurses in oncology found low levels of self-reported confidence and actual use regarding "using assistive devices and technology (ie, eHealth) to provide remote guidance" (ie, Web-based self-management tools), perhaps indicating a form of role ambiguity and therefore low levels of use [41]. Greenhalgh et al postulated that new interventions can have a "hard core" (the innovation itself) and a "soft periphery" (the organizational structures and systems required for the full implementation of the innovation) [42]. Role ambiguity may occur, as the innovation lacks a "hard core" [43] or as clear working instructions or role boundaries are lacking. Role ambiguity may therefore also be addressed by providing education and training, as well as contextually relevant education aids (eg, wallet cards with instructions) [23].

Social pressure was a significant driver of both passive and active resistance. Institutional social pressure reduced both types of resistance, especially among nurses with a low level of expertise, which is in line with findings that coercive institutional pressure results in positive intentions in the adoption process [24]. In addition, social pressure from patients was found to reduce active resistance, especially among nurses with a high level of expertise. In contrast, social pressure from peers was found to significantly enhance active resistance, especially among nurses with high levels of expertise. One explanation could perhaps be found in the psychological reactance theory, which suggests that when an individual perceives a message as threatening to his or her ability to enact free behavior (ie, an experienced nurse being told what to do, ie, by peers), the said individual experiences reactance. This could consequently lead to restorative behaviors (ie, resistance), to restore their threatened freedom [44,45].

Incompatibility was not found to be a significant driver of resistance in this study. This is perhaps partially caused by the perception that the usage of self-management tools can be modified to be compatible with current ways of working.

Moderating effects on drivers of resistance were staff related (nurses' expertise), organization related (managerial support), and environment related (governmental influence). The moderating effect of expertise suggests that social pressure should be used with caution in implementation interventions, as active resistance among nurses with high levels of expertise can only be reduced by social pressure from patients and the institution, but not from peers. This finding sheds light on the commonly used practice of "implementation champions" [46], suggesting that this is not always the straightforward choice; however, more research is needed to understand this process. Managerial support and governmental influence may be viewed as important sources of stimulation. When these are perceived to be high, the effect of social pressure from patients to reduce resistance disappears, whereas the reducing effects of social pressure from patients on resistance remain when this stimulation is perceived as low. Social pressure from the institute only seems effective in reducing passive and active resistance among nurses with low levels of expertise, when managerial support is perceived to be high, or when governmental influence is perceived to be high. This is in line with current views that when implementing an innovation, both executive vision and strategic vision are of key importance (which could be expressed through social pressure from the institute, managerial support, and governmental influence) [47-49].

Managerial Implications

Implementation interventions that aim to reduce passive resistance would probably be most effective, addressing the complexity, lack of value, risk, and role ambiguity surrounding the innovation. This could involve, for example, facilitating trial, communicating relative advantages in a better manner, offering testimonials, providing clear instructions for working with the innovation, or even by making (small) changes to the innovation itself. The process of reducing passive resistance can be accelerated when the organization as a whole (including management) makes its positive position about the innovation clear. This would mainly be effective for those organizations in which employees have a low level of expertise. In case of high expertise, endorsement from the organization (and management) may not be as effective.

Implementation interventions that aim to reduce active resistance on the contrary (and not primarily passive resistance), should especially address complexity, as well as lack of value and risk. Making (drastic) changes to the innovation itself (besides earlier mentioned activities to better the evaluation of certain drivers) becomes a more viable option to consider with active resistance, considering the potential consequences of active resistance. In the case of active resistance, institutional pressure does not seem to work for people with high expertise, whereas pressure from peers even enhances it. However, pressure from patients does seem to work for the high expertise group; therefore, this can be an effective "pull" toward usage.

Limitations

Although this study provided valuable first insights into drivers of resistance among nurses toward Web-based self-management tools, there are some limitations that need to be addressed. Initially, role conflict was included as a driver, but the variable was excluded from further analysis because of problems with the measurement properties. Furthermore, those who completed all questions, compared with those who did not, differed significantly on training and type of hospital, which is a possible indication of participation bias. In addition, as there is no information about nonrespondents, potential selection bias cannot be completely ruled out. Moreover, we did not reach the 400 respondents we initially aimed for. Furthermore, in the survey, the participants were given short and concise descriptions of the tools that were subject to potential resistance. This is of course different from real-world experiences in evaluating innovations, where context also plays an important role. In addition, this cross-sectional study put participants in an "evaluation mindset," with static information for the duration of filling out the survey. Real-world adoption processes are dynamic however, these keep changing over time, when new information becomes available. The cross-sectional design of the study does not allow to make concrete statements on dynamic effects. In addition, general perceptions on innovative concepts, such as the use of Web-based self-management tools in routine care, are also likely to shift over time (ie, to a more accepting mindset). Future studies should therefore aim to use a longitudinal design, operationalizing the examples that are studied closer to what could be encountered in the real world. Furthermore, generalizations about these findings should be made with caution, as processes like these are very context dependent.

This study contributes to better understanding the drivers of passive and active resistance among nurses who are pivotal stakeholders in the implementation of Web-based self-management tools in routine cancer care. The results of this study are highly relevant to health care organizations that aim to implement Web-based self-management tools.

Conclusions

Passive resistance and active resistance are driven by functional and psychological drivers, and these drivers are moderated by expertise, managerial support, and governmental influence.

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Authors' Contributions

All authors designed this study. MW collected all responses from participants, both on the Web and offline. BL performed all analyses. All authors were involved in interpretation of the data and read and approved the final paper.

Conflicts of Interest

IMVdL is named as the inventor of Oncokompas, a self-management portal for patients with cancer used in this study (institutional), and IMVdL obtained funding for research related to Oncokompas from the Dutch Cancer Society/Alpe d'HuZes Fund, Pink Ribbon, Achmea Health Care Assurance, Nutricia, and Redkite (all institutional funding). The other authors declare that they have no competing interests.

Multimedia Appendix 1
Overview of all results and statistics.
[PDF File (Adobe PDF File), 118 KB - jmir_v21i12e14985_app1.pdf]

Multimedia Appendix 2
Questionnaire used in this study.
[PDF File (Adobe PDF File), 3557 KB - jmir_v21i12e14985_app2.pdf]

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Abbreviations

CFA: Confirmatory Factor Analysis
CFI: Comparative Fit Index
eHealth: electronic health
GP: general practitioner
PROM: patient-reported outcome measure
RMSEA: Root Mean Square Error of Approximation
RTI-model: Resistance to Innovation model
SRMR: Standardized Root Mean Square
TLI: Tucker Lewis index

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Original Paper

Attitudes Toward Blockchain Technology in Managing Medical Information: Survey Study

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Abstract

Background: The recently developed blockchain technology uses a peer-to-peer network to distribute data to all participants for storage. This method enhances data safety, reliability, integrity, and transparency. To successfully introduce blockchain technology to medical data management, it is essential to obtain consent from medical doctors and patients.

Objective: The aim of this study was to examine medical doctors' and patients' attitudes toward the use of blockchain technology and interpret the findings within the framework of expectancy theory.

Methods: In this questionnaire survey, we examined medical doctors' (n=90) and patients' (n=90) attitudes toward the use of blockchain technology in the management and distribution of medical information. The questionnaire comprised 8 questions that assessed attitudes toward new means of managing and distributing medical information using blockchain technology. Responses were rated on a scale that ranged from 1 (very negative) to 7 (very positive).

Results: Medical doctors (mean 3.7-5.0) reported significantly more negative attitudes than patients (mean 6.3-6.8). Furthermore, self-employed doctors reported more negative attitudes than employed doctors and university professors.

Conclusions: To successfully introduce blockchain technology to medical data management, it is necessary to promote positive attitudes toward this technology among medical doctors, especially self-employed doctors.

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KEYWORDS

electronic health records; attitude; medical staff; patient; surveys and questionnaires

Introduction

Background

In addition to an increase in life expectancy and use of health care services, medical advances have also led to an exponential growth in the amount of patient medical information available [1]. At present, different hospitals store and manage different fragments of a patient's medical information. This method of managing medical information entails 4 disadvantages [1]. First, it makes it difficult for medical doctors to fully identify patients' medical information. Second, as doctors do not have access to patients' complete medical records, they may subject patients to redundant medical examinations that they have previously undergone in other hospitals. Third, when an interhospital transfer occurs, a patient or his/her guardian will be required to print the medical information on paper, transfer or copy imaging scans onto a CD, and submit them to another hospital. This process is not only inconvenient to the patient or guardian, but the process also carries the risk of omission of certain aspects of patient medical information. Finally, there is a risk that the information that is stored in the hospital may be hacked and leaked.

The recently developed blockchain technology differs from the conventional method of data storage in a central server or specific institution. Specifically, it uses a peer-to-peer network that distributes the data to all participants for storage; these users are responsible for hosting and managing the data [2,3]. This technology enhances data safety, reliability, integrity, and transparency [2,3]. Conventional centralized networks store data in a central server so that only a single central institution has access to the information. In contrast, blockchain-based distribution networks assign an account that contains distributable data to each user [4,5]. This renders hacking virtually impossible because anyone who wishes to modify the stored data will have to simultaneously hack into a vast number of user accounts [4,5]. Given this advantage, blockchain technology has been applied in diverse fields, such as finance, distribution, logistics, public services, and arts [6].

Recently, technology has gained a growing interest in the field of medicine [7-11]. Particularly, the use of blockchain technology in the transfer of medical data allows the patient rather than the hospital to own medical data. As a result, the patient rather than the hospital has control over medical data [1,4,7]. This enables patients to conveniently submit a complete set of medical data to any hospital upon transfer, and it helps physicians gain a better understanding of patients on the basis of the submitted data and plan suitable treatments [1,4,7]. In addition, it can reduce health care costs because patients are less likely to be subjected to redundant medical examinations when complete medical information is available. Moreover, it greatly reduces the risk of potential disclosure of patient medical information [1,4,7]. These advantages of blockchain technology are expected to have a positive influence on clinicians and patients.

Objectives

However, the initial stages of introduction of blockchain technology to medical practice may involve challenges. Particularly, the introduction of blockchain technology to medical data management necessitates the fulfillment of 2 criteria: (1) it must solve technical problems, and (2) health care service providers (ie, medical doctors) and consumers (ie, patients) must consent to its use. According to expectancy theory [12], which is a widely used theory of human motivation in the field of psychology, medical doctors and patients are more likely to use blockchain technology when they hold positive attitudes toward it, and they are less likely to use it when they hold negative attitudes toward it. In this regard, medical doctors' and patients' attitudes are salient factors that must be examined in research studies on the application of blockchain technology to medical data management because a person's attitude toward using a new information technology is indicative of their likelihood of using it [13]. However, the extant research on the introduction of blockchain technology to the health care sector has not shed any light on medical doctors' and patients' attitudes. Therefore, this study attempted to examine medical doctors' and patients' attitudes toward the use of blockchain technology and interpret the findings within the framework of expectancy theory [12].

Methods

Survey

The investigations were carried out following the rules of the Declaration of Helsinki of 1975. We conducted a questionnaire survey among practicing medical doctors who were between the ages of 30 and 49 years. Before the participants responded to the questionnaires, they viewed a video. The authors do not have any associations or relationships with the company that produced the video. In addition, a questionnaire survey was conducted among patients who were between the ages of 30 and 49 years. We think that the medical doctors under the age of 30 years are not experienced in the medical field enough to conduct this survey, and some doctors and patients over the age 49 years might find it difficult to understand blockchain technology. These participants were recruited from the lobby of a university hospital, and they provided consent before their participation in the survey.

The questionnaire comprised items that assessed attitudes toward new means of managing and distributing medical information using blockchain technology [1,14,15]. The questionnaire comprised the following items: (1) unlike traditional methods of medical data management, which bestow complete control over medical information to the hospital, blockchain technology allows a patient to choose the extent to which their medical information is stored, distributed, and managed; (2) blockchain technology delivers each aspect of a patient's medical information to medical doctors; (3) as blockchain technology renders it impossible for one to hack medical information, it enhances the security of patient medical information; (4) blockchain technology prohibits anyone from revising a medical chart without patient consent once it has been created by a medical doctor; (5) blockchain technology allows patients to access information anywhere and at any time; (6) as blockchain technology allows hospitals to exchange medical information, patients do not have to print medical charts on paper, copy imaging scans onto a CD, and submit them to another hospital; (7) as blockchain technology reduces the likelihood of patients being subjected to redundant medical examinations, it lowers health care costs and reduces the time that patients spend at a hospital; and (8) blockchain technology makes it possible for one to use standardized medical big data to enhance the precision and personalization of medical treatments.

The items that were used to measure attitudes toward blockchain technology were adapted from a validated measure that has been used in previous studies, such as those that have been conducted by Venkatesh et al [13] and Min et al [16]. Responses to each item were recorded on a scale that ranged from 1 (*very negative*) to 7 (*very positive*). Higher scores were indicative of more positive attitudes, whereas lower scores were indicative of more negative attitudes.

The item that was used to gauge the levels of medical doctors' and patients' previous knowledge about blockchain technology was adapted from a validated measure in a similar previous study by Bettman and Park [17]. The level of previous knowledge about blockchain technology was gauged on a scale ranging from 1 (*do not know it at all*) to 7 (*know it very well*).

Statistical Analysis

The collected data were analyzed using SPSS Version 24.0 (IBM Corporation). The data were analyzed in 2 steps. In the first step, the demographic characteristics and attitudes of medical doctors and patients were compared using the Mann-Whitney *U* and Chi-square tests. In the second step, Kruskal-Wallis and Mann-Whitney *U* tests were conducted to compare the demographic characteristics and attitudes of self-employed and employed doctors and university professors; the least significant difference test was used as a posthoc test. The level of statistical significance was specified as $P<.05$.

Results

Demographics

A total of 90 medical doctors from 16 different departments and 90 patients participated in this survey. Table 1 presents their demographic characteristics, and Table 2 summarizes the distribution of medical doctors across the 16 different departments that they represented.

The results of the first step of data analysis revealed no significant differences in the demographic characteristics of medical doctors and patients (Table 1).

Table 1. Significance of the difference in the demographic characteristics of medical doctors and patients.

Demographic characteristics	Medical doctors (n=90)	Patients (n=90)	*P* value
Age (years), 30s:40s, n	62:28	60:30	.75
Gender, male:female, n	62:28	60:30	.75
Level of prior knowledge[a], mean (SD)	3.0 (1.4)	3.0 (1.5)	.69

[a] Level of prior knowledge about blockchain technology was rated on a scale that ranged from 1 (Do not know it at all) to 7 (Know it very well). Higher scores are indicative of a higher level of prior knowledge about blockchain technology.

Table 2. Distribution of medical doctors across the departments that they represented (N=90).

Department	Frequency, n (%)
Rehabilitation and physical medicine	27 (30)
Pediatrics	14 (16)
Neurosurgery	6 (7)
Anesthesiology	6 (7)
Family medicine	6 (7)
General practice	6 (7)
Internal medicine	5 (6)
Orthopedics	3 (3)
Dermatology	3 (3)
Plastic surgery	3 (3)
Obstetrics and gynecology	3 (3)
Diagnostic medicine	3 (3)
Psychiatry	2 (2)
General surgery	1 (1)
Radiology	1 (1)
Radiation oncology	1 (1)

Result of Survey

The emergent means for all items that measured attitudes toward blockchain technology (ie, >3.5) were indicative of positive attitudes among both medical doctors and patients (Table 3).

Table 3. Significance of the difference in attitudes toward the use of blockchain technology in the management of medical information between medical doctors and patients.

Blockchain technology application	Medical doctors, mean (SD)	Patients, mean (SD)	*P* value[a]
(1) Unlike traditional methods of medical data management, which bestow complete control over medical information to the hospital, blockchain technology allows a patient to choose the extent to which their medical information is stored, distributed, and managed.	3.9 (1.9)	6.4 (0.8)	*<.001*
(2) Blockchain technology delivers each aspect of a patient’s medical information to medical doctors.	4.4 (1.9)	6.3 (0.9)	*<.001*
(3) As blockchain technology renders it impossible for one to hack medical information, it enhances the security of patient medical information.	4.4 (1.8)	6.8 (0.5)	*<.001*
(4) Blockchain technology prohibits anyone from revising a medical chart without patient consent once it has been created by a medical doctor.	3.7 (1.9)	6.4 (1.0)	*<.001*
(5) Blockchain technology allows patients to access information anywhere and at any time.	4.2 (1.9)	6.7 (0.6)	*<.001*
(6) As blockchain technology allows hospitals to exchange medical information, patients do not have to print medical charts on paper, copy imaging scans onto a CD, and submit them to another hospital.	5.0 (1.9)	6.8 (0.5)	*<.001*
(7) As blockchain technology reduces the likelihood of patients being subjected to redundant medical examinations, it lowers health care costs and reduces the time that patients spend at a hospital.	4.7 (2.0)	6.8 (0.5)	*<.001*
(8) Blockchain technology makes it possible for one to use standardized medical big data to enhance the precision and personalization of medical treatments.	4.7 (2.0)	6.7 (0.8)	*<.001*

[a] Values in italics are significant at the .05 level of significance.

However, medical doctors reported significantly more negative attitudes than patients across all items (mean 3.7-5.0; Table 3). Medical doctors reported the most negative attitude (mean 3.7) for the following item (ie, item 4): “blockchain technology prohibits anyone from revising a medical chart without patient consent once it has been created by a medical doctor.” The second most negative attitude (mean 3.9) was reported for the following item (ie, item 1): “unlike traditional methods of medical data management, which bestow complete control over medical information to the hospital, blockchain technology allows a patient to choose the extent to which their medical information is stored, distributed, and managed.” Meanwhile, patients reported more positive attitudes than medical doctors across all items (mean 6.3-6.8; Table 3).

The results of the second step of data analysis revealed no significant difference in the demographic characteristics of self-employed and employed doctors and university professors (Table 4).

Self-employed doctors reported significantly more negative attitudes than employed doctors and university professors on the following two items (Table 5): “since blockchain technology allows hospitals to exchange medical information, patients do not have to print medical charts on paper, copy imaging scans onto a CD, and submit them to another hospital” (item 6) and “since blockchain technology reduces the likelihood of patients being subjected to redundant medical examinations, it lowers health care costs and reduces the time that patients spend at a hospital.” (item 7). There was no significant difference among the 3 groups on the other items (Table 5).

Table 4. Significance of the difference in the demographic characteristics of self-employed and employed doctors and university professors.

Demographic characteristics	Self-employed doctors (n=14)	Employed doctors (n=54)	University professors (n=22)	*P* value
Age (years), 30s:40s, n	7:7	13:41	14:8	.15
Gender, male:female, n	12:2	36:18	14:8	.32
Level of prior knowledge[a], mean (SD)	3.1 (1.5)	3.0 (1.5)	2.8 (1.4)	.74

[a] Level of prior knowledge about blockchain technology was rated on a scale that ranged from 1 (*Do not know it at all*) to 7 (*Know it very well*). Higher scores are indicative of a higher level of prior knowledge about blockchain technology.

Table 5. Significance of the difference in attitudes toward new methods of managing medical information using blockchain technology among self-employed doctors, employed doctors, and university professors.

Blockchain technology application	Self-employed doctors, mean (SD)	Employed doctors, mean (SD)	University professors, mean (SD)	*P* value
(1) Unlike traditional methods of medical data management, which bestow complete control over medical information to the hospital, blockchain technology allows a patient to choose the extent to which their medical information is stored, distributed, and managed.	3.0 (1.9)	4.0 (1.9)	4.4 (1.7)	.09
(2) Blockchain technology delivers each aspect of a patient's medical information to medical doctors.	3.5 (2.4)	4.5 (1.9)	4.8 (1.6)	.10
(3) As blockchain technology renders it impossible for one to hack medical information, it enhances the security of patient medical information.	4.5 (2.0)	4.4 (1.8)	4.5 (1.8)	>.99
(4) Blockchain technology prohibits anyone from revising a medical chart without patient consent once it has been created by a medical doctor.	3.1 (1.9)	3.9 (2.1)	3.5 (1.5)	.42
(5) Blockchain technology allows patients to access information anywhere and at any time.	3.3 (2.1)	4.3(1.9)	4.7 (1.6)	.07
(6) As blockchain technology allows hospitals to exchange medical information, patients do not have to print medical charts on paper, copy imaging scans onto a CD, and submit them to another hospital.	3.5 (2.4)	5.2 (1.8)	5.4 (1.3)	*.02*[a,b]
(7) As blockchain technology reduces the likelihood of patients being subjected to redundant medical examinations, it lowers health care costs and reduces the time that patients spend at a hospital.	2.9 (2.4)	5.0 (1.9)	5.1 (1.7)	*.02*[a,b]
(8) Blockchain technology makes it possible for one to use standardized medical big data to enhance the precision and personalization of medical treatments.	3.8 (2.4)	4.9 (2.0)	5.0 (1.9)	.14

[a] Mean item score for self-employed doctors < mean item score for employed doctors and university professors.

[b] Values in italics are significant at the .05 level of significance.

Discussion

Principal Findings

This study examined medical doctors' and patients' attitudes toward new methods of managing and distributing medical information using blockchain technology. The major findings of this study can be summarized into 3 points. First, medical doctors reported significantly more negative attitudes than patients across all items that measured attitudes toward the application of blockchain technology to the management and distribution of medical information (Table 3). Second, self-employed doctors reported significantly more negative attitudes than employed doctors and university professors on the sixth and seventh items, which pertain to 2 advantages of blockchain technology, namely, convenient exchange of medical information among hospitals and lower number of redundant medical examinations (Table 5). Third, patients obtained means that ranged from 6 to 7 across all the items; this indicates that they held very positive attitudes toward the application of blockchain technology to medical data management (Table 3).

The 3 major findings of this study can be interpreted within the framework of the expectancy theory of psychological motivation [12], which suggests that people are motivated to pursue positive outcomes and avoid negative outcomes [12,18]. In this regard, the first finding can be interpreted to mean that medical doctors have more negative attitudes about blockchain technology than patients as they expect its use to lead to negative outcomes. For example, medical doctors' attitudes were most negative for the fourth item, which delineates how blockchain technology makes it difficult for one to revise medical charts (Table 3). This feature of blockchain technology may be disadvantageous to medical doctors, when there is a medical dispute between them and a patient or guardian. Similarly, the second most negative attitudes were reported for the first item, which articulates the fact that blockchain technology allows patients to have complete control over their medical data (Table 3). This may have caused medical doctors to be concerned about potential misuse of patient medical information. The second major finding of this study has practical implications as it suggests that the use of blockchain technology may lead to negative outcomes among self-employed doctors. According to expectancy theory [12], there is a perceived association between a person's actions and their consequent rewards [12,18]. Rewards may be of various types (eg, money and praise from other people) [12,18]. Self-employed doctors reported significantly more negative attitudes than employed doctors and university professors on the sixth and seventh items (Table 5). These items pertain to 2 advantages of blockchain technology: (1) it facilitates convenient transfer of medical information among hospitals, and (2) it lowers health care costs and reduces the time that patients spend at a hospital by minimizing the need for redundant medical examinations. As the profits that are earned from medical examinations contribute to self-employed doctors' incomes, they may worry that the use of blockchain technology will lower their income. More specifically, patients may decline undergoing a medical examination that has been recommended by a smaller clinic if they have already undergone similar examinations in a larger hospital, even when such examinations are required to make an accurate medical diagnosis.

The third finding of this study suggests that patients hold very favorable attitudes toward the use of blockchain technology. This may be because of the fact that the application of blockchain technology to medical data management will yield outcomes that are beneficial rather than harmful to patients. Expectancy theory suggests that people cognitively analyze the gains and losses of behaviors in which they intend to engage [12,18]. In this regard, blockchain technology may offer patients several gains and lead to only a few losses. For instance, it grants patients direct control over their medical information and enhances the transparency and stability of their medical records [2,3]. Moreover, blockchain technology can decrease health care costs by diminishing the need for redundant medical examinations and making it easier to transfer patient medical information to another hospital [1]. In addition, it can contribute to medical research by granting researchers access to patients' personal medical data [1,4].

The 3 major findings of this study, which are consistent with the premises of expectancy theory [12], suggest that to successfully introduce blockchain technology to medical data management, it is necessary to promote positive attitudes toward this technology among medical doctors. This can be achieved by alleviating their concerns about the adverse outcomes of the introduction of blockchain technology to medical data management and raising awareness about its potential advantages to medical doctors. In addition, the findings suggest that it is especially necessary to alleviate self-employed doctors' concerns about potential problems that may result from introducing blockchain technology to medical data management.

At present, many companies worldwide are researching the means by which blockchain technology can be introduced to the health care sector [4,6]. Some pilot projects have been conducted in the domains of management and distribution of medical data. Although various studies have actively examined the new means by which blockchain technology can be applied to medical data management in the health care sector [2-7], none of the past studies have examined the attitudes of direct users of blockchain technology in health care sectors, namely, medical doctors and patients.

Conclusions

In this study, we ascertained the extent to which the attitudes of medical doctors and patients are favorable toward the use of blockchain technology in the management and distribution of medical information. We found that medical doctors reported more negative attitudes than patients. Therefore, to introduce blockchain technology to medical data management, it is necessary to alleviate the concerns that medical doctors (especially self-employed doctors) have about the use of blockchain technology. Our study has some limitations. First, we did not examine the specific factors that lead to negative and positive attitudes toward the use of blockchain technology in medical data management. Second, diverse age groups were not represented in the study sample. Third, the number of doctors working in a specific department (physical medicine and rehabilitation) is disproportionately high. Fourth, the number of included subjects was relatively small. Fourth, a qualitative analysis method, such as a qualitative survey, can be effectively used to clearly show medical doctors' and patients' attitudes toward blockchain technology. However, we analyzed them by using only the quantitative analysis method using a questionnaire-based survey. Future studies that address these limitations will be able to enrich the present findings.

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Conflicts of Interest

None declared.

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Abbreviations

NRF: National Research Foundation

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Original Paper

Identifying and Overcoming Policy-Level Barriers to the Implementation of Digital Health Innovation: Qualitative Study

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Abstract

Background: High-level policy barriers impede widespread adoption for even the most well-positioned innovations. Most of the work in this field assumes rather than analyzes the driving forces of health innovation. Objective: The aim of this study was to explore the challenges and opportunities experienced by health system stakeholders in the implementation of digital health innovation in Ontario.

Objective: The aim of this study was to explore the challenges and opportunities experienced by health system stakeholders in the implementation of digital health innovation in Ontario.

Methods: We completed semistructured interviews with 10 members of senior leadership across key organizations that are engaged in health care–related digital health activities. Data were analyzed using qualitative description.

Results: A total of 6 key policy priorities emerged, including the need for (1) a system-level definition of innovation, (2) a clear overarching mission, and (3) clearly defined organizational roles. Operationally, there is a need to (4) standardize processes, (5) shift the emphasis to change management, and (6) align funding structures.

Conclusions: These findings emphasize the critical role of the government in developing a vision and creating the foundation upon which innovation activities will be modeled.

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KEYWORDS

health care; policy; implementation; health technology

Introduction

Background

Digital health innovation is the cornerstone of health care modernization efforts in a number of countries internationally [1-3]. Notwithstanding select evidence of impact on quality and efficiency [4,5], its application in practice has been described as a *plague of pilots* where innovations fail to become part of routine practice because of limited funding or inability to scale to broader sectors of the health care system [6-11]. Translating evidence into practice remains a challenge despite the accumulating body of evidence regarding factors underlying success and failure [12,13]. The Ontario government began developing the Digital Health Strategy in 2015 and unveiling the strategy and its guiding principles in 2016 (see Table 1). In this strategy, the Ontario government outlined a Digital First philosophy as 1 of the 7 guiding principles, which considers new and existing programs and asks, “How can we do it with digital health?” [14]. The creation of this strategy addressed a previously unmet need for provincial guidance on the adoption and integration of digital innovation within the public system, signaling a potential inflection point that hinges on the ability to both understand and overcome barriers to digital health innovation.

Table 1. Guiding principles for the Ontario digital health strategy.

Principle[a]	Description
Put patients first	Focus efforts on faster access to care, innovative and integrated care, empower patients and caregivers, and ensure a fiscally sustainable public health care system
Adopt a “Digital First” philosophy	Approach new and existing programs and discussions by asking, “How can we do it with digital health?”
Make solutions about quality care	Design new policies, care models, funding structures, and workflows that are best for patients and providers—then think about how technology can help
Be transparent	Use open, evidence-based standards to guide governance and investment decisions; report progress publicly and regularly
Be innovative	Use the full scope of creativity of what is possible with contemporary technology to support patient and provider decision making, virtualize processes, and deliver services
Build on what we have already	Leverage existing assets as a starting point when possible
Be pragmatic	Strive for solutions that are “good enough” and processes, such as governance, that are not needlessly burdensome

[a] Adapted from Bell R. Ontario’s Patients First: Digital Health Strategy. Canada Health Infoway Partnership Conference 2016 [14].

Overarching Barriers to Digital Health Innovation

Obstacles in the digital health innovation process stem from features of the innovation itself and the broader implementation context, which includes the divergent interests of a variety of stakeholder groups [14]. Innovations that establish proof of concept often lack a strategic plan for diffusion, which complicates uptake and adoption into routine care [15,16]; however, high-level policy barriers impede widespread adoption more broadly for even the most well-positioned innovations [17]. For the purposes of this paper, we refer to adoption at the organizational level, recognizing that this cannot be achieved without engagement of and support from frontline clinicians. Context and culture drive changes in the use of technology [18], highlighting the central role that policy reform will play in the success (or failure) of the digital health agenda. Despite this, policy (or a lack thereof) is conspicuously missing from studies examining the drivers of failure when it comes to scaling digital health innovations. For example, Sundin et al [11] categorize failures according to financial, technical, organizational, employee, customer, or contextual barriers.

Policy is a Central Driver of Change

Greenhalgh et al [19] highlight that health and fiscal policy often underpinned the inability to move from a successful pilot to mainstream service and explicitly outline the need to identify and attend to potential drivers (or roadblocks) at a policy level to avoid nonadoption or abandonment. Attention has been paid to practical guidance for health system modernization, outlining approaches to funding reform and the organization of services [20]. The same attention and rigor devoted to the mechanics of the activity must be paid to the overarching policy context [21]. An array of organizational and institutional arrangements underpins the innovation process, which includes both innovation development and facilitating the implementation of advancements into clinical practice [22]; however, most work assumes rather than analyzes the underlying components and driving forces of health innovation [22]. Guiding theories, such as Rogers Diffusion of Innovation [23], highlight that the process of adoption is at the level of the individual, which is driven by communication through social channels. Diffusion occurs across several stages that include knowledge, persuasion, decision, implementation, and confirmation, highlighting that an individual’s decision to adopt or reject an innovation depends on receiver variables, social system variables, and perceived characteristics of innovation [23]. Organizational factors, such as the capacity to innovate, readiness for the digital health innovation, availability of funding, and extent of changes required to implement the innovation [20], also influence the adoption process [24] and thereby impact the uptake of digital health innovations in practice. Therefore, the objective of this study was to understand the challenges and opportunities in the implementation of digital health innovation from the perspective of organizations as the adoption unit, and the potential policy-level actions that might promote enhanced uptake of digital health innovation at scale in Ontario.

Shifting From an Economic to a Health System Lens

The major contributions to the body of literature on *Health Innovation Systems* are driven by an economic perspective and thereby frame innovation achievements against the backdrop of economic change [22]. In contrast to that work, we are focused on innovations that enable *health systems* to better achieve their goals of providing better outcomes alongside improved patient and provider experience, at controlled or reduced costs [25] (ie, a digital innovation that allows for real-time image sharing across institutions and providers, reducing the need for duplicate imaging). In this way, we fundamentally adopt a health system perspective in our paper, as opposed to a view that might focus on economic development more generally. For the purposes of this paper, a health system is defined as a functionally related group of interacting organizations and providers that share a common aim [26] of providing the best possible care for a population at the lowest possible costs.

Methods

Study Design

Our approach was informed by a constructivist paradigm [27] and used thematic analysis [28] to understand how current challenges and opportunities impact the implementation of digital health innovations in Ontario. For the purposes of this study, we focused on the organization as the “adopter” and therefore the subsequent unit of study. These insights informed subsequent recommendations to overcome these challenges and capitalize on opportunities. Ethical approval was obtained from the Women’s College Hospital Research Ethics Board.

Our study was conducted in the province of Ontario, Canada, where the majority of health care is publicly funded and privately delivered. However, despite the fact that our data collection took place in a single Canadian province, we focused our analytic strategy on identifying challenges and opportunities that apply to health care systems across high-income countries.

Participants

A purposive sampling strategy was used to select participants, whereby the research team generated a preliminary list of key organizations that are engaged in health care–related digital health activities in Ontario, Canada. Participants were required to occupy a position of senior leadership within their organization to ensure their ability to speak to system-level barriers. This list was then circulated to a broader advisory group to elicit suggestions to ensure a wide range of perspectives. A total of 9 potential participants were then sent an introductory email, outlining the purpose of the study and requesting their participation or asking them to identify an appropriate alternative within their organization. All 9 potential participants expressed interest and contacted the study authors directly to be scheduled for an interview.

Data Collection and Analysis

Interviews were conducted in person by 2 experienced qualitative scientists (LD and JS). A semistructured interview guide was used (see Multimedia Appendix 1). The interview questions were open ended to elicit participant experiences related to the policy and strategy dimensions of the implementation of digital health innovations. Interviews were audio recorded and transcribed verbatim. A total of 3 team members (LD, CS, and JS) analyzed data iteratively and inductively. The first 4 transcripts were independently read and coded before the meeting to discuss an initial coding scheme. As interviews continued, original themes identified in the first 4 interviews were further explored and refined to the point of theoretical saturation while giving participants an opportunity to identify new insights. No new themes emerged after the initial 4 interviews; therefore, no additional participants were recruited after initial themes reached saturation. The findings are presented in terms of the key aspects of policy, which require attention to best promote the adoption of digital health innovations at a system level.

Results

Participant Breakdown

A total of 10 participants were interviewed across 9 interviews (1 participant invited a colleague to their interview), with an average duration of 40 min (range 21-61 min). Participants included representatives of key organizations within the digital health landscape (see Table 2 for descriptions), including the Ontario Ministry of Health and Long-Term Care (MOHLTC), the Ontario Telemedicine Network, Ontario MD, Canada Health Infoway, and the MaRS Excellence in Clinical Innovation Technology Evaluation program, as well as key leaders in health innovation.

Participants were unanimous in their belief that “what we’re doing at a system level is not working.” The importance of strong leadership at an organizational and system level was viewed as critical for the successful implementation of digital health innovation, with an emphasis on establishing a culture of innovation. Participants described 6 key priorities requiring action at the policy level to catalyze digital health innovation, including the following: (1) a system-level definition of innovation, (2) a clear overarching mission for digital health innovation, and (3) clearly defined organizational roles. Operationally, there is a need to (4) provide guidance on standardized processes, (5) shift the emphasis to change management, and (6) align funding structures. A participant summarized the problem as follows:

> *It’s still not a case of build it and they will come. I’ve been working in this space for 20 years and truly if you look at the penetration of virtual care—there’s still tremendous opportunity at the system level ...you know we are a broken system.* [P03]

Table 2. Organizational representation.

Organization	Description[a]
Ontario MOHLTC[b]	Provincial ministry responsible for administering the health care system and providing services to the province of Ontario
Ontario MD	Helping physician practices advance electronic medical records, products, and services so that we collectively enhance the delivery of patient care
Ontario Telemedicine Network	Develop and support telemedicine solutions that enhance access and quality of health care in Ontario and inspire adoption by health care providers, organizations, and the public
Canada Health Infoway	Improve the health of Canadians by working with partners to accelerate the development, adoption, and effective use of digital health solutions across Canada
MaRS EXCITE[c]	Foster the adoption of innovative health technologies in Ontario and leverage those successes and experiences into global markets

[a] Descriptions reflect organizational missions taken directly from respective organizational websites where available.

[b] MOHLTC: Ministry of Health and Long-Term Care.

[c] EXCITE: Excellence in Clinical Innovation Technology Evaluation.

A System-Level Definition of Innovation Is Needed to Align Innovation Efforts

Innovation was defined differently across participants in our sample, with each definition exhibiting unique nuances that reflected the participant's past experience and organizational perspective. For example, one arm's-length policy organization was focused on understanding and modifying components of the health innovation system that could better promote the generation, testing, and ultimate adoption of new technologies:

> *The real innovation for us is the way of aligning all of the bits and pieces of the sector—from everything from policy and payment all the way down to the actual solution.* [P05]

In contrast, a representative from yet another organization took an even broader approach, defining innovation simply as changing processes of problem solving:

> *People are now understanding that innovation is just doing things differently—right, like changing your process, changing you're approach, changing how you think about the problem and what you do to solve that problem.* [P08]

These varied definitions of innovation across key stakeholders are a consequence of a nonexistent, shared conceptual foundation for both digital health innovation and what the health system is supposed to do more broadly. This lack of shared understanding about the nature of health innovation impedes effective communication and collective action, making it extremely difficult to achieve alignment across activities.

A Clear Mission is Needed to Drive Innovation Efforts

Drivers of innovation varied across participants and were largely reflective of their organization's current direction and leadership. Approaches to virtual care were primarily driven by the needs of these individual organizations (ie, reduced cost or improved efficiency). The importance of patient experience was highlighted by several participants, but it was rarely highlighted as the primary driver for innovation. The tension between system needs and patient benefit was accentuated by the nature of a publicly funded health care system, where the distinction between payer and end user complicated the value proposition:

> *It's classic virtual care things where the benefits accrue to the patient largely but the patient doesn't pay. So any time you've got that not perfect alignment in incentives, then you've got work to do. To try and figure out how to get people motivated to grow the service.* [P05]

Virtual care initiatives were characterized by a top-down approach, despite the recognition that a "grassroots" or "frontline" approach to innovation is more likely to support effective problem solving and adoption. Despite highlighting clinician resistance as a key barrier to adoption, participants often described decision-making processes that failed to engage relevant end users (ie, clinicians and/or patients):

> *One of the biggest groups that resists process is clinicians. The way they function—they're workflow, is disrupted when you put in a disruptive technology—so that's one of the difficult groups [...] so you know that is sort of one area that we would be struggling with likely in all our technologies is the end user of the technology.* [P07]

Organizational Roles Need to Be Clearly Defined

Participants described a poorly organized system with respect to the introduction, adoption, and scale of virtual care innovations. The key players within the system's virtual care space are fragmented and function strategically and operationally as independent organizations. Participants felt that unclear roles and responsibilities perpetuated this fragmentation, and they proposed effective governance and accountability as a potential solution:

> *I think—in Ontario—this is a real problem is because ownership is often not taken or not clear, and so who's driving that agenda is not clear- and [who is] accountable for it and when they do become accountable for that. [Organizations] take a very narrow space of it, where it's just their thing that they can do and that's a problem.* [P09]

The MOHLTC’s Digital Health Board, an advisory committee tasked with providing advice with respect to priorities, was described as a “sponsor” of the province’s digital health strategy but devoid of “any formal accountability.” Participants emphasized that, although priority setting begins to address the issue, a general lack of accountability persists, which hinders collaboration and progress. In extreme cases, this leads to organizations having competing or overlapping priorities, resulting in an inefficient use of system resources:

> *There’s another layer around prioritization around the big agencies in this eHealth space, and the ministry did say these are your roles in a letter last year to all of us, that has never been enforced, we’re kind of still figuring it out.* [P01]

Provide Guidance on Processes to Standardize Across Organizations

The fragmented nature of processes and infrastructure related to virtual care was attributed to the operational silos that characterize virtual care organizations and health care institutions. Fragmentation results in a virtual care landscape that includes a heterogeneous assortment of technologies with limited interoperability, driven by disparate, institutionally specific procurement processes that are widely acknowledged as onerous and not conducive to early-stage innovations:

> *Every different hospital is different, taking a different approach, working with different partners, and in some respects, that’s promoted by the chief innovation officer of programs is that they do want institutional partnership between institutions and innovators—but that ends up being less collaborative across institutions.* [P09]

In the absence of a shared vision and shared processes, organizations engage in procurement decisions independent of one another, which contributes to the lack of interoperability among technological innovations within the broader system. This was unanimously viewed as a significant barrier to a virtually enabled health care system, complicating the landscape for new innovations for which interoperability is fundamental to their functionality and value proposition.

The Emphasis Needs to Shift From the Technology to Change Management

The existence of microcultures within organizations (and therefore the system) presents both an opportunity and a challenge, as some of these microcultures push for change, whereas others try to maintain the status quo. Strategies to enable a broader culture shift included collaborative approaches to innovation, entry-level education, and modifications to existing incentives:

> *Basically they are different elements of the system and different structures in the system and any time you try to make change there is a tendency for those individual structures or nodes to try to revert back to the current state—the status quo. So, there’s a kind of system stability. I think that it’s possible to give sufficient pushes at different nodes and changing the incentives at each node to move to the different state within the system.* [P02]

Establishing buy-in from clinicians is “*all about the change management.*” The importance of this shift in mindset from implementation to change management was recognized by many participants; however, it was only operationalized by a few. The current emphasis was primarily placed on the solution and the proposed payment model—a mindset that was viewed as a barrier to successful adoption. Although the payment model was highlighted as a key barrier to adoption and scale (as the system lacks a mechanism for clinicians to bill for virtually enabled care), this was not viewed as a significant challenge from a change perspective:

> *Just changing the care model—or the payment model—will not make that happen, you have to actually have an adoption plan and you know to actually promote that to occur and so there really has to be change management strategies to make that occur—so you have to have both of them to make that actually happen.* [P09]

Funding Mechanisms Must Evolve to Reflect the Nature of Innovation

Siloed funding for virtual care initiatives and innovation further contributes to the fragmentation of activities across the sector. Siloed program funding creates a barrier to establishing a business case, as many virtual solutions that are designed for one setting (eg, the community) will result in savings realized in another setting (eg, acute care):

> *There aren’t many mechanisms in place where they can flow budget from one group to another and when you’ve got these silos around the way dollars flow, that can be a real hurdle in how innovation is taken up.* [P07]

The primary funding mechanisms for organizations interested in innovation are institutional operating budgets or public grant funding through national agencies (ie, Canadian Institutes of Health Research). Unfortunately, institutional budgets are considerably strained, and “there are very few central points of knowledge around how [grant] funding works” across the range of funding sources. Funding is usually given for a defined period, and it leaves the responsibility of sustainability and ongoing funding to the organization itself. Precarious funding impacts the likelihood of sustainability and results in siloed investments that ultimately undermine the implementation and adoption of innovation efforts.

Discussion

Advancing the Understanding of Policy-Level Barriers to Digital Innovation

Our results build on previous literature by illustrating how a lack of system guidance, both conceptually and structurally, contributes to the inability of many digital health innovations to move beyond local success to realize their impact at scale. Despite technological advances and rapidly accumulating evidence on the value of digital health, the development of policy-level guidance has lagged behind. Against the backdrop of Ontario's *Digital First* strategy, policy-level gaps undermine the potential success of digital health innovations. First, there is a need for system-level clarity around the definition of innovation, the primary mission underlying innovation efforts, and organizational roles and responsibilities. In addition to these governing principles, the strategies to support the uptake of innovation in practice must evolve to align with the objectives of the broader system. These strategies include, but are not limited to, organizational procurement processes, funding models and innovation incentives, and broader implementation strategies. As specific recommendations for funding reform (the finding *Funding Mechanisms Must Evolve to Reflect the Nature of Innovation*) have been outlined previously [20], we will devote the discussion to exploring the remaining recommendations.

Establishing a Definition of Digital Health Innovation

Health care organizations' pursuit of their missions is often fraught with complexity. Failure to achieve full realization often extends beyond funding issues and is attributable to organizational structures and interactions or competing policy pressures [29,30]. An overarching definition of innovation and its agenda are needed at a system level to help organize and align innovation efforts across the many organizations that make up the system. Innovation refers to novel products, processes, business models, methods of communication, or origination of novel markets (ie, those that were not previously known or used in a given setting) [31]; therefore, digital health innovation could be described as novel *digitally enabled* products, processes, business models, methods of communication, or origination of new markets in health care. Novel innovations do not have to be new but can be borrowed from other industries and applied in different contexts or could be used in different ways. Digital health innovations should be evidence informed and show a positive impact to support spread and scale across organizations.

Articulating a Clear Mission

Articulating a vision and establishing a clear direction are central to the ability to achieve health care transformation [32,33]. An absence of clearly defined goals undermines accountability [34] and the ability of individuals and organizations to achieve broader system goals. Furthermore, there is a need to clarify what should be done when conflict arises among the range of competing demands (eg, access, quality, cost control, and customer satisfaction) [35]. The implementation of innovation at scale depends on the co-ordination of various types of knowledge within a system or, more explicitly, the connection of various organizations and institutions [22]—a coordinated effort that relies on a common mission and understanding. We propose an explicitly stated guiding principle, whereby health system innovations *must improve at least one dimension of* the Institute for Healthcare Improvement's "Quadruple Aim" [25] (outcomes, patient experience, provider experience, and cost), *without adversely affecting the remaining dimensions* from a system perspective (note that this may mean that while costs are increased in one area of the system, cost reductions are realized in another).

Provide Overarching Guidance on Institutional Processes

The interactions among individuals, institutions, and organizations contribute to coherent trajectories of system change over time [22]. Analogous to the concept of technological interoperability, the processes and structures that guide innovation activities within the system must exhibit some degree of synergy. In the absence of synergistic processes, the resulting system complexity creates an inadvertent barrier to innovation [36]. Changes to existing institutional structures are crucial to the viability of a true *Health Innovation System*, which depends on effective co-ordination across a range of industries and specializations [22]. Much like the Ontario government's *Digital First* philosophy [37], organizational processes should be developed (or revised) by asking "how can this align with similar processes or structures within the system?" We suggest that the system would benefit from policy-level guidance on key elements to include (ie, demonstrated system-level interoperability for institutional procurements), which will facilitate alignment across organizational activities and provide the foundation upon which organizational processes will be built [33].

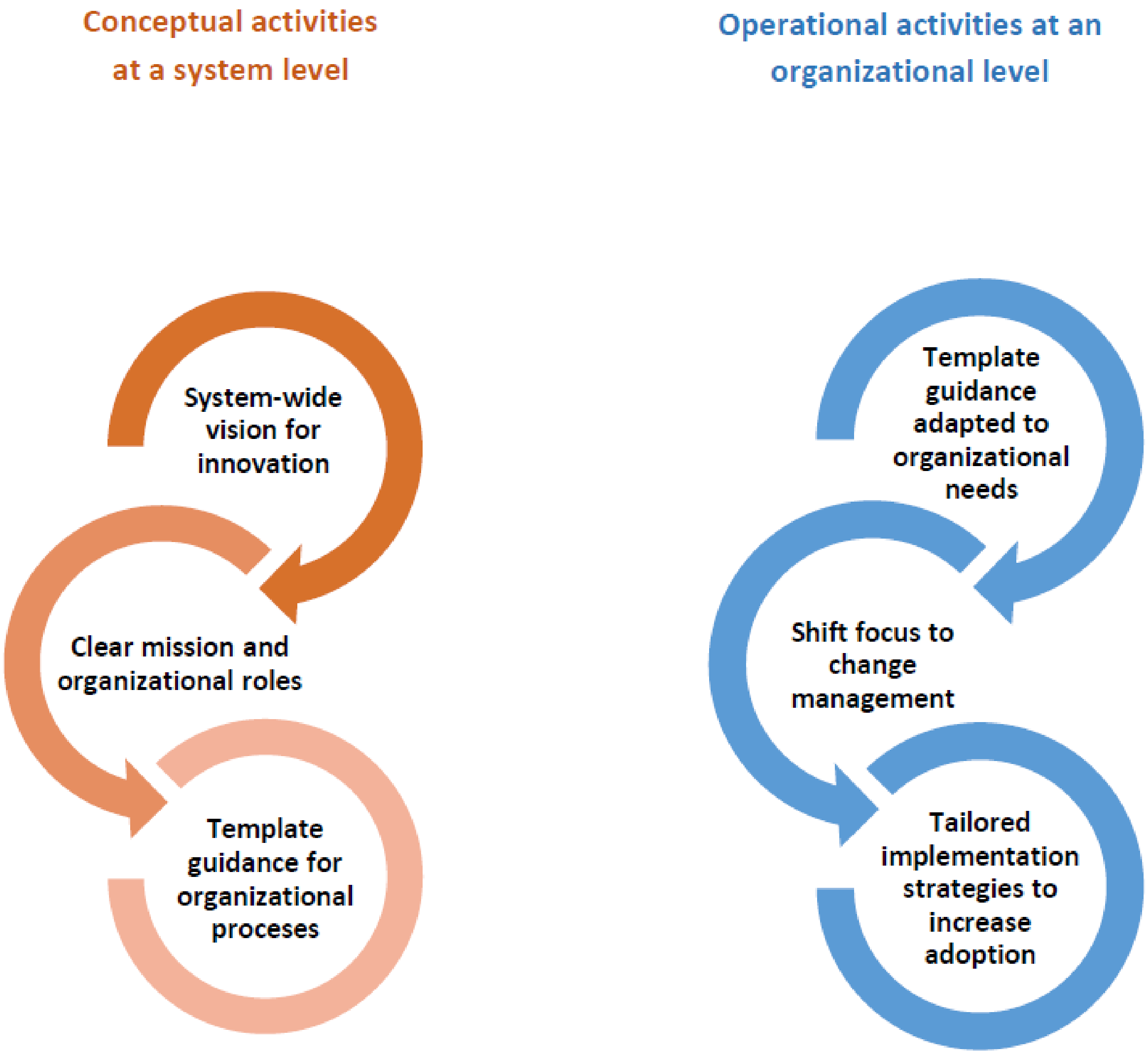
Shift the Emphasis to Change Management

Taking these policy-level implications of our research down to the level of the organization, we observed the following: "One-size-fits-all" strategies often translate into suboptimal engagement, underscoring the need for a change management approach that tailors implementation strategies to the varied needs of end users [38] (see Figure 1). Beyond the demonstrated need for strategies to engage clinicians and end users, a parallel need exists for investment in "internal" capabilities for transformation [39]. Implementation agents must acknowledge that the introduction of digital health innovations necessitates changes to service delivery, and change management is part of the process. As such, it is critical to attend to the central considerations of tool, team, and routine throughout the implementation process [40] to understand how successes can not only be achieved but also be spread, scaled, and sustained. The adoption of digital health innovation is an iterative process that involves complex interactions among these central factors, among others. We suggest that those individuals responsible for implementing innovations in practice utilize existing approaches [19,40-42] to assist in the systematic consideration of key factors to develop their implementation strategy in a way that mitigates the impact of unanticipated obstacles. Notably, although these tools can strengthen the development of implementation strategies, achieving transformative change through health system innovation will unequivocally require creative and bold leadership [33,36,43]. Furthermore, only 0.3% of research funding from the Canadian Institutes of Health Research (a national research funding body) has supported change management strategies or scaling up innovation [44], signaling a disconnect between system priorities and investment and underscoring the need for an aligned strategy.

It is important to note that the findings of this study depict a cross-sectional state in time. Organizations and systems are dynamic (and not time invariant); therefore, their activities are linked and informed by a grid of evolving connections. Notwithstanding, our results highlight the current system gaps, and we propose related policy-level activities that will promote the broader uptake of digital health innovation.

Although we achieved theoretical saturation in our sample, participants were mainly from urban organizations in Ontario; therefore, our findings may not reflect the challenges of implementing digital health innovations in rural organizations. Our results are not intended to be generalizable to every example of digital health innovation in Ontario, and future work would benefit from the validation or refinement of these themes from the perspectives of those responsible for technology adoption (ie, patients and health care providers). Although these findings reflect the local health system context in Ontario, Canada, many health care systems are pursuing increased quality through innovative modification of current delivery systems [2,3,20,45]. Fragmented service delivery and a lack of standardization plague health systems internationally [46], further highlighting the broad relevance of our findings.

Figure 1. System and organizational activities to facilitate the adoption of digital health innovation.



Conclusions

Despite much policy-level talk of triggering a revolution in service delivery and many small-scale proof-of-concept examples, digital health innovations are rarely mainstreamed or sustained [47]. Our findings build on previous work on health system capacity planning, which emphasizes the role of the government in charting the digital course by developing a vision and creating the foundation upon which (currently fragmented) innovation activities will be modeled [33]. It is important to note that transformative change does not necessitate growth in size or the addition of resources; instead, it may be achieved by thoughtful and efficient reconfiguration of existing practices [48,49]. Health care systems around the world and their stakeholders can reflect on these findings and recommendations to consider their utility in advancing local health innovation agendas. To support policy efforts, evaluations of digital health innovations should focus on identifying the factors that influence adoption of a given innovation (as outlined in Roger’s Diffusion of Innovation Theory) to support the evolution beyond the pilot stage to broader adoption.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview guide.
[DOCX File , 16 KB - jmir_v21i12e14994_app1.docx]

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Abbreviations

MOHLTC: Ministry of Health and Long-Term Care

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Viewpoint

Open Access as a Revolution: Knowledge Alters Power

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Abstract

The slogan "Gimme My Damn Data" has become a hallmark of a patient movement whose goal is to gain access to data in their medical records. Its first conference appearance was ten years ago, in September 2009. In the decade since there have been enormous changes in both the technology and sociology of medicine as well as in their synthesis. As the patient movement has made strides, it has been met with opposition and obstacles. It has also become clear that the availability of Open Access information is just as empowering (or disabling) as access to electronic medical records and device data. Knowledge truly is power, and to withhold knowledge is to disempower patients. This essay lays out many examples of how this shows up as we strive for the best future of care.

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patient engagement; empowerment; patient empowerment; participatory medicine; open access; patient portals; EMRs; EHRs; Patient-clinician relationship

Introduction

As I write these words on September 17, 2019, it has been ten years since I gave my first keynote speech at a medical conference in Toronto, at Medicine 2.0. My opening slide had the date wrong, but this was it: the first time Gimme My Damn Data was spoken on stage [1].

It was ten years into the Journal of Medical Internet Research's (JMIR) long history, the midpoint between today and its founding. Most of what I wrote in my blog post about that speech [2] is still valid; most importantly, "there's still no way for me to get all the data out" of my hospital, Boston's Beth Israel Deaconess. Ironically, they are considered a leader in health information technology. Sociologically they are, as it is the home of OpenNotes; however, that is a social movement, not a technology.

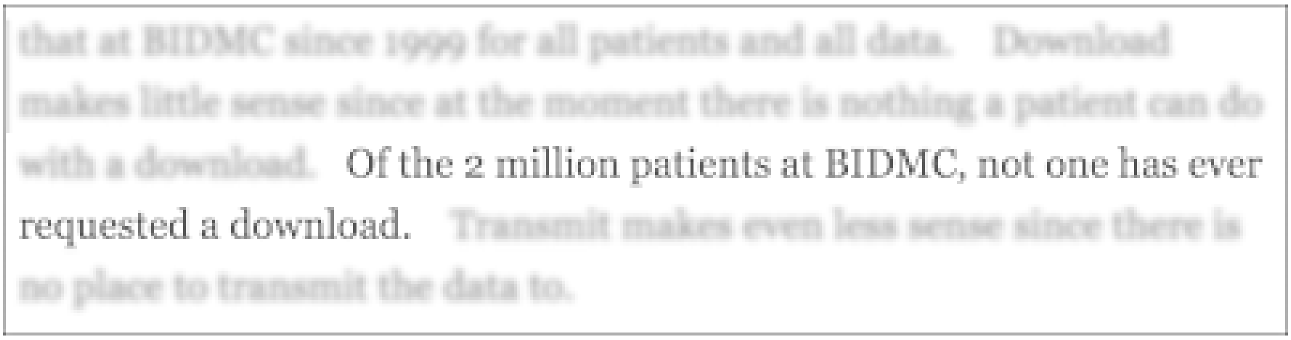
The genesis of my advocacy for data rights is a story of its own: I believed my hospital's (former) Chief Information Officer (CIO) when he blogged [3] that I could move my medical data into the old Google Health site, and they were wrong. In short, a blog post I wrote about garbage that showed up in Google Health landed on the front page of the Boston Globe. The resulting social media furor led to a speaking invitation from Gunther Eysenbach, Editor-in-Chief of JMIR. He kept asking what title I would use, and in frustration, I told him to "Just call it 'gimme my damn data,' because you guys can't be trusted with it." The first part stuck.

That speech turned into a movement, a music video by Ross Martin, MD, and his band [4], and an unplanned global speaking career. Along the way, Ross's wife Kym, a multi-cancer survivor, made it more polite and descriptive by changing it to DaM data: Data About Me. However, health care institutions mostly do not get it yet, so I say that it is time for a revolution.

That former CIO, who knows me personally, has nonetheless blogged that patients do not want their information and that there is nothing they could do with it if they had it [5,6]. He wrote that not a single patient at our hospital has ever tried to download their record (Figure 1), and then we learned he does not have a way to do that [7]. I am fed up with this kind of "leadership," even though I am not in a health crisis. If I were in an emergency, I would be furious because knowledge and information are power, so to withhold patient data is to disempower the person for whom the profession exists. I will not stand for it anymore. To me, the withholding of information from patients is the same issue as putting general medical information behind paywalls, an issue that favors Open Access journals that freely provide knowledge, a model which JMIR has pioneered.

In this article, I will write briefly about ten significant developments that have concurred with JMIR's first twenty years, with the developments divided into three categories: technological, sociological, and the convergence of the two. In the technological category, these developments include the arrival of electronic medical records (EMRs) and government mandates, particularly in the United States. The sociological category has to deal with the awakening of the patient movement, which includes developments such as the empowered, engaged, equipped, and enabled patient (e-patient) movement (citing Eysenbach), uncovering what empowerment is, the #PatientsIncluded movement ("Nothing about me without me" scales up), resistance from the establishment, parallels with the women's movement, and the British Medical Journal's Patient-Public Partnership. Finally, the convergence between the two involves the awakened and empowered seeking their data, with new technology enabling it, and includes the emerging standard of Fast Health care Interoperability Resources (FHIR).

Figure 1. Blurred screen capture with extract "Not one patient".



that at BIDMC since 1999 for all patients and all data. Download makes little sense since at the moment there is nothing a patient can do with a download. Of the 2 million patients at BIDMC, not one has ever requested a download. Transmit makes even less sense since there is no place to transmit the data to.

Development 1: Health Information Technology Regarding Electronic Medical Records and Mandates

Undeniably the first significant development in the ten years since my speech was the arrival of US $40 billion in subsidies and then penalties that pushed the country toward finally computerizing our medical data. The first electronic medical record systems had arrived in the previous century, but they did not take off until the industry was forced to acknowledge them. I shudder to think what the state of adoption would be today if it were not for that $40 billion.

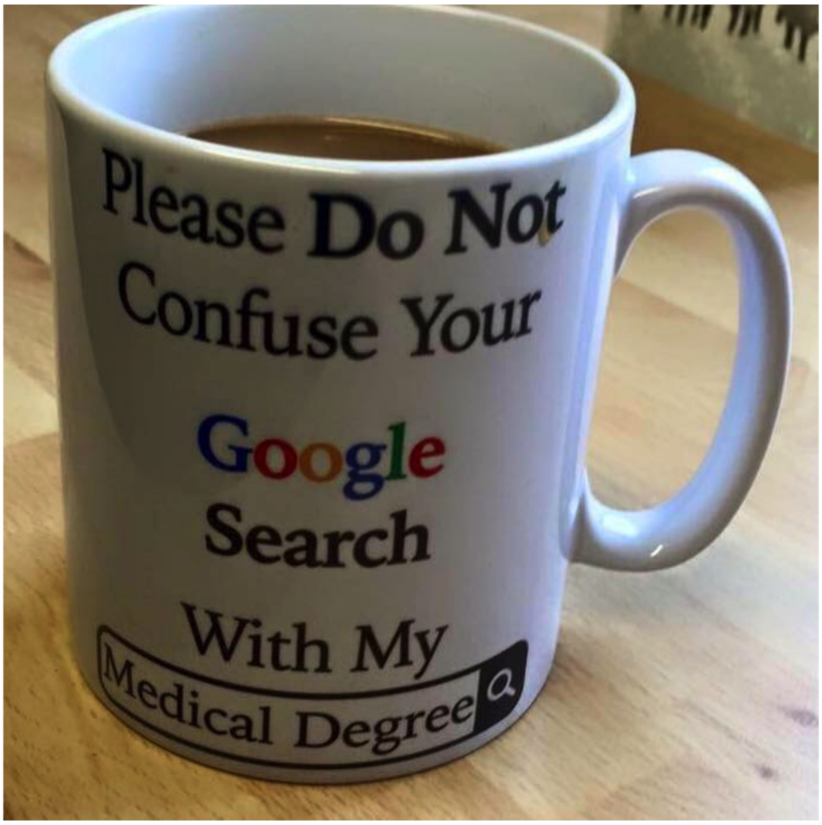
The usability of these systems is widely considered to be horrible [8]. However, as I previously said on Twitter [9], blaming the government is off target. A few months after my speech in Toronto, while in Washington D.C., I referred to rumors that an EMR vendor Chief Executive Officer (CEO) had said usability would be a system criterion "over my dead body." The vendor won, but though adoption has been ugly, the situation has progressed to the point where we do have information systems. For the first time, it is possible to move data around, and though we are nowhere near the finish line, we have finally moved off the starting line.

Development 2: The E-Patient Movement and Participatory Medicine

"Doc Tom" Ferguson was a visionary who saw that access to information via the internet would transform what patients could do to contribute to their family's health and care. His "e-Patient White Paper" [10], published posthumously in 2007, cited Gunther Eysenbach's remarkable DAERI [11] project, which established that Googling does not lead to a flood of deaths. He found zero deaths in years of seeking horror stories, even when he offered a €50 (US $55.02) bounty. Trying not to view internet research done by patients negatively is a lesson that could still be learned by medical students today, as highlighted by the Google mug meme that has been circulating online (Figure 2) [12].

To my knowledge, Eysenbach and Doc Tom produced the first crack in the armor of the idea that only doctors can know what is worth knowing. All else has stood on their shoulders. The same year of that Medicine 2.0 speech, Ferguson's founders formed the Society for Participatory Medicine [13].

Figure 2. Google mug.



Development 3: Understanding What Empowerment Is

One of the potential definitions of the “e” in Ferguson’s e-patient concept that is often cited is empowerment. However, in my first years of conference travels, I found universal uncertainty about what we mean by it. If we are not clear about what empowerment is, how can we even tell whether someone is doing it? Then, at the 2013 World Parkinson Congress in Montreal, Swedish e-patient Sara Riggare told me about a definition she had seen in a speech the previous day. This was a definition that the World Bank has been using since 2002 when they help a developing nation become self-reliant [14]:

> *The process of enhancing an individual’s or group’s capacity to make purposive choices and to transform those choices into effective actions and outcomes.*

Isn’t that precisely what we seek in empowering patients? Increase their capacity to make choices and produce results? Someone who can do that has power, and someone who does not is disempowered. With this straightforward definition, we can evaluate any intervention: does it increase or diminish one’s capacity? I believe that withholding one’s medical data diminishes their ability to manage their medical lives. Access is empowering. I assert that the same applies to medical literature, which can be inaccessible to patients because of paywalls. It is bluntly disempowering to the patient who has the problem because the publisher has a higher priority than directly empowering the sick person and their carers.

I asked Sara which scientist or sociologist had presented this at the conference. She said it was a fellow patient, Fulvio Capitanio, who said it during his presentation. It is important to note that it was not a scientist who was moved to present this as a topic of significance, but a patient.

Development 4: The Genesis of #PatientsIncluded

In 2013, the Dutch visionary Lucien Engelen posted that he had seen the future and would no longer speak at any health conference, not even for a hefty fee, if it did not actively include patients, on stage or in the audience, which included paying their expenses [15]. He was the first leader I know of who said we could not do health care right (or plan or manage it) if patients are not involved in the process. Today, among other things, this includes patient data management.

As with many social issues, #PatientsIncluded is the latest expression of an earlier principle: Nothing about me without me. This concept started with the disability rights movement in South Africa in the 1980s [16], but they had another potent line about showing up to advocate for yourself: “When someone else speaks for you, you lose” [16]. The women’s suffrage movement found the same in the 1800s when they let some men speak for them in Congress [17]. The men made compromises that the women would not have accepted.

Development 5: Discovering Parallels With the Women’s Suffrage Movement

Speaking of the women’s movement, I was in the Boston college scene when feminism rolled through, and I have noticed many parallels with the participatory medicine movement. One such favorite parallel of mine is that at dances, we had to shift from "boy leads, girl follows" to a bit more collaboration, just as participatory medicine tells us to share taking the lead. Also, in 1912, some people resisted women's suffrage by saying, "Most women aren't asking for it" [18], just as some clinicians today say, "My patients aren't asking for access." Seeing the potential for improvement, and enabling it, requires vision. Saying "I don't see the potential yet" is a favorite way to stay secure in the past. That never improves things.

Development 6: Resistance

When you are in a revolution, at first, they ignore you. When they start to strike back, it is a sign that those you are fighting against are waking up. I was appalled in 2014 when Dutch visionary Lucien posted about two award-winning commercials (published by the Belgian government) that said, "Don't google it. Check a reliable source", as if that was an either-or proposition. e-patients who are using Google to get information are trying to supplement their knowledge, not ignore doctors; we may google it, and we can also check a reliable source. However, in both commercials, the citizen falls for an incorrect website and does not think to ask their clinician [19,20]. Not to be outdone, Israel's largest health maintenance organization, Clalit, produced a commercial [21] showing a "search victim" rolled into an emergency room. A doctor yells, "Clear!" and slams the patient's laptop shut as if turning off the computer was as potent as cardioversion.

Savvy e-patients know there is incorrect information on the internet, and they know not to swallow everything they see. In 1999, I found my wife on match.com. Before I found her, I got some suboptimal search results, but I knew enough to check before acting. If you have ever taught a child how to be careful online, you know that when someone is inexperienced, the remedy is not to keep them naïve but instead to teach them how to watch out for themselves. Paternal caring is essential when someone cannot make choices, but it is cruel and foolish when they have grown up.

There is a sad side to getting this wrong. The NHS Trust in Nottingham, England, had to apologize to the family of 19-year-old liver cancer patient Bronte Doyne, who died after her doctors told the family to stop going to Google for information, even though the family had found valid information that the clinicians did not know [22]. Ironically, these physicians had never received training about how valid information can be found online. Physician naïveté about this issue is a legitimate challenge to physician credibility and authority.

In an era of constant and overwhelming change, it is unfair to put all the burden on the health system. Sometimes a patient might discover something the doctors have not seen, and an enlightened doctor will know that and not squander the opportunity. This is not about ignoring doctors. It is about patient participation to help health care achieve its potential.

Development 7: Discovering Parallels With Radically Rethinking Education

The radical education book "Pedagogy of the Oppressed" [23] discusses how you teach people, under the old model of "teacher knows everything useful; student is an ignorant puppet, a bucket to be filled properly." The book asserts that this is oppressive. The more "right" approach, it says, is to teach the student to question, to think critically for themselves. Can you sense the parallels with "doctor knows best" medicine and participatory medicine?

The Society for Participatory Medicine's cofounder Sarah Greene penned a post in 2009 called, "Participatory Medicine as Revolution: Think Critically! Communicate!" [24] She replaced the book's use of student and teacher with patient and provider:

> *Patients, having adopted guidelines of their health care provider and internalized his images, [become] fearful of freedom. Freedom would require them to eject this image and replace it with autonomy and responsibility.*

Only this year did I connect the dots between this and how information empowers, which in turn enables revolution. When we have limited access to information, we are dependent, whether anyone intended us to be or not.

A note that is relevant to JMIR, in particular, is that information behind a paywall impedes growth and empowerment. Open access to information is empowering because it enables the citizen.

Development 8: Convergence of Technology and the Social Awakening With the Science of Behavior Change

For years, my mind has itched at the complaint, "My patients aren't asking for this." But then I remembered meeting Stanford behaviorist BJ Fogg in 2010, with his model of behavior change: Behavior change is a function of motivation to change, ability to take the requested action, and some trigger (or prompt). Someone might write it out as:

However, he writes it as B=MAT (in later versions prompt replaces trigger). He developed this into a useful 3 × 5 matrix of types of behavior change, which I have rarely heard discussed in health care and never regarding health data. He breaks it up as follows:

- Y-axis: "Dot, span, or path." Are we talking about doing something once (dot), or for a specific time (span), or permanently (path)?
- The X-axis is a type of change: start something, end something, do more or less of something, or do something they already know how to do (once, or for a while, or permanently).

With this model, if someone complains that patients “don’t do as they’re told,” we are able to ask, “Well, what type of change were you requesting?” Moreover, if they say patients are not asking for something (such as data), we can explore differences between observed groups rather than assuming that all patients are the same. In behavior change as in biology, a more thoughtful diagnostic approach has a better chance of helping patients.

I suspect we will discover a role for Freire’s advice to awaken the “student.” As he said, that will never happen if we think patients are mindless vessels to be filled by somebody else. Could it be that our paradigm of patient is a principal cause of the behaviors people complain about [25]?

Development 9: Motivation for Action Due to the Business Side of US Health Care

I am not happy to say this, especially since I have come to know many good, committed people who work in this system, but there are many instances of mistreatment in the system:

- “If Grandma Is on the Table, No One Will Blink at the Price”: A Former Drug Company Manager Explains Industry Price-Setting [26]
- “Is curing patients a sustainable business model?” (Investment company Goldman Sachs) [27]
- Stories of hospitals suing their patients to preserve their health at the cost of the patient’s health
    - “‘UVA Has Ruined Us’: Health System Sues Thousands Of Patients, Seizing Paychecks And Claiming Homes” [28]
    - “When Hospitals Sue For Unpaid Bills, It Can Be 'Ruinous' For Patients” [29]
    - “As Patients Struggle With Bills, Hospital Sues Thousands” [30]

We must revolt against this, or the businesspeople who run parts of the health care system shall surely crush us. However, to revolt and strive for autonomy, we need information.

Development 10: Fast Health Care Interoperability Resources

At this twentieth anniversary of JMIR, and the tenth anniversary of my first speech, there is new hope for autonomy and independence due to a revolution empowered by information. A new software standard for data mobility, FHIR, is maturing. In my personal view, this is the most significant change in these past ten years; the signs are that FHIR might make real what I was trying to do in 2009 with Google Health. I say this in part because a familiar origin story for a patient’s newfound empowerment is their discovery of a significant mistake in their medical information, or even discovering that vital information from one care provider never made it to the next. Sometimes the failure of that data to move to the point of need causes horrific harm.

Tying it All Together

So much has changed since September 2009, but the business side of health care still says that patients should do as they are told. A few years ago, Judy Faulkner, founder and CEO of EMR vendor Epic, famously argued with former US vice president Joe Biden, saying, “Why do you want your medical records? They’re a thousand pages of which you understand 10.” Nevertheless, Biden replied, “None of your business.” [31] Biden’s motivation trumped her apparent belief that he (and his son’s doctors) could not make use of the asset. Biden had lost his son Beau to brain cancer, and the final efforts to save him were impeded by the inability to move Beau’s data around. So, one can imagine that it would be upsetting to Biden when someone criticizes his desire to help people save their families. There is a video of Biden’s speech that same year at Health Datapalooza, where you can sense the mood of someone who tried to help save his son’s life and was blocked [32].

Just this September, both the American Medical Association and the American Hospital Association cautioned against letting patients have their data [33]. In summary, they said, “something bad might happen” if it leaked. That is paternalism at its finest, or in Fogg’s model, “Ability is zero, so no change is possible—why even try?” Empowered patients might respond: “Let me decide!”

It is not just EMR data, too. Many patients have devices wired into their bodies. These are real medical wires and sensors under their skin, and some of these patients want to see the data their devices are generating. They are empowered, an attitude that has converged with the knowledge that there is data about their body’s functions and their health, and they want to see it. Hugo Campos is a famous example. An implanted cardioverter-defibrillator (ICD) manages his life-threatening heart condition, something he is happy about, but he does not want to wait around passively for the next time it shocks him. He wants to know how to manage his life, but the device’s maker, Medtronic, will not give him the data that comes out of his own heart. Thus, they keep the information and block Hugo from managing his own life. The extraordinary health researcher/anthropologist/thinker Susannah Fox has just capped off the ten years I have known her with a new post about Hugo and their related issues, “Why should anyone care about health data interoperability?” [34]

However, the most spectacular example of empowered patients is the OpenAPS open-source pancreas system. These people invented something that works better than a healthy pancreas at managing their blood sugar, with no doctors or scientists or device makers involved [35,36]. Their original hashtag is a perfect expression of liberation, #WeAreNotWaiting, which, when merged with technology, has produced a new, patient-created way to manage a life-threatening condition [37,38]. The most hopeful development on the horizon, to me, is that Sloan School of Management professor Eric von Hippel has begun applying his thinking on “Free Innovation” (a book about consumers modifying products or creating inventions) to health care. In February, he, his daughter, and others authored, “When Patients Become Innovators” in the Sloan Management

Review. The featured patients were Dana Lewis and the OpenAPS group, and Sean Ahrens of Crohnology, which is a community of Crohn's Disease patients.

Open Access Embodies All the Issues of the Past Decade

We have learned that if EMR information is held only by third parties, then we the patients will depend on them for everything. We have learned that getting our hands on EMR data, such as through OpenNotes, enables real change and contribution. Similarly, if access to medical journals is available only to professionals (health care providers and researchers), then we, the patients, for whose benefit they work, are oppressed, whether that is intentional or not. However, we have seen, through JMIR and others, that Open Access journals can accelerate the dissemination of new knowledge, which increases the aggregate potential of what health care can achieve.

We must revolt against the limits that constrain progress. We must speak up, say what is important to us, and argue ceaselessly for the change we want in the world. Often, we may only shift from that dependent role when some trigger provides motivation, but this is not a shift someone can perform while their boat is metaphorically sinking. Empowerment through information can be revolutionary, but it is not instantaneous; when we acquire a new asset, we must learn to use it. Let us educate each other before trouble strikes, so that when it does, we have the best odds of the kind of success other highly engaged patients and I have achieved: to help health care achieve its potential.

Conflicts of Interest

None declared.

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Abbreviations

CIO: chief information officer
EMR: electronic medical record
e-patient: electronic patient
FHIR: Fast Health care Interoperability Resources
ICD: implanted cardioverter-defibrillator
JMIR: Journal of Medical Internet Research

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Viewpoint

Building Capacity and Training for Digital Health: Challenges and Opportunities in Latin America

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Abstract

Tackling global health challenges demands the appropriate use of available technologies. Although digital health could significantly improve health care access, use, quality, and outcomes, realizing this possibility requires personnel trained in digital health. There is growing evidence of the benefits of digital health for improving the performance of health systems and outcomes in developed countries. However, significant gaps remain in resource-constrained settings. Technological and socio-cultural disparities between different regions or between provinces within the same country are prevalent. Rural areas, where the promise and need are highest, are particularly deprived. In Latin America, there is an unmet need for training and building the capacity of professionals in digital health. This viewpoint paper aims to present a selection of experiences in building digital health capacity in Latin America to illustrate a series of challenges and opportunities for strengthening digital health training programs in resource-constrained environments. These describe how a successful digital health ecosystem for Latin America requires culturally relevant and collaborative research and training programs in digital health. These programs should be responsive to the needs of all relevant regional stakeholders, including government agencies, non–governmental organizations, industry, academic or research entities, professional societies, and communities. This paper highlights the role that collaborative partnerships can play in sharing resources, experiences, and lessons learned between countries to optimize training and research opportunities in Latin America.

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KEYWORDS

digital health; capacity building; training program; education; public health; telehealth; Peru; Latin America

Introduction

Digital health has made a wide range of technologies (eg, the use of computers, tablets, and mobile phones) readily available around the globe, and could contribute significantly to both improving the quality of health care for populations and enabling better health outcomes [1]. In this viewpoint, the term digital health could be used synonymously with electronic health (eHealth) and mobile health (mHealth).

Although there is growing evidence of the benefits of digital health for strengthening health systems and improving health outcomes in developed countries, significant gaps remain in resource-constrained settings. Technological and socio-cultural disparities between different regions or provinces within the same country are prevalent. Rural areas, where the promise and need are highest, are particularly deprived.

Latin America is still recognized as the most unequal region in the world [2]. According to the 2019 Global Multidimensional Poverty Index report by the United Nations Development Programme and the Oxford Poverty and Human Development Initiative, 39 million people in Latin America experience multidimensional poverty [3]. Latin America is a region with particular local characteristics related to economy, employment, housing, education, cultural context, and health care [4].

Information and communication technologies can help reduce those inequalities in Latin America, being essential tools to promote innovation and knowledge generation in societies, especially to disadvantaged groups and rural areas. Latin American countries must properly incorporate information and communication technologies to address the health needs of their population. In October 2019, the 57th Directing Council of the Pan American Health Organization (PAHO), through Resolution CD57/9, adopted the Plan of Action for Strengthening

Information Systems for Health 2019-2023 [5] to ensure better collection and management of data. This was done to inform decision-making, policy development, monitoring, and evaluation. This highlights the need for strengthening resource capacity for the proper implementation of health information systems, considering the context, needs, vulnerabilities, and priorities of countries [5]. Objective 42.2 is related to improving human resource training in all aspects of health information systems, and is the [5]:

> *Number of countries and territories with ongoing professional training strategies or digital literacy programs for the use of new technologies.*

Excepting the countries of the Americas that have made substantial progress in improving health information systems [5], there are still many technological, organizational, and socio-cultural challenges in Latin America. These challenges include poor infrastructure, low Internet connectivity, inequalities in access to electricity, and adult illiteracy [6]. This lack of efficient health innovation projects and programs has been recognized as one of the main challenges of the health sector in the region [7]. On top of that, the World Health Organization (WHO) and the International Telecommunication Union identified the lack of qualified and experienced professionals in digital health as one of the main barriers for digital health application at the global level [8]. In general, doctors are unevenly distributed across Latin American countries, and most health care professionals are concentrated in urban areas [7].

Therefore, we need a skilled workforce not only to understand health care and information and communication technologies, but also to implement effective digital health systems that can achieve national, regional, and local goals. This is especially important when considering the socio-economic, socio-cultural, and organizational challenges involved. This viewpoint paper aims to present a selection of experiences in building resource capacity for digital health in Latin America to illustrate a series of challenges and opportunities for strengthening digital health training programs in resource-constrained environments.

The Need for Strengthening the Digital Health Workforce in Latin America

The need for training and building the capacity of health care professionals in digital health remains one of the most significant public health challenges in Latin America [9]. Digital health training and research programs in this region are scarce [10] and poorly documented. However, some remarkable initiatives and programs have been implemented in Latin America. For example, the PAHO has carried out essential actions regarding digital health in the region, which included not only capacity-building activities but also research. These activities included regional workshops on digital health, the development of knowledge networks and technical guidelines, the promotion of information sources on the internet, the establishment of digital health sustainability models, the support for the development of electronic health records, the promotion of standards on health data and related technologies that ensure exchange of information, the promotion of mobile devices to improve health, and the improvement in quality of care through telemedicine [11].

Moreover, the PAHO has developed a series of virtual courses such as: “eHealth for Managers and Decision Makers,” the “Virtual course on properly completing death certificates,” and “Access and Use of Scientific Information on Health.” All these courses are available through the Virtual Campus of Public Health. With those initiatives, thousands of health workers have already been trained throughout the region [12].

Experiences for Building Capacity in Digital Health in Latin America

A proper health workforce trained in digital health will strengthen health systems and ensure adequate service delivery. There is growing evidence around the world of the value that well-trained personnel in digital health can offer to tackle global health challenges [13], including evidence from Latin America [14,15]. Latin American countries have carried out a wide range of digital health initiatives, including educational initiatives and training programs for digital health resource capacity building [5,10,16-19]. Despite the discontinuity of several projects and initiatives, many collaborative courses and research projects related to digital health have been developed between international institutions promoting North-to-South, South-to-North, and South-to-South collaborations [5,10,20-24].

The Informatics Training for Global Health (ITGH) program from the Fogarty International Center has played a significant role in expanding the informatics workforce based on the health and informatics needs of countries. Over the years, the ITGH has supported informatics research training in low- and middle-income country institutions in partnership with US institutions and investigators and has funded several collaborative research and training programs in Latin America [10,13,15].

The American Medical Informatics Association (AMIA)’s Global Partnership Program (GPP), funded by the Bill and Melinda Gates Foundation, aims to develop project-centric approaches to training in developing countries to expand local resource capacities and to promote collaboration [25]. As part of the meetings conducted with AMIA GPP committee members, several Latin American experts on digital health actively participated and contributed to the discussions and activities [26].

There is also “Regional Protocols for the Formulation of Public Telehealth Policies for Latin America,” funded by the Inter-American Development Bank, which involved 16 Latin American countries and identified that the training of professionals in telehealth was a priority for its development in the region [16]. To contribute to the development of telehealth in the region an international telehealth training course (via long-distance education) was conducted with the participation of Latin American universities, the PAHO, and the United Nations Economic Commission for Latin America and the Caribbean, [16].

It is essential to highlight that Brazil once hosted the oldest resident informaticist program in Latin America, at the Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, from 1988-1997 [27]. The clinical pathology service had a 2-year clinical informatics residency mainly focused on hospital software project management, the design of electronic health records, and epidemiological information technologies [27]. Brazil also launched electronic learning programs for the National Telehealth Program and in partnership with the Open University of the Unified Health System [10], and they also promoted the development of nursing education programs with nursing informatics topics [10].

It is also important to point out that the Department of Health Informatics at Hospital Italiano de Buenos Aires, in Argentina, created in 2001, developed a 4-year residency program that has been accredited by national authorities as a “bridge” between health care and information technology [10]. The curriculum includes two years in internal medicine, computer science, health care information systems, electronic health records management, epidemiology, knowledge-based databases for clinical terminology and standards, biostatistics, and decision-making theory [10]. Likewise, the Hospital Italiano de Buenos Aires developed courses for digital literacy oriented towards information retrieval and other similar disciplines. A Spanish version of the AMIA’s 10×10 initiative was developed in collaboration with Oregon Health and Science University’s Department of Medical Informatics and Clinical Epidemiology [10].

Training programs on digital health in Latin America should consider the results from a survey conducted in 2011 by Blas et al from the Andean Global Health Informatics Research and Training Center [21], which surveyed 142 experts from 11 countries regarding the need for health informatics training. The top-ranked courses were: “Introduction to Biomedical Informatics,” “Data Representation and Databases,” “Mobile Health,” and “Security, Confidentiality, and Privacy.” The research topics reported as a priority were: evaluation of health information systems, policy in health informatics, interoperability and standards, evidence-based decision making in informatics, rural telemedicine, mobile health, electronic health records, sequence analysis and gene finding, tele-education, and the analysis of cost-effectiveness in biomedical informatics [21].

Challenges and Opportunities for Strengthening Training Programs and Initiatives in Latin America

Overview

A remarkable 2003 review paper by Rodrigues, published at the Journal of Medical Internet Research [28], and entitled “eHealth in Latin America and the Caribbean: Development and Policy Issues,” described trends and issues regarding the deployment of electronic health solutions in Latin America and the Caribbean. Since people are central to the value-added creation of digital health services, skilled and committed human resources were identified as an essential component for the deployment of the digital health ecosystem in Latin America [28]. Therefore, Latin American countries should invest in digital health training programs to overcome main health care challenges. Rodrigues proposed that systems professionals, technology products, services providers, and project teams must have superior skill levels and experience. He also proposed that efficient and robust government and academic institutions should be committed to investing in education, scientific and technological development, and public services [28]. Some of the critical things that Latin American governments should focus on developing and implementing include developing a national vision, mission, and plan of action for the public and private sectors, and the promotion of education, training, and national planning capacity in information systems and technology [28].

Latin America faces several challenges regarding digital health. For example, telehealth has not yet been scaled up broadly at the national and regional level due to organizational, physical, and technological challenges in Latin America [29]. Moreover, the cultural context and core cultural values in the health care process play a significant role and could have important implications for digital health adoption [29]. Data sharing among health professionals also remains a limitation due to the restricted use of technology for communication, training, and decision-making [30].

Some risks for training programs on digital health might include lack of clarity about the scope of the training program and the responsibilities, insufficient capacity to carry out the program and develop an appropriate curriculum, inability to retain skilled staff, participation of experts with very little or no knowledge of the local needs and socio-cultural issues, dependency on external support, and insufficient planning for sustainability [31]. One of the key points to address those risks effectively is to establish cooperative partnerships that need to be addressed and planned [32,33].

In 2008, the Rockefeller Foundation launched a month-long conference series called “Making the eHealth Connection: Global Partnerships, Local Solutions,” held at the Rockefeller Foundation Bellagio Center in Italy. It hosted 200 global experts on digital health from 34 countries, including Latin American researchers and experts [34]. The report from the conference series entitled “From Silos to Systems” [35] presented a chapter on “eHealth Capacity Building,” which defined a vision with three objectives: (1) create an international network of eHealth informatics practice, education, training, policy, and research; (2) educate government leaders about the importance of eHealth capacity and informatics to help develop national health goals, economic goals, and to cultivate and sustain support for eHealth resource capacity growth and informatics activities; and (3) develop a blueprint for initiating and executing activities in resource-poor countries to rapidly create eHealth initiatives.

The mHealth Alliance was seeded at the conference and has promoted summits, technical working groups, and other informal networking activities to strengthen links among Latin American researchers and global digital health stakeholders [36]. In this sense, there are tremendous opportunities to boost the promotion of research and training through networking between countries in Latin America and beyond. Some experiences of collaborative initiatives in Latin America that could be fostered and even applied to other countries are described below.

The AMAUTA Program and the QUIPU Network

In 1999, the AMAUTA Global Training in Health Informatics program was developed to train Peruvian health care professionals in the application of informatics to health [37]. This collaborative program was an institutional partnership that involved Universidad Peruana Cayetano Heredia, Universidad Nacional Mayor de San Marcos, and the University of Washington, Seattle, Washington, with the support of the Fogarty International Center and the National Institutes of Health. The AMAUTA program achieved considerable success in the development and institution of informatics research and training programs in Peru [37]. Courses and projects supported by the AMAUTA program led to the development of sustainable training opportunities for biomedical informatics in Peru [38] and contributed to their development in other low- and middle-income countries.

This program later expanded to other Latin American countries through the QUIPU Center, which worked to promote South-to-South collaborations [37]. As part of The Andean Global Health Informatics Research and Training Center, the QUIPU network was created in 2010. The objectives of QUIPU were to: (1) develop and implement short- and long-term training opportunities in biomedical informatics for global health in the Andean region; (2) engage new researchers in the Andean region to research health informatics and bioinformatics; and (3) expand and consolidate a research network in the Andean region, promoting South-to-South collaboration and collaborative initiatives with United States–based universities and institutions [39]. This Center has developed several face-to-face and virtual courses [39] and has supported the establishment of a diploma and a Master’s program on Biomedical Informatics [40], the first of such training programs in Peru.

Federation of Health Informatics for Latin America and the Caribbean

The International Medical Informatics Association (IMIA) has a Federation of Health Informatics for Latin America and the Caribbean called IMIA-LAC. As of January 2018, 12 medical informatics societies were members of the Federation [41]. The regional activities of IMIA-LAC have been scarce, but it is desirable to strengthen regional ties with close links to universities and societies at the international level [42].

The Central American Health Informatics Network

The Central American Health Informatics Network (RECAINSA), established in 2013, is a network of volunteers working in technology-related public and private health services [43]. One of its objectives is to support national digital health strategies, including generating networking spaces for the exchange of experiences and best practices. Another objective of RECAINSA is to strengthen digital health governance through legal and strategic frameworks through the participation of key stakeholders within the health sector [43]. RECAINSA also promotes the strengthening of human resources in universities, certified training centers, and other specialized organizations [43].

The Latin American and Caribbean Network for Strengthening Health Information Systems

The Latin American and Caribbean Network for Strengthening Health Information Systems (RELACSIS), established in 2010 [44], is a community of best practices to improve data quality. It is made up of members from over 25 countries, comprising both health information users and managers [11]. RELACSIS promotes the strengthening of information systems for health through face-to-face and virtual courses (eg, ICD coding, complete death certificates), discussion forums, working groups, webinars, software solutions, and other low-cost tools. In this context, PAHO has organized several virtual seminars with experts to learn about the current status of electronic health records in the region [11].

Ibero-American Network of Mobile Technology and Health

The Ibero-American Network of Mobile Technology and Health (CYTED-RITMOS) is an international network led by the Open University of Catalonia and composed of 17 research groups from six countries (Argentina, Bolivia, Chile, Colombia, Ecuador, and Spain), the PAHO/WHO, Doctors Without Borders, Telefónica, the Mobile World Capital Barcelona Foundation, and the University of Michigan. This network aims to promote research and development of mHealth in Latin America [45]. In October 2015, the International RITMOS Workshop took place in Barcelona, intending to determine the priority areas of Latin America in which research, development, and innovation projects in mHealth could be developed [45].

Others

Several other international organizations are involved with a vast number of professionals who work on digital health projects and services in Latin America. Health Level Seven Latin America (HL7 LATAM) is a regional coordinating body that promotes the use of interoperability standards in Latin America to improve health care institutions in the region [46]. The current activities of HL7 LATAM are available through their website and on their social networks (HL7 LATAM). Healthcare Information and Management Systems Society (HIMSS) Latin America is an international organization focused on promoting initiatives and events on leadership, community building, and professional development [47]. Their main initiatives are holding conferences in Costa Rica, Brazil, and Chile, and supporting Latin American countries through the digital transformation of their health services [47].

There are also collaborative partnerships, such as the e-Government Cooperation Center (eGCC) (launched as a cooperative project between Korea and partner countries, such as Peru), which has supported digital health resource capacity building, the exchange of information technologies, and joint research projects. The Ministry of Interior and Safety and The National Information Society Agency of the Republic of Korea have worked together to provide support to international countries in e-Government related areas, such as smart cities and telemedicine [48].

Finally, the World Health Organization has established a new roster of experts in various areas related to digital health, which shows promise for boosting collaboration between experts from Latin America and abroad. Its goal is to share expertise and lessons learned regarding the development, implementation, and evaluation of capacity-building programs for digital health [49].

Final Remarks

Training programs on digital health in Latin America should incorporate the local context, consider the local needs, and be sensitive to the local economic, social, cultural, and organizational factors. There is a need to develop innovative intercultural and multilingual educational tools and solutions according to the health needs of populations, especially in underserved areas.

Given the limited resources in the Latin American region, the creation and strengthening of the existing networks of public and private institutions with academic centers who have experience in digital health training and research should be promoted. They should also seek to work in close collaboration with local, regional, and national governments. Partnerships with developed institutions as part of a well-planned strategy have shown encouraging results. It is essential to point out that each partnership is unique, and each program has to ensure that the curriculum is relevant to address local needs and country priorities.

Training programs should promote and encourage international exposure and internships or clerkships in excellent digital health centers around the world. Potential outcomes of those experiences could be research projects conducted in a wide variety of topics, such as electronic medical records, telemedicine, mobile health, artificial intelligence, the internet of things, simulation and virtual reality, augmented reality, big data, digital repositories, smart cities, ethical challenges, and socio-technical and cultural issues, including resistance to change. Additionally, at the end of the programs or electives, a publication could be established as a deliverable that could be later submitted to peer-reviewed journals [50]. Writing in English could be a challenge for Latin American researchers, but publishing helps one's chances of getting future funding and helps build new multidisciplinary collaborations [50].

International and national funding agencies could play a key role in supporting interoperable, scalable projects at Latin American academic and research institutions. An important message to spread is that policymakers, funding agencies, and donors should stop funding isolated or stand-alone projects and initiatives. Skill development should be viewed as a continuous process discussed among stakeholders, including the Ministry of Health, academia, and private institutions [51,52].

e-Learning programs could help communication, provide knowledge acquisition for large numbers of trainees, and allow access to up-to-date knowledge to any person [10]. It could be an excellent resource for people with disabilities or those who are in remote or rural areas. Health care hackathons have also been reported as a reliable source of solutions to health care challenges, boosting the process of "co-creation" [53], and should be organized and evaluated in Latin American countries. Future studies of educational programs on digital health in the region could add valuable insights about training needs at different levels (decision-makers, digital health implementers, and users), the profile of trainees (including leadership skills), and highlight the urgent need for monitoring, evaluating, and publishing the lessons learned of those experiences.

Evidence from developing countries has shown the benefits of digital tools for strengthening health systems and improving decision-making by providing access to digital health training content, better support with health professional networks, and better case detection using disease surveillance systems [30], even in real-time [54]. Capacity-building programs should be viewed as a complex intervention and need proper funding, a network of colleagues, a clear career path, a multidisciplinary team, financial incentives, and a political commitment to support it and sustain [55,56]. Evaluation could be difficult, and they should consider context and how long after the program is initiated should the evaluation be started [55,56].

One of the biggest challenges is to ensure the sustainability and continuity of digital health initiatives, which should be documented with proper scientific evidence to raise awareness among decision-makers [30]. As Long et al pointed out [30]:

> *Large-scale or nationwide coverage of digital health interventions to support health workforce development is still rarely reported in the literature.*

We would like to see more academic projects that become national digital health programs, such as Wawared in Peru [57-61].

Finally, Long et al proposed key areas of digital health research [30] for low- and middle-income countries, such as: (1) the value of scaling up digital health approaches to human resources for health management and support; (2) better evidence on the return of investment of digital health; (3) the effect of current donor and government procurement policies on scale-up of digital health technologies for health workforce development; and (4) the role of the private sector and philanthropists in digital health.

We hope to inspire and encourage Latin American decision-makers, innovators, and researchers to build together on the work already done through digital health solutions (eg, artificial intelligence, big data analytics) and find innovative ways for public and private partnerships to improve health workforce capacity. We also want them to focus on accelerating the pace at which they can further improve the health of populations.

Conflicts of Interest

None declared.

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Abbreviations

AMIA: American Medical Informatics Association
CYTED-RITMOS: The Ibero-American Network of Mobile Technology and Health
eGCC: e-Government Cooperation Center
eHealth: electronic health
GPP: Global Partnership Program
HIMSS: Healthcare Information and Management Systems Society
HL7 LATAM: Health Level Seven Latin America
ICD: International Classification of Diseases
IMIA: International Medical Informatics Association
IMIA-LAC: Federation of Health Informatics for Latin America and the Caribbean
ITGH: Informatics Training for Global Health
mHealth: mobile health
PAHO: Pan American Health Organization
RECAINSA: The Central American Health Informatics Network
RELACSIS: The Latin American and Caribbean Network for Strengthening Health Information Systems
WHO: World Health Organization

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Original Paper

Trends and Visibility of “Digital Health” as a Keyword in Articles by JMIR Publications in the New Millennium: Bibliographic-Bibliometric Analysis

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Abstract

Background: Digital health has become an advancing phenomenon in the health care systems of modern societies. Over the past two decades, various digital health options, technologies, and innovations have been introduced; many of them are still being investigated and evaluated by researchers all around the globe. However, the actual trends and visibility of peer-reviewed publications using “digital health” as a keyword to reflect the topic, published by major relevant journals, still remain to be quantified.

Objective: This study aimed to conduct a bibliographic-bibliometric analysis on articles published in JMIR Publications journals that used “digital health” as a keyword. We evaluated the trends, topics, and citations of these research publications to identify the important share and contribution of JMIR Publications journals in publishing articles on digital health.

Methods: All JMIR Publications journals were searched to find articles in English, published between January 2000 and August 2019, in which the authors focused on, utilized, or discussed digital health in their study and used “digital health” as a keyword. In addition, a bibliographic-bibliometric analysis was conducted using the freely available Profiles Research Networking Software by the Harvard Clinical and Translational Science Center.

Results: Out of 1797 articles having “digital health” as a keyword, published mostly between 2016 and 2019, 277 articles (32.3%) were published by JMIR Publications journals, mainly in the *Journal of Medical Internet Research*. The most frequently used keyword for the topic was “mHealth.” The average number of times an article had been cited, including self-citations, was above 2.8.

Conclusions: The reflection of “digital health” as a keyword in JMIR Publications journals has increased noticeably over the past few years. To maintain this momentum, more regular bibliographic and bibliometric analyses will be needed. This would encourage authors to consider publishing their articles in relevant, high-visibility journals and help these journals expand their supportive publication policies and become more inclusive of digital health.

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KEYWORDS

bibliometrics; review literature; JMIR Publications; telemedicine

Introduction

Background

Digital health has become an advancing phenomenon in the health care systems of modern societies [1]. As a keyword, the US Food and Drug Administration defines “digital health” as “a broad scope which includes mobile health (mHealth), health information technology, wearable devices, telehealth and telemedicine, and personalized medicine” [2]. Of note, it is the increasing adoption of “digital health” as a specific keyword, which has shown itself in the utilization of the term by international organizations, such as the World Health Organization [3,4].

Globally, many academics and researchers are increasingly being involved in doing research on, utilizing, evaluating, or taking advantage of the benefits of digital health and its various related technologies for their studies on individuals, populations, or health organizations. This increasing involvement has reflected itself in the utilization of “digital health” as a keyword in published peer-reviewed literature. More specifically, in the past two decades, a growing number and diversity of research projects, study protocols, publications, and dedicated journals have played important roles in the digital health domain [5]. In addition, the empowerment of health care system clients, including patients, and the progressive desire for innovation by industries and enterprises [6] have continued to reinforce the need for valid and trustworthy scientific evidence on digital health for the benefit of public health.

Over the past two decades, various digital health options, technologies, and innovations have been introduced; many of them are still being investigated and evaluated by researchers all around the globe [7]. These research endeavors typically reflect themselves in peer-reviewed publications of various kinds. However, the actual trends and visibility of those publications on digital health, published by major relevant journals, still remain to be quantified in detail.

Aims

This study aimed to take a more methodical approach to answering this question, by conducting a bibliographic-bibliometric analysis on the publications focused on using “digital health” as a keyword. We evaluated the trends, topics, and citations of research publications in different journals, with the hope to identify, and ultimately help to increase, the share and contribution of major relevant journals in publishing articles on digital health. Thereafter, for the purpose of providing an unbiased comparison among different journals on the trends and visibility of their publications, we conducted detailed subgroup analyses, individualized to specialized journals or journal publishers. This paper summarizes the specific outcomes of our analyses on articles published by JMIR Publications. The main reasons behind focusing on JMIR Publications in this study are the following: (1) JMIR Publications has been an active publisher in the digital health space since 1999, which overlaps entirely with the intended time frame of our study; (2) it has a collection of correlated journals, which covers diverse aspects of digital health research; and (3) it publishes open-access articles, which gives the authors more chances of visibility and knowledge translation and the readers more chances of verifying the results of all analyses.

Methods

Rationale Behind Choosing “Digital Health” as a Keyword

On the basis of expert opinions, “digital health” is considered a relatively new term in research publications, as its appearance as a keyword seems to have increased fairly recently in peer-reviewed articles. Before this trend becomes commonplace, keywords such as “Internet research,” “cybermedicine,” “eHealth,” or “mHealth” have been (and are still being) used by authors and editorial boards of various scientific journals, including journals by JMIR Publications.

To address this recency in the adoption of “digital health” as a more common term, we followed a staged, multistep literature search strategy, implemented separately for each journal or journal group or publisher, to ensure that using “digital health” as an identifying keyword does not harm the inclusiveness of numerous options, technologies, and innovations in this space. An effort was made to find the sensitivity of using “digital health” as a keyword in identifying articles that could have otherwise been classified differently under internet search, cybermedicine, mHealth, or similar keywords had “digital health” not been assigned as a keyword by the authors or the databases.

Literature Search Strategy

The time frame of search was January 2000 to August 2019.

Owing to its open-access nature, we decided to use PubMed database to identify general and specialized journals and find articles published in English language, in which the focus was on using “digital health” as a keyword.

The initial, implicit assumption was that if “digital health” has been mentioned by the authors as a keyword in an article or assigned by the database organizer, for example, as Medical Subject Heading (MeSH)–assigned keyword, the topic of the article will be related to digital health. However, as mentioned above, to reduce the bias in finding relevant articles because of the recency of “digital health” being used as a term, we followed a staged search strategy, which is summarized below.

Stage 1

This stage involved finding all articles with “digital health” in their metadata: (1) Searching with only the keyword “digital health” in All Fields to identify all articles in PubMed, which could have the term in their metadata and (2) importing the results to a library in a bibliographic management software.

Stage 2

This stage involved identifying keywords/topics/subjects relevant to digital health: (1) Performing a subject bibliography analysis by extracting all author-assigned plus MeSH-assigned keywords, sorted according to their decreasing frequencies of appearance and (2) identifying and refining keywords/topics/subjects relevant to the definition of “digital health," as provided by Murray et al [8] and later highlighted by Zanaboni et al [7]. The alphabetical list of relevant, refined keywords that we eventually identified appears in Multimedia Appendix 1.

Stage 3

This stage involved finding all articles that had used any of the keywords identified in the previous stage: Searching PubMed, using OR between all the keywords from Multimedia Appendix 1.

Stage 4

This stage involved finding all articles published by JMIR Publications: Searching with only the keyword "JMIR" in All Fields to identify all articles in PubMed, which were published by JMIR Publications.

Stage 5

This stage involved combining stage 3 AND stage 4: Searching PubMed, using OR between all the keywords from Multimedia Appendix 1 AND "JMIR" in All Fields to reidentify all articles published by JMIR Publications, which could have any of the relevant keywords in their metadata.

Stage 6

This stage involved comparing the results of stage 5 and stage 4: Determining the difference between the number of articles retrieved in stage 4 and stage 5 to check the inclusiveness of our terms list.

Stage 7

This stage involved combining stage 1 and stage 4: (1) After ensuring the sensitivity of our search strategy, on the basis of the outcome of stage 6, we searched with the keyword "digital health" in All Fields AND the keyword "JMIR" in All Fields to identify all articles by JMIR Publications, which have the word "digital health" assigned to any of their metadata; (2) importing the results to the same library in the bibliographic management software; and (3) basing the bibliographic-bibliometric analysis on this last group of articles.

A flowchart summarizing the outputs of this staged literature search is available in Multimedia Appendix 2.

Bibliographic–Bibliometric Analysis

For bibliographic management and analysis of the references, we used EndNote X8 (Thompson Reuters Inc) software, mainly its "Subject Bibliography" functionality.

For bibliometric analysis to quantify the trends and visibility of published articles using "digital health" as a keyword, we used one of the free, publicly available Web-based solutions, that is, the Profiles Research Networking (PRN) Software by the Harvard Clinical and Translational Science Center [9]. The details of the methodology behind this specific solution and the range of services the PRN Software provides are explained on its dedicated website. In brief, we used the "Bibliometric Summary Report" functionality of the PRN Web-based software after (1) extracting the PubMed IDs of all articles found in stage 7 of our search strategy and stored in our EndNote library; (2) pasting the IDs onto the PRN Software's website (in a dedicated box); (3) getting calculations for common metrics, including citation counts and h-index; and (4) analyzing the report metrics and parameters, as per the PRN Software [9] defined in Table 1.

Table 1. Bibliometric parameters as provided in the output by the Profiles Research Networking Software in its Bibliometric Summary Report.

Variable	Definition
Num Pubs	Number of recognized PubMed IDs, overall, for each journal, or for each year, as specified in the report subsections
First Year	Earliest article year
Last Year	Latest article year
Avg Authors	Average number of authors per article
Exp Authors	Expected number of authors, matched on journal and year
Ratio Authors	Ratio of the average number of authors to the expected number
Avg Cites All	Average number of times an article has been cited, including self-citations
Avg Cites	Average number of times an article has been cited, not including self-citations
Exp Cites	Expected number of times an article has been cited, not including self-citations, matched on journal and year
Ratio Cites	Ratio of average number of citations (no self-citations) to expected number, matched on journal and year
Exp Cites PT	Expected number of citations (no self-citations), matched on journal, year, and publication type
Ratio Cites PT	Ratio of average number of citations (no self-citations) to expected number, matched on journal, year, and publication type
H-Index	Hirsch-index (using total citations, including self-citations)
M-Index	Hirsch-index divided by the number of years since the first publication
%Pubs	The percentage of the total publications for each journal
Ratio Exp Pubs	The ratio of the number of publications in the field compared with the expected number, matched on year
Num Cites All	For each year, the number of times any article was cited, including self-citations, in that year
Num Cites	For each year, the number of times any article was cited, not including self-citations, in that year
Cum Pubs	For each year, the cumulative number of publications
Cum Cites All	For each year, the cumulative number of times any article was cited, including self-citations
Cum Cites	For each year, the cumulative number of times any article was cited, not including self-citations

Results

Overall Findings

Overall, with August 31, 2019 as the last publication date, we found 1797 articles indexed in PubMed, with “digital health” being assigned as one of the keywords in their metadata.

Exporting the keywords from 1797 articles provided a list of 5138 author-assigned and MeSH-assigned keywords, out of which 312 keywords were directly relevant to “digital health” options, technologies, and innovations (Multimedia Appendix 1).

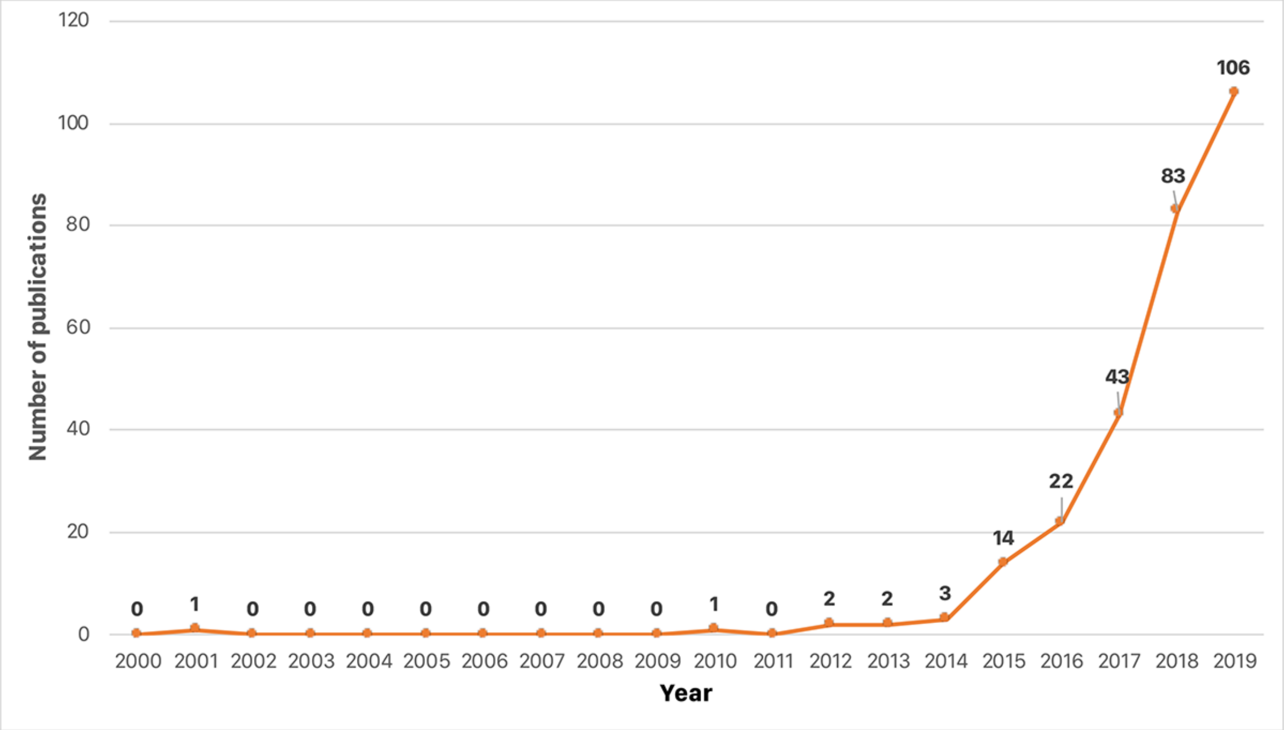
In the same time frame, JMIR Publications had 7556 articles indexed in PubMed, mainly in the *Journal of Medical Internet Research* and its sister journals. Using OR between the 312 relevant keywords AND JMIR, we were able to identify 7468 (98.8%) of articles by JMIR Publications, an indicator of the high sensitivity of “digital health” as a keyword in an article to represent a diverse range of technologies discussed in their corresponding articles.

Out of the 1797 articles, 277 articles had both characteristics of (1) being published by JMIR Publications and (2) having “digital health” as an assigned keyword. The rest of the bibliographic-bibliometric analysis was performed on these 277 articles.

Bibliographic Analysis

Figure 1 visualizes the temporal trend of the 277 articles published by JMIR Publications in the study’s time frame. A total of 10 journals by JMIR Publications published most of these articles, the top three being the *Journal of Medical Internet Research* (117/277, 42.2% articles), *JMIR mHealth and uHealth* (57/277, 20.6%), and *JMIR Research Protocols* (41/277, 14.8%).

Figure 1. Temporal trend of the number of publications from January 2000 to August 2019 by JMIR Publications, having “digital health” as a keyword.



Subject Focus of the Articles

Using EndNote’s Subject Bibliography, a total of 1101 MeSH- and author-assigned keywords were extracted for assessing the topics of articles. Table 2 summarizes the top 30 keywords in the published articles and their corresponding number of appearances.

Bibliometric Analysis

Table 3 summarizes the bibliometric statistics for the published articles having “digital health” as a keyword.

All articles were classified under “medical informatics” as the most frequent field/discipline of focus.

Table 4 summarizes the bibliometric statistics for all articles published between January 2000 and August 2019 by JMIR Publications having “digital health” as a keyword in the study’s time frame (the citation variables have the same meaning as the ones summarized in Table 3).

Table 5 summarizes the yearly cumulative citation statistics for all articles published between January 2000 and August 2019 by JMIR Publications having “digital health” as a keyword (the citation variables have the same meaning as the ones summarized in Tables 2 and 3).

Table 2. Cumulative number of appearances for the top 30 keywords, in descending order of appearance, in research articles having "digital health" as a keyword, published from January 2000 to August 2019 in JMIR Publications journals.

Rank	Keyword	Number of appearances
1	mhealth	60
2	Telemedicine	57
3	Internet	42
4	eHealth	37
5	mobile health	36
6	self-management	18
7	mobile phone	15
8	depression	15
9	physical activity	14
10	smartphone	14
11	Mobile Applications	13
12	Chronic Disease	13
13	Social Support	12
14	electronic health records	12
15	psychology	12
16	Health Behavior	11
17	medication adherence	11
18	exercise	10
19	Social Media	10
20	text messaging	9
21	obesity	9
22	education	9
23	mental health	9
24	Health Promotion	8
25	mobile apps	8
26	diabetes	8
27	Diabetes Mellitus	8
28	telehealth	7
29	Cell Phone	7
30	Health Personnel	7

Table 3. Bibliometric summary statistics for all articles published between January 2000 and August 2019 by JMIR Publications having "digital health" as a keyword.

Variable	Value
Num Pubs[a]	277
First Year[b]	2001
Last Year[c]	2019
Avg Authors[d]	6.007
Exp Authors[e]	6.212
Ratio Authors[f]	0.967
Avg Cites All[g]	2.848
Avg Cites[h]	2.354
Exp Cites[i]	1.451
Ratio Cites[j]	1.623
Exp Cites PT[k]	1.688
Ratio Cites PT[l]	1.394
H–Index[m]	12
M–Index[n]	1.091

[a] Num Pubs: number of recognized PubMed IDs, overall, for each journal, or for each year, as specified in the report subsections.

[b] First Year: earliest article year.

[c] Last Year: latest article year.

[d] Avg Authors: average number of authors per article.

[e] Exp Authors: expected number of authors, matched on journal and year.

[f] Ratio Authors: ratio of the average number of authors to the expected number.

[g] Avg Cites All: average number of times an article has been cited, including self-citations.

[h] Avg Cites: average number of times an article has been cited, not including self-citations.

[i] Exp Cites: expected number of times an article has been cited, not including self-citations, matched on journal and year.

[j] Ratio Cites: Ratio of average number of citations (no self-citations) to expected number, matched on journal and year.

[k] Exp Cites PT: Expected number of citations (no self-citations), matched on journal, year, and publication type.

[l] Ratio Cites PT: Ratio of average number of citations (no self-citations) to expected number, matched on journal, year, and publication type.

[m] H-Index: Hirsch-index (using total citations, including self-citations).

[n] M–Index: Hirsch-index divided by the number of years since the first publication.

Table 4. Bibliometric statistics for all articles published between January 2000 and August 2019 by JMIR Publications having “digital health” as a keyword.

Journal	Num Pubs[a] (%Pubs)[b], n (%)	First Year[c]	Last Year[d]	Avg Cites[e]	Exp Cites[f]	Ratio Cites[g]	Exp Cites PT[h]	Ratio Cites PT[i]
Journal of Medical Internet Research	117 (42.2)	2001	2019	3.79	2.02	1.88	2.34	1.62
JMIR mHealth and uHealth	57 (20.6)	2014	2019	1.11	1.24	0.90	1.23	0.90
JMIR Research Protocols	41 (14.8)	2014	2019	1.12	0.65	1.74	0.65	1.72
JMIR Mental Health	12 (4.3)	2016	2019	1.83	1.69	1.09	1.49	1.24
JMIR Medical Informatics	10 (3.6)	2015	2019	0.50	0.62	0.81	0.59	0.86
JMIR Diabetes	8 (2.9)	2017	2019	0.00	0.04	0.00	0.03	0.00
JMIR Public Health and Surveillance	7 (2.5)	2016	2019	0.29	0.77	0.37	0.79	0.36
JMIR Formative Research	7 (2.5)	2017	2019	0.00	0.00	1.00	0.00	1.00
JMIR Human Factors	5 (1.8)	2017	2019	0.40	0.43	0.94	0.43	0.93
JMIR Serious Games	4 (1.4)	2013	2018	16.75	7.87	2.13	15.66	1.07

[a] Num Pubs: Number of recognized PubMed IDs, overall, for each journal, or for each year, as specified in the report subsections.

[b] %Pubs: The percentage of the total publications for each journal**.**

[c] First Year: Earliest article year.

[d] Last Year: Latest article year.

[e] Avg Cites: Average number of times an article has been cited, not including self-citations.

[f] Exp Cites: Expected number of times an article has been cited, not including self-citations, matched on journal and year.

[g] Ratio Cites: Ratio of average number of citations (no self-citations) to expected number, matched on journal and year.

[h] Exp Cites PT: Expected number of citations (no self-citations), matched on journal, year, and publication type.

[i] Ratio Cites PT: Ratio of average number of citations (no self-citations) to expected number, matched on journal, year, and publication type.

Table 5. Cumulative citation statistics for all articles published between January 2000 and August 2019 by JMIR Publications having “digital health” as a keyword, by year.

PubYear[a]	Num Pubs[b]	Num Cites All[c]	Num Cites[d]	Cum Pubs[e]	Cum Cites All[f]	Cum Cites[g]
2018	83	309	253	171	789	652
2017	43	249	197	88	480	399
2016	22	108	94	45	231	202
2015	14	55	42	23	123	108
2014	3	32	31	9	68	66
2013	2	19	19	6	36	35
2012	2	8	7	4	17	16
2011	0	6	6	2	9	9
2010	1	1	1	2	3	3
2009	0	1	1	1	2	2
2008	0	0	0	0	0	0
2007	0	0	0	0	0	0
2006	0	0	0	0	0	0
2005	0	0	0	0	0	0
2004	0	1	1	1	1	1
2003	0	0	0	0	0	0
2001	1	0	0	1	0	0
2000	0	0	0	0	0	0

[a] Authors excluded 2019 from this table as the cumulative citations might be incomplete because of the study time frame being up to August 2019.

[b] Num Pubs: Number of recognized PubMed IDs, overall, for each journal, or for each year, as specified in the report subsections.

[c] Num Cites All: For each year, the number of times any article was cited, including self-citations, in that year.

[d] Num Cites: For each year, the number of times any article was cited, not including self-citations, in that year.

[e] Cum Pubs: For each year, the cumulative number of publications.

[f] Cum Cites All: For each year, the cumulative number of times any article was cited, including self-citations.

[g] Cum Cites: For each year, the cumulative number of times any article was cited, not including self-citations.

Discussion

Principal Findings

Both trends and visibility of research publications containing “digital health” in their keywords and published by JMIR Publications journals increased dramatically, especially over the past 2 to 3 years, with more than two-third of the articles being published in 2018 and 2019. This important finding shows how “digital health” is becoming a mainstream theme and an established terminology in peer-reviewed publications.

The *Journal of Medical Internet Research* had the highest number of articles and longest duration of publication in this time frame, among all the journals of JMIR Publications. This reflects the overall aim and willingness of the editorial board to lead in peer review, and ultimately in the publication, of the manuscripts that are focused on digital health to disseminate their ideas and research results. It may also reflect improvement in the methodologies of the published articles [10], which might have made them strong and robust enough to be accepted for publication in the JMIR Publications journals.

Interestingly, “mHealth” and “mobile health” as specific keywords, appeared in 96 out of 277 articles (34.6%), followed by “Telemedicine” and “Internet,” both appearing in 57 (20.5%) and 42 (15.2%) articles, respectively. In addition, there appeared to be cumulatively repetitive or redundant keywords, either author-assigned or MeSH keywords (eg, “mobile phone,” “smartphone,” “Cell Phone,” “Mobile Applications,” and “mobile apps”), all appearing with different frequencies in collective articles. We decided to present these keywords as raw as possible in Table 2 to show how different some of these keywords still are, in appearing in the topics of research manuscripts. This highlights the fact that the authors and/or manually indexing databases, such as National Library of Medicine (NLM), can take advantage of the conceptual trends and assign more appropriate keywords to improve their accuracies in retrieving and combining relevant search results.

The dramatic increase in the cumulative number of citations over the study years is a helpful indicator of the overall interest in referring to the articles pertaining to the keyword “digital health.” Moreover, an H-index of 12, plus an average number of citations of all articles being >1.6 times more than the expected number of citations, highlights the increasing interest in referring to articles on digital health.

Expectedly, “medical informatics” was found to be the most frequent field/discipline of focus in research publications having “digital health” as a keyword. This finding, in addition to considering the *Journal of Medical Internet Research* as ranking first in the category “Medical Informatics” in *Journal Citations Report*, highlights the suitability of this study to be presented to the audiences of the journal.

The *Journal of Medical Internet Research* and *JMIR Research Protocols* had the highest ratio of average number of citations (no self-citations) to expected number, matched on journal, year, and publication type (PT). This highlights the higher visibility of research publications in the abovementioned journals.

Increasing the Accuracy of Interpreting Bibliometric Outputs

We followed the hints provided by the PRN Software team [9] to increase the reliability and validity of interpreting the bibliometric outputs:

1. The PRN Software compares the average number of authors per article and the average number of times the articles have been cited with an expected value, which is “the averages of all articles in PubMed, matched on journal and year of publication” [9]. To control for the various PTs (eg, Journal Article, Review, and Editorial), the software also calculates “PT” expected values. As PubMed may assign multiple PTs to the same article, articles are matched on all PTs for calculating the PT expected values.
2. In addition, if self-citations are included in the analysis subsections, they are explicitly being noted.
3. To determine the field/discipline of a specific journal, the NLM assigns Broad Journal Heading values to the journal, which are MeSH terms, summarizing the overall subjects of that journal. Similar to PT, a journal can be assigned to multiple Broad Journal Headings; consequently, a single publication of that journal might be listed more than once in the output tables about filed/discipline, causing the Num Pubs field to add up to more than the total number of publications. This was not the case in our analysis as all the journals by JMIR Publications were classified under Medical Informatics by the NLM.

Limitations

Our study focused on English language–based journals that were indexed in PubMed as a freely available database and published by JMIR Publications. PubMed is not essentially a citation-tracking database. However, solutions such as the bibliometric solution that we used in our methodology, that is, the PRN Software by the Harvard Clinical and Translational Science Center, have been developed, which provide bibliometric outputs on PubMed-indexed articles. Other citation-based databases, specifically subscription-based bibliometric databases, such as Scopus and Web of Science, could be included in future research projects to expand the scope of this analysis.

Another main reason behind focusing only on PubMed, apart from being freely available to the public, was that PRN Software only accepts PubMed IDs for citation analysis. This held us back from using other bibliographic databases as they could not have any PubMed ID for non-PubMed-indexed journals.

In addition, the citation metrics by PRN Software were coming from one publicly available free data source and were limited to commonly used parameters. For the provision of a comprehensive bibliometric outlook on publications by JMIR Publications having the keyword “digital health,” other citation databases and metrics could also be utilized in future studies.

Conclusions

The reflection of “digital health” in JMIR Publications journals has been on the rise over the past few years. More comprehensive and comparative bibliographic and bibliometric analyses, with broader ranges of keywords to include eHealth, mHealth, and similar concepts, would be needed to visualize whether “digital health” continues to remain a rising keyword in the future or not.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
List of refined keywords relevant to digital health, to reduce bias in the search strategy.
[DOCX File , 31 KB - jmir_v21i12e10477_app1.docx]

Multimedia Appendix 2
Search flowchart.
[DOCX File , 157 KB - jmir_v21i12e10477_app2.docx]

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Abbreviations

HDR: higher degree research
MeSH: Medical Subject Headings
NLM: National Library of Medicine
PRN: Profiles Research Networking
PT: publication type
QUT: Queensland University of Technology

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Original Paper

Infrastructure Revisited: An Ethnographic Case Study of how Health Information Infrastructure Shapes and Constrains Technological Innovation

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Abstract

Background: Star defined infrastructure as something other things “run on”; it consists mainly of “boring things.” Building on her classic 1999 paper, and acknowledging contemporary developments in technologies, services, and systems, we developed a new theorization of health information infrastructure with five defining characteristics: (1) a material scaffolding, backgrounded when working and foregrounded upon breakdown; (2) embedded, relational, and emergent; (3) collectively learned, known, and practiced (through technologically-supported cooperative work and organizational routines); (4) patchworked (incrementally built and fixed) and path-dependent (influenced by technical and socio-cultural legacies); and (5) institutionally supported and sustained (eg, embodying standards negotiated and overseen by regulatory and professional bodies).

Objective: Our theoretical objective was, in a health care context, to explore what information infrastructure is and how it shapes, supports, and constrains technological innovation. Our empirical objective was to examine the challenges of implementing and scaling up video consultation services.

Methods: In this naturalistic case study, we collected a total of 450 hours of ethnographic observations, over 100 interviews, and about 100 local and national documents over 54 months. Sensitized by the characteristics of infrastructure, we sought examples of infrastructural challenges that had slowed implementation and scale-up. We arranged data thematically to gain familiarity before undertaking an analysis informed by strong structuration, neo-institutional, and social practice theories, together with elements taken from the actor-network theory.

Results: We documented scale-up challenges at three different sites in our original case study, all of which relate to “boring things”: the selection of a platform to support video-mediated consultations, the replacement of desktop computers with virtual desktop infrastructure profiles, and problems with call quality. In a fourth subcase, configuration issues with licensed video-conferencing software limited the spread of the innovation to another UK site. In all four subcases, several features of infrastructure were evident, including: (1) intricacy and lack of dependability of the installed base; (2) interdependencies of technologies, processes, and routines, such that a fix for one problem generated problems elsewhere in the system; (3) the inertia of established routines; (4) the constraining (and, occasionally, enabling) effect of legacy systems; and (5) delays and conflicts relating to clinical quality and safety standards.

Conclusions: Innovators and change agents who wish to introduce new technologies in health services and systems should: (1) attend to materiality (eg, expect bugs and breakdowns, and prioritize basic dependability over advanced functionality); (2) take a systemic and relational view of technologies (versus as an isolated tool or function); (3) remember that technology-supported work is cooperative and embedded in organizational routines, which are further embedded in other routines; (4) innovate incrementally, taking account of technological and socio-cultural legacies; (5) consider standards but also where these standards come from and what priorities and interests they represent; and (6) seek to create leeway for these standards to be adapted to different local conditions.

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KEYWORDS

information infrastructure; structuration theory; video consultations; neo-institutional theory; organizational ethnography; hidden work; actor-network theory

Introduction

Background

It has been 20 years since Star defined infrastructure as something other things "run on" and proposed nine defining characteristics: embeddedness, transparency, reach or scope, learned as part of membership, links with conventions of practice, embodiment of standards, built on an installed base, becomes visible on breakdown and fixed in modular increments [1,2]. The information infrastructure for health care needs to satisfy multiple use cases, such as personal health management, health care delivery (including assuring the quality and safety of care, audits, and billing), public health, research [3], and the formation of the scaffolding for a learning health system [4]. Sittig et al observed that this infrastructure consists not only of hardware and software but also the language of clinical applications, a human-computer interface, people who interact with it (including developers, support staff, staff-users, and patient-users), internal organizational features (eg, environment, policies, procedures, and culture), external rules and regulations, and the measures and metrics with which it is monitored [5].

In this paper, we seek to synthesize and extend these earlier theorizations. We begin by describing the clinical, organizational, and technical features of health care infrastructure. We then outline some central concepts in critical social science that inspired Star's original work on infrastructure before offering a new theorization of health information infrastructure consisting of five key features. We illustrate this with a detailed contemporary case study of how this infrastructure influenced attempts to implement and scale up a video consultation service. After discussing these findings, we offer suggestions for those who seek to improve health services by introducing infrastructural innovations.

An Overview of Health Information Infrastructure

Contemporary health care environments are saturated with technologies, many of which are highly sophisticated. However, health care infrastructure has a reputation for being convoluted, conservative, failure-prone, and lacking integration, for numerous interacting reasons [6-8]. Health care is complex, patients are unique, and the pace of change is rapid; new devices, procedures, service models, and policies are continually emerging, rendering elements of existing infrastructure obsolete. Safety (including the maxim "first, do no harm") is an overriding concern, reflected in stringent design requirements and regulatory standards. A high proportion of clinical encounters are exceptions (ie, they deviate from the base case); technologies that assume an uncomplicated patient with a single, textbook condition and over-specify tasks and processes tend to be too brittle to support clinical work. Integration between specialties and sectors is expected but usually proves elusive, partly because it tends to be framed in technical and logistical (rather than socio-political) terms.

Health information infrastructure typically has hybrid roots, with incremental additions funded variously by local (public or private) providers, government, commercial suppliers, publicly funded research, and philanthropic sources [3,6]. It requires an exceptionally high level of security, reliability, and interoperability, and the resources to support repairs and developments to it (eg, redesigning routines and appointing and retraining staff). For all these reasons, the value proposition for heavy/traditional information technology (IT) (core, slow-moving, remote from a customer or patient [9]) in health care may be adverse, and the infrastructure supporting health care systems may be weak and fragmented. Some commercial suppliers prefer to focus on the more agile and less risky, customer-facing light/digital IT (including the growing wellness and wearables market).

In the United Kingdom, an advanced information infrastructure has emerged to support the public sector, nonprofit National Health Service (NHS) through in-house development, and a variety of contractual arrangements with different commercial suppliers [10]. Recent technological advances have made new service models possible, such as a commercially driven "doctor-in-your-pocket" video consultation service accessible via a smartphone app (which, controversially, bypasses much of the traditional NHS infrastructure) [11].

The Critical Social Science of Information Infrastructure

Star was a cofounder of the "Society for People Interested in the Study of Boring Things" [2]. By this, she meant lists, classification schemes, ordering devices (eg, timetables), and the wires and connections that make an information system work. Many of these "boring things" inscribe the values, expectations, conflicts, and power relations of particular groups in society [2,12]. Developing standards, for example, is a social and political (ie, value-laden and power-charged) process in which a more-or-less agreed-upon version of the world is constructed and negotiated [13,14].

Star proposed that ethnographers can learn a lot by exploring how "boring" infrastructure plays out in real-world settings [1,2]. A primary focus of such work is the ever-present tension between the general (standardized) and the local (situated), which people attempt to bridge through articulation or tinkering (the steps taken to get things done as work unfolds in real-time, despite material limitations, regulatory constraints, imperfect data, conflicting priorities, reluctant colleagues, etc) [15], and via boundary objects (things that are differently interpreted and used by different groups, while retaining a shared sense of what the object is) [16].

As Berg and Timmermans have pointed out, the universal aspects of information infrastructure are not preexisting [17]. Instead, they need to be codeveloped through dialogue among those who will use, or be affected by, the infrastructure [17]:

> *…disorder preexists and precedes the emergence of order. The phoenix of universality rises from the ashes of local chaos. In the structure of these accounts, the local is the generic, natural state that is subsequently transformed; it is the unquestioned base from which the analysis starts.*

Not only is order more arbitrary than is often assumed, suggest Berg and Timmermans, but any creation of order in one part of the system will create disorder somewhere else [17]. Because of this, the scaling up of a technology-supported service model to new settings is likely to be an unexpectedly tricky process and one that will not be easy to research, since ethnographic methods cannot be easily applied across multiple settings [18,19]. In sum, the health information infrastructure in many countries is characterized by state of the art individual technologies which need to interface with (but have often been designed with little awareness of) a legacy infrastructure and restrictive regulatory standards, all in the context of a complex, fast-changing, unpredictable, and underfunded service environment.

A New Theorization of Health Information Infrastructure

Overview

In this section, we outline our theorization of health information infrastructure, which adapts and extends original work by Star [1,2] and subsequent scholars [3,5,6]. It consists of five essential characteristics, listed below.

A Material Scaffolding, Backgrounded When Working and Foregrounded Upon Breakdown

What Star called the installed base of infrastructure comprises both hardware and software as well as the rooms, desks, tunnels, pipes, and other things that host it. It is typically large and extensive (eg, allowing communication at a distance), but tends to drift into the background as it provides the mundane means to the ends of an organization, and because significant parts of it are buried, kept in a back office, or found in the cloud. To the familiar user, infrastructure is what Star called transparent (in the computer science sense of being invisible, taken for granted, and ready to hand). It does not have to be reinvented each time, but it becomes visible on breakdown (such as when a server crashes or a software upgrade reveals a bug) [2]. Breakdown in this context can also mean situations where the material or nonmaterial features of infrastructure prove too inflexible to allow a clinician to exercise autonomy to deliver care.

Embedded, Relational, and Emergent

Star observed that infrastructure is “sunk into, and inside of, other structures, social arrangements and technologies” [2]. She considered infrastructure a fundamentally relational concept, becoming real in relation to organized practices. Organizational knowing (the knowledge on which members draw when deciding how to act) is, to a large extent, tacit and embodied [20]. It draws on shared schemas and practices but also the material scaffolding of buildings, rooms, computers, records, charts, and other aspects of infrastructure [21]. The medical record, for example, is best conceptualized not as an isolated and static container of data but as a dynamic, evolving map of what is, was, and will be happening to the patient; this record links to other human and technological actors and to documents and practices [7]. This relational network evolves dynamically over time.

Collectively Learned, Known, and Practiced

Organizational work is complicated. It involves multiple actors who must share an understanding of context (primarily which technical and sociocultural actions are possible, allowable, and required) [22]. Such knowledge is built through collective learning and sensemaking, and it becomes embedded through both hard (eg, protocols or algorithms) and soft (eg, organizational routines, processes, practices, and norms) mechanisms. Indeed, organizational work can be conceptualized as multiple collective routines that are embedded within, and influenced by, one another; they are supported by shared material artifacts and social expectations that either harmonize or create conflict [23].

Maniatopoulos et al, drawing on Bourdieu and Schatzki, used the term “field of practice” to describe the nexus of interconnected and interdependent practices and arrangements, distributed across social, cultural, and material orders, that form the context for organizational work in a health care setting [24]. Infrastructure, according to Star, embodies such fields of practice and is learned as a part of membership [2]. The relationship between the physical (material) and knowledge/practice (nonmaterial) features of infrastructure is interdependent and reciprocal, as each shapes and is shaped by the other [24,25]. Both aspects of infrastructure, in turn, need to be differentiated from the purposive content of the interactions and practices they enable. A video consultation, for example, relies on infrastructure to provide its conditions of possibility, but the consultation itself also has its *sui generis* content intrinsic to its purpose. The conditions of possibility that the infrastructure provides will be more or less adequate to the clinician’s view of this purpose.

Patchworked and Path-Dependent

Hanseth and Monteiro described infrastructure as “a layered patchwork of components and associated routines which emerge historically” [26]. It is rarely installed or replaced wholescale, and it cannot be fixed all at once or globally. New components are continually added, and they must be designed for backward compatibility with existing components. Importantly, these legacy components are not just technical. They contain embedded standards and assumptions that reflect historical socio-cultural influences (eg, a drug ordering system that fails to consider nurse prescribing because it was designed when only doctors could prescribe). Legacy systems also reflect historical strategic decisions (eg, to invest, or not, in bandwidth, or to award an exclusive contract to a particular supplier), which set an organization on a particular path from which it is difficult to deviate. Because of such challenges, and because nobody is really in charge of infrastructure, changes to it typically take time and negotiation; they may involve substantial power struggles and unanticipated financial costs, but they may sometimes turn out to be impossible.

Institutionally Supported and Sustained

Institutional theorists distinguish between technical environments, in which organizations produce a product or service with a focus on effective and efficient performance, and institutional environments, which are characterized by the need to conform to particular rules and requirements to receive legitimacy and support [27,28]. As March and Olsen put it, “institutions reflect the routine way in which people do what they are supposed to do” [29]. In institutional environments, the technical components of the infrastructure are constructed and connect in a highly standardized fashion. Asking questions about which standards are used and where they came from can surface a narrative about the roles of, and conflicts among, societal macroactors, including government, industry, professional bodies, and others [2].

Scott identifies three institutional pillars that operate with health care: regulative (statutory and legal requirements/what we must do), normative (professional norms, values, and definitions of excellence/what we should do), and cultural-cognitive (internalized scripts/what we unconsciously recognize as what everyone does) [28]. The standards, norms, and scripts of a particular health care system (eg, what is deemed safe, medical-grade, evidence-based, high-quality, confidential, etc) are enduring and hard to change, more so because they are materially inscribed in infrastructure.

Aims, Objectives, and Research Questions

Against this background, we sought to study health information infrastructure in a contemporary case study of innovation and change. Our theoretical objective was to explore, in the context of a heavily institutionalized health care environment, what infrastructure is, and how it influences technological innovation. Our empirical objective was, in partnership with front-line clinical and informatics staff at a self-proclaimed digital innovator hospital trust, to explore the challenges of scaling up a video consultation service across different clinical specialties and spreading this model to other sites. Our research question was: What was the nature of the infrastructure in this setting, and how did it shape (and become shaped by) the implementation of video consultations in different clinical and geographical settings?

Methods

Study Design and Setting

This study is a naturalistic case study with an action research component in Petroc Health (pseudonym), a UK hospital trust, along with three other trusts (anonymized as Eastern, Southern, and Northern), all of which are seeking to emulate the described model. Data sources (summarized in Table 1) included ethnographic field notes, interviews, documents, and material artifacts.

Provenance, Management, and Governance of the Research

This work incorporated and extended the VOCAL (Virtual Online Consultations—Advantages and Limitations) study, which ran from 2015 to 2017. Its methods [30] and findings [31,32] (including details of ethics approval) have been published previously. An extension study called “Scaling Up VOCAL” began in 2017 with ethics approval from London Riverside Research Ethics Committee (reference 19/LO/0550; IRAS project ID 258679) and will complete in 2020.

In the early stages of this research, action research meetings were held approximately every three months. However, as the study progressed, these were incorporated into the trust’s existing governance structures, including a Transforming Services Together (TST) Outpatient Working Group, whose goal was to drive improvements in outpatient care. In 2018, a subcommittee of this group formed a Virtual Consultation Unit to focus specifically on local scale-up and a broader spread of video consultations. We supported these groups to articulate a theory of change, collect and periodically review data on the project’s progress, and amend ongoing plans and targets. The work included developing resources and horizon-scanning wider system issues and developments (eg, technology platforms, national policies). The research was overseen by a steering group with a lay chair and patient representation, and a separate patient advisory group gave periodic feedback.

The constraints of infrastructure at the microlevel of the clinical consultation have been described in previous papers [10,32]. For this paper, we focused primarily on efforts to achieve translation by organizational actors at the meso level, that is, to engage interest and mobilize other actors (human and technological) to achieve the task of making video consultations business as usual [33].

The Case

The leading case site, Petroc Health, is a large, multi-site acute hospital trust and a recognized digital innovator, located in a deprived and multi-ethnic part of London. At the time of this study, NHS organizations were experiencing year-on-year reductions in their budget at a time of rising need, worsening staff shortages, and political and economic uncertainty. All departments were under pressure to deliver services more cost-effectively, and technologies were depicted, both nationally and locally, to achieve this. Outpatient clinics at Petroc were crowded, and there was huge pressure on the availability of consulting rooms. Travel between the trust’s dispersed sites was difficult and time-consuming. The did not attend rate for some outpatient clinics exceeded 50%. Video consultations were introduced initially to try to reduce did not attend rates, though only some clinicians engaged with the new model, and many patients were considered unsuitable for the video option for clinical (eg, high-risk) or socio-cultural (eg, low health literacy) reasons [31,32]. A cyberattack in 2017 led to a devastating and widely reported collapse of the trust’s information system [34].

Eastern, Southern, and Northern NHS trusts, based in different parts of England, had all approached Petroc intending to emulate their virtual consultation service model in one or more clinics. As part of the Scaling Up VOCAL project, members of the Petroc team supported clinicians and managers in these trusts, which presented different cases in terms of size, geography, patient population, and use of digital technology.

Participants, Sampling, and Dataset

We followed the introduction of video consultations initially in three clinical departments (diabetes, antenatal diabetes, and cancer surgery) and subsequent attempts to roll this model out to an additional ten departments in Petroc Health, including hematology, endocrinology, rheumatology, and neurology, and to a further six departments in the other three sites. Data were collected at a macro level (eg, national stakeholder interviews, policy documents), meso level (interviews, field notes, and internal documents from organizational ethnography), and microlevel (eg, observation and video-recording of clinical consultations). The full dataset and its contribution to our analysis and theorization are shown in Table 1.

Table 1. Overview of multi-level data collection and analysis (including the earlier VOCAL study).

Data level	VOCAL[a] study (2015-17)	Scaling Up VOCAL study (2017-20)	First-order interpretation	Higher-order categories
Microlevel study of virtual consultations and efforts to deliver these on a clinic-by-clinic basis	• 30 videotaped remote consultations • 16 face-to-face consultations (field notes linked to those)	• Analysis of design and material properties of five video technology platforms used across participating sites: Adobe Connect, Skype (consumer), Skype for Business, Attend Anywhere, Microsoft TEAMS. • Interviews and think aloud observations using the technology within six clinical services (diabetes, endocrinology, hematology, rheumatology, orthopedics, cancer).	• What is said and done in consultations, and the local setting-up of video consultations • How technology influences clinical work and how individual agency influences technology use, including examples of paradoxes (eg, a small change in technology has a significant effect), breakdown (where infrastructure becomes visible). invisible work, and articulation (eg, tinkering to deliver a service despite local contingencies)	• Institutional assumptions built into the material and technological infrastructure (eg, about the capability of users, access rights, costs and payments, privacy and consent laws, and nature of clinical work) • Internal social structures (habitus) of clinicians, such as personal and professional codes, and perspectives on illness. Specific knowledge of particular patients, and local system knowledge • How the tension between standardization and contingency plays out as clinicians use technologies in clinical care (or find they cannot use them as anticipated)
Mesolevel study of organizational change	• 24 staff interviews • 300 hours of clinic observation • 16 trust-level documents. • Throughput and demographic data (eg, number and percent of consultations done via video).	• Main site: 150 hours of ethnographic observation, 23 interviews with 17 staff, activity, and patient demographic data for six participating clinics. • Secondary sites: 20 hours of ethnographic observation, 14 interviews with ten staff	• Departmental-level case studies of efforts to introduce and mainstream a video consultation service • Human actors' attempts at translation (problematization, interessement, enrolment and mobilization [33]) • How competing interests and agendas played out in each case study	• How organizational values, traditions, and routines (embodied in scripts) change over time, and why they endure • Role of individual agency in both embodying and challenging institutional structures • How the micropolitics of the institutional setting shapes and constrains an implementation effort
Macrolevel study of the wider context for introducing video consulting	• 48 stakeholder interviews • 50 national-level documents from 2000-2017 (including policies, guidance, and national-level announcements)	• One further stakeholder interview • Ten additional policy and guidance documents published 2017-19	• Historical and policy drivers for, and barriers to, the introduction of video consultations in UK's National Health Service • Reasons for emergence of alternative service models involving video consultations (eg, in new models of general practice)	• Institutional pillars which help sustain traditional face-to-face modes of consulting, including regulative (laws, tariffs, standards), normative (eg, professional, ethical codes and definitions of excellence), and cultural-cognitive (master-narratives of what a medical consultation is and how to behave in it) • How these institutional pillars are inscribed in the National Health Service information infrastructure

[a] VOCAL: Virtual Online Consultations—Advantages and Limitations.

Theoretical Framework

As described previously in our VOCAL publications [30-32], and in common with Orlikowski [35] and Scott [28] (but in contrast to actor-network theorists who prefer a flat ontology [33]), we used a theoretical approach which assumes both microactors (human and technological agents) and macroactors (within broader social structures) who interact and coevolve in a dynamic and recursive (mutually-influencing) way [36].

Stones' adaptation of Giddens' work in strong structuration theory [37], and its extension by Greenhalgh and Stones to include technologies [38] considers both external social structures (such things as laws and regulations, societal and professional norms, and socio-cultural expectations) and how those structures are internalized as habitus by people (as knowledge, acquired dispositions, experience, normative orientations and morals, and patterns of learned behavior) and by technologies (as encoded rules, standards, access controls, and role assumptions). Teasing out these internalized social structures helps us to theorize the different priorities and agendas of different individuals, depending (for example) on their professional allegiance, role and status in the organization, prior training, experience, and so on.

In deciding how to act in any social situation, human actors – variously positioned within the configurations and hierarchies of organizations – draw on both their habitus and on their assessment of the here-and-now strategic terrain. There will often be a tension between the generalized socio-cultural frames of habitus and knowledge of the immediate field of practice. Some actions will appear possible, expected, and required, while some will seem impossible, inappropriate, or unimaginable. Similarly, the internalized social structures of technologies will (in some cases) extend what can be contemplated and achieved, and (in other cases) place limits on what is possible.

Like actor-network theory, strong structuration theory envisages humans and technologies as linked in dynamically evolving networks, which are inherently unstable but can potentially become stabilized when a particular configuration of people and technologies becomes aligned. The institutional aspects of health information infrastructures described above confer a high degree of stability on them, meaning that introducing a significant change to infrastructure requires substantial realignment of people, technologies, standards, procedures, training, incentives, and others. This process occurs in four stages: problematization (defining a problem for which a particular technology is a solution), interessement (getting others to accept this problem-solution), enrolment (defining key roles and practices in the network), and mobilization (engaging others in fulfilling the roles, undertaking the practices and linking with others) [33].

Analytic Approach

We took a two-stage approach to data analysis. First, we analyzed interviews, documents, and field notes thematically to gain familiarity and identify broad themes and categories. Second, we used reflection and team discussion to undertake a more theoretical analysis using technology-enhanced strong structuration theory as a guiding framework. We sought to identify macrostructures (Scott's regulative, normative and cultural-cognitive institutional pillars [28]), how these structures were internalized within the habitus of human actors (as beliefs, values, attitudes) and in technological actors (as algorithms, access privileges, menus, quality of particular functions), and how they shaped and constrained action in particular encounters and events. We also considered how human actors sought, successfully or unsuccessfully, to change and stabilize the sociotechnical network in their effort to routinize and scale-up video consultations.

To hone our focus on health information infrastructure, we sought to construct rich ethnographic accounts of cases within the case (such as recurring problems with bandwidth) that illustrated and explored one or more of the five characteristics of infrastructure set out above. We followed some guiding principles of the ethnography of infrastructure suggested by Star: surface master-narratives (the overarching discourses that shape decisions), apply infrastructural inversion (eg, foreground things that are usually kept in the background), surface invisible work (eg, work done by low-grade staff such as secretaries and administrators), and study paradoxes (eg, why a simple change makes the whole system unworkable, perhaps because it generates additional hidden work) [39]. We also built on Star's original approach to add a more specific institutional dimension to the analysis, considering, for example, how institutional roles and identities generated particular agendas and priorities and showing how these agendas and priorities sometimes clashed.

We used narrative methods to organize our different data elements into a coherent temporal account, which made sense of unfolding actions and events in both a local and broader context [40,41]. Narrativizing helped illuminate the unique and subtle socio-technical interdependencies hidden within technology-supported change programs [42] since the significance of seemingly mundane or unrelated data items (eg, a short exchange of emails, field notes from different clinics, minutes of meetings held over months or years) often became evident only when incorporated into a story that spanned both time and space. This is especially true since infrastructural problems typically took months or years, not days or weeks, to resolve (and in many cases remained unresolved). The narrative form also allowed us to tease out and emplot micropolitical events and actions (such as how both conflicts and collaborations emerged between clinical services and the IT department).

Results

Description of Dataset and Overview of Findings

Our final dataset (to date) of 450 hours of ethnographic observation, 61 staff interviews, over 50 wider stakeholder interviews, and a large body of documents (Table 1) was characterized by a striking prominence of "boring things" [1,2], such as small material details, protocols, standard operating procedures, and seemingly banal rules and regulations. Repeatedly, implementation and spread efforts were stalled or distorted by things that were so mundane we initially hardly noticed them. In the early months of our research, we unconsciously backgrounded these "boring things" as our research gaze was drawn to more conventional subjects of ethnographic observation: the talk and action of human actors. However, as the study unfolded, we recognized a recurring pattern: human actors often found themselves unable to act in a way that would have helped implement and spread the video consultation model. It was when we began to explore the causes of these delays and bottlenecks that the infrastructural themes described in this paper began to emerge.

Below, we describe four examples of how infrastructural issues repeatedly stalled this translational effort within Petroc Health and the other provider organizations that were seeking to emulate its video consultation model.

Selection of a Platform to Support Video-Mediated Consultations

This subcase describes various challenges with four different platforms that have been considered over the years for supporting video consultations in Petroc Health. It illustrates many of the features of infrastructure described in the introduction, including the importance of its material features and dependability, its embeddedness in systems and organized practices, the incremental, patchworked, and path-dependent way it is built and added to, the close interdependency of technical components and standards (eg, the need for top management endorsement that its components are approved, safe, and formally supported by the information and communication technologies [ICT] department), and the micropolitical nature of software choices (especially how senior management is minded to reject what clinicians see as a more patient-centered platform because it is less compliant with regulatory standards).

Video consultations were first piloted in the diabetes clinic in 2011 by a consultant diabetologist, anonymized as TW. A commercial videoconferencing tool, Adobe Connect (Adobe, San Jose, California, United States), was initially used because the project funder (NHS Choices, part of the English Department of Health) had already obtained these licenses. Like most corporate videoconferencing tools, Adobe Connect required a host to set up a conference call slot using a calendar schedule. It also offered session recording, instant messaging, and screen sharing (intended for presentations). The trust's ICT department were reassured by the program's end-to-end encryption and the company's security credentials. Clinicians chose not to use the video-recording function, and the consultations were not captured on the patient's electronic record except via conventional clinical notes. Screen-sharing was occasionally used to show patients on-screen data, such as test results.

Adobe Connect's video connection was technically reliable but fraught with difficulties. For example, the need to invite patients to a conference meeting by sending a URL link added a layer of administrative overhead (hidden work) for the clinician. The software was unfamiliar to both clinician and patient, and it used a metaphor (conference room) that jarred with the institutional purpose of the call (a confidential medical consultation). While the new video consultation service was popular with patients and staff, the platform was not.

Accordingly, the diabetes team tried using the consumer version of Skype (Skype Communications S.A.R.L., Luxembourg City, Luxembourg) as part of a one-year feasibility study funded by the Health Foundation, a large medical charity. This decision proved to be more popular. Many patients already used Skype, and the rest generally knew someone who could show them how to download and use the platform. In 2013, the team obtained further funding from the same organization to explore the use of Skype-based consultations in routine care. Unlike Adobe Connect, Skype is an open-ended, point-to-point, video call application that allows users to customize the structure of the interaction. In addition to booking video consultations, it allowed patients to see when the clinician was online and send them an instant message. This was a function that was seen as empowering patients who had been reluctant to attend clinic:

> *The advantage of seeing who is around is useful for us – it has allowed a lot of ad hoc contacts with patients who never turn up physically to clinics, but Skype the nurse to say "Hi – saw you were online and wanted to check this with you." This has contributed significantly to patient engagement with the service and them taking control.* [TW]

By 2015, Skype consultations had become business as usual in TW's diabetes clinic. However, our ethnographic observations showed that this apparent embedding was the result of elaborate workarounds by clinical and administrative staff for aligning the clinical consultation with documenting attendance and booking a repeat appointment. In a regular consultation, this would have been triggered by the patient physically appearing at the booking desk. This finding illustrated the deep embeddedness of the clinical routine within other, more administrative routines [23].

The Skype demonstration project described above had been informally supported by the ICT department (who had installed Skype on outpatient computers as a favor to TW, who was well-liked). The project was popular and widely highlighted (the UK Secretary of State for Health, for example, used it as an example of digital innovation in high-profile speeches [43]). However, efforts to roll out this model to other departments within Petroc Health quickly stalled when senior management raised concerns about the technical and regulatory implications of using the consumer version of Skype. They pointed out the lack of information governance rules or guidance on the use of Skype within the NHS, the absence of service level agreements or protocols for managing installation and upgrading of the software, and the unknown local impact of video streaming on network connectivity. The practical impact of the absence of agreed standards and procedures was that, for example, a clinician would arrive to do a booked video clinic and find that because of a forced upgrade overnight, Skype no longer worked on the local terminal. This reflected the fact that some aspects of the infrastructure were controlled by players outside the organization, such as Microsoft. This problem could be fixed only when the clinician could cajole someone from the ICT department into attending in person and manually overriding the block.

TW used her experience, skill, and personal qualities to work through Latour's four stages of translation in her effort to transform and stabilize the socio-technical network needed to make video consultations a reality: problematization (defining the problem as accessibility of services and a particular technological intervention as the solution to this), interessement (getting others to accept this problem-solution, specifically by engaging top management and board members as well as her fellow clinicians), enrolment (defining key roles and practices in the network, such as establishing a cross-departmental working group that included ICT and business elements), and mobilization (engaging others in fulfilling the roles, maintaining dialogue, and creative troubleshooting).

As part of our action research, we helped produce the standardized procedures and documentation demanded (and subsequently approved) by senior management at Petroc Health. This, along with TW's perseverance, led to Skype eventually being formally approved for running video consultations across the trust, which was a victory over the reluctant senior management. In 2017, its rollout formed part of the Transforming Services Together program. This strategic-level initiative was coincidentally given a boost because upgrades to some parts of the trust's internet network were occurring as part of a separate initiative to support multidisciplinary team meetings between different sites using a different video-conferencing technology. This serendipitous event illustrates that infrastructure, as defined by Star, is a fundamentally relational concept, the reciprocal embeddedness of infrastructural elements, and the patchworked and path-dependent way in which the installed base evolves.

By the end of 2017, various additional videoconferencing applications had become available, some of which had been purpose-designed for medical use, and Skype was coming to be outdated and limited in comparison. Initially, there was little appetite by the project leads to replace Skype as the preferred platform, as they felt that after much effort, they had secured the necessary changes for supporting this particular software (the standard operating procedures and information governance approvals, for example, were specific to Skype).

However, during 2018, the trust encountered several technical problems running Skype (described further in subcases 2 and 3) and began to consider moving to a different platform. There was much discussion about the possibility of switching to the licensed version of Skype, Skype for Business, which at the time was the package of choice recommended by NHS Digital. Eventually, however, a trust-level decision was made to pilot Microsoft TEAMS (Microsoft, Redmond, Washington, United States) (a workplace collaboration tool with video call functionality), on the basis that this would form part of the Microsoft Office 365 package, which the ICT department was already planning to purchase on behalf of the trust (another example of the emergent, patchworked, and path-dependent nature of the installed base). Furthermore, our stakeholder interviews with Microsoft executives had revealed a plan to adapt the TEAMS software for clinical settings, including video consultations, and their plans to integrate this function with other parts of the electronic record. From May 2018, a series of meetings occurred between Petroc Health's top management and Microsoft until a third-party broker organization was contracted to negotiate and mediate formal agreements.

During the same period, the project team became aware of another technology platform, Attend Anywhere (Attend Anywhere, Melbourne, Australia), which was purpose-built for clinical use. It had a design focus on emulating clinic workflows (eg, a single button on the trust website enabled patients to gain access to a virtual waiting room, potentially managed by a receptionist, for the patient to be joined virtually by the clinician when ready). Attend Anywhere had been developed by an Australian SME and was already being implemented in several sites in Scotland. In May 2018, Attend Anywhere was procured centrally by NHS Improvement to pilot within selected NHS trusts in England.

Petroc Health volunteered to be one of these pilot sites, creating an opportunity to explore and evaluate both Attend Anywhere and Microsoft TEAMS in parallel, and work out the business case for these two very different options (one custom-designed for this purpose but requiring purchase of additional licenses after the pilot period; the other a product that was free as part of a wider package but would need extensive customizing). At the time of writing, the Attend Anywhere versus TEAMS pilot is ongoing.

The Introduction of Virtual Desktop Infrastructure Technology

Our next subcase describes how a technology (virtual desktop infrastructure [VDI]) introduced with the goal of improving efficiency and security through a standardized, lean (thin client), and centrally-controlled process led to both anticipated consequences (greater central oversight and control of local activity, some efficiency improvements for the IT department) and unanticipated ones (local breakdowns and knock-on problems elsewhere in the system). For poorly understood reasons (a hoped-for panopticon view never materialized), the Skype video consultation platform became unreliable and lost safety-critical audit-trail data, such as text messages and missed calls. At one point, the video consultation service could only be sustained through a single legacy terminal in one room that entirely bypassed the modern VDI solution. As Star predicted, this paradox proved revealing.

During 2016, the rollout of virtual clinics using Skype as part of the trust's Transforming Services Together program, helped by a strongly positive national policy context, was primarily driven by TW, who had introduced the model in her clinic back in 2011. As part of this initiative, Skype had been made accessible on clinic computers for approved services that had been brought into the rollout initiative. Because of pushback from the overstretched IT department (who required more resources and wanted clear governance processes established before agreeing to a full scale-up), it was otherwise not supported on trust computers. By mid-2017, ten video consultation services were approved across Petroc's five hospital sites.

At around the same time, many of the hospital computers (referred to by the ICT department as fat clients) in Petroc's main central London site were being replaced with VDI units (thin clients). VDI is a virtualization technology that hosts a desktop operating system on a centralized server; the user's VDI profile can be customized and run on any machine within the organization. The VDI deployment was a significant undertaking, with plans to cover all five hospital sites over three years. It was seen by ICT leads as a way of improving network efficiency, security, and cost-effectiveness, as well as providing clinical staff with a more consistent computer experience when working across different sites:

> *From an IT side of things, it is easier to manage because you don't have to update the machine every time there is an update to Windows, or an application. It's all done centrally. So, from an IT perspective it is easier to update and proceed. Also, for security. I mean when we got the cyberattack [May 2017], we got affected really badly. And so, all the security is managed on the server side, so it can't get infected on the individual machine. So, there's a lot of factors in there.* [ICT Service Delivery Manager]

In this new VDI environment, Skype needed to be installed centrally on individual staff members' user profiles, as opposed to manually on specific computers. The clinical teams affected were assured that Skype would still be accessible through their personal VDI, and arrangements were put in place to install the application onto relevant staff VDI profiles.

By September 2017, VDI had been deployed across two hospital sites covering 2000 users. Only one non-VDI PC remained within the Diabetes center where TW was based. When she first logged onto her VDI profile, she was relieved to find Skype still available on her desktop. For two months, she continued to run video appointments as part of her weekly clinic, which constituted 10-20% of her follow-up appointment activity. However, in November 2017, she started to experience a problem where her Skype contact list would completely disappear. It was as if her Skype account had been completely wiped, which made it impossible to run video consultations, as both parties need to be established contacts. The history of all Skype interactions with that patient (including text messaging, contact requests, and missed calls) also disappeared.

As Skype appeared to work normally on the one remaining standalone PC, TW attributed the problem to VDI deployment. She emailed the ICT helpdesk seeking urgent assistance, anxious to retrieve her contact list before her next set of appointments. The ICT Service Desk Manager (after discussing with the Network team) concluded that Skype would not work on VDI and advised TW to continue running video appointments using the one remaining PC. However, this was not a realistic option, since TW did not have the authority to use a specific room:

> *Clinic rooms are not yours. You only use the one room allocated to you. Someone else might be using it.* [TW]

She escalated the issue, emailing the ICT manager (anonymized as GF) along with other senior members on the TST program, emphasizing the “serious clinical risk” of this problem and implication for their plans to scale up the use of virtual consultations across the trust. The ICT manager recognized the problem and assured TW that efforts were being made to get Skype working on the VDI.

Through December 2017 and January 2018, various members of the ICT team became involved in addressing the issue. As a temporary workaround, they set up a User Acceptance Testing (UAT) pool on TW's VDI profile, from which she was asked to run Skype. The UAT pool is effectively a separate virtual machine used to run tests and reconfigure settings without impacting the wider live production VDI environment. Such pools had also been developed for other applications that were either new or posed problems for the VDI environment.

This period was a “constant irritation” for TW. Determined to keep her video clinic running, she continued to have video appointments with selected patients, while engineers sought to test and troubleshoot different ways of synchronizing her local Skype application with her central account. At times they managed to retrieve the contact list. However, often, it would disappear when she rebooted the machine, requiring further assistance through the ICT helpdesk.

As time went on, TW made sure this remained a priority issue on the Transforming Services Together agenda, raising it at meetings and sending group emails to various ICT and strategic actors. The ICT team continued to investigate but could not provide a clear idea of how or when it would be resolved.

By February 2018, one of the End User Computing engineers (anonymized as OB) who had been tasked to lead on this issue began to make some progress. By shadowing TW and reviewing background operating processes while she used the Skype application through her VDI profile, he identified that while some of her contacts appeared on loading the application, many did not. After some time, he worked out that the local machine was saving a profile of any Skype contacts used. If the same user logged in again on that machine, those contacts would be found again, and this would prevent additional contacts from the user's wider Skype profile being copied across from Microsoft Cloud. Having identified the problem, OB anticipated that a fix could be found.

In February 2018, OB and other members of the ICT team invited TW to their office to show her how to run the Skype application from the UAT profile they had installed. OB documented his fix in a Word document as a script for the service support team to use in future cases. While TW was able to return to using Skype more readily, she now had to relaunch Skype every time she wanted to use it (to sync it with her online account), and from a specific local drive on her UAT pool (where the fix was implemented), rather than letting it run in the background. She considered this clunky compromise worthwhile to ensure the contact list remained intact and up to date.

Unfortunately, this promising fix did not last long. After a few months, TW's contact list disappeared again. TW contacted OB, who reimplemented his script, which rectified the issue. Nevertheless, after a few weeks, the problem occurred again. In the months that followed, it became a routine practice for TW to call upon various ICT engineers whom she got to know, asking them to reimplement OB's script whenever the issue occurred. This was frustrating and awkward, not least because the Skype clinic ran from 8:45-9:30 am, but the ICT helpdesk did not open until 9:00 am. During that time, TW purposefully restricted the service to existing and familiar patients in the hope that a more permanent solution would be found.

However, in August 2018, this issue was further confounded by another problem. TW noticed that Skype was running particularly slowly, and it also slowed down the other clinical applications. Sometimes it ran so slowly that it was impossible to use. On other occasions the application crashed altogether:

> *The whole thing would slow down. And that was terrible because the patient would call in. And I could see they were calling in. But I couldn't even accept the call because the whole thing was so slow. By the time I got the cursor on the icon and click, the patient would call off. So, it was just awful. They could see I was online. They could see that I would have seen the call. But I wasn't picking up the call. And normally, when that happens – because if I am talking to another patient, I would type them a message to say I'm busy I will reply in ten minutes. But in this case, I wasn't even able to do that. The whole thing was terrible. Even if I was able to manage to connect. Everything was slow. I couldn't open patient records.* [TW]

Consequently, TW and other members of her team stopped running video appointments completely. TW and other members of the rollout program were beginning to consider other technology options (see subcase 1). However, this would take time to establish. In the meantime, TW was asked to launch Skype on her VDI profile every day for six weeks and keep logs of her experience to try and develop a clearer picture of what kept happening. Partly because the problem largely resolved over the Christmas period (when network usage dropped), the ICT team concluded that the Skype application used more memory than had been anticipated and increased the central processing unit (CPU) for TW's UAT pool. While this appeared to resolve the problem, TW considered this fix too precarious to justify expanding the service to new patients or encouraging other staff to use it. The fact that she was not under pressure to push the pace of implementation illustrates that the project, while formally Trust policy, was not an overriding priority.

A member of the ICT department summed up the prevailing sense of confusion and impasse:

> *The challenge we have with VDI is lots of patchy fixes and never really clear what exactly they have done to fix it… And we have hundreds of applications that we use across the trust. And this will be happening with lots of other programmes. … It is very very difficult to isolate what is happening. A lot of it is feeling around in the dark as to what may or may not be happening. Even when you get an answer, it will change tomorrow…* [ICT Project Manager]

At the time of writing, the trust, and the IT support team are still struggling with the challenges of VDI technology. A reviewer of a previous draft of this paper suggested that the kind of technical analysis described in this case could have been done in a more automated way using situated analytics had the IT department been aware of such approaches [44], though these may well bring their own challenges.

This case illustrates how even in digital-exemplar health care organizations, breakdowns are frequent, and repairs are not merely technological but also social and political. The clinical entrepreneur (TW) achieves repairs by using her status and relationships within the organization to mobilize the ICT support infrastructure and persuade support staff to agree to bespoke solutions (eg, allowing the use of the legacy desktop machine to run Skype). In other cases, lower-status junior doctors and nursing staff had less power and influence in this regard, and in that sense, carried a heavier infrastructural burden (ie, their work was more vulnerable to constraints and delays when breakdowns occurred). Such staff were, for example, dependent on a response from the generic IT helpdesk support email address (because they either lacked the seniority to contact anyone else directly, or lacked knowledge of whom to speak to), and progress tended to be slow unless the problem could be escalated to someone with better connections.

Video Call Quality in a Peripheral Hospital

This subcase relates to a rheumatology clinic in one of the peripheral hospitals of Petroc Health (anonymized as Eastern General). It illustrates the patchworked and incrementally fixed nature of health information infrastructure. Previously a separate, small district general hospital 20 miles away on the outskirts of London, Eastern General merged with the main Petroc Health Trust in 2013. As this case illustrates, the distant site has become swept up in the wider modernization effort of this digital innovator organization, a perhaps typical experience for the smaller and weaker partner in a merged organization. The learning curve for the team at Eastern General is long and steep. For the clinicians in the narrative, the goal is not merely to make the video connection work technically but to ensure that it works reliably and to a sufficient standard to support professional work. Despite many time-consuming test calls to try to optimize the technology, it fails on the day, and she, in turn, feels she has failed her patients.

Eastern General was widely viewed as both clinically and technologically backward by those in the main central London site. In September 2017, CB, the physiotherapist, met with GT (Service Delivery Manager) and LT (Patient Pathway Coordinator) in the staff meeting room to test Skype on her computer and familiarize herself with the application. Her first video appointment was booked for the following week. After spending some time tinkering (eg, finding USB ports that worked, positioning webcam, setting the correct audio output devices), navigating (eg, how to find contact, initiate calls, send messages) and test calling (using the Skype test call audio playback service), they got the technology to work.

After months of preparation, the team was excited to finally launch their new video clinic, which was the first on this site. For six months, GT had worked with the local Service Manager (FI) to get everything in place. Among other things, they had to submit requests to the ICT department to incorporate video appointment slots into CB's electronic scheduling tool, generate new appointment letters, and gain access to the Skype application on the clinic desktop computer (the peripheral hospital was yet to be modernized with VDI technology).

On the morning of the first video clinic, CB arrived at work earlier than usual. She needed to collect the webcam and headset from the administrative office, load up Skype, and check it was working on the clinic computer. The one video appointment was deliberately scheduled to take place at the end of her clinic so as not disrupt her face-to-face appointments. When that time came, Skype was slow to respond. When the patient answered CB's call, his face was severely pixelated. At times, the video froze or dropped altogether. The audio was also broken and distorted. Clinician and patient struggled on, but only by disabling the video function at both ends.

CB did not want a repeat of this challenging and embarrassing situation. She decided to run some more test calls before the following week's clinic. She wanted to know if this was a one-off glitch or a problem with the hospital connection that was likely to be recurrent; she strongly suspected the latter. Over the next few days, she found time to perform test calls (with colleagues and members of the implementation team) from the consultation room, with variable and inconclusive results. She would have liked to have done more tests, but time was limited because the consultation room was rarely free to use, and she needed to fit in with the availability of the person on the other end. The following Tuesday, she ran another video appointment with a patient. This one was just as bad. She decided to discontinue video appointment bookings until she could trust the technology.

> *And I guess it's frustrating because you are messing around for a few minutes and it doesn't look very professional for the patient, where I'm having to hang up the call and pick up the call again, and say why can't I see them.* [CB]

FG (Service Manager) escalated the problem with the ICT manager (GF), who passed it to the program lead responsible for supporting the roll-out of video clinics (BN). For the ICT team, this was not a simple technical fix. There appeared to be no objective way of assessing bandwidth requirements; they could only "suck it and see." Video streaming was a new demand on Eastern General's overstretched network, which had been designed historically for much lighter information traffic but had recently become (organizationally and technically) part of the digital innovator Petroc Health. Various attempts to modernize Eastern General by installing new technologies had not gone well:

> *Eastern General has a very – a network under pressure. It's organically grown to support the service but not necessarily with the nuts and bolts required on the network. So what we have is a lot of people hanging off the network more than what it can manage. […] People are competing for the bandwidth that's there […]. What you'll get is limited bandwidth at different locations depending on the size of the fibres that have been put in, or the connections that have been put in. […] [T]hat bit of spaghetti may have been a 10 meg link. Whereas some people had, I don't know, linguini which was the fatter one, and that's a 100 meg link. And then you sit on a much bigger pipe which is the fibre. So if you sit there, you've got a weaker link.* [ICT Support Manager]

The above quote illustrates how the clinicians, patients, managers, and relevant ICT people, along with elements of the technical network, have all been enrolled into an effort to get a new, video-based rheumatology service up and running at Eastern General, but the known limits on capacity in this historically low-tech site were somehow not factored into the planning. Batteau [45] has pointed out:

> *Heterogeneity of expectations, artifacts, infrastructure, support, skills, management, and system planning … is an inevitable consequence of the variable rates of diffusion [of innovations] in a large-scale technological system within an articulated social field.*

The task is to rise to the challenges that are posed by such inescapably complex relations and processes.

CB continued to try test calls when she could, to gain a better idea of how the video call quality varied. On one occasion, this was done with an ICT engineer present, who went on to speak with the server team to ascertain how call quality corresponded with wider network usage. Despite initial plans to run these tests more frequently, in practice, it was too difficult to organize and coordinate them alongside the availability of the clinic room.

With limited data and multiple interacting influences (eg, variations in network capacity and traffic within different sections, and at different times, across the network, and the CPU demand of Skype and other systems running on the local terminal), it was difficult for the ICT department to confidently establish the underlying cause of the problem. GF decided to postpone any further deployments of video consultation technology at Eastern General. The hospital was due to have two major IT upgrades within the year, so it made sense to wait before progressing with the video clinics. The ICT support manager was upbeat about this:

> *In the next six months they will have a whole new network and their Skype will be singing and dancing. Because effectively we are giving them a motorway in terms of provision of bandwidth.*

For the ICT team, their experience at Eastern General highlighted the value of what they referred to as a "controlled rollout." This involved working with a few services, each running a small number of consultations, to understand how Skype impacts the network and manage or restrict activity where necessary.

For CB and her team, it was felt that some momentum still needed to be maintained for their new virtual clinic service. CB believed video quality was far better during her Friday morning clinic than the Tuesday clinic, perhaps due to less demand on the network at this time. She asked GT to prepare and submit another clinic template change form to incorporate video slots into her Friday clinic.

By November 2017 (which was before the two major upgrades), the new (Friday) video slots had been implemented, and CB began offering video appointments. On 30 November, she ran two successful video appointments. The video quality, though not perfect, was enough to run the consultation. In the knowledge that the Eastern General network will be improved at some point, she has continued to press ahead cautiously with Skype in a small number of carefully selected patients.

CB's frustration reflects several features of what we have previously (following MacIntyre) called medicine's internal goods [46]: being available for the patient (as a professional standard, the risk of not being available must be zero), assuring continuity of care (rheumatology patients generally have lifelong conditions and stay with their specialist clinician for years), and providing professional presence (via a technically adequate video connection). Given that the unreliable connection jeopardized all these internal goods, it was small wonder that the clinician felt that "it doesn't look very professional."

Access Rights to Use Video Conferencing Software

Our final subcase highlights how the embeddedness of infrastructure in local systems poses challenges to spreading a technology-supported service model to other organizations. Adoption required distributed reconfigurations across multiple levels of practice, which were reciprocal and interlocking. The technical infrastructure (including a licensed Skype technology acquired through a previous purchasing decision) afforded and constrained actions in ways that played out differently to the main case site, in which particular organizational routines, processes, knowledge, standards, and workarounds had emerged. In this last case, information governance concerns and standards constrained technological choices and slowed the implementation of solutions.

Southern Trust, a large, multi-site provider in a university city that had won awards as a digital innovator, was supported by the Video Consultation Unit at Petroc Health to try to introduce video consultations in various clinical services. One of these was a sarcoma (bone and soft tissue tumor) clinic, where a consultant surgeon, SB, led the implementation. After signing up, implementation was put on hold for several months due to a significant increase in clinic demand alongside senior staff changes and recruitment delays.

In April 2018, after SB was able to secure some additional operational staff time, progress was made to set up the technology. Skype for Business had been part of a recent NHS Mail integration, so it was available free to all staff users. This platform offered similar management and security functionality as Adobe Connect, but also interfaced with Skype and allowed people without an account to join as guests, avoiding the need to set up patient accounts. The additional call encryption capabilities and integration with NHS Mail (secure email accounts for NHS staff) were also considered an advantage over the consumer version of Skype, which had not been designed with the privacy needs of medical consultations in mind.

By September 2018, Skype for Business was installed on a dedicated laptop (specifically purchased for running video appointments), to be held by an administrator and taken to the clinic by SB. This was because most clinic computers used VDI profiles, and there were uncertainties about the reliability of Skype on these (reinforced by the experiences at Petroc). Use of the laptop required governance approvals with the recently introduced Data Protection Impact Assessment tool to comply with the UK's General Data Protection Regulations.

SB identified some suitable patients to run his first video appointments but wanted to run dummy calls and familiarize himself with the technology before booking them in. However, his series of attempts to test the technology repeatedly failed. The application was on his desktop, but he could not get past the login page, as it had not been configured to his account. A Helpdesk request to IT resulted in him being able to sign in and contact colleagues. However, when he tried to call members of the Petroc team supporting him, he was confronted with a generic pop-up error message to "contact operational support for further information."

After unsuccessfully calling ICT support, he stopped the tests. The operational support manager was tasked with finding someone in ICT to help:

> *[W]e've had to sort of drive and chase every, sort of, step…. At the moment the IT is the stumbling block… Our managers are running around with their own priorities and I don't know who will practically help us… You just don't feel – it hasn't been allocated to anyone… Our IT requests just go to a generic call desk.*

With no response to email requests and continuing demand on the clinic team, progress on developing the virtual consultation service stalled. After two months of chasing, a member of the ICT team investigated the issue. It emerged that, while Skype for Business was available as part of the NHS Mail integration, the default configuration was for internal communications. External communication required additional enterprise licenses, of which the trust had a limited number.

After some weeks, the application on SB's clinic laptop was successfully configured to enable external video calls. SB managed to run some dummy calls, followed by a single video consultation with a carefully selected patient, which went well. Based on his experience over the last 18 months, he remained concerned about the reliability of the technology and routine use within this busy clinic.

Similar challenges confronted other services at Southern Health. One clinician resorted to purchasing an iPad and using Facetime (with patients who owned Apple devices), thus bypassing the NHS technical infrastructure. All teams expressed a pessimistic outlook on the prospect of routinely running video appointments. While there was no active resistance to using the technology, there was perceived to be an absence of senior-level engagement and leadership:

> *The technology is there. It is ready and waiting. But we need someone to drive it as their own priority getting these clinics up and running and looking at the various technical issues that come with it… and ironing those out.* [Physiotherapist]

The subcase illustrates a key finding: that the contingent and emergent qualities of infrastructure mean that it will never be possible to develop a standard pathway to implementation.

While support from Petroc Health played an important role, this could not make virtual consultations happen locally. Indeed, this example illustrated that spreading the model to other sites needs to center on the process of translation in the new site, which will never be fully scripted by generic models and implementation guides.

Discussion

Main Findings

This paper has described four detailed subcases within a wider case study of scaling up video consultation services in a multi-site London hospital trust and spreading this model to other UK sites. The subcases illustrate how "boring things" (such as internal procedures, locally-endorsed standards, aspects of software functionality, mundane administrative issues such as room bookings, general pressures on the system, cash-constrained departments fighting their corner, and historical decisions to invest in particular platforms) influenced the fortunes of a technological innovation. Infrastructural challenges included intricacy and lack of dependability of the installed base; interdependencies of technologies, processes, and routines, such that a fix for one problem generated problems elsewhere in the system; the inertia of established routines; the constraining effect of budgets and legacy systems; and delays and conflicts relating to regulatory and professional standards, especially around clinical quality and safety.

Our rich ethnographic data revealed the importance of entrepreneurial clinicians, who were committed to introducing new technology to deliver excellent care and who made persistent and creative efforts to interest, enroll, and mobilize others to help align technologies, standards, routines, and processes in the pursuit of that goal. Despite these efforts, and notwithstanding, prevailing, master-narratives of efficiency, standardization, and control, the health information infrastructure in Petroc Health, in particular, was revealed as heterogeneous and unstable, with the various elements pulling apart (drift) and an absence of effective central control (distribution), resulting in what Berg [47] has called:

> *A fragile, never static equilibrium, characterized by never ending frictions, loose ends, and unforeseen consequences.*

Our findings affirmed previous research, which showed that when video consultations work, they can be clinically high-quality and safe. However, for this eventuality to be achieved, the physical (material) and knowledge-practice (nonmaterial) conditions of possibility must be adequate. When (and to the extent that) these infrastructural preconditions are inadequate (eg, when technical breakdown precludes or compromises a video consultation), the purposive interactions of clinical care become awkward and risky. The clinician's lack of trust in the reliability of the infrastructure is accompanied by a constant undercurrent of anxiety about being unable to care for patients to appropriate standards. As one reviewer commented, "we seem to have created a new form of professional shame."

To the extent that the precarious infrastructure that characterized our study sites was able to support the innovation and maintain excellence in clinical care, this was in no small part due to creative and persistent work undertaken by individual human actors to bridge, through human and technical workarounds, the gap between standardization and contingency. This articulation work was never-ending; it often had a political component; and it sometimes succeeded only to the extent that the innovation remained confined to a local setting, protected from the wider system. In some cases, the gap between standardization and contingency could never be bridged (eg, when administrative permissions to use a technology were not forthcoming or when internet connectivity proved rate-limiting), resulting in suspension or abandonment of the project.

Strengths and Limitations

This study has both empirical and theoretical strengths. Empirically, it is based on extensive ethnographic fieldwork conducted over many years and oriented to explore the contingent and emergent qualities of health care infrastructure. The study's theoretical strength is the extension of Star's foundational work on infrastructure to include a central emphasis on its institutional elements. We have combined different but related theoretical perspectives, namely, strong structuration theory, neo-institutional theory, social practice theory, and aspects of actor-network theory, and applied these to a rich, longitudinal dataset to tease out how the institutional aspects of information infrastructures emerge and unfold over time.

The limitations of this study include the question of how far we can generalize from a single, unique case to make claims about infrastructure more generally. The five defining components of health information infrastructure set out in the introduction were built on, refined, and developed to explain our empirical data; they may not explain all aspects of such infrastructure in all contexts. We encourage others to apply and extend our theoretical framework to contrasting countries and settings.

Comparison With Previous Literature

Our work resonates strongly with Star's original theoretical work on information infrastructure [1,2], as well as that of other founding scholars who have taken a social practice perspective on technology [6,17,24,47].

Hartswood et al, drawing on various ethnographic studies of health information systems in the United Kingdom, introduced the notion of "design in use," in which design is reconceptualized from a discrete phase that occurs before the technology is implemented to a never-ending effort to achieve and maintain embedding by coadapting the technology and the work processes it aims to support. Facilitated partnerships between ICT specialists and clinician-users are needed to address [48]:

> *…the ongoing struggle of making this particular system work for these particular users, in this particular workplace and at this particular time.*

These authors emphasize the importance of making ICT work more visible to nontechnical users, allowing them to take a more informed leadership role, and, conversely, how making clinical work visible to ICT specialists allows the latter to become attuned to the nuances of technology use, thereby understanding the importance (or not) of particular features or adaptations.

Grisot et al describe a 10-year ethnography of the design, development, and initial use of a web-based solution for patient-hospital communication at a Norwegian hospital [6]. Like the solutions in our case studies, this began as a bottom-up initiative from a small and motivated team, though in the Norwegian case, the entrepreneurs were ICT, not clinical, staff. Numerous challenges and setbacks are described, but overall, the solution grew gradually and in a locally adaptive way as the ICT team assessed and addressed specific user needs and use cases. The authors conclude that ICT innovations that are part of the infrastructure cannot merely be "installed." Instead, they must be organically "cultivated" in a way that acknowledges changing organizational needs and the inertia and constraints of the installed base [6]. Maniatopoulos et al had similar findings when studying the spread of new diagnostic technology for breast cancer across NHS oncology and pathology units. They concluded that [24]:

> *It is difficult - if not impossible - to propose a standard pathway for its [lymph node biopsy technology's] embedding into healthcare practice.*

These findings from other research groups mirror our own in highlighting the need to create spaces in which generic elements of solutions can be adapted to local needs and circumstances. However, they differ in that, in our case study, there was a tendency for clinical and informatics staff to talk past one another, with the former (at least to some extent) failing to fully appreciate the technical elements of infrastructure and the latter not fully appreciating the clinical (eg, quality and safety) aspects. This highlights the need to positively promote shared interests and mutual comprehension between the different groups essential to processes of implementation. The scaling-up program for video consultations is, however, at an early stage in its evolution, and there is scope for introducing additional measures to support design-in-use and emergent cultivation. However, this would require, at the very least, attention to the severe staffing shortages that underlie long response times in some participating sites.

The Institutional Elements of Infrastructure

The UK National Health Service was established in 1947 and remains a cherished national institution among both professionals and the public [49]. Using Scott's taxonomy [28], the institutional pillars which support the NHS are threefold: formal (including legal) regulations, enduring professional values and codes of conduct, and expected patterns of behavior. Our data revealed that all three pillars are retained and consolidated in the technical elements of NHS information infrastructure as well as in the habitus of NHS staff. This was evident in the nonnegotiable way that rules and regulations (regarding privacy and data protection) were imposed, often in a way that could not be materially overridden, in clinicians' commitment to providing a "professional" service and the lengths to which they were prepared to go to prevent "embarrassing" violations of the standards they set themselves, and in the long-established patterns of action and interaction that delivered traditional outpatient services. It is for these institutional reasons, of legitimacy and support, and not merely for technical connectivity issues, that the information infrastructure of the NHS has proved so hard to change and why the implementation of new infrastructure often plays out in political ways (eg, as battles between clinical departments, ICT departments, and top management).

UK policy on health technology is currently placing considerable emphasis on light IT innovations such as apps and devices, which are presented as having the potential to improve the quality and efficiency of care. For example, the NHS Innovation Accelerator was established in 2015 [50]:

> *To speed up adoption of innovations which have proven potential for high impact throughout the NHS and wider healthcare economy.*

Such an approach, which places limited emphasis on cultivating the underlying infrastructure with which such novel technologies will need to connect, is deterministic and naïve. Critics have, for example, condemned the new "doctor-in-your-pocket" smartphone video consultation service mentioned in the introduction [11] as both unsafe (because the symptom-checker app is alleged to be unreliable) and unethical (because the service is marketed to young adults, allegedly taking this group and leaving the NHS to care for older and sicker individuals) [51,52]. While a full analysis of this particular controversy is beyond the scope of this paper, the question arises as to whether this controversial service has succeeded precisely because it is not merely technology-light but also regulation-light and value-light. In other words, it has been designed to bypass, rather than integrate with, the institutionalized infrastructure of the NHS.

The challenge of spreading technological innovation through a national public health care system raises the question of how to balance (on the one hand) providing a high degree of stability and commonality through typified inbuilt models, categories, and processes, and (on the other hand) providing sufficient leeway for flexibility to accommodate local contexts (including clinical and geographical particularities, historical path dependencies, and local political agendas) and also allowing the clinician to exercise the necessary autonomy during the consultation. Ellingsen and Monterio observe that "extensive local adaption does not scale, resulting in constraints stemming from one local setting spilling over to the next" [53]. Either we must abandon completely the vision of scaling up innovations that have worked in one setting, or we need to rephrase the scale-up challenge in a more nuanced way, for example: how can we build leeway into technologies to maximize scope for adaptation to different local infrastructures and (at the point of technology use) clinical microcontexts?

Conclusion

This paper has revisited Star's classic work on information infrastructure, has developed its theoretical underpinnings particularly concerning institutional influences and has used a contemporary case study to illustrate its continued relevance to the challenges of medical and health informatics. In a 2001 review paper, Orlikowski and Iacono showed that most information system research published at the time had treated technologies in isolation (eg, as tools), while only a small fraction had studied them as ensembles, that is, as part of wider socio-technical systems [54]. We have recently produced similar findings in a health care context (Papoutsi et al, paper submitted). The empirical findings presented in this paper emphasize the importance of an ensemble view of technologies and show how, particularly in a public-sector health care setting, that ensemble incorporates and reproduces institutional rules, norms, and ways of working.

These findings suggest that much could be learned from further ethnographic studies of health information infrastructure in different contexts. While the popular randomized trial design has its place, it tends to reinforce a tool rather than ensemble view of technology and downplay the importance of infrastructure. A case study design is needed to illustrate, for example, how newly introduced technology is initially equivocal [55]. However, through much local negotiation, interpretation, and on-the-job support can become both technologically and institutionally stabilized [56].

Our findings also suggest that innovators and change agents who wish to introduce new technologies in health services and systems could distill some working principles from our retheorization of infrastructure. First, it is essential to attend to materiality, such as to expect bugs and breakdowns and prioritize basic dependability over advanced functionality. Second, the technological artifact should be considered relationally and as part of a system, rather than as an isolated tool or function. Third, it should be remembered that technology-supported work is cooperative and embedded in organizational routines, and that clinical routines are embedded, sometimes inextricably, in other clinical and administrative routines. Fourth, innovation should generally occur incrementally and organically, with careful attention to technological and socio-cultural legacies. Finally, the institutional nature of infrastructure suggests that it is important to attend not just to standards but to where these standards come from, whose priorities and interests they represent, and whether there is sufficient leeway for them to be appropriately adapted to different local conditions.

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Conflicts of Interest

None declared.

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Abbreviations

CPU: central processing unit
ICT: information and communication technologies
IT: information technology
NHS: National Health Service
TST: Transforming Services Together
UAT: User Acceptance Testing
VDI: virtual desktop infrastructure
VOCAL: Virtual Online Consultations—Advantages and Limitations

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Viewpoint

A Call for a Public Health Agenda for Social Media Research

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Abstract

Research has revealed both the benefits and harms of social media use, but the public has very little guidance on how best to use social media to maximize the benefits to their health and well-being while minimizing the potential harms. Given that social media is intricately embedded in our lives, and we now have an entire generation of social media natives, the time has come for a public health research agenda to guide not only the public's use of social media but also the design of social media platforms in ways that improve health and well-being. In this viewpoint we propose such a public health agenda for social media research that is framed around three broad questions: (1) How much social media use is unhealthy and what individual and contextual factors shape that relationship; (2) What are ways social media can be used to improve physical and mental well-being; and (3) How does health (mis)information spread, how does it shape attitudes, beliefs and behavior, and what policies or public health strategies are effective in disseminating legitimate health information while curbing the spread of health misinformation? We also discuss four key challenges that impede progress on this research agenda: negative sentiment about social media among the public and scientific community, a poorly regulated research landscape, poor access to social media data, and the lack of a cohesive academic field. Social media has revolutionized modern communication in ways that bring us closer to a global society, but we currently stand at an inflection point. A public health agenda for social media research will serve as a compass to guide us toward social media becoming a powerful tool for the public good.

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KEYWORDS

social media; online social networks; health information; health communication

Introduction

Recent leaks of Facebook Chief Executive Officer (CEO) Mark Zuckerberg warning employees about the implications for Facebook if a top Democratic candidate became president resulted in yet another wave of negative press for the company [1], a continuing backlash initially provoked by a 2014 Facebook research study that manipulated user newsfeeds [2,3]. The hashtag "#deleteFacebook" often goes viral following these incidents, as angry users publicly vow to disconnect their accounts [4]. Despite the backlash, in 2019, the Pew Research Center reported no decline in Facebook users over this period [5]. Although many people seemingly have serious concerns about Facebook and other social media platforms, social media bring a particular value to people's lives that make us reluctant to disconnect. To the extent that people enjoy and even depend on the community and resources that social media bring to their lives, disconnecting may be felt like more of a loss than a gain. We know surprisingly little about the value that social media bring to people's lives.

Social media is a burgeoning area of study in the field of public health; however, much research covered in the popular media has focused on its harms [6-9]. Persistent negative headlines drive a narrative about social media that likely deteriorates public sentiment. To be sure, enough research has been conducted to know that some uses of social media are indeed harmful, but the public has very little guidance on how to modify their use to maximize the benefits to health and well-being while minimizing the potential harms. Given that social media are intricately embedded into our lives and we now have an entire generation of social media natives, the time has come to create a public health research agenda to guide the use and design of social media in ways that improve health and well-being. In this viewpoint, we propose such a public health agenda for social media research that is framed around three broad questions (Textbox 1):

- How much social media use is unhealthy, and what individual and contextual factors shape that relationship?
- What are the ways social media can be used to improve physical and mental well-being?
- How does health (mis)information spread, how does it shape attitudes, beliefs, and behavior, and what policies or public health strategies are effective in disseminating legitimate health information while curbing the spread of health misinformation?

Textbox 1. A public health agenda for social media research: three areas of inquiry and specific research questions.

1. How much social media use is unhealthy, and what individual and contextual factors shape that relationship?
    - Which social media activities lead to positive versus adverse health outcomes?
    - What are the individual and contextual determinants of social media use leading to positive versus adverse health outcomes?
    - What factors predict change in time spent in health-promoting versus harm-promoting social media activities?
    - What is the impact of change in time spent in health-promoting versus harm-promoting social media activities on health outcomes?
    - How can we develop more granular measures that capture users’ time spent engaging in specific social media activities?
2. What are the ways social media can be used to improve physical and mental well-being?
    - What is the impact of health-related initiatives led by social media platforms and public health organizations?
    - What strategies are most effective in generating meaningful patient engagement (ie, the type of engagement that leads to healthy changes in knowledge, attitudes, and behavior) in online communities?
    - What factors influence whether health-related advocacy on social media is efficacious at shifting public attitudes or influencing the development and implementation of public health policy?
    - How can commercial platforms and public health organizations harness effective social media interventions in scalable ways that can impact public health?
3. How does health (mis)information spread, how does it shape attitudes, beliefs, and behavior, and what policies or public health strategies are effective in disseminating legitimate health information while curbing the spread of health misinformation?
    - What are the characteristics of health misinformation and disinformation, of their messengers, and the means they are using to do so?
    - How do we characterize the social bot and troll ecosystem around health-related messaging and how it evolves?
    - What are the characteristics of accurate health information messages that spread on social media, and how do these spread?
    - Who are the audiences of health-related organizations’ social media feeds, and to what extent does their messaging reach people who are at the highest risk for the target health condition?
    - What are the characteristics of social media spaces in which health misinformation and disinformation are rare, and how has that occurred?
    - How does legitimate health information shared on social media impact attitudes, beliefs, and behavior, and how does this compare to the impact of health misinformation and disinformation?
    - How do the characteristics of both the messenger and the message recipient affect message receptivity?
    - What are effective health literacy education programs that can decrease susceptibility to health misinformation and disinformation?
    - How do we develop effective counter-messaging to health misinformation and disinformation that adapts to the evolving challenges of the modern social media landscape?

Public Health Agenda for Social Media Research

How Much Social Media Use Is Unhealthy and What Individual and Contextual Factors Shape That Relationship?

Although studies demonstrating an association between greater social media use and poor health outcomes (eg, depression, loneliness, poor body image) [10-13] are plentiful and make for popular headlines, the literature on social media use and well-being is quite mixed [14]. Indeed, a recent meta-analysis of 31 studies found that higher social media use was associated with more significant online and offline social support [15]. Nonlinear relationships have also been observed such that both heavy and no social media usage have predicted worse mental health. Increasingly studies are pointing to moderating variables that influence the relationship between social media use and health-related outcomes [16,17]. At this point, studies that report simple associations between time spent broadly on social media and a specific health outcome do little to advance our knowledge about the impact of social media use on health [18]. More research on specific types of social media activities, the individual and contextual determinants of these activities, and how they lead to positive versus adverse health outcomes is now very much needed [19]. Further, longitudinal studies that identify factors that predict change in time spent in health-promoting versus harm-promoting social media activities and the impact of changes in time spent in these activities on health outcomes would create knowledge that could inform public health guidelines [19].

Given how little we know about how to define the boundaries of problematic social media use, it is premature to devise solutions to curb it. Nevertheless, solutions are being proposed, most of which involve calls to limit social media use [20]. Notably, Senator Josh Hawley proposed the Social Media Addiction Reduction Technology (SMART) Act [21]. If it is passed, it will ban social media platform features assumed to promote compulsive use, such as infinite scrolling and autoplay, while requiring platforms to include features that implement time limits. However, little research has explored whether infinite scrolling and autoplay features negatively impact users.

Further, encouraging time limits on social media usage overlooks that not all users have negative experiences on social media, and not all social media uses are inherently harmful. Policy and public health recommendations that focus on quantity instead of quality essentially equate a patient spending 6 hours a week engaging with her cancer Facebook group to help her cope with treatment to a cyberbully spending the same amount of time harassing classmates on Snapchat. Evidence-based guidelines are needed to prevent real harm that can result from discouraging or shaming social media use in people whose well-being is enriched by, or even dependent upon, their social media activities.

New self-report measures are emerging that allow researchers to assess the degree to which one's social media experiences are negative or positive [22,23]. Tools like this could be useful as we attempt to understand which specific uses are associated with negative and positive experiences and health outcomes. More objective and granular measures that capture time spent engaging in specific social media activities, such as engaging with a particular Facebook feed or group, are also needed to advance the research agenda. Currently, no such tools exist [24]. While self-reported measures are easy to administer, self-reported estimates of time spent in activities that are brief, unplanned, and unstructured (such as typical social media use [25]) are less accurate compared to estimates of time spent in more structured and prolonged activities, such as time spent working or commuting [24]. While there are software programs and mobile tools that track time spent using Facebook via a mobile app or web browser on a computer (eg, Screen Time [iPhone], Stay Free app [Android]) [26], these tools do not capture use across multiple devices. Software-tracked time also does not capture how much time the participant spent engaging in different activities. Until new tools to objectively measure specific social media use becomes available, ecological momentary assessment could be leveraged to track time spent engaging in specific social media uses, along with factors such as positive and negative affect, body dissatisfaction, sense of belonging, and loneliness, to provide insights into the relationship between specific uses and these outcomes. This approach could also be leveraged in interventions in which users self-monitor their social media activities and these factors, receive feedback about these relationships and set goals that maximize positive uses while minimizing negative uses.

What Are Ways Social Media Can Be Used to Improve Physical and Mental Well-Being?

Some commercial social media platforms are investing in health-related tools that have promising public health implications. For example, Facebook partnered with the American Blood Centers and the American Red Cross to produce a blood donation tool that alerts users to blood supply shortages in their area and notifies them of locations where they can donate [27]. Also, Facebook, Instagram, Pinterest, and Twitter all provide suicide hotline information to users who use suicide-related search terms. Pinterest removed antivaccine content on its platform and adopted a policy where vaccine-related searches produce health information from leading public health organizations [28]. Related, Facebook and Instagram reduced the ranking of groups and pages that spread misinformation about vaccines, rejected ads for vaccine-related misinformation, and provided pop-ups for searchers using vaccine-related search terms [29]. YouTube has pulled ads from videos containing antivaccine content to prevent sites from monetizing this content [30]. That commercial social media platforms are taking actions to improve public health is a promising trend. Very little research has explored the impact of these initiatives, most of which are very new. Facebook offers research awards on specific topics [31], but the public health community should attempt to shape their agenda. As is beginning to occur in the social sciences [32], partnerships between commercial platforms and public health scientists are needed to research the impact of these initiatives and to inform the development of new public health initiatives.

Users are also discovering unique ways to leverage social media to improve their health. Online patient communities have proliferated on social media as a way for patients to connect with one another on specific health topics. "Peer-to-peer healthcare," a term coined in 2011 by Susannah Fox at the Pew Research Center, refers to patients using social media to connect with other patients about their health [33]. Online patient communities have organically formed on nearly all social media platforms. They are often patient-initiated, patient-moderated, and open forum, meaning conversation threads can be initiated by members as they wish. Research has begun to examine online patient communities, and the benefits members gain from participation. For example, a review of 47 studies of online diabetes communities on multiple platforms found evidence for positive clinical, behavioral, psychosocial, and community outcomes, and very few negative outcomes [34]. A survey study of a breast cancer community on Twitter found that 80.9% of respondents reported that participation increased their breast cancer knowledge, 66% learned of clinical trial opportunities, 31% learned information that led them to seek a second opinion, 71.9% reported being inspired to increase their advocacy efforts, and 67% of those with high anxiety about their diagnosis reported declines in anxiety [35].

Online patient communities may even impact health care costs. A longitudinal study of new enrollees of HealthUnlocked, a collection of online patient communities in the United Kingdom, revealed declines in emergency room visits [36]. Much more research is needed to fully understand the range of benefits people experience in these communities and how to amplify beneficial experiences. This research faces logistical and ethical challenges because many online communities are private, and the sheer size of them makes obtaining informed consent from all members difficult and unlikely. Further, the presence of researchers may not be desirable in spaces created by patients for patients [37]. For this reason, a community-based participatory research model, adapted for online communities, may be needed to create partnerships. Nevertheless, researchers must establish the value proposition for online community leaders and members to engage with them.

Online patient communities are used not only for peer-to-peer support but also for advocacy efforts. Donna Helm Regen, moderator of the Pull the Plug on Tanning Beds Facebook page [38], lost her daughter, a tanning bed user, to melanoma before the dangers of tanning beds were well-publicized. She uses her Facebook page to inform the public about the harms of tanning beds and advocate for tanning bed legislation, often in partnership with nonprofit organizations and other advocacy groups with whom she has connected with on social media. Her efforts afforded her opportunities to make a national public service announcement [39] and to testify at state legislative hearings supporting tanning legislation. Social media give grassroots health advocacy efforts a platform to shore up support for their cause. This is another example of how encouraging arbitrary social media use limits may inadvertently squelch important public health efforts. People have discovered ways to use social media to impact their health, their community’s health, and public health, much of which has gone entirely unstudied. Research on what makes these efforts work and how to enhance their efficacy is needed to strengthen their impact on changing individual behavior, shifting public attitudes, and influencing public health policy.

Patients are not the only ones creating online health communities. Researchers have begun to create online patient communities to implement and evaluate the efficacy of social media-delivered behavioral interventions and public health campaigns [40]. Typically, investigators will start a private online forum on a commercial social media platform (eg, private Facebook group), recruit members of a target population to join the group, host a feed that delivers behavioral intervention or public health messaging for some time, and then measure outcomes. Often these programs employ a health care professional or health coach as a moderator. Systematic reviews of studies evaluating such interventions for weight management [41], smoking [42], HIV testing [43], and cancer prevention [44] reveal promising outcomes. These online communities provide the benefit of both peer-to-peer support and evidence-based health information. However, this model has drawbacks. Researcher-derived communities are smaller than online patient communities in the real world, which raises concerns about scalability. They are also time-limited, which necessitates aggressive engagement strategies to strengthen ties between members of the community.

Further, we know of no examples of evidence-based social media interventions having been implemented in a real-world setting. Many nonprofit public health organizations have online patient communities, but do not provide health promotion interventions within those communities, which presents an opportunity for partnerships with intervention researchers. The closest example is the Truth Initiative’s “Become an Ex” community for smokers [45]. Their platform provides evidence-based online resources for smoking cessation that community members can use to assist their attempts to quit. Much research is needed to examine how to generate meaningful patient engagement in online communities and how to scale these models for implementation at the community or population level [46].

The promising data emerging about the health benefits of online patient communities support the notion that online social interactions that occur in tighter-knit communities created based on shared life experiences may have the most potential to impact health and well-being. A movement towards a tighter community-focused model of social media appears to be afoot at Facebook and Instagram. In March 2019, CEO Mark Zuckerberg announced [47]:

> *Over the last 15 years, Facebook and Instagram have helped people connect with friends, communities, and interests in the digital equivalent of a town square. But people increasingly also want to connect privately in the digital equivalent of the living room. As I think about the future of the internet, I believe a privacy-focused communications platform will become even more important than today's open platforms. Privacy gives people the freedom to be themselves and connect more naturally, which is why we build social networks.*

To the extent that social media use shifts toward private forums built around shared life experiences, the quality of interactions and impact on well-being is likely to improve, which may, by design, diminish negative experiences. Research should inform the type of shift in platform features, tools, and design needed to shape users’ experiences in this way.

How Does Health (Mis)information Spread, how Does It Shape Attitudes, Beliefs and Behavior, and What Policies or Public Health Strategies Are Effective in Disseminating Legitimate Health Information While Curbing the Spread of Health Misinformation?

Overview

Long before the term “fake news” was coined, concerns were expressed regarding the veracity of health claims online and elsewhere [48]. Bogus health claims come in two forms: misinformation and disinformation. Health misinformation refers to information that is false and spread by someone who believes it to be true, whereas health disinformation refers to information that is false and spread by someone aware it is false and is intent on misleading people [49]. The volume of both on social media has grown into a public health epidemic [50]. While research is nascent on strategies to combat this problem, a multi-prong approach is needed, including curbing its spread, inoculating people against false messages, and developing effective counter-messaging. Tackling this complex and urgent public health problem will require an interdisciplinary research agenda.

Curbing the Spread of Health Misinformation

To curb the spread of health misinformation and disinformation on social media, we must first have the means to identify three things: (1) false messaging; (2) messengers who spread them and the reasons why (ie, misinformation or disinformation); and (3) the means they are using to do so. While studies of health misinformation on social media have covered a variety of health topics, including infectious disease (eg, vaccines [51], antibiotics [52], cancer [53,54], electronic cigarettes [55], eating disorders [56,57], and nutrition [58,59]), a recent systematic review of 57 health misinformation studies revealed this area of work is dominated by infectious disease studies [60]. This review reported that the most common purveyors of health misinformation appear to be from people with no institutional affiliations.

Studies of "social bot" activity reveal that these accounts flood the conversation on particular health topics [61,62]. Social bots are social media accounts designed to appear to be manned by a human, but they are automated to put forth or respond to content in specific ways [63]. Not all social bot accounts have nefarious intentions, with some instead serving helpful purposes, such as content aggregation [63] or gamifying health challenges [40]. Trolls are accounts operated by humans who are intentionally disruptive towards others and may or may not be compensated for doing so [64]. One study of antivaccination content spread by "social bots" and "trolls" found that these accounts are pervasive and designed to create false equivalency and sow discord about vaccines [61]. Social bot and troll accounts rapidly proliferate, which gives them extraordinary power to flood social media with messaging in ways that convey the false sense that a certain message is popular or well-accepted [63]. The use of social bots to conduct misinformation campaigns may be one reason health misinformation (and disinformation) is so much more plentiful on social media than legitimate health information [60].

Commercial platforms have developed algorithms to identify the nefarious activities of bots and trolls, to reduce these activities and delete their accounts [65]; however, new accounts designed to circumvent the algorithms eventually emerge, making for a seemingly never-ending cat and mouse game [63]. Troll accounts are exceptionally resistant to algorithm detection, being manned by real people who may be paid to do so [64]. Surveillance studies are needed to understand the bot and troll ecosystem around health-related messaging and how it is evolving. Further, while social bots have been used for ill-intentions, research should examine how they may be used for good. For example, as part of an anti-bullying public service announcement, Monica Lewinsky released the "Goodness Bot," a Twitter account that, when mentioned in reply to a bullying tweet, responds with a positive message [66].

Research is also needed to improve our understanding of how legitimate health information is produced and spreads on social media. When it comes to health misinformation, a strong defense may require a strong offense. Many public health departments and nonprofit organizations use social media to disseminate health messaging. A study of state public health departments revealed that most have a social media presence [67]. Another study specifically focusing on state public health departments' use of video-based messaging found that 43/51 departments have YouTube channels with a total of 6302 subscribers, 3957 videos, and 12,151,720 views [68]. Most large, health-related, nonprofit organizations also have a social media presence. A study of 24 of the largest nonprofit skin cancer organizations' Facebook feeds found that the organizations had a collective total of 225,113 followers and in one year produced 824 posts that received 92,004 likes, 4148 comments, and 82,791 shares [69]. Interestingly, the message types that received the most shares were fear appeals and myth busters. While these organizations seem to be producing impressive reach, it is unclear how these numbers compare to the reach of health misinformation on the same topics. For example, a recent study of 1000 tweets using the words "tanning bed" and "tanning salon" revealed that most were made by tanners expressing positive sentiment about tanning, with only 4.3% of the tweets containing health warnings [70]. This suggests that skin cancer organizations messaging may not be penetrating social media spaces where people at risk are discussing their habits. More research is needed to understand the audiences of health-related organizations' social media feeds, the extent to which their messaging reaches people who are at highest risk for the target health condition, and the impact of their messaging on attitudes, beliefs, and behavior. Research is also needed to inform health organizations' social media–messaging content strategy.

While health misinformation and disinformation may be abundant in some spaces on social media, we do not know much about the social media spaces that have very little and how that has occurred. For example, a review of online diabetes communities revealed very low rates of health misinformation [34]. This suggests that health misinformation is not a given in online spaces where patients connect but instead may have the tendency to flourish under specific circumstances. Some communities may self-police health misinformation, but how effective they are depends on their ability to identify it. Moderators of online patient communities, who are essentially a self-appointed army of volunteer community health workers, have very little training and guidance on how to identify and stem health misinformation, but many are likely motivated to do so. Public health researchers can inform the work of moderators, but we see few examples so far of such partnerships.

Health Misinformation Inoculation

Inoculating the public against health misinformation (and disinformation) requires an understanding of whether and how they influence attitudes, beliefs, and behavior, and who is susceptible to being duly influenced. The mere existence of health misinformation on certain topics does not necessarily mean it is changing people's attitudes and behavior, and the same goes for legitimate health information. However, exposure to health misinformation may strengthen preexisting misinformed beliefs. Some evidence suggests that users seek out messaging and online communities that confirm their preexisting beliefs [51]. That said, certain message characteristics may influence message effectiveness. Recent measles outbreaks strongly suggest that antivaccination messages have had an impact on beliefs and behavior [71,72]. These messages often stoke fear or leverage conspiracy theories, which we know to be particularly effective message strategies [73]. Message effectiveness also depends on the characteristics of the messenger and the recipient. Transportation theory suggests that narrative messages are particularly powerful at affecting beliefs, attitudes, and behavior to the extent that people identify with the person sharing their story [74]. Research on the extent to which misinformed narratives versus health misinformation conveyed in other forms (eg, links) is more powerful for affecting message recipients is needed. Chou and colleagues at the National Cancer Institute have called for research into how characteristics of both the messenger and the message recipient affect message receptivity [75].

Scientists, health care professionals, and medical journal editors have been called on to be messengers of evidence-based health information [76]; however, they have little evidence-based guidance on how to do so. One study of the impact of scientist demeanor on message credibility revealed that scientists exhibiting hostility in a debate were found to be less credible and trustworthy [77]. Knowledge about the complex relationships between message, messenger, and recipient is necessary to inform strategies that inoculate people against health misinformation. Finally, health literacy training is an inoculation strategy that may be useful in primary to post-secondary educational settings [75,78]. Low health literacy has been shown to affect how people evaluate health information they encounter online [79]. Given the volume of health information on social media (and the internet in general), children and adults alike require skills for sorting, vetting, and processing this information, as well as an understanding of how cognitive biases affect information processing. Research on health literacy education that effectively decreases susceptibility to online health misinformation is much needed.

Developing Effective Counter-Messaging

Some, albeit limited, research has focused on developing effective counter-messaging. For example, one study found that platform-based warnings such as “this tweet may contain misinformation” decreased the likelihood of the post being shared [80]. Similarly, another study revealed that misinformation correction by platforms and peers reduced misperceptions [81]. A significant challenge to developing effective counter-messaging is that some groups may be especially resistant to it, such as those who have already strongly embraced misinformation. Individual characteristics, such as the sunk cost investment in the misinformation (eg, time and resources spent disseminating it), the negative consequences of changing positions (eg, embarrassment, loss of community/social capital, shame about harm that may have occurred from action or inaction relating to the misinformation), and literacy, likely affect resistance [60]. Researchers focused on developing counter-messaging campaigns should leverage the expertise of human computing interaction and social media marketing experts who can help guide design and dissemination strategies that are best matched to the social media platform. A great need exists to update traditional health communication theories and strategies that were not informed by the unique form of communication afforded by social media and the ever-evolving challenges of the modern social media landscape.

Challenges to a Public Health Agenda for Social Media Research

Overview

Four key challenges constrain progress on a public health agenda for social media research: (1) negative sentiment about social media and villainization of social media companies among the public and scientific community; (2) a poorly regulated research landscape; (3) inadequate access to social media data; and (4) lack of a cohesive academic field.

Negative Sentiment

Negative public sentiment about social media may be part of society’s general tendency to push back on new technology, a phenomenon that has a long history [82]. To be sure, scandals involving how social media companies handle privacy and data access have amplified the public response. The consequences of a persistently negative narrative are that it makes it difficult to shore up support for healthy solutions, which may result in an abrupt dismissal of signs of progress. To the extent that the academic community adopts a defeatist view about social media, we may squander our opportunity to shape the social media landscape in ways that improve public health.

Poorly Regulated Research Landscape

Research involving social media platforms is emerging rapidly in a poorly regulated landscape [83]. Federal guidelines for the ethical conduct of research do not specifically address the unique ethical challenges of working with social media data [84]. As such, scientists and institutional review boards (IRBs) have little guidance for addressing the ethical, legal, and social implications of social media data use. A qualitative study of university IRB members revealed concerns that investigators do not adequately describe potential risks or have clear plans to minimize risks in IRB applications, IRB members often do not have the knowledge to review such protocols adequately, and that IRBs are having difficulty keeping pace with rapidly changing technologies used in research [85].

As discussed in two recent reviews [86,87], privacy, confidentiality, and informed consent are key ethical issues in social media research [88-90], though specific ethical considerations differ across study types (eg, surveillance, surveys or interviews, interventions) [91]. While not all research involving social media data meet the federal definition of human subjects research, and thus do not require informed consent, researchers still need to be aware that users may not realize that their public social media content can be used in research studies and may prefer that it not be used this way [88]. Even though use agreements address the potential for public social media content to be used in research and otherwise, the majority of users accept lengthy, difficult-to-read, use agreements without reading or understanding how their data can be accessed and used [92]. Standard rules and protocols to guide social media data use, as well as data sharing between industry and academia, are needed and must be rigorous in terms of privacy and data security. One collaborative working towards this goal is

ReCODE Health [93], an academic group that has created a community for resource-sharing (eg, sample IRB documents) and education about the protection of human subjects [94]. For studies that require informed consent, we encourage researchers to add detailed information about the procedures for the collection, storage, and analysis of social media data [89]. For studies involving publicly posted content, we suggest researchers refrain from including exact quotes, which can be traced back to users in ways that could have the potential for harm [88-90].

Data Access

Access to much social media data is limited, including both public data and data that users give researchers consent to access. Following the Cambridge Analytica scandal, Facebook and Instagram changed their application program interfaces (APIs) to restrict data access by third parties [95]. While restricting data access seems to be a plausible solution, it also limits how data can be used for the public good. Furthermore, frequent changes to data access rules require researchers to face the exorbitant costs of acquiring data from third party applications that are agile to API changes but typically geared for commercial use. Such tools also add another layer of risk for privacy breach. When data access changes during a research study, it can compromise the ability to answer key research questions, forcing researchers to redesign studies midstream or compromise research quality.

Facebook's partnership with Social Science One, an organization designed to facilitate academic-industry partnerships "to advance the goals of social science in understanding and solving society's great challenges," [96] is a promising example of how such partnerships can work [97]. Social Science One has developed an industry-academic partnership model that is designed to navigate barriers to data access, such as consumer privacy, trade secrets, and proprietary content, within a structure that is committed to securing the trust of the academic community and the general public [32]. Facebook partnered with Social Science One to allow scientists to access Facebook data to study how social media influences democracy. Progress has moved slowly [98], and results of the partnership remain to be seen, but this effort is the first of its kind to tackle the challenges of academic-industry partnerships involving social media data.

The barriers to access to social data by academic researchers is deeply troubling. Academic researchers have limited ability to conduct rigorous research that could change the way people use social media for the better. Technology and marketing companies have a greater ability to afford and access social media data, face fewer regulations, and have less oversight, particularly as it relates to protecting users. Companies also monetize this data in ways that are not transparent to the public [78]. More research is critically needed to develop new business models and technologies to protect user privacy while facilitating collaboration and data sharing between industry and academia [99].

Lack of a Cohesive Academic Field

Social media research has flourished in recent years, but a cohesive field has not yet emerged to bring this scientific community together. A cocitation analysis of 121 journals that have been cited at least five times in studies of health misinformation on social media revealed four disciplinary clusters: social psychology/communication, general science/medicine, infectious disease/vaccine and public health, and medical internet and biomedical science [60]. While the breadth of fields involved in this research is encouraging, several important fields are missing, including human computing interface, engineering, data science, and computer science. The researchers also found limited cross-citations between the psychology/communication cluster and the general science and medicine cluster, suggesting that researchers in different silos may not be exposed to each other's work. The lack of a scientific field not only disperses this research across disparate journals but also across myriad scientific conferences, which provides few opportunities for scientists doing this work to build collaborations. Scientific networking opportunities are needed, as well as more transdisciplinary training programs. For example, public health training programs that offer coursework in analytic approaches, such as machine learning, natural language processing, and social network analyses, would better equip public health scientists to do this work; just as ethics, social science, health communications, and health policy coursework could better equip computer scientists, engineers, and data scientists to do this work.

Discussion

Social media has revolutionized modern communication in ways that bring us closer to a global society than ever before. How social media has been used thus far reflects the full range of human proclivities. However, we have the power to shape its course. The field of public health is an obvious leader in the charge to inform the use and design of social media to benefit public good. We put forth a public health agenda for social media research, not to be exhaustive, but to start a dialogue about the need for such an agenda. Other areas of research to be further explored include public health surveillance with social media data, social media marketing of healthy and unhealthy products, behavioral pattern analysis, social-behavioral biometrics, and pharmacoepidemiology, to name a few. Federal funding agencies can take the lead in shaping the course of this work by prioritizing it in their strategic plan and among their funding opportunities. The vast range of uses of social media data speak to the need to finally convene an interdisciplinary scientific field devoted to public health social media research.

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Conflicts of Interest

None declared.

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Abbreviations

API: application program interface
CEO: Chief Executive Officer
IRB: institutional review board
SMART: Social Media Addiction Reduction Technology

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Viewpoint

Quality and Safety in eHealth: The Need to Build the Evidence Base

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Abstract

Research in the area of health technology safety has demonstrated that technology may both improve patient safety and introduce new types of technology-induced errors. Thus, there is a need to publish safety science literature to develop an evidence-based research base, on which we can continually develop new, safe technologies and improve patient safety. The aim of this viewpoint is to argue for the need to advance evidence-based research in health informatics, so that new technologies can be designed, developed, and implemented for their safety prior to their use in health care. This viewpoint offers a historical perspective on the development of health informatics and safety literature in the area of health technology. I argue for the need to conduct safety studies of technologies used by health professionals and consumers to develop an evidence base in this area. Ongoing research is necessary to improve the quality and safety of health technologies. Over the past several decades, we have seen health informatics emerge as a discipline, with growing research in the field examining the design, development, and implementation of different health technologies and new challenges such as those associated with the quality and safety of technology use. Future research will need to focus on how we can continually extend safety science in this area. There is a need to integrate evidence-based research into the design, development, and implementation of health technologies to improve their safety and reduce technology-induced errors.

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KEYWORDS

patient safety; technology-induced error; health technology

Introduction

Health informatics research has made significant contributions to our health care system. From its earliest beginnings in the 1950s and 1960s in Germany and the United States, when health care researchers first began to study the design of software for supporting clinical work and integrating computers into hospitals, to our current work in professionalizing the health informatics and health technology workforce, much work has been done. Today, there is a growing body of research describing a unique area of knowledge (ie, health informatics or biomedical informatics) that has emerged and evolved over the past 70 years [1]. Health informatics (or biomedical informatics) and health technology professionals can be found in every regional health authority, government, and health technology vendor business worldwide. Health informatics (and biomedical informatics) programs are present in many countries worldwide [2]. Nonetheless, many challenges remain as new health technologies are innovated, designed, and implemented and evolve over time. Challenges have arisen from the emergence of quality and safety issues involving newly innovated and existing implemented technologies.

Health Technologies

Modernizing Health Care

Technological innovation in health care has modernized how we treat patients globally and how health professionals work across regions and countries [1]. Over the past decades, since the first publications of journal articles and academic texts in the field of health informatics, the body of research and literature has grown considerably [1]. The launch of health informatics journals over the past 20 years has been critical to helping establish our current evidence base and demonstrating the impact of health informatics research internationally on health care and citizens. The design, development, and implementation of new health technologies and innovations remain important areas of study and add to the growth of our discipline and field.

Considering the Evidence Base

The evolution of knowledge in the area of health informatics has grown considerably. Researchers have designed and developed technologies and studied their implementation. Health technologies such as electronic health records and their subsystems (eg, clinician order entry, laboratory information systems, diagnostic imaging systems, clinical documentation systems, and decision support systems) have improved the quality and safety of health care [1]. Clinician order entry [3] and clinical documentation systems have reduced medical error rates by improving the legibility and readability of clinician orders and activities [4].

Decision support systems have prevented medical errors arising from drug-drug interactions and drug-allergy interactions and have reduced the costs of prescribed medication [1,3]. Laboratory information and diagnostic imaging systems are providing test and imaging results in real time, so that physicians can diagnose diseases and conditions and immediately respond with lifesaving interventions [5,6]. Despite this, we need to continue advancing research in health informatics to study the safety of health informatics in supporting health care processes and its effectiveness in improving wellness, as new technologies are designed and developed or repurposed by health care consumers, health professionals, and health care administrators for use in health care [7,8].

Further research is needed to ensure that technologies provide evidence-based interventions and that health technologies are designed, developed, and tested using accepted, evidence-based research methods, so that they can improve or support the health of individuals, families, and populations [9]. In addition, more research is needed to guide consumers in their purchase of health technologies [7]. To date, research has shown that the purchase of health technologies without any demonstrated health or wellness benefits may lead to unnecessary financial losses or consumer harm in an already vulnerable population [10]. Research has already shown that health technologies, when not properly and safely designed, developed, and implemented, can lead to death and disability, with reports of incidents involving technology (ie, technology-induced errors) increasing worldwide as the number of technologies used to support care increase [11,12]. Several studies focusing on incident reports involving technology-induced errors have identified a link between poorly designed and implemented technologies and safety incidents [13-15]. As such, the need to use health informatics (or biomedical informatics) disciplinary research to support evidence-based technology innovation, design, procurement, implementation, and maintenance by health care administrators, policy makers, and consumers has become critical to ensuring the quality and safety of health care when new technologies are introduced [16,17].

There is a considerable need to continue to conduct research and change health care administrator and policy-maker culture. This involves moving away from the procurement and purchasing of health technologies on the basis of perceived innovations and potential improvements (ie, the latest and greatest technology "fad") to meaningfully evaluate the quality and safety of a technology before it is implemented and used. There is also a need to move away from studying technologies after they have been designed and developed to examining and studying the quality and safety of a technology during its design and development through to its implementation and use before widespread scale up and spread [16-18]. As research has identified, poor systems design and development processes can lead to consumer death and disability and diminish the effectiveness of the technology intervention where health and wellness are concerned [13,19]. With such knowledge, we can improve the quality of patient care and prevent technology-induced errors that lead to death and disability [13].

Future Research Directions

In 1992, the seminal publication of "To Err is Human" by the National Academies of Sciences launched health care into the modern world by recommending that health information technologies (eg, clinician order entry) be used to prevent medical error and improve the quality of patient care [20]. By 2005, the first publications emerged for documenting the existence of technology-induced errors [11]. In 2011, the "Health Information Systems Safety" report by the National Academies of Science suggested that we need to develop a strategy for ensuring the quality and safety of health technologies from their design through their development [21]. Today, researchers have found that safety incidents in fully digitized health care systems involve health technologies [13]. Researchers have found that 0.1%-17% of safety incidents involve technology-induced errors [13-15]. Future health technology applications involving artificial intelligence (AI) will also need to be thoroughly innovated and studied to determine if the technology is safe and improves the quality of patient care, health professional work, and health care systems performance. Research identifies that AI does not fully respond to the range of health care issues that a patient may experience and that there is still a need for health professionals to be "in the loop" to validate diagnoses and actions to be carried out by AI applications in different health care contexts [22].

With the introduction of the Internet of Things (IoT), new challenges will emerge in the area of quality and safety. IoT encompasses sensors, devices, wearables, and smartphones. Essentially, these technologies speak to each other via the internet, and it is through these combinations of devices and automated systems that information can be gathered and analyzed and responses can be created to help individuals with tasks or processes [19]. IoT technologies have been found to have some important applications, but also need to be critically studied. There is a need to innovate, design, and develop IoT that is effective and integrates these technologies into the system of patient self-care and the health care system care. New IoT systems are being designed and developed to support those patients with chronic illnesses such as diabetes and those with multiple comorbidities. There is a need to study what devices work best to improve health outcomes while maintaining health safety [23]. Algorithms used in devices and software need to be studied in this context to determine their effectiveness in one health care setting versus another, as reproducibility and reusability have emerged as issues. Such research is needed to study the utility of algorithms and what changes need to be made to the algorithm itself to be effective in a given health context [24]. The integration of robotics in health care also requires extensive study. Innovation involves not only designing and developing the technology, but also identifying and studying the disease contexts, settings, and methods of using robotics to deliver health care interventions (eg, the use of robotic surgery) on patient circumstance and outcomes and to develop safe practices [25].

Finally, there is a need to study the use of existing technologies (ie, mobile health apps, wearable devices that support wellness and fitness) that have been deployed to identify technologies that provide no added benefit or may introduce new risks and to use this evidence in health policy making. Here, the design, development, implementation, and use of these devices needs to be researched [26]. In addition, new ways to educate consumers about these health technologies and ways to best select a health technology that will improve health and wellness rather than mislead consumers to engage in risky behaviors (eg, disregarding physician recommendations, poor medication adherence) are needed. Without research in health informatics (and biomedical informatics), we would not have our present understanding of the evidence base supporting health technologies. More research is needed to inform consumers, health care administrators, and policy makers, so that funds are not spent on ineffective and unsafe technologies. Disseminating this research to administrators and policy makers is essential to begin the process of using decision making for evidence-based health technology, based on the growing health informatics (and biomedical informatics) research.

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Conflicts of Interest

None declared.

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Abbreviations

AI: artificial intelligence
IoT: Internet of Things

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Viewpoint

Old-Fashioned Technology in the Era of “Bling”: Is There a Future for Text Messaging in Health Care?

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Abstract

In the quest to discover the next high-technology solution to solve many health problems, proven established technologies are often overlooked in favor of more “technologically advanced” systems that have not been fully explored for their applicability to support behavior change theory, or used by consumers. Text messages or SMS is one example of an established technology still used by consumers, but often overlooked as part of the mobile health (mHealth) toolbox. The purpose of this paper is to describe the benefits of text messages as a health promotion modality and to advocate for broader scale implementation of efficacious text message programs. Text messaging reaches consumers in a ubiquitous real-time exchange, contrasting the multistep active engagement required for apps and wearables. It continues to be the most widely adopted and least expensive mobile phone function. As an intervention modality, text messaging has taught researchers substantial lessons about tailored interactive health communication; reach and engagement, particularly in low-resource settings; and embedding of behavior change models into digital health. It supports behavior change techniques such as reinforcement, prompts and cues, goal setting, feedback on performance, support, and progress review. Consumers have provided feedback to indicate that text messages can provide them with useful information, increase perceived support, enhance motivation for healthy behavior change, and provide prompts to engage in health behaviors. Significant evidence supports the effectiveness of text messages alone as part of an mHealth toolbox or in combination with health services, to support healthy behavior change. Systematic reviews have consistently reported positive effects of text message interventions for health behavior change and disease management including smoking cessation, medication adherence, and self-management of long-term conditions and health, including diabetes and weight loss. However, few text message interventions are implemented on a large scale. There is still much to be learned from investing in text messaging delivered research. When a modality is known to be effective, we should be learning from large-scale implementation. Many other technologies currently suffer from poor long-term engagement, the digital divide within society, and low health and technology literacy of users. Investing in and incorporating the learnings and lessons from large-scale text message interventions will strengthen our way forward in the quest for the ultimate digitally delivered behavior change model.

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KEYWORDS

text messaging; mHealth; behavior change; digital health

Background

> *Text messaging is old fashioned, let’s use Facebook instead.* [Health researcher, 2018]

The evolution of digital technologies, and ubiquity of personal mobile phones, has seen a proliferation in potential options for digital health delivery. The quest among health care organizations is to discover the next high-technology solution to many of the health problems that have been vexing health professionals and researchers for decades.

The increasing availability of consumer-accessible technologies, along with the expectations of an increased consumer role in managing their own health, is contributing to the increased digitalization of health care [1]. Moreover, financial constraints on expensive health services, including the decreased time health providers have in direct patient-provider interaction [1], is changing the health education and information delivery paradigm. The significant increase in digital health investment by the commercial industry [2] is moving the trusted voice of the health providers to the open market. For example, only 10% of health smartphone apps available in major app stores are produced by universities, nongovernment organizations, and educational organizations [2]. To participate in this market, researchers and health providers need to find ways to digitally connect with consumers in a trusted, meaningful, and cost-effective manner.

Many digital health companies and researchers are attempting to find the next neatly packaged behavior change app or device. As academics, we would like to think that we are immune to fashion and trends, but are we? Craig Fleming [3] notes in his provocative essay, “The Tyranny of Trendy Ideas: Academics pretend to be above cheap and trivial fads,” that the drive of “innovation” tends to move academic groups because fashions are “difficult to resist,” but this prevents us from fully investigating phenomena before moving onto the next idea and “distract(s) us from slower changes.” Too often, the focus of research is on the digital delivery modality driving the intervention, often neglecting the complex nature of the behavior change on which it is designed to focus.

Health-related behaviors and behavioral risk factors for disease prevention and management are complex, influenced by multiple individual, socioeconomic, societal, cultural, and environment factors, making it difficult to change [4]. Digital health technologies allow us to accommodate many of these factors with significant potential for digital health solutions to better support prevention and management of disease. Health behavior science provides insight into factors that influence specific actions that can be used to guide digital health design [5]. There are many simple digital technologies that connect directly to consumers and offer benefits for behavior change but have been discarded by funders, health services, and researchers because they are not considered “innovative” or “shiny” enough. Research on proven, more established technologies is often overlooked in favor of what is more “technologically advanced,” even if the use of the new technology is not fully explored, not underpinned by behavior change theory, and not routinely used by or considered of value to the health consumer. Text messages (or SMS) are one example of an established technology, frequently used by consumers, that is often overlooked by many researchers and funders as part of their mobile health (mHealth) toolbox. Often, these authors have been told by funders that it is proven that text messaging works, but it is just “not shiny enough” for their boards, donors, clinicians, or consumers.

Text messaging is the real-time exchange of alphanumeric messages of up to 160 characters via mobile phones or computer. Text messaging is ubiquitous and continues to be the most widely adopted and least expensive technological function on mobile phones [6]. **The use of d**irect text messaging has remained constant despite the exponential rise of message apps [7]. Paraphrasing Mark Twain [8], the prediction of the death of text messages has been greatly exaggerated. Although digital health innovators may be discarding text messaging for its “low” technology, text messaging interventions have underpinned a significant piece of the mHealth research landscape. It behooves us to examine what text messages and their interventions offer us as researchers and what lessons may be taken forward and incorporated into new and disruptive technologies.

The purpose of this paper is two-fold. First, we describe the present-day benefits of text messages as a health promotion modality, such as high consumer familiarity and usage, functionality to prompt behavior change, and ability to reach hard-to-reach populations. Second, we advocate for broader-scale implementation of efficacious text message programs and continued research to refine and enhance the impact of text messages for health promotion. In this paper, we use quotes and colloquial language communicated to us in research studies and by funders and fellow researchers, to contextualize current-day dialogue concerning the use of text messaging within the research and implementation science research environment.

Text Messages Connect Directly With Consumers Through a Familiar Modality That They Frequently Use

> *They will always check their text messages in an appointment, they prioritise them over me.* [Health professional, 2016]
>
> *A digital health intervention program needs to be easy to access...but there’s so many things you have to login so much yeah passwords…whereas if…it’s just link to the website or game in a text, like it just took you straight there rather than, oh I need to remember to check that website or app once every week.* [Focus group research participant, 2016]

Text messages are elegant in their simplicity and connectivity. They offer many advantages over other digital modalities and are currently the most expeditious way to provide just-in-time information. Text messages are a “push” technology, where intervention messages are delivered to individuals without any effort from the individual [9] and exhibit a 98% open rate and a response rate double that of email, phone, or social media [10].

In contrast, technologies such as apps or games require active participation, that is, the user is required to download the technology, open it, and do something (eg, add data). Moreover, an app or game may be deleted and the automated functions, such as push notifications, can be turned off, or the linked wearable sensors may be not be worn [11,12]. Much like internet health programs, apps only work for those who actively engage with them over a period of time and exhibit the necessary level of digital literacy. More work is required to develop “sticky” apps, which induce return traffic and maintain user engagement, such as Google Maps, that are used most days on smartphones [13,14].

The simple digital user interface for text messaging offers a communication platform that a majority of consumers are comfortable and familiar with. Although it is acknowledged that more work is required to better understand message requirements for those with physical disabilities or low literacy [15], the interface is standardized and reduces the need for learning interaction with a new interface. In contrast, complex digital tools (including apps, wearables, and games) encompass the technological device and the technology interface and performance (interface design, navigation, notifications, data collection methods and tools, goal management, depth of knowledge, system rules, and actionable recommendations) [16], exposing a complex phenomenological structure for user engagement and perception [17]. The lack of a user-centric design is a common criticism of more complex technologies [17]. How consumers engage and perceive digital health interventions still requires much more investigation but, in general, the simpler the interface is, the easier it is to engage and retain consumers [17-19].

Text Messages Directly Support Behavior Change

> *Text messaging is just a few words sent to someone. Who is going to send them? Too much money and bother. We want to spend money on something much more impressive such as an app or a robot.* [Public health manager/researcher, 2018]

As an intervention modality, text messaging has taught researchers substantial lessons about tailored, interactive, and scalable health communication; reach and engagement; and embedding of behavior change models into digital health. Text messaging appears to support behavior change through the ease of application of proven behavior change techniques such as reinforcement, prompts and cues, goal setting, feedback on performance, support, and progress review [20]. The interactivity of text messages allows individuals to log their health information in response to text messages and, in turn, receive tailored feedback. They also have the potential to provide two types of “sticky” content or content that induces return engagement and holds user attention [14]. They can deliver attracting (such as health information updates) and “entrapping” (such as behavioral reminders and bidirectional engagement with a health team) content, which research suggests attracts users and keeps them engaged with a digital platform [13,14].

Text messaging works alone or as a component of an mHealth toolbox. Consumers are seeking simple and intuitive digital solutions to support their health care management [21,22]. In research contexts, individual digital health interventions are often used alone and compared with others, instead of considering how best to meet holistic needs with more effective and efficient health care [23]. It is likely that the digital solutions to complex health behavior change will be multifaceted with the need to draw on the communication, behavioral, and human-computer interaction theory [19]. Real-world needs are likely to be met by a range of interoperable digital platforms or tools integrated with brick-and-mortar health services. Text messaging can be part of this solution, offering many facets to a mobile health (mHealth) toolbox where otherwise high attrition rates, digital divide of society, and the health and technological literacy of the users are key issues.

Although text messaging has proven to be effective when used singularly, evidence suggests that text interventions were efficacious when combined with supplementary intervention components [24,25]. Text messages offer opportunities to optimize interventions and link between components. For example, in one of our studies involving multiple digital components, the most frequently accessed Web pages and Youtube videos were those linked to a directly delivered text message [26]. They also offer a “nudging” capability as per Pew Research Center [27], demonstrating an improved response time for survey completion with text message notifications in comparison to email only [27]. Opportunity exists to exploit text messaging features for better uptake and engagement of other digital health tools when systematically assessing the digital tool delivery required to meet consumer health needs [28]. Although many moderators at a behavioral level require confirmation, we need to still learn about the frequency of contact, wording, content, tone of delivery, and personal tailoring of the short messages [29]. There is potential value in systematically assessing these moderators to allow the learnings to be incorporated into newer technology tools and interventions.

Text Messages Have the Potential to Reduce Health Inequities at a Low Cost

> *It’s capturing the people that miss out…the marginalised people that always slip through the system, you can catch them.* [Midwife, 2016]

If our role as health researchers is to positively impact those who carry the disproportionate burden of poor health outcomes [30], it is crucial for us to consider which digital platforms may best serve those in greatest need. Mobile phones have been widely adopted among virtually all demographic groups, including previously difficult-to-reach populations [29,31-33]. However there remains a digital access disconnect and a usage gap between groups of users with access to the internet (data plans) and the use of smartphone apps that require a greater burden on the consumer. Even in text messaging, there can be difficulty with literacy [15], and more work is required to engage particularly those with physical and intellectual disabilities. The intricacy of more complex digital interactions and expectations may work against accessibility in many population groups.

The appeal and efficacy of text messaging is demonstrated across age, sociodemographic status, and cultures [33,34]. Of note, text messaging interventions can appeal to, connect with, and achieve positive health outcomes for the most difficult-to-reach communities including those that do not connect with traditional health services [35,36]. Due to the ease of tailoring text messaging interventions, programs can be delivered in multiple languages, locations, and cultural versions to ensure relevance and appropriateness for a wide range of populations [32,37].

Although text messaging may be considered relatively expensive to deliver due to "per text message" costs and short code fees, text messaging programs are cheaper to develop: The cost of the average commercial health app (the consumer expected standard of app) is around US $425,000, and higher costs are generally associated with better design, resulting in higher engagement [2]. Furthermore, text messaging can be received at no cost to the end user regardless of phone type, capacity, or data access. Where needed, reply messaging can be charged back to the program to ensure no cost to the recipient and therefore reduce engagement barriers. There is little recognition of the ongoing upkeep and maintenance needed for other digital tools; for example, smartphone apps require updates for every operating system update. These maintenance and development costs have had a negative impact on the business cases for these tools.

The uptake of text messaging in developing countries suggests opportunities in resource-poor settings where expensive technology and internet access is lacking [38]. There is already evidence of the potential health uplift in developing countries where text messages have been utilized in smoking cessation, antenatal, diabetes, and retroviral interventions as well as communication with health workers [39-41].

Text Message Interventions Demonstrate Effectiveness in Health Promotion and Disease Management

> *Text messaging works but it's not shiny enough. We need an app.* [Health researcher, 2017]

Publication of text message—delivered behavioral intervention studies started to emerge in the early 2000s, gaining traction over the last decade [42], which is a long time in terms of agile technology but not in evidence-based, academic literature. There is significant evidence to support the effectiveness of text messaging alone as part of an mHealth toolbox or in combination with face-to-face health services, to support healthy behavior change. Systematic reviews and meta-analyses have consistently reported positive effects of text message interventions for health behavior change or promotion [25,42-46] and disease management [43,45,47,48]. High-quality evidence may be found across health issues for smoking cessation [24], medication adherence [49] including antiretroviral therapy [47,50], and self-management of long-term conditions and health including diabetes and weight loss [42,46,51,52]. For example, the latest Cochrane review of 26 smoking cessation studies (n=33,849) provides continued evidence for automated app-based interventions resulting in improved cessation rates (increasing quit rates by 50%-60%), while highlighting the persistence of a lack of evidence to conclude the effectiveness of smoking cessation appb—ased interventions [24].

In contrast, systematic reviews of smartphone apps have thus far reported mainly pilots and studies with small sample sizes with limited evidence of effectiveness [24,53,54], although their application in mental health [55], schizophrenia [56] and weight loss [57] is promising. The majority of the 300,000 health apps in app stores have never been tested, and many lack the behavior theory or clinical guidelines to underpin their education frameworks and content [58]. Several research trials have shown apps to be ineffective in achieving significant primary outcomes [59-61]. The lack of a body of evidence for effectiveness currently limits the "prescribablity" of health apps [22,62].

These effective text message interventions provide insights regarding other important aspects of study design including feasibility and target group acceptance. The high levels of retention, acceptability, feasibility, and likelihood of recommending the interventions to peers reported in many studies emphasize the value of using text messaging in health behavior change interventions [26,36,63]. Participants frequently report that they think that text messaging is a good way to deliver these types of prompts, information, and support [32,36,64,65].

Long-term intervention effectiveness and cost-effectiveness studies for all digital interventions remain scarce, and text messaging interventions may offer some guidance and learnings [24,25]. Our recent 2-year follow-up of a text messaging diabetes self-management support program found sustained improved results following the initial trial [66], but that is not always the case, and long-term follow-up needs to be encouraged and further investigated. With the low cost of delivery, smoking cessation support by text messaging has been shown to possibly be one of the most cost-effective health services that could be provided [67,68]. Free and colleagues [67] recruited, via community advertising, smokers willing to quit (n=5800) and randomized them to either the txt2stop intervention, comprising motivational messages and behavioral change support, or the control group that received text messages unrelated to quitting. Biochemically verified smoking cessation rates at 6 months were doubled in the txt2stop group (10.7% in the txt2stop group vs 4.9% in the control group; risk ratio: 2.20; 95% CI 1.80-2,68; *P*<.001). The cost-effectiveness analysis found that when future health service costs were included, text message—based smoking cessation support would save costs to the national health service. Few other cost-effectiveness analyses have been published. Further research is required to determine how to best optimize outcome and cost effectiveness in larger and longer-term trials.

Implementation of Large-Scale Text Messaging Programs is Required

> *That's great that the program was found to be effective but why hasn't it been rolled out yet?* [Clinician, 2019]

Implementation of research findings is an ongoing problem for health-related research [69]. The translation and implementation of technology-driven interventions have the added pressure of convincing funders and health bodies that the technology will remain relevant and viable [70]. Although significant evidence for text messaging interventions exists, few large-scale roll outs have been realized or evaluated. There are a small number of examples of smoking cessation interventions proven in research that have been implemented at a large scale internationally [71-73] and offer learnings. The Indian government has implemented a national mobile cessation (smoking cessation) and mobile diabetes (diabetes control) program promoted through their national email network and using the free “missed call” system for people to register [71]. Study process lessons were learned from the evaluation of that program: A large number of nonsmokers initially registered, due to promotion and the ease of registration, and a large number subsequently dropped out due to the high burden of evaluation questions, which has since been removed.

More work is required both to optimize the effectiveness of text message interventions and to build conceptual frameworks for larger-scale implementation. Through its *Be He@lthy, Be Mobile* program [74], the World Health Organization is supporting the establishment of large-scale text message programs in developing countries from a range of regions and income levels, tackling health issues relevant to the country, from cervical cancer awareness to smoking cessation [71]. This group provides toolkits, expert assistance, international connections, and programs as well as links to more general advice on aspects such as frameworks for prioritization, monitoring, and evaluation [75,76].

Although translational research has become a focus for many, there remain roadblocks in implementing research on a large scale, especially while, as Wolf [77] notes, “spectacular new devices are more fascinating to the public and more lucrative for industry.” The study of implementation science in the digital health field would be enhanced by funding and implementing large-scale community-centered digital models within the world of practice. This will allow the identification of crucial activities and delivery methods for conducting an intervention tailored to the unique needs and contexts of different at‐risk populations and health agencies and further the field of implementation science in the digital space [78]. These could include the key components within the study environment that affect the intervention’s primary outcome, changes in outcome variables over time, and potential confounders external to the study environment [79].

Conclusions

When it comes to digital interventions, evidence supporting the use of text messaging for health behavior change is substantial. In addition to a wide population reach, text messaging is relatively low cost, can be individually tailored, can be delivered anywhere, is appropriate for low digital literacy, and allows instant delivery and feedback. Text messages are omnipresent in the lives of consumers and offer a simple and connected gateway to encourage positive health behaviors. Their effectiveness in supporting health behavior change across population groups and health areas has not yet been paralleled by any other technologies. For digital platforms to assist consumers with positive health behavior change, the appropriate mix of digital delivery needs to be understood and tested. Text messages offer a subset of features that should be considered in any approach. If health organizations have the courage, there is opportunity and value in implementing text messaging interventions, alone or as part of an mHealth toolbox, and learning from their engagement with consumers. These learnings can then be transferred to new effective technologies as they emerge. Health researchers and health organizations can own this simple technology and control it until newer “shinier” technologies are developed, which can replace the widespread connectivity and persistence of a text message.

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Conflicts of Interest

None declared.

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Abbreviations

mHealth: mobile health

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Viewpoint

Preserving the Open Access Benefits Pioneered by the Journal of Medical Internet Research and Discouraging Fraudulent Journals

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Abstract

The *Journal of Medical Internet Research* (JMIR) was an early pioneer of open access online publishing, and two decades later, some readers and authors may have forgotten the challenges of previous scientific publishing models. This commentary summarizes the many advantages of open access publishing for each of the main stakeholders in scientific publishing and reminds us that, like every innovation, there are disadvantages that we need to guard against, such as the problem of fraudulent journals. This paper then reviews the potential impact of some current initiatives, such as Plan S and JMIRx, concluding with some suggestions to help new open-access publishers ensure that the advantages of open access publishing outweigh the challenges.

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KEYWORDS

open access; predatory journals; knowledge management; scientific journals; mobilizing computable knowledge; fraudulent journals

Introduction

Background

Scientific journals have a 355-year history, with the first, Le Journal des Sçavans, appearing in 1665, followed the same year by Philosophical Transactions of the Royal Society. Now there are more than 5000 scientific publishing companies with 25,000 journals publishing 1.5 million articles per year, generating revenues of US $25 billion [1]. Even more surprising are the changes in the last 20 years. Many *Journal of Medical Internet Research* (JMIR) authors and readers will have forgotten that, just two decades ago, JMIR was one of the very first scientific journals in any field to demonstrate the value and sustainability of open access publishing. JMIR remains the top-cited journal in the discipline of medical informatics, partly due to that bold decision by its editor, Gunther Eysenbach. Readers may have also forgotten the dark days of universal pay-for-access and the paper publishing model that preceded online publishing. Back then, a researcher periodically visited libraries to photocopy articles out of bound journals or waited weeks for an article from an obscure journal to arrive from an interlibrary loan service. So, it is timely to remind ourselves of the many advantages of open access publishing, consider some of the pitfalls, and explore some potentially fundamental changes in the publishing landscape over the next few years.

Advantages of the Open Access Publishing Model in Medicine

Open access publishing brings many advantages for authors, researchers, research funders, publishers, the environment, and the patients (Textbox 1). For the author, publication in an open-access journal means that their work is 90% more likely to be read and 42% more likely to be downloaded as a PDF in the six months following publication than a comparable subscription-access article in the same journal [2]. The precise impact of open access publishing on citation rates is still debated [3]. For example, in a recent cohort study of 5835 medical journals, open access journals had a significantly higher

CiteScore, percent cited, and source normalized impact per paper, but the non–open access journals had a higher scholarly output [4]. The broader societal impact of research is also significant, with higher Altmetric scores for open access articles [5]. As always, in cohort studies, association is hard to distinguish here from causation; however, the only trial which could answer this question rigorously by randomizing incoming articles to open or subscription-only access journals was carried out a decade ago in 11 physiology journals [2]. Thus, it may have limited generalizability today. This trial showed no real citation benefit for open access articles compared to comparable subscription-access articles during the year following publication [2].

For researchers, open access dramatically reduces the hassle of obtaining access to the full text, which is vital as openly accessible abstracts do not always fairly represent article contents [6]. However, structured abstracts have now potentially reduced this mismatch. For those who carry out and fund systematic reviews, such as guideline development groups, access to the full text to extract details of the study methods and results is particularly important. For this group, there was no apparent difference in the methodological quality of either primary or secondary research articles published in open access or subscription-only journals [7], at least in cancer epidemiology. For publishers, open access guarantees a steady flow of readers to their site, allowing them to experiment over time with different methods of indexing or presenting information in their journal using A-B testing and similar methods. This makes continuing quality improvement and enhancing reader impact much more straightforward than when articles sit behind a paywall. It also dramatically extends the reach of journals beyond researchers in Western countries with well-funded libraries, to researchers working in low- and middle-income countries, and to people who are not researchers at all. These new readers may include health professionals seeking an answer to a clinical question, or they might want to produce a Critically Appraised Topic (CAT) to add to an institutional CATBank.

Textbox 1. Some advantages of open access publishing for various stakeholders.

Individual patients and members of the public

- Easy to locate and access primary and secondary research results to inform their own health-related decisions or advise friends and family.

Patient groups

- Empowers patient and public involvement groups to engage in reshaping health care or clinical service delivery and get involved in formulating research questions (eg, James Lind Alliance) and how researchers address these questions (eg, INVOLVE).

Health professionals

- Allows health professionals to rapidly access primary or secondary research to answer clinical questions at the point of care and thus deliver more evidence-based care.

Guideline development groups and other evidence-based policy developers

- Reduces the costs and lowers the barriers to producing evidence-based practice guidelines and incorporating evidence into other policies (eg, for health promotion).

Health systems

- Lower cost of incorporating evidence-based thinking into the structure and function of a health system.

Researchers carrying out research

- Allows more frequent searching from the researchers' desktop of a broader range of literature, thus enhancing multi-disciplinary research and helping researchers stay up to date.

Researchers writing articles

- Gives greater reassurance that their research will be read.

Research funders

- Enhances the uptake of results of the research they fund, reassuring patients and the public that their donations or taxes lead to published results with impact.

Journal publishers

- Widens the reach of journals to low- and middle-income countries and nonresearchers (eg, health professionals, patients, and the public). Promotes faster accumulation of data about article readership, enabling rapid-cycle learning (a Learning Publishing System) and enhanced impact.

However, perhaps the most important new reader category that open access supports is patients and the public, allowing them to access research results to guide their self-management decisions. In my view, open access to research results is probably the most critical factor that has led to the global growth of patient involvement networks that influence clinical science.

These include groups such as the National Health Service England's Patient and Public Voice group for clinical service delivery and the National Institute for Health Research's INVOLVE group for clinical research.

Potential Disadvantages of the Open Access Model

However, the open-access model can also lead to several new pitfalls for authors and readers, as well as for publishers (see Textbox 2).

One issue here is fraudulent (formerly labeled as "predatory" [12]) publishers and their journals, which can be defined as "spurious scientific outlets that charge fees for editorial and publishing services that they do not provide" [13]. These services include peer review, author retention of copyright, editorial input, copy editing, and a commitment to making articles available online for the long term [13]. Such journals send spam emails to solicit articles for plausible-sounding journals, which can mislead naive authors into submitting their work to a journal that provides few, if any, of the expected services. In turn, this leads to articles with a low probability of citation or clinical impact, thus contributing to the problem of research waste [14]. Worse, because of the lack of effective peer review, some articles in these journals include results that are incorrect or biased, leading to clinical actions that are at best a waste of time, and at worst are potentially harmful [15]. Evidence for the poor quality of peer review comes from a 2013 study in which a journalist sent a seriously flawed, concocted article to 304 open access journals [16]. A total of 157 (52%) journals accepted the article, with only 36 (12%) providing peer reviews that recognized the article's flaws, though 16 of those journals would still accept the article [16].

Another characteristic of these journals is their willingness to appoint anyone to their editorial board, sometimes in return for cash. Sorokowski et al submitted a fictitious resume for an unqualified scientist applying for membership of 360 journal editorial boards and were surprised to be accepted by 33% [17]. Shamseer [18] developed an empirically based list of differences between fraudulent and legitimate open access journals, based on a study of over 90 of each type. The fraudulent journals showed the following characteristics:

- Spelling errors on the journal home page (66% fraudulent versus 6% legitimate)
- Distorted or unauthorized images (63% versus 5%)
- Promoting a bogus impact factor, the Index Copernicus (33% versus 3%)
- Unverified editor or editorial board affiliation (73% versus 2%)
- Lower article processing fee (median fee US $100 versus US $1865)

Textbox 2. Some potential disadvantages of the open access publishing model.

Readers

- Tendency to ignore closed-access articles, which mainly affects older material pre-2000. This may lead to higher rates of research duplication, or to failure to incorporate tested classical theories into the design of digital interventions [8].

Authors

- Fraudulent or so-called "predatory" journals.
- The ability to publish is limited by cost (mean article processing fee in health informatics is €2200 [US $2441] [9]), meaning that unfunded research by MSc or PhD students and early career researchers may not get published.

Researchers

- Pressure from funders to publish in open access publishers rather than those journals in which they know their research might have a more significant impact.

Public and patients

- It may be unclear to those lacking critical appraisal skills which journals publish high-quality material and which are fraudulent/"predatory" publishers, thus leading to the spread of pseudo-science or fake news (eg, the global anti-vax movement) [10].

Publishers

- Article processing fees may act as a barrier to authors from low- and middle-income countries or those who are carrying out unfunded research, leading to a Western bias in journal content.
- Added complexity of payment processing.
- Authors now expect faster response times and better service quality from the journal team as they are paying for the service.
- Some scientific society journals may experience insufficient submissions due to authors declining to pay the article processing fee, and thus declining readership [11].
- A stronger emphasis on journal position in article metric, and impact factor league tables may overrule other publishing values.

As a result, authors need to be vigilant and check the rigor of a journal's refereeing processes and the quality of published articles before they submit, especially if they are responding to one of the numerous emails soliciting articles. They can also check if their intended journal appears on one of the many white lists of journals that are likely to be genuine, such as the Web of Science Journal citation reports, MEDLINE, or the Directory of Open Access Journals. Some professional bodies also publish whitelists of journals relevant to their areas of interest including, for example:

- The Association of Vision Science Librarians [19]
- The International Committee of Medical Journal Editors' list of journals that claim to follow its Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals [20]

Research funders should only support publication in journals that commit to high-quality science, and the National Library of Medicine and other bibliographic databases should continue to reject indexing requests from those journals they judge to be fraudulent. However, bibliographic databases and research funders should not presume that all small independent publishers are fraudulent, which has been a barrier to the acceptance of high-quality journals such as JMIR in the past. Senior researchers should reject offers of gift editorship or board membership, however attractive, from fraudulent journals, as that will give the journal spurious authenticity. However, this may not be the case if they genuinely believe that their influence will lead to better quality publications.

However, researchers face a dilemma when approached by an unknown open access journal to referee an article. On the one hand, they can add authenticity by adding their name to the list of reviewers. On the other, by rejecting a poor-quality article, they can improve the quality of the science that the journal publishes and help its editorial staff to better distinguish good from bad science in the future. However, since one of the hallmarks of fraudulent journals is that they tend to carry out refereeing internally if at all, this dilemma will probably not often occur.

Some Recent Innovations in Open Access Publishing

There are a several important innovations in open access publishing, one of which, Plan S, has significant potential to disrupt scientific publishing fundamentally [21]. Plan S started as a European initiative to overcome some open access publishing challenges, especially for authors seeking funds for article processing fees (APCs), but it is now gathering traction further afield. Plan S proposes that, by 2021, every research funder member of the organization Coalition S, who is promoting this plan, will require all the research they support to be published in one of a list of supported open access journals. Also, the Consortium will directly fund these journals to publish such articles, subject to specific requirements [21]. While this has many advantages, especially for those authors seeking funds to pay APCs, it will only apply to research funded by members of Coalition S. In the United States this currently only includes the Gates Foundation, while in the United Kingdom, this currently includes UK Research and Innovation (the former Research Councils) and the Wellcome Trust. This will leave most US and UK researchers funded by many other bodies, like smaller medical charities, as well as through their own account and student research. However, in January 2019, the United Kingdom's National Institute for Health Research, the largest clinical research funder in Europe (with a budget of over €1 billion [approximately US $1.3 billion]), pledged support for Plan S and announced that its current open access policy would be reviewed [22].

While many academic organizations have broadly welcomed these principles, some key concerns about Plan S have been raised by publishers, both large and small. This is because Plan S may mean that some publishers (eg, smaller independent publishers such as JMIR or specialist societies such as European Federation for Medical Informatics, International Medical Interpreters Association, or the American Medical Informatics Association) will be sidelined, as major research funders will not recognize their unique contributions towards supporting emerging disciplines, such as health informatics. However, larger publishers are also concerned, with Plan S being described as, "ballistic" by one commentator and Elsevier's stock price falling by 13% in autumn 2018 after Plan S was mooted [23]. Even the American Association for the Advancement of Science stated that Plan S "will not support high-quality peer-review, research publication and dissemination," that it "would disrupt scholarly communications, be a disservice to researchers, and impinge academic freedom," and that it, "would also be unsustainable for the *Science* family of journals" [24,25]. The Open Access Scholarly Publishers Association stated that Plan S puts smaller and emerging fully open-access publishers at a competitive disadvantage and potentially harms their prospects. Thus, they have been lobbying on behalf of the long tail of small open-access publishers whose needs have been ignored by Coalition S [23]. There is even bigger concern over variants of Plan S, such as Projekt DEAL in Germany [26], in which German funders and libraries are making deals with large publishers (and only large publishers) to force them to transition to open access, eradicating in the process smaller publishers and society journals. If, for example, JMIR is not included in this deal, that would make it harder for German health informatics researchers to submit their work to the highest impact journal in the field. Table 1 lists some potential advantages and disadvantages of Plan S, for the same stakeholder groups as before.

Table 1. Some advantages and disadvantages of Plan S for various stakeholders.

Stakeholder	Advantages	Disadvantages
Individual patients and members of the public	Easy to locate and access results to inform their own health-related decisions or advise friends and family.	Will only apply to results of research funded by members of Coalition S.
Patient groups	Empowers PPI[a] groups to engage in reshaping health care or clinical service delivery and get involved in formulating research questions and in how researchers address these questions.	Will only apply to research funded by members of Coalition S.
Health professionals	Allows health professionals to rapidly access primary or secondary research to answer clinical questions at the point of care and thus deliver more evidence-based care.	Will only apply to results of research funded by members of Coalition S.
Guideline development groups and other evidence-based policy developers	Reduces the costs and lowers the barriers to producing evidence-based practice guidelines and incorporating evidence into other policies (eg, for health promotion).	Will only apply to results of research funded by members of Coalition S.
Health systems	Lower cost of incorporating evidence-based thinking into the structure and function of the health system.	Will only apply to results of research funded by members of Coalition S.
Researchers carrying out research	Allows more frequent search from the researchers' desktop of a broader range of literature, thus enhancing multi-disciplinary research and helping researchers stay up to date.	Will only apply to research funded by members of Coalition S, excluding work funded by smaller organizations and unfunded or student research. May even threaten the existence of some academic disciplines, such as health informatics.
Researchers writing articles	Gives greater reassurance that their research will be read.	Will only apply to researchers funded by members of Coalition S.
Research funders	Enhances the uptake of results of the research they fund, reassuring patients and the public that their donations or taxes lead to published results with impact.	Will only apply to research funded by members of Coalition S.
Journal publishers	Widens the readership of some journals to low- and middle-income countries and nonresearchers. Provides a reliable income stream from Coalition S to journals.	Funding from Consortium S will be subject to meeting several requirements, some of which may be challenging. Likely to favor large, established publishers; could add significant barriers to market entry or growth for small or new publishers, ultimately eradicating smaller publishers and society journals.

[a] PPI: patient and public involvement.

A second innovation for open access is publishing the details of an algorithm (eg, the R syntax or pseudocode) alongside the article which describes its development and validation [27]. This is part of the global movement to "Mobilise Computable Biomedical Knowledge" (MBCK) [28] and was developed analogously with the practice in bioinformatics of publishing gene and protein sequences alongside the article describing their discovery. A third innovation, designed to incentivize reviewers and recognize the effort that peer review takes, is to reduce the APC for peer reviewers through "Karma credits", which was pioneered by JMIR [29]. Ultimately, APCs may disappear as other organizations, such as universities or research funders, pick up the bill for scientific publishing, as proposed by Plan S.

A final innovation with even wider potential consequences is JMIRx [30]. This novel approach inverts scientific publishing so that instead of the author seeking a journal and submitting their article, journal editors scan preprint servers and other sources of research content and contact authors of interesting material requesting a journal-ready article [30].

Conclusions

There is no doubt that, since JMIR pioneered this new publishing model 20 years ago, open access has led to many benefits for different stakeholders and even opened up new areas of activity, such as patient and public involvement in research and self-management. Of course, open access has led to side effects and unintended consequences, such as the growth of fraudulent journals, but it is now clear that the significance of this challenge has been overstated. More importantly, several recent innovations described above, led by respected brands, such as JMIR, with its impressive record of accomplishment and exciting plans for the future, build on the open-access model and demonstrate its continuing importance and value.

Thinking about how a new open source publisher and editor might ensure that the advantages of open access outweigh its disadvantages for their journal, some suggested principles include: (1) agree with all staff and funders that the core purpose of the journal is help identify, promote, and disseminate high-quality research and its application to improve society and the environment; (2) develop a business model and partnerships that build brand reputation and encourage scientific rigor, originality, and integrity in pursuit of the core purpose, which needs to take higher priority than commercial profit or other short-term considerations; (3) make details of the article review and publishing process, including peer review criteria and scores, open to both authors and readers, and preferably to automated search agents; (4) lower cost barriers to authors where possible, especially to students, early career researchers, and others carrying out unfunded research, using a range of strategies to reduce or eliminate APCs; (5) lower the barriers to readers, especially members of the public, clinicians, and those in low- and middle-income countries, to help them easily locate and access as much of the content as possible; and (6) strive to ensure that all content is well indexed by the major bibliographic services as soon as possible, and that content is retained online long term in third party archives, such as PMC.

Finally, we should encourage all scientific publishers, whether subscription only, open access or hybrid, to develop, test, and share publishing innovations to support the principles outlined above, in the way that JMIR has so clearly demonstrated in its first two decades.

Conflicts of Interest

JCW has been a member of the Editorial Board of JMIR since it was founded.

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Abbreviations

APC: article processing charge
CAT: critically appraised topic
JMIR: Journal of Medical Internet Research
MBCK: Mobilise Computable Biomedical Knowledge

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Editorial

Celebrating 20 Years of Open Access and Innovation at JMIR Publications

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Abstract

In this 20th anniversary theme issue, we are celebrating how JMIR Publications, an innovative publisher deeply rooted in academia and created by scientists for scientists, pioneered the open access model, is advancing digital health research, is disrupting the scholarly publishing world, and is helping to empower patients. All this has been made possible by the disintermediating power of the internet. And we are not done innovating: Our new series of "superjournals," called JMIRx, will provide a glimpse into what we see as the future and end goal in scholarly publishing: open science. In this model, the vast majority of papers will be published on preprint servers first, with "overlay" journals then competing to peer review and publish peer-reviewed "versions of record" of the best papers.

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KEYWORDS

JMIR; internet; medical informatics; ehealth; digital health; participatory medicine; open access; electronic publishing; scholarly publishing; science communication; journalogy; history of science; overlay journal; preprints; open science

Twenty Years Ago...

Twenty years ago, JMIR (originally the *Journal of Medical Internet Research*, the journal; now, JMIR Publications, the publisher) started an unprecedented journey to disrupt the medical informatics and publishing world with a new kind of journal and a new type of business model. The term "open access" was not invented back in 1999; most journals were still published and distributed on paper, and I remember the days of having to courier 10 copies of a manuscript on paper to a journal office, which then sent out the same hardcopies by postal mail to peer-reviewers. Creative Commons was in its infancy, and authors routinely signed away their copyright to publishers. A paper I submitted to a medical informatics journal took 2 years to be published. In this environment I was excited about the possibilities of the internet but also frustrated by the obvious inefficiencies and anachronisms of how we communicate in science. Having already worked as editor and book author in my student days, I decided to create a radically different, new journal for the internet age, with the intention of innovating on *form*, *content*, and *business model*.

In terms of *form*, the journal was free, rapid, and online only, and communication with authors and reviewers was exclusively electronic (we take that for granted now, but back then, most communication was still done via mail). This new form also opened up content to nontraditional audiences, ultimately contributing to a shift in the power distribution between doctors versus patients [1].

In terms of *content*, I solicited and encouraged original research focusing on "eHealth" (electronic health) [2,3] (called "digital health" by some today), which is a much broader concept than the "electronic medical record," "decision support for clinicians", or "hospital information systems"—topics that dominated and defined the original discipline of medical informatics then (and partly still do now). I clearly saw already back then that information and communication technologies related to the internet would have an impact far beyond billing and record management [2,3].

In terms of the *business model*, my original idea was something like "we'll figure it out, but it shouldn't be subscription," which only later morphed into "author/funder pays." As a side note, here is one truth about innovators: When they say they "innovated" a business model, they often mean that at the time, they did not have a clue about how to get their money back, and the business model simply did not exist. This is, perhaps, what happened here—the journal was a product of academic passion and did not aim to make money.

The *Journal of Medical Internet Research* was one of the first journals worldwide to use a new publishing model that empowers academics and enables end users like patients to access scientific information without going through a library. How early our contribution to this historic shift in scholarly publishing was can be illustrated by recalling some key dates in the short timeline of open access history: I conceived JMIR in 1998, with the first issue published in 1999, one year before early well-funded publishers like PLOS (incorporated as an advocacy organization in 2000 and a publisher in 2003) or BioMed Central (founded in 2000) entered the field. Because they were better funded and had marketing departments, they became the poster children for open access, but JMIR Publications certainly deserves credit for being an open access pioneer, as also evidenced by our role in cofounding the *Open Access Scholarly Publishers Association* (OASPA) [4], a nonprofit organization that promotes open access to health research and functions as a white list. Open access helps knowledge dissemination and uptake [5], but some overzealous publishers used questionable methods that threatened the credibility of open access. Concerns about the “black sheep” in the industry (later called “predatory” by Beall) arose about 10 years into our existence [6], and OASPA, created shortly after, was an important step to “whitelist” credible open access publishers.

Twenty years ago, the *Journal of Medical Internet Research* predicted that in the internet age, information needs to be open and free, and it went on to become extremely successful. It was soon named the leading eHealth journal in its category by Thomson Reuters (now Clarivate Analytics). Four journals, all published by JMIR Publications, are ranked within the top eight journals in the field, and two JMIR journals rank first (*Journal of Medical Internet Research*) and second (*JMIR mHealth and uHealth*) in this list. Although we warn people not to misuse the impact factor to assess researchers and institutions (there are better methods to rank the most impactful scientists [7]), publishing in a reputable journal remains critical for the career of an academic, and we would argue that all JMIR journals are reputable, irrespective of the impact factor. As one author put it, “publishing in JMIR is like getting on the honor roll.”

Soon after, the number of submissions started to increase exponentially, and we expanded our journal portfolio to cover a wide range of clinical specialties, to engage like-minded academics as editors-in-chief and to illustrate that “medical informatics” is not a “vertical” discipline but a horizontal theme that penetrates all areas of medicine—with JMIR as the journal brand that stands for innovation and digital progress in every single medical discipline. Today, JMIR Publications publishes over 2500 articles annually in nearly 30 journals.

It has not been an easy journey, and we faced opposition from expected and sometimes unexpected forces. Expected was pushback from scholarly publishing societies and large publishers, who are dependent on subscription revenues, and who did everything they could to delay the arrival and success of open access. Unexpected lack of support came from medical informatics societies, who have of course vested interests with their competing society-backed subscription/membership journals. But this may, perhaps, be a story for a different editorial.

Now is the time to celebrate our achievements in a positive light. We are celebrating our 20th anniversary with a special theme issue [8], which contains a remarkable mix of invited commentaries and original research, reflecting on the past and opening new perspectives for the near future. Of course, we are also celebrating JMIR itself while reflecting on our achievements and planning our direction for the future.

The 20th Anniversary Special Issue

This special issue is truly remarkable, with exceptional articles and authors.

First, we provide a glimpse into the future of disruptive technologies, by publishing Elon Musk (yes, that one!) and his Neuralink team’s [9] paper about their groundbreaking *brain-machine interface (BMI)*—how to connect machines to the brain—for possible “read and write” access. The possibility to link ourselves directly to computers may address the bandwidth problem (especially for computer input), and we can even start dreaming about downloading apps that may directly program healthy habits into our brains or allow us to communicate with machines and each other wirelessly. The authors announced in a press conference earlier this year that they intend to start the first clinical trials as early as 2020. We are possibly on the brink of another revolution—the BMI revolution—the third revolution after the internet and mobile health (revolutions chronicled by 20 proud JMIR years).

The implications are equally fascinating and concerning, which is why Musk’s white paper is accompanied by four invited commentaries reflecting on the societal and scientific impact of this transformative technology [10-13]. They are scary, perhaps, because if we have not even figured out how to address the quality problem on the internet and in app stores, how can we ever hope to regulate and perform quality assessments for apps that may control our brains and are influenced by our brains, and work differently in each person—how do we assess their safety? There are many questions, so we are not concerned about running out of papers for the next 20 years.

Several papers in this issue also reflect on the rapid progress in *artificial intelligence* research in medicine [14-18]. Although these technologies have been around for decades, it seems that a tipping point has been reached, with these applications now becoming truly useful and mainstream in medicine. This is, in turn, partly fueled by the internet and the trillions of data points and textual information on it, giving machines the ability to understand the world better or, rather, to understand the world as *modelled on the internet* better. We have to stay mindful of the fact that the model of the world reflected on the internet is not a true representation of the world. Perhaps, herein lies a rarely discussed danger of artificial intelligence, in that machines will execute machine decisions based on a biased model of the world: Will *digital inequity* lead to or reinforce real-word inequity? This provides another angle on the importance of building capacity for digital health in resource-poor settings, as described by Walter Curioso in this issue [19].

Another section in this theme issue deals with the impact of the internet on patient empowerment. We are, for the first time, publishing the transcript of e-Patient Dave's historic keynote at the Medicine 2.0 conference 10 years ago, which kicked off the #gmdd rallying cry and fueled the *participatory medicine* movement (JMIR Publications now also publishes the official journal of the Society for Participatory Medicine, the *Journal of Participatory Medicine*). Dave overcame cancer not least with the help of the internet and reminds us that patients need access to their medical data [20] - a goal that 10 years after his keynote is still not achieved [1].

We are also publishing the personal story of Andre Kushniruk, the editor-in-chief of *JMIR Human Factors*, who describes how the internet saved his life [21]. One morning, he woke up and had difficulties swallowing. A few weeks later, he started bleeding from his throat so profusely that he had to be rushed into the emergency department. The diagnosis was devastating—inoperable tongue cancer. The options he was given were chemotherapy and radiation, and these would be palliative only, with a slim chance of full recovery. However, with his wife, Elizabeth Borycki, who is also a professor at the School for Health Information in Victoria (and editor-in-chief of *JMIR Nursing*), the couple sprang into action, and after hours of searching on the internet, found a surgeon in the United States who specialized in surgically removing exactly the kind of cancer Andre had. The couple travelled to the United States for the surgery and today, Andre is free of cancer. "Freely available health information on the Internet saved his life," says Elizabeth Borycki (who also contributed a paper to this theme issue on safety and error prevention in health care, which is not entirely unrelated to the power of informed patients to make health care better [22]).

It is stories like these that validate our belief in the power of the internet and digital technologies to "disintermediate" and not only disrupt the medical industry but also change the way researchers communicate their research results and patients retrieve information. However, open access to research information is not enough: Patients also need access to their personal health information, and the fact that we are not there yet is painfully illustrated in Dave DeBronkart's latest article [1], which sometimes sounds bitter about the lack of progress and the forces resisting change. Disappointment and disillusionment are also reflected in the paper by Alex Jadad and his daughter [23]. These perspectives are sobering and refreshing at the same time, given the overly optimistic hype around digital health in other journals or news media, partly peddled by the "digital health" industry.

Speaking of hype and buzzwords, in this 20th year anniversary theme issue, Alireza Ahmadvand and colleagues [24] present a study on the increasing use of the *"digital health"* moniker in JMIR journals, a term I personally find problematic (not only because the word "digital" has another meaning in medicine, as anybody who has had a prostate exam can attest to that). Although we are not policing what terms people use in their papers, we gently try to dissuade authors from using these new buzzwords. We are also resisting the temptation to rename our flagship journal from *Journal of Medical Internet Research* to *JMIR Digital Health*, as buzzwords have a way of coming and going. More importantly, the term is not helpful, as it obfuscates the actual technologies used: For example, is it a Web-based intervention, a mobile intervention, or something connected to our brain? To write about a "digital intervention" is a little similar to writing about a "pharmacological intervention" without specifying the ingredients. Most importantly, having witnessed several terms come and go ("information and communication technologies [ICT]," "telemedicine," "cybermedicine," "eHealth," "connected health," "digital medicine," etc), I now better understand the dynamics of why people create (and abandon) these new terms, and they are often related to money: venture capital funding for private companies or grants for funding research. Investors (of private companies) and peers (at funding agencies and journals) are often more impressed by something "new," unencumbered by failures of the past, and eHealth is full of failures. But it is also full of success stories, and the reverse may happen as well: That something that works is forgotten and traded in for the next best shiny "digital health" thing. This sentiment is echoed in the paper by Jane C Willcox and colleagues [25], who remind us that textmessaging is still one of the most effective health interventions, but funding bodies tend to turn down proposals with technologies that are not new and sexy enough. Thus, my biggest concern with the new "digital health" hype and -more broadly- with constantly rebranding something that has been around for decades, is that it affects our ability to learn from failures or successes of the past. To abandon a term like electronic health/electronic medicine in favor of "digital health" or "digital medicine," only to appear cutting edge and prevent people from googling or researching past failures and successes associated with the field is dishonest and antiscientific, and we will not stand for it. Although the word "internet" in our flagship journal title may no longer adequately and exhaustively describe what we publish, the internet remains the fuel for innovation and the infrastructure that enables global communication, and we will continue publishing cutting-edge research no matter what the buzzword *du jour* is.

Open Access is Knowledge, and Knowledge is Power

The stories of e-Patient Dave [20] or Andre Kushniruk [21] exemplify what I tried to change 20 years ago, why the journal was created in the first place, and why I decided to make it open access. JMIR Publications is not only a business, but also a social enterprise: We try to instigate social change, as evidenced by our vision statement, which is engraved on the wall of our head office in Toronto, Canada (Figure 1):

> *We envision a world where people are empowered by health research and technology to make effective, informed decisions, take control of their health and well-being, and live happier and healthier lives.*

Figure 1. Vision of JMIR Publications at the wall of the editorial office.

John Torous, our brilliant Editor-in-chief of *JMIR Mental Health*, writes wonderfully about our impact beyond the impact factor [26], but what I am most proud of is our role in advancing two important social movements of our time: Open Access (to free general medical knowledge from being behind paywalls) [4,5], and participatory medicine (which includes and necessitates freeing personal health information from the vaults of institutional medicine) [20]. As publisher, we are helping likeminded leaders in the health technology space collaborate and disseminate their ideas and research results, facilitating progress and change. Some of our readers indeed recognize our role as social change agent: "JMIR is an interesting and socially engaged enterprise worthed to publish with" writes Alberto J. Revolware in a Google review [27]. Others call us "a very forward-thinking publication (..). A true beacon of light for the digital health industry." (Jessica Shull) [27]. Most authors also appreciate the innovations we made to streamline the review and publishing process, with industry-leading turnaround times and impact: "JMIR has completely optimized the process of reviewing and publishing manuscripts. Other journals should follow suit." writes Jereme Wilroy [27].

To achieve our vision, we not only publish research papers, but also create and apply additional tools that connect vetted, quality research outputs in novel, effective, and timely ways for those who need it, and that includes patients. Therefore, in addition to its 30 peer-reviewed journals, JMIR Publications maintains a blog site for end users and plans to translate scientific research into consumer-understandable, actionable information (watch our forthcoming product announcements). Organizing and supporting medical and scientific conferences; developing new software, databases, and resources for researchers and patients alike; and even angel investment in small digital health and digital science companies are all part of our toolbox toward that goal and go beyond publishing.

Academic societies take notice of these efforts and increasingly move their journals to JMIR Publications. When the nonprofit *Society for Participatory Medicine* was looking for a new home for its *Journal of Participatory Medicine*, JMIR Publications was a natural fit, and the society moved the journal to JMIR Publications. The movement in which networked patients shift from being mere passengers to responsible drivers of their health and where providers encourage and value patients as full partners, goes well beyond digital medicine, but information technology is a catalyst to enable that paradigm shift.

We also forge partnerships with research institutions and libraries; for example, owing to a recent deal with the California Digital Library at the University of California (UC), the article processing fees for authors from all 10 UC campuses throughout California are subsidized or fully covered through this agreement. We will continue to try to make similar institutional or even national agreements, but we will also need the help of librarians, faculty, and our readers to advocate such deals at their institutions or national libraries.

The Future of Publishing: Our Innovations for 2020 and the Next 20 Years

We are not done innovating, and we are very excited to announce the launch of the new JMIRx journal series, which expands our scope beyond electronic health to all areas of medicine, and even biology and psychology, and provides an entirely new publishing experience for authors.

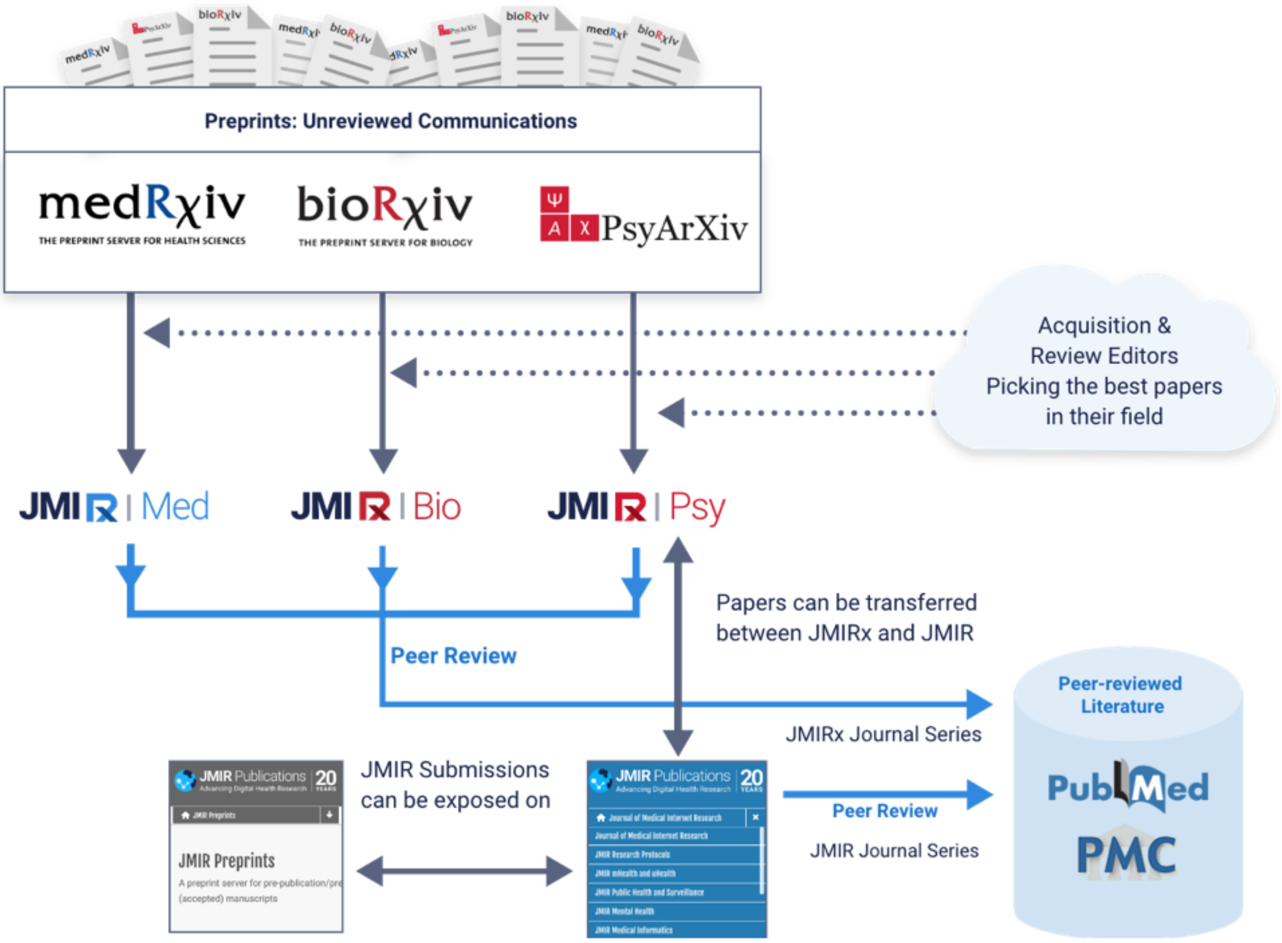
JMIRx is a new journal series and new type of journal, which we call "superjournals" (others may call them "overlay" journals; Figure 2). Superjournals are operating "on top" of preprint servers and offer peer review and copyediting/archiving/indexing services; as such, they do everything a "normal" journal does, except that authors no longer have to submit their manuscript to a journal. Instead, our acquisition and review editors find the papers they want to publish and extend conditional offers of publication to interesting articles published in preprint servers as well as solicit reviews and commentaries. In addition to the "editorial prospecting" workflow, authors can self-nominate their existing preprints for publication (which is equivalent to a traditional journal submission) without going through another submission process. If superjournals ask for revisions, these revisions are also uploaded to the preprint server.

We see this model, which includes radical openness during the entire manuscript preparation and revision process, as the future of publishing, as predicted 20 years ago in the year 2000, when I reflected on the power of preprint servers and the blurring boundaries between what constitutes a "publication" (rather than the traditional dichotomy of "published" versus "unpublished" articles I posited that the internet age calls for a distinction between "type 1" [informal] and "type 2" [version of record, peer-reviewed] publications):

> *Researchers could submit type-1 electronic papers [preprints] to preprint servers for discussion and peer-review, and journal editors and publishers would pick and bid for the best papers they want to see as "type-2 papers" [version of record] in their journal.* [28]

This is what I still believe may be the future of publishing, and JMIRx may illustrate this. Combined with other innovations, such as our *JMIR Research Protocols* journal, which increases accountability and transparency in research through registered protocols and registered reports, we are confident that once again, we are at the at cutting edge of an open-science revolution, and we look forward to take that journey in the next 20 years with our growing base of readers, editors and reviewers.

Figure 2. JMIRx, a new series of superjournals (overlay journals) offering peer review and publication services for preprints.



Conflicts of Interest

The author is founder and president of JMIR Publications.

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Abbreviations

BMI: brain-machine interface
eHealth: electronic health
ICT: information and communication technologies
JMIR: Journal of Medical Internet Research
OASPA: Open Access Scholarly Publishers Association
UC: University of California

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Original Paper

Blockchain-Enabled iWellChain Framework Integration With the National Medical Referral System: Development and Usability Study

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Abstract

Background: Medical referral is the transfer of a patient’s care from one physician to another upon request. This process involves multiple steps that require provider-to-provider and provider-to-patient communication. In Taiwan, the National Health Insurance Administration (NHIA) has implemented a national medical referral (NMR) system, which encourages physicians to refer their patients to different health care facilities to reduce unnecessary hospital visits and the financial stress on the national health insurance. However, the NHIA’s NMR system is a government-based electronic medical referral service, and its referral data access and exchange are limited to authorized clinical professionals using their national health smart cards over the NHIA virtual private network. Therefore, this system lacks scalability and flexibility and cannot establish trusting relationships among patients, family doctors, and specialists.

Objective: To eliminate the existing restrictions of the NHIA’s NMR system, this study developed a scalable, flexible, and blockchain-enabled framework that leverages the NHIA’s NMR referral data to build an alliance-based medical referral service connecting health care facilities.

Methods: We developed a blockchain-enabled framework that can integrate patient referral data from the NHIA’s NMR system with electronic medical record (EMR) and electronic health record (EHR) data of hospitals and community-based clinics to establish an alliance-based medical referral service serving patients, clinics, and hospitals and improve the trust in relationships and transaction security. We also developed a blockchain-enabled personal health record decentralized app (DApp) based on our blockchain-enabled framework for patients to acquire their EMR and EHR data; DApp access logs were collected to assess patients’ behavior and investigate the acceptance of our personal authorization-controlled framework.

Results: The constructed iWellChain Framework was installed in an affiliated teaching hospital and four collaborative clinics. The framework renders all medical referral processes automatic and paperless and facilitates efficient NHIA reimbursements. In addition, the blockchain-enabled iWellChain DApp was distributed for patients to access and control their EMR and EHR data. Analysis of 3 months (September to December 2018) of access logs revealed that patients were highly interested in acquiring health data, especially those of laboratory test reports.

Conclusions: This study is a pioneer of blockchain applications for medical referral services, and the constructed framework and DApp have been applied practically in clinical settings. The iWellChain Framework has the scalability to deploy a blockchain environment effectively for health care facilities; the iWellChain DApp has potential for use with more patient-centered applications to collaborate with the industry and facilitate its adoption.

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KEYWORDS

medical referral; electronic referral system; blockchain; decentralized application; electronic medical records; electronic health records; interoperability

Introduction

A medical referral is the transfer of a patient’s care from one physician to another upon request. This process involves multiple steps that require provider-to-provider and provider-to-patient communication [1,2]. A well-designed and robust medical referral system may improve comprehensive health care for all patients by prioritizing those who need it, reducing health inequity, and limiting unnecessary hospital visits as well as the financial burden of health services [3,4]. However, the performance of a medical referral system varies with the level of the health system, efficiency of communication and the referral management process, and costs of different levels of care [5,6].

The Taiwan National Health Insurance (NHI) system, a universal health insurance program implemented in 1995, is characterized by comprehensive population coverage, accessibility, short waiting times, and relatively low costs. However, the weaknesses of this health care system include inconsistent quality of care, weak gatekeeper roles, and increasing financial pressures [7-10]. For the past 20 years, both the average number of hospital visits per person per year and the average number of drug prescriptions per visit have been over two times greater than those in the high-income countries of the Organisation for Economic Cooperation and Development [11]. The immoderate use of health resources and services has become a critical problem for Taiwan. Therefore, leveraging a medical referral system at each level of a health care institution to provide patients with the most appropriate care is one of the most urgent challenges for Taiwan.

In 2017, the Taiwan National Health Insurance Administration (NHIA) launched a national medical referral (NMR) system that encourages physicians to request patient referrals between clinics and hospitals online to reduce unnecessary hospital visits as well as total health care expenditures. Numerous studies have indicated that adopting electronic medical referral systems can improve the referral management process, accessibility of specialty care, and communication between family doctors and specialists, resulting in increased patient and physician satisfaction [3,12,13]. Since May 2018, the NHIA has been provided incentives to encourage physicians at each level of health care facility to issue referrals using the NMR system. Currently, this system supports two operation modes for authorized clinical professionals using their national health smart cards through the NHIA virtual private network (VPN). One mode is online operation through a Web browser interface; the other mode provides an application programming interface (API) to support the integration of the legacy electronic medical record (EMR) systems of hospitals and clinics. In the online operation mode, a physician can use a Web browser to fill in a patient’s referral data when issuing a referral. Subsequently, when the patient visits a health care facility, the referring physician can review the referral data on the Web browser, request that the patient receives treatment, and complete the referral report by replying to the initial health care facility. In the API mode, referral data can be downloaded from or uploaded to the NMR system through batch processing using functions of the API. Therefore, referral data from legacy EMR systems, such as computerized physician order entry (CPOE), can be integrated using the API instead of through the NMR system.

Currently, medical referrals through the NMR system represent a small percentage of the total referrals of hospitals and clinics. Several obstacles limit the use of the existing NMR system. First, physicians are generally too busy to use the online operation mode during a patient consultation; thus, this mode is infeasible. Second, even if referral data can be integrated from the NMR system into the legacy EMR systems, family doctors may hesitate to issue such patient referrals because of concerns about losing the referred patients or corresponding revenue. Third, hospitals may not provide proper patient referral information when they reply to initial facilities because the additional efforts required to collect and prepare the data are extensive. Most importantly, patients who do not have complete medical or health records cannot fully understand their own general health situations. Thus, patients continue seeking health care providers and specialists support independently when they are unsatisfied with the diagnosis or treatment options provided by their initial physicians.

In recent years, blockchain technologies have been characterized as transparent, immutable, and having consensus properties; they are assumed to enable verified, accountable, and pseudoanonymous transactions and as establishing trust and transaction security without any intermediary or middleware [14-18]. These new technologies have been gradually adapted to many industries, especially in health care [19]. According to the distributed ledger model, the blockchain has attracted a lot of attention in health care for its secure, interoperable, and more efficient access to EMR and electronic health record (EHR) data between patients, providers, and relevant participating entities [20-23]. Compared with the existing health information exchange model, patients preferred to adopt the blockchain-enabled applications because of their characteristics of the decentralized data repository, privacy protection, data security, and access control of their EMR and EHR data [24-26]. Thus, blockchain technologies have triggered extensive research interests and applications in finding ways to improve or integrate existing health care workflows and processes [27,28]. Previous studies have proposed to adopt blockchain technologies for facilitating electronic medical referral process [26,29-33]. Some work are conceptual studies [30,31]; the others were being proposed to use the blockchain technologies to construct a flexible architecture of a secured network to improve system efficiency while optimizing security, scalability, and resource allocation. Such examples might be applied in urgent care network, referral network, and primary care physician network [29,33]. Besides, the use of blockchain can extend the existing personal health record (PHR) data management system to combine with event-driven smart contracts to support transactional services (eg, repeat prescription, appointment booking, and referral requests) [26]. Some others have implemented a blockchain-enabled decentralized app (DApp) and framework to address interoperability challenges in health care facilities, and thus, patients can use the DApp to share their clinical information as the basis of decision making for remote support [20,32,34]. Studies about blockchain proposed various technical aspects in the medical referral services; however, health care literature regarding such real-world use cases is lacking in clinical settings [35]. Accordingly, more should be implemented and proven in the health care environment.

According to the Taiwan single-payer NHI system, there are no regulations to force medical referrals for each level of different health care providers. Consequently, patients are free to seek clinical services without referrals, and family doctors can also choose favorable hospitals for patient referrals. Thus, we consider that the establishment of trusting relationships between patients and health care providers is a precondition of EMR and EHR data interoperability [36]. In this study, we aimed to develop a blockchain-enabled framework for building an alliance-based medical referral service connecting health care providers. With this framework, all participants (eg, patients, family doctors, and specialists) who are willing to join the alliance-based medical referral system can create their own blockchain accounts. It is the first step to tighten trust in the relationships for all participants. With the deployment of our framework to health care facilities, it can integrate patient referral data from the NHIA's NMR system with EMR and EHR data of hospitals and community-based clinics, enhance patients' EMR and EHR data interoperability across different health care facilities, and make all medical referral processes more efficient. Moreover, we developed a blockchain-enabled PHR DApp based on our framework for patients to acquire their EMR and EHR data. Then, the DApp access logs were collected to assess patients' behavior and investigate the acceptance of our personal authorization-controlled framework.

Methods

Overview

In this study, we adopted the Go Ethereum version 1.7.3-stable [37] to construct the iWellChain Framework, which is a permissioned consortium blockchain with trusted parties to ensure consensus by proof-of-authority. Hence, our framework can limit participants who transact on the blockchain and define users who can serve the network by writing new blocks into the chain. Afterward, we can deploy the framework to hospitals or clinics to build an alliance-based medical referral service. Moreover, regarding the interoperability of EMR and EHR data [38], since 2004, the Taiwan Ministry of Health and Welfare has published EMR and EHR exchange standards based on Clinical Document Architecture, Release 2 (CDA R2) of Health Level 7 (HL7) [39]. Therefore, we followed the HL7 CDA R2 standards when pursuing structural and semantic interoperability of EMR and EHR data. In addition, based on the iWellChain Framework, we developed a DApp, the iWellChain DApp, which can operate on both iOS and Android mobile platforms. Since September 2018, the studied hospital has released five types of EMR and EHR data that patients can acquire through the iWellChain DApp. To extend our understanding of patient-centered interoperability of EMR and EHR data, we analyzed the access logs of the iWellChain DApp to understand patients' activities during a 3-month study period.

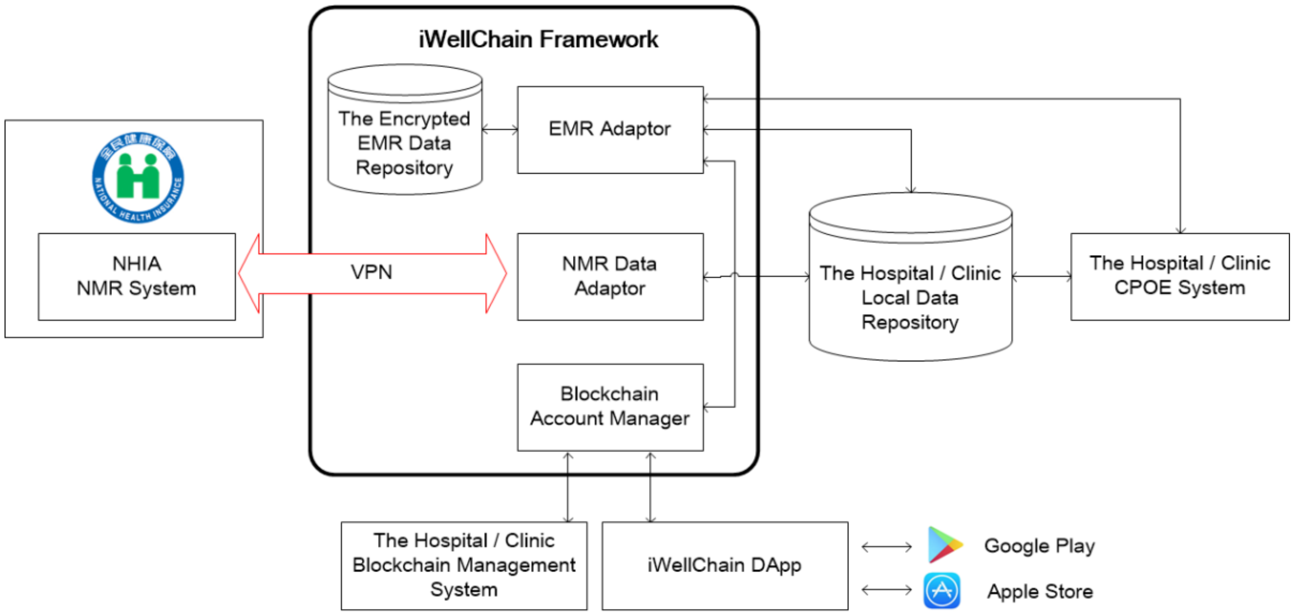
Settings

For this study, the iWellChain Framework was developed and installed at Taipei Medical University Hospital (TMUH) and four collaborative clinics. TMUH is a teaching hospital with nearly 800 beds and a satisfactory information infrastructure; in addition, it is a certified Health care Information and Management Systems Society hospital using EMR Adoption Model Stage 6 [40]. In this hospital, most medical and health records are stored electronically because the hospital is trying to fully digitize its records. However, when physicians refer patients to other physicians, most patients must acquire paper-based referral forms and related medical documents to be processed manually by clinics and hospitals.

The iWellChain Framework and Interactions With the National Health Insurance Administration's National Medical Referral System

The iWellChain Framework and its interactions with the NHIA's NMR system are presented in Figure 1. The implemented iWellChain Framework comprises the following 4 major components: EMR Adaptor, Encrypted EMR Data Repository, NMR Data Adaptor, and Blockchain Account Manager (BAM).

Figure 1. The iWellChain Framework and its interactions with the National Health Insurance Administration's national medical referral system. CPOE: computerized physician order entry; DApp: decentralized application; EMR: electronic medical record; NHIA: National Health Insurance Administration; NMR: national medical referral; VPN: virtual private network.



Electronic Medical Record Adaptor

The EMR Adaptor is used to monitor and copy a patient's EMR and EHR data stored in the local data repository of a hospital or clinic. Moreover, the adaptor can request the patient's public key from the BAM to encrypt copies of the EMR and EHR data. Subsequently, the adaptor stores these encrypted copies in the Encrypted EMR Data Repository. For example, when a physician uses the CPOE system to complete a patient's treatment, EMR data are generated. When the patient's EMR data are ready, the EMR Adaptor verifies the access permissions for each type of EMR data according to the patient's signed Ethereum-based smart contracts [41], which are provided by the BAM. If permitted, the EMR Adaptor copies the patient's EMR data and uses the patient's public key to encrypt these copies. These encrypted copies of the patient's EMR data are subsequently stored in the Encrypted EMR Data Repository.

The EMR Adaptor also provides a connection that can pose access requests of the CPOE system of a hospital or clinic. For example, when a physician wants to acquire additional EMR or EHR data for a referral patient, the patient can use the iWellChain DApp to determine whom to authorize and select an approved period for the physician to access the EMR and EHR data. Accordingly, the selected EMR and EHR data are decrypted by the patient's private key. With the patient's permission, the EMR Adaptor can request the physician's public key from the BAM to encrypt the copies of the patient's selected EMR and EHR data. Subsequently, the EMR Adaptor stores these encrypted copies in the Encrypted EMR Data Repository. Afterward, the physician can use his or her private key to open the selected patient EMR and EHR data through the CPOE system of a hospital or clinic until the time at which access to the patient's EMR and EHR data expires.

Encrypted Electronic Medical Record Data Repository

The Encrypted EMR Data Repository is implemented using the InterPlanetary File System (IPFS) [42,43] to store encrypted copies of EMR and EHR data. The IPFS provides a high-throughput content-addressed block storage model with content-addressed hyperlinks, which enable completely distributed applications. When the Encrypted EMR Data Repository receives copies of a patient's encrypted EMR and EHR data, a unique hash code is generated for each copy, and it corresponds to an accessible hyperlink. The hash code is registered on the BAM for the iWellChain DApp to access and acquire further data.

National Medical Referral Data Adaptor

The NMR Data Adaptor is used in cooperation with the NMR's API functions to process patient referral data and reports obtained in batch mode from the NHIA's NMR system over the VPN. This adaptor can retrieve referral data through batch download from the NHIA's NMR system and store these data in the local data repository of a hospital or clinic. When patient referral reports are completed and the physician must reply to the initial health care facility, the NMR Data Adaptor can access these reports from the local data repository through batch upload to the NMR system.

Blockchain Account Manager

The BAM module was designed to access Ethereum blockchain ledgers [44], and it provides the registration function of the iWellChain DApp. The BAM was installed at the information desk of TMUH with the Ethereum node client software [45] to access the full ledgers of Ethereum. When a patient downloads and installs the iWellChain DApp from Google Play or the Apple Store, a wallet address (a patient's identification [ID] in the Ethereum World) is generated. Patients can register an account from the iWellChain DApp to the BAM using their national ID (a unique personal ID in Taiwan) and medical record number (unique patient ID at TMUH). Accordingly, the registration information and the patient's ID mapping table are deposited into and managed by the BAM. Patients can grant access to their EMR and EHR data to whomever they choose through the iWellChain DApp; these permissions are recorded in the ledger.

Log Data of the iWellChain Decentralized App

To investigate patients' use of the iWellChain DApp, an access log was created, and information on their actions through the iWellChain DApp was collected. We added Google Analytics for Firebase [46] to the iWellChain DApp to capture patients' click data. Once the data are captured, the access log can be linked to Google BigQuery for analysis and reporting [47]. Besides, all physician access logs are stored in the event logs of a smart contract through the iWellChain Framework. When a physician acquires a patient's EMR or EHR data via the CPOE system, the iWellChain Framework signs access logs in the event logs of a smart contract using the physician's private key. The Joint Institutional Review Board of Taipei Medical University and TMUH approved this study.

Results

Workflow for Referral Between Clinics and Hospitals Based on the National Health Insurance Administration's National Medical Referral System and the iWellChain Framework

Patients wishing to access and control their EMR and EHR data must create a blockchain account at a health care facility and sign and submit the appropriate smart contracts to the health care facility. The patients can subsequently download the iWellChain DApp and use it to access their EMR and EHR data. In addition, family doctors and specialists willing to join TMUH's alliance-based medical referral system can create their own blockchain accounts. The objective is to enhance EMR and EHR data sharing among facilities, with patients' permission. The novel workflow of patient referral between clinics and hospitals with the iWellChain Framework is described in Figure 2.

Figure 2 illustrates the workflow of the alliance-based medical referral service used by patients, clinics, and hospitals using the iWellChain Framework. First, when visiting a health care facility, the patient inserts his or her health smart card into a card reader to initiate the clinical encounter. The CPOE system reads the basic information on the card, including name, sex, and national ID. Patient information is compared with the downloaded referral data to determine whether the patient has been referred. If the patient has been referred (denoted by the *R* icon in Figure 3, left part of the left panel), the physician can click on the *R* icon to review the patient's referral data (Figure 3, right panel). The indexes of the patient's EMR and EHR data (Figure 3, right part of the left panel) can be accessed, including laboratory test reports, outpatient notes, discharge notes, pathology reports, and health check reports. However, if the patient is not a referral case, the physician conducts the usual patient assessment, forms a diagnosis, and prescribes treatment for the patient.

If requesting additional EMR or EHR data for a referral patient, a physician clicks on the *M* icon (Figure 3, right part of the left panel) to send a push notification to the patient's mobile phone. As the push notification is received by the patient via the iWellChain DApp, the patient can use the DApp to select specific EMR or EHR data (Figure 4, left panel), determine whom (ie, physicians or health care workers) to authorize (Figure 4, middle panel), and select the approved period for the physician to access the EMR and EHR data (Figure 4, right panel). Subsequently, the physician can click the *O* icon (Figure 3, right part of the left panel) to access the EMR and EHR data provided by the initial facility via the CPOE system. If the physician's access to the patient's EMR and EHR data is not permitted or has expired, a notification window will appear when the physician clicks on the *O* icon. In this case, the physician can revert to using the CPOE system to assess, diagnose, and treat the patient. After treatment, the physician can use the CPOE system to complete the patient's treatment and referral reports (if applicable), generate the patient's EMR data, and store these data in the local data repository of the clinic or hospital. The iWellChain Framework can then assist in subsequent tasks. For example, patients can obtain their EMR data in real time using the iWellChain DApp, and referral reports can be uploaded to the NHIA's NMR system to complete the referral process for NHIA reimbursement claims.

Figure 2. Workflow of the alliance-based medical referral service using the iWellChain Framework. CPOE: computerized physician order entry; DApp: decentralized application; EHR: electronic health record; EMR: electronic medical record; NHIA: National Health Insurance Administration; NMR: national medical referral.

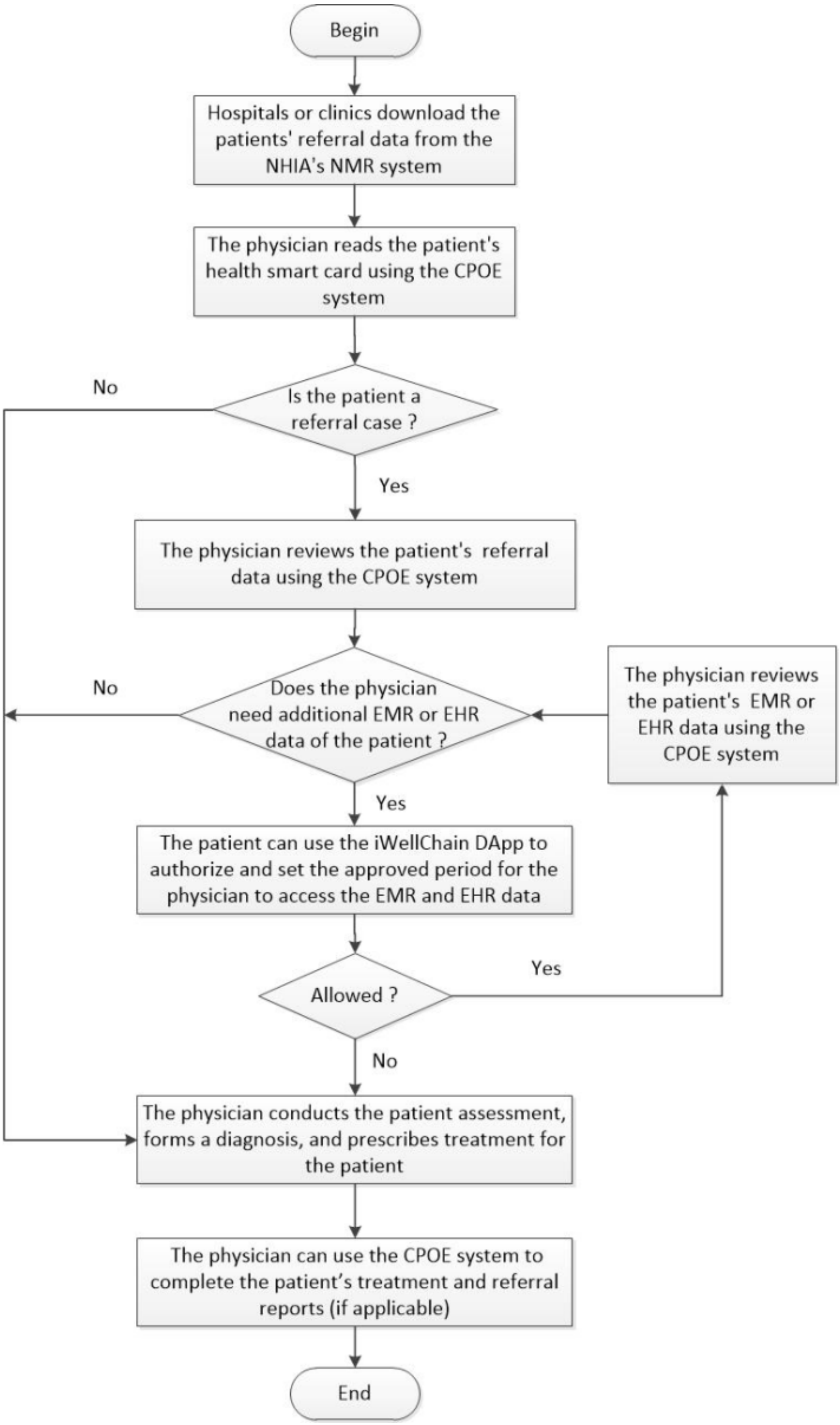
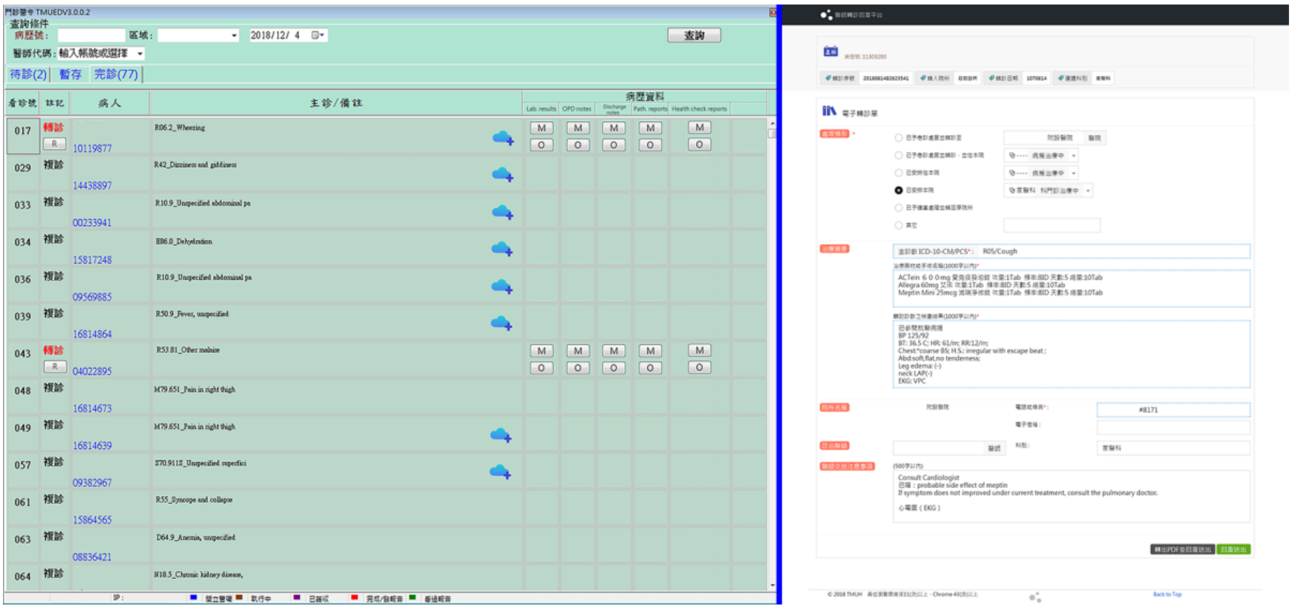


Figure 3. Screenshot of patient list screen showing the R icon that appears when an outpatient has been referred. The screen presents information including the patient list (left panel), referral cases with R icons (left part of the left panel), and display area for referral data from the National Health Insurance Administration’s national medical referral system (right panel).



門診醫令 TMUEDV3.0.0.2

查詢條件

病歷號：

區域：

2018/12/ 4

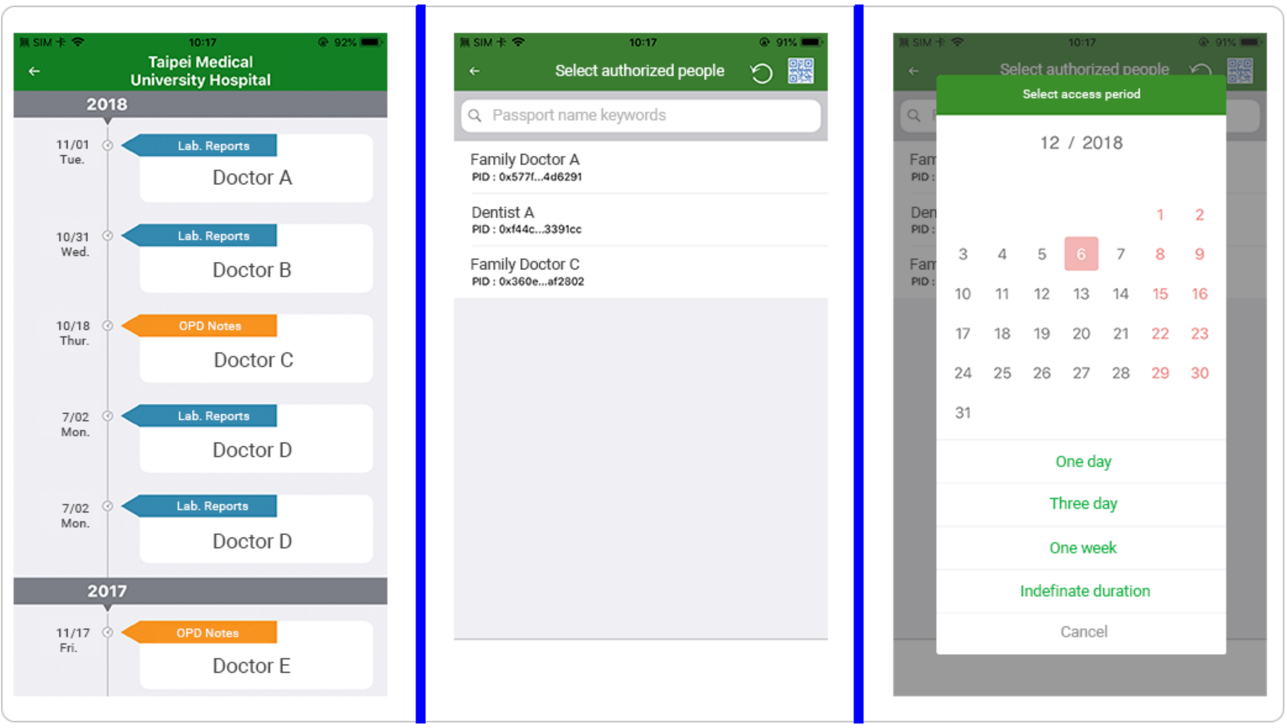
查詢

醫師代碼：輸入帳號或選擇

待診(2) 暫存 完診(77)

看診號	註記	病人	主診/備註	病歷資料 Lab. results	OPD notes	Discharge notes	Path. reports	Health check reports
017	轉診 R	10119877	R06.2_Wheezing	M O	M O	M O	M O	M O
029	複診	14438897	R42_Dizziness and giddiness					
033	複診	00233941	R10.9_Unspecified abdominal pa					
034	複診	15817248	E86.0_Dehydration					
036	複診	09569885	R10.9_Unspecified abdominal pa					
039	複診	16814864	R50.9_Fever, unspecified					
043	轉診 R	04022895	R53.81_Other malaise	M O	M O	M O	M O	M O
048	複診	16814673	M79.651_Pain in right thigh					
049	複診	16814639	M79.651_Pain in right thigh					
057	複診	09382967	S70.911S_Unspecified superfici					
061	複診	15864565	R55_Syncope and collapse					
063	複診	08836421	D64.9_Anemia, unspecified					
064	複診		N18.5_Chronic kidney disease,					

Figure 4. Screenshot of the patient iWellChain decentralized application screen. The screen presents information including a timeline of the patient’s electronic medical record and electronic health record data (left panel), an authorization list (middle panel), and the approved access time for the selected electronic medical record and electronic health record data (right panel). Lab.: laboratory; OPD: outpatient department.



Taipei Medical University Hospital

2018

11/01 Tue.	Lab. Reports	Doctor A
10/31 Wed.	Lab. Reports	Doctor B
10/18 Thur.	OPD Notes	Doctor C
7/02 Mon.	Lab. Reports	Doctor D
7/02 Mon.	Lab. Reports	Doctor D

2017

11/17 Fri.	OPD Notes	Doctor E

Select authorized people

Passport name keywords

Family Doctor A
PID : 0x577f...4d6291

Dentist A
PID : 0xf44c...3391cc

Family Doctor C
PID : 0x360e...af2802

Select access period

12 / 2018

					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31						

Access Log Data Analysis of the iWellChain Decentralized App

The iWellChain Framework and iWellChain DApp were launched on September 16, 2018. At this time, TMUH informed the public about the possible application of blockchain technologies to support medical referral services and the use of the iWellChain DApp to access patient EMR and EHR data [48,49]. Accordingly, when patients visited TMUH to seek clinical services, the hospital’s staff, which mainly included workers from the health check department, community medicine department, and customer service department, suggested these patients create a blockchain account. The health check department encouraged customers who received high-end health check services (>US $1000) to create blockchain accounts to deliver the health check reports rapidly. On average, the number of high-end health check customers was approximately 150 to 250 per month. The community medicine department encouraged patients who were referred via the NHIA’s NMR system to create blockchain accounts to facilitate referral report completion and NHIA insurance reimbursement. On average, the number of such referral patients was approximately 250 to 350 per month. Moreover, patients who wished to create the blockchain accounts were free to seek help from the information desk of the customer service department. The information desk staff helped patients install the iWellChain DApp and offered assistance through technical tutorials. In the initial stages, TMUH released only five types of EMR and EHR data for the patients to retrieve: laboratory test reports, outpatient department (OPD) notes, discharge notes, pathology reports, and health check reports. We collected the blockchain account data from the 3 months following implementation (September 16, 2018, to December 15, 2018) to explore the patients' application of their accounts. We also analyzed the iWellChain DApp access logs for these accounts to determine which EMR and EHR data patients required the most.

Over the 3-month period, the total numbers of high-end health checkup customers, referral patients through the NHIA's NMR system, and individual apps were 581, 912, and 118, respectively. Table 1 reveals that over this 3-month period, 392 users registered iWellChain DApp accounts; the health check department, community medicine department, and individual application channels were used by 175 (175/392, 44.6%), 99 (99/392, 25.3%), and 118 users (118/392, 30.1%), respectively. The highest proportion of users who requested an account was from the health check department channel. This can be explained by the fact that the health check department promoted the iWellChain DApp service as a new customer service capable of delivering health check reports to customers within 1 day. The service also enhances the personal security and privacy of patients by allowing them to access health check reports using a secured blockchain network instead of a paper-based health document. Moreover, computed tomography and magnetic resonance imaging images from a compact disc often take weeks to be delivered. Per our understanding, most users who applied independently were young and thus might be attracted to or interested in blockchain technologies. They wanted to understand how blockchain technologies can be applied to health care. Most users referred by the community medicine department were from family groups, including older patients who were attracted by the hospital's newsletter. The caregivers of older patients wanted to understand the patients' general health to avoid returning to the hospital and to reduce the time spent accompanying and waiting with patients and associated medical costs.

Over this 3-month period, as Table 2 indicates, the total numbers of laboratory test reports, OPD notes, discharge notes, pathology reports, and health check reports were 406, 1358, 2, 134, and 175, respectively. Table 2 displays the total user access logs of the iWellChain DApp over this 3-month period. Overall, there were 4540 (80.09%), 721 (12.85%), 7 (0.12%), 4 (0.07%), and 340 (6.06%) clicks on the laboratory test reports, OPD notes, discharge notes, pathology reports, and health check reports, respectively. Laboratory test reports being the most frequently accessed is likely explained by the fact that most patients are focused on the value of laboratory tests, especially when they have been examined in multiple hospitals or when their tests results require constant monitoring of the condition. Some patients may even doubt the accuracy of their laboratory tests. The high access to OPD notes and health check reports we observed corresponds to patients or their families wanting to understand the patients' long-term medication history and health status. The lowest access to discharge notes and pathology reports is related to the fact that these types of medical documents are long text descriptions; therefore, patients have difficulty understanding them. In addition, patients often applied for these documents in paper form before discharge because they needed the documents to claim private insurance paybacks.

Table 1. Descriptive statistics of blockchain accounts registered through various application channels.

Time period	Total users, n (%)	Health check department			Community medicine department			Individual application (total registered users, n [% of total users])
		Total visits[a]	Total registered users, n (% of total visits)	Total registered users/total users (%)	Total visits[b]	Total registered users, n (% of total visits)	Total registered users/total users (%)	
Entire period	392 (100)	581	175 (30.1)	44.6	912	99 (10.9)	25.3	118 (30.1)
Period I[c]	231 (100)	158	88 (55.7)	38.1	325	54 (16.6)	23.4	89 (38.5)
Period II[d]	56 (100)	215	8 (3.7)	14.3	314	25 (8.0)	44.6	23 (41.1)
Period III[e]	105 (100)	208	79 (38.0)	75.2	273	20 (7.3)	19.1	6 (5.7)

[a] Total number of high-end health check visits.

[b] Total number of referral patients via the National Health Insurance Administration's national medical referral system.

[c] Period I: September 16, 2018, through October 15, 2018.

[d] Period II: October 16, 2018, through November 15, 2018.

[e] Period III: November 16, 2018, through December 15, 2018.

Table 2. Descriptive statistics of user access logs to iWellChain decentralized app.

Time period	Total clicks, n (%)	Laboratory tests reports		Outpatient department notes		Discharge notes		Pathology reports		Health check reports	
		Total reports[a], n (%)	Total clicks, n (%)	Total notes[b] (%)	Total clicks, n (%)	Total notes[c], n (%)	Total clicks, n (%)	Total reports[d], n (%)	Total clicks, n (%)	Total reports[e], n (%)	Total clicks, n (%)
Entire period	5612 (100)	406 (100)	4540 (80.90)	1358 (100)	721 (12.85)	2 (100)	7 (0.12)	134 (100)	4 (0.07)	175 (100)	340 (6.06)
Period I[f]	2878 (100)	116 (28.6)	2302 (79.99)	281 (20.69)	362 (12.58)	1 (50)	2 (0.07)	19 (14.2)	1 (0.03)	88 (50.3)	211 (7.33)
Period II[g]	906 (100)	82 (20.2)	789 (87.1)	530 (39.03)	88 (9.7)	0 (0)	2 (0.2)	31 (23.1)	0 (0)	8 (4.6)	27 (3.0)
Period III[h]	1828 (100)	208 (51.2)	1,449 (79.27)	547 (40.28)	271 (14.82)	1 (50)	3 (0.16)	84 (62.7)	3 (0.16)	79 (45.1)	102 (5.58)

[a] Total number of laboratory test reports.

[b] Total number of outpatient department notes.

[c] Total number of discharge notes.

[d] Total number of pathology reports.

[e] Total number of health check reports.

[f] Period I: September 16, 2018, through October 15, 2018.

[g] Period II: October 16, 2018, through November 15, 2018.

[h] Period III: November 16, 2018, through December 15, 2018.

Discussion

Principal Findings

In this study, we developed the iWellChain Framework to access and integrate patients' referral data, including EMR and EHR data from hospitals and clinics, from the NHIA's NMR system. We used blockchain technology to render the data interoperable and practical. Our framework has the scalability to deploy a blockchain environment effectively for health care settings. It is an independent architecture that does not affect the legacy EMR systems of hospitals or clinics. Although some literature has proposed adopting blockchain technology to support medical referral processes, researchers have focused on improving the system efficiency by optimizing security and scalability but have not applied the technology practically in clinical settings. On the basis of what we learned, this study is the pioneer of blockchain applications for medical referral services, and the constructed framework and DApp have been applied practically in clinical settings [49]. Using the batch processing mode of the NHIA's NMR system, our framework can make all medical referral processes automatic, paperless, and thus more efficient; in addition, it can assist health care facilities with NHIA reimbursements.

According to Taiwan's NHIA policies announced in 2017, the number of outpatient visits to hospitals must decrease by 2% per year for a total decrease of 10% over 5 years. The NHIA aims to curb the overuse of health resources and discourage patients with minor ailments from seeking treatment at major hospitals. In other words, if a hospital has a higher proportion of outpatients with minor ailments, its NHI reimbursements will be reduced. Therefore, hospitals are encouraging patients to avoid unnecessary outpatient visits to conform with the regulations. Thus, trusting relationships and patient-centered data interoperability between patients and health care facilities are becoming crucial [20]. The NHIA's NMR system provides a government-based electronic medical referral service. However, its access and exchange of referral data are limited only to authorized clinical professionals. Thus, the system lacks flexibility and is not suitable to establish an alliance-based referral service connecting patients, community-based clinics, and hospitals. Accordingly, we intend to deploy our iWellChain Framework gradually in cooperative clinics to make improvements in data interoperability and tighten trust in the relationships among patients, family doctors, and specialists. Although more than 100 community clinics collaborated with the study hospital, we deployed the iWellChain Framework at only four clinics in the initial stage (September 2018 through January 2019). Therefore, the participants have been limited, and the total transaction volume of EMR and EHR data has not become a bottleneck. However, we consider that blockchain scalability is a major challenge, especially in relation to the volume of health data involved. In this study, we tested the transaction capacity of the iWellChain Framework. Regarding Ethereum, the average transaction time to mine a block is approximately 15 seconds; however, the time cost varies significantly with the network environment. Currently, the average transaction execution time for the iWellChain Framework is 5 to 7 seconds, and its performance will increase gradually because of the novel consensus mechanism. Therefore, blockchain scalability must be further observed and improved considerably. In the next stage of iWellChain Framework implementation, we will gradually extend the alliance-based referral service and use blockchain technologies to address common challenges in health care, such as the physician referral process and data interoperability among health care facilities and patients.

Conventionally, the interoperability of EMR and EHR data in health care has mostly been the ability of health care providers to access patients' relevant clinical data to provide a high-quality of care [50,51]. This interoperability is, therefore, institution-centered and motivated by financial incentives or regulatory pressure [9,52,53]. However, the current trend of interoperability in health care is to transform this institution-centered interoperability into patient-centered interoperability [36]. Blockchain technology can be used to promote this change to patient centricity, which concerns both data sharing and patients' privacy and security [35,41,54]. The iWellChain DApp is a blockchain-enabled PHR tool for patients to acquire their EMR and EHR data securely and electronically. It empowers patients to control these data as health data assets and selectively share or sell them [27,55]. As described in the Results section, the high-end health checkup customers (n=581), patients referred via the NHIA's NMR system (n=912), and individual applications (n=118) represented 1611 potential users; however, in the initial stage (3 months), only 392 users (24.33%) created blockchain accounts (Table 1). According to our observations, although most older patients would like to install the iWellChain DApp to acquire their EMR or EHR data, most of their cell phones are not sufficiently modern to install it. Another observation is that patients were especially interested (Table 2) in acquiring their EMR and EHR data for laboratory test reports. In a clinical scenario, through the TMUH alliance-based referral network, patients who previously visited TMUH for OPD services can use the iWellChain DApp to check laboratory test results and authorize these clinical data to be shared with their cooperative family doctors. If necessary, patients can first consult family doctors, instead of going to hospitals, especially for those with chronic conditions or long-term illnesses. Accordingly, blockchain technology may reduce costs by increasing speed and efficiency in the management of health data. We analyzed use of the app from the health check department channel by comparing clicks on EMR and EHR data. Although the total number of health check reports was low (n=175), such users presented greater interest in health check reports, as evidenced by the total clicks (n=340) using the iWellChain DApp (Table 2). We believe that the number of blockchain users who care about their health data will increase gradually.

Using a blockchain-enabled approach to design an electronic medical referral service with patient-centered principles was our first exciting experience in health care. We may be able to achieve patient-centered interoperability of practical EMR and EHR data. As with numerous other new frontiers in information technology, we should be ambitious but should take measured early steps with blockchain. Accordingly, with the increased adoption of blockchain technology, more meaningful patient-centered applications will require the involvement of multiple stakeholders, including health providers, health participants, and individual governments, and have the potential to revolutionize health care.

Conclusions

In this study, we constructed the blockchain-enabled iWellChain Framework for integrating patients' referral data from the NHIA's NMR system with the EMR and EHR data of hospitals and clinics. This framework can render all medical referral processes automatic, paperless, and efficient, facilitating NHIA reimbursements. In addition, the iWellChain Framework possesses the scalability to deploy a blockchain environment effectively for hospitals and community-based clinics. The framework assists in the establishment of an alliance-based medical referral service to promote trusting relationships and transaction security among patients, family doctors, and specialists. We also developed the iWellChain DApp, which is a blockchain-enabled PHR tool, focused on patient-centered interoperability, that allows patients to access and control their EMR and EHR data securely and electronically. Crucially, we observed that in the initial stage, patients were highly interested in acquiring their health data using the iWellChain DApp, especially data from laboratory test reports. Future research should further explore patient-centered interoperability and involve multiple stakeholders, including health care providers, health participants, and governments.

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Conflicts of Interest

None declared.

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Abbreviations

API: application programming interface
BAM: Blockchain Account Manager
CDA R2: Clinical Document Architecture, Release 2
CPOE: computerized physician order entry
DApp: decentralized application
EHR: electronic health record
EMR: electronic medical record
HL7: Health Level 7
IPFS: InterPlanetary File System
NHI: National Health Insurance
NHIA: National Health Insurance Administration
NMR: national medical referral
OPD: outpatient department
PHR: personal health record
TMUH: Taipei Medical University Hospital
VPN: virtual private network

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Original Paper

An Electronic Screening and Brief Intervention for Hazardous and Harmful Drinking Among Swedish University Students: Reanalysis of Findings From a Randomized Controlled Trial Using a Bayesian Framework

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Abstract

Background: Due to a resurgent debate on the misuse of *P* values, the *Journal of Medical Internet Research* is hosting a standing theme issue inviting the reanalysis of (primarily digital health) trial data using a Bayesian framework. This first paper in this series focuses on an electronic screening and brief intervention (eSBI), targeting harmful and hazardous alcohol consumption, which student health care centers across Sweden have routinely administerd to all students during the past decade. The second *Alcohol Email Assessment and Feedback Study Dismantling Effectiveness for University Students* (AMADEUS-2) trial aimed to assess the effect of the eSBI on alcohol consumption among students who were harmful and hazardous drinkers. A two-arm randomized controlled trial design was employed, randomizing eligible participants to either a waiting list or direct access to an eSBI. Follow-up assessments were conducted 2 months after randomization. Subsequent analysis of the trial followed the conventional null hypothesis approach, and no statistical significance was found between groups at follow-up with respect to the number of standard drinks consumed weekly. However, in an unspecified sensitivity analysis, it was discovered that removing three potential outliers made the difference between the groups significant.

Objective: The objective of this study is to reperform the primary and sensitivity analysis of the AMADEUS-2 trial using a Bayesian framework and to compare the results with those of the original analysis.

Methods: The same regression models used in the original analysis were employed in this reanalysis (negative binomial regression). Model parameters were given uniform priors. Markov chain Monte Carlo was used for Bayesian inference, and posterior probabilities were calculated for prespecified thresholds of interest.

Results: Null hypothesis tests did not identify a statistically significant difference between the intervention and control groups, potentially due to a few extreme data points. The Bayesian analysis indicated a 93.6% probability that there was a difference in grams of alcohol consumed at follow-up between the intervention and control groups and a 71.5% probability that the incidence rate ratio was <0.96. Posterior probabilities increased when excluding three potential outliers, yet such post hoc analyses were not necessary to show the preference toward offering an eSBI to harmful and hazardous drinkers among university students.

Conclusions: The null hypothesis framework relies on point estimates of parameters. *P* values can therefore swing heavily, depending on a single or few data points alone, casting doubt on the value of the analysis. Bayesian analysis results in a distribution over parameter values and is therefore less sensitive to outliers and extreme values. Results from analyses of trials of interventions where small-to-modest effect sizes are expected can be more robust in a Bayesian framework, making this a potentially better approach for analyzing digital health research data.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN) 02335307; http://www.isrctn.com/ISRCTN02335307

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KEYWORDS

Bayesian analysis; telemedicine; digital health; internet interventions; alcohol; randomized controlled trial

Introduction

Background

During the past decade, student health care centers across Sweden have routinely invited all students they serve to complete an electronic screening and brief intervention (eSBI) targeting harmful and hazardous alcohol consumption. Students are, on a yearly basis, invited via email to complete a 10-item questionnaire, after which they are given personal feedback alongside some advice on behavior change. The evidence for eSBIs generally indicates that they may have a small, yet positive effect on the amount of alcohol consumed in the short term (Cohen d=−0.17, 95% CI −0.27 to −0.18 [1]; Cohen d=−0.14, 95% CI −0.24 to −0.03 [2]) and the weighted mean difference of alcohol in grams (−16.59, 95% CI −23.70 to −9.48 [3]).

In 2011, the first *Alcohol Email Assessment and Feedback Study Dismantling Effectiveness for University Students* (AMADEUS-1) trial aimed to investigate the effect of this routine practice. An unconventional study design was used to target both treatment and non–treatment-seeking individuals as well as to mask trial participation and allow for baseline assessment effects to be measured. The trial, reported originally in 2013 [4-6], identified a small reduction in alcohol consumption and risky drinking among those who had been invited to assess their consumption compared to a no-contact control. A Bayesian reanalysis of the AMADEUS-1 trial has also been reported [7].

The unconventional trial design employed in the AMADEUS-1 trial necessitated inclusion of many individuals at follow-up who had decided not to complete the baseline assessment, as well as of nonharmful drinkers and abstainers. This prompted the AMADEUS-2 trial [8,9], which aimed to assess the effect of an eSBI on harmful and hazardous drinking among students.

AMADEUS-2

The AMADEUS-2 trial [8,9] followed a more conventional two-arm randomized controlled trial design than did its predecessor AMADEUS-1. In March 2013, students in semesters 2, 4, and 6 at 9 colleges and universities in Sweden were sent an email (n=54,507) with an invitation to answer a single screening question regarding their alcohol consumption. The third item of the Alcohol Use Disorders Identification Test [10], which asks about the frequency of heavy episodic drinking, was used to screen participants for inclusion. Students were eligible if they had consumed at least four (female) or five (male) standard drinks twice a month or more often on a single occasion in the past 3 months. One standard drink is in Sweden defined as 12 grams of alcohol.

Eligible students who gave consent to take part in the trial were randomized into two groups: intervention and control. The intervention group was offered an eSBI immediately after randomization. They were asked to complete a 10-item questionnaire, which assessed their current consumption, after which they received feedback on their responses, including graphical representations of their current risk level, normative comparison with other students, and personal advice on how to reduce one’s consumption. The control group was told that they would receive the intervention in 2 months.

At follow-up, 2 months after the initial invitation, both groups were sent identical emails with an invitation to participate in the follow-up survey. The survey consisted of the same questionnaire and feedback that was offered to the intervention group at baseline.

Concerns over the (Mis)use of *P* values

In 2017, Benjamin et al [11] (signed by 71 authors) recommended that the conventional threshold used for determining statistical significance should be lowered from .05 to .005. This recommendation was motivated by a growing concern that scientific findings are becoming less credible. Furthermore, the authors recommended that findings with *P* values between .05 and .005 should be considered suggestive evidence rather than being outright rejected.

This recommendation met critique, as others believed that trichotomization of evidence does not solve the issue of P-hacking, selective reporting, and publication bias [12,13]. These concerns resonate with the recent clarification from the American Statistical Association on the principles underlying *P* value reporting [14], Nuzzo’s summary in Nature [15], and a series of articles in the Journal of the American Statistical Association [16-20].

One approach that could potentially replace the *P* value dichotomization is the use of Bayesian inference, where evidence is considered as a continuous entity [21-25]. For this reason, the *Journal of Medical Internet Research* is inviting submissions to a special issue where authors are asked to reanalyze data from previous trials using a Bayesian framework and compare the analytical results with those of the original *P* value.

Objective

The primary outcome in the AMADEUS-2 trial was self-reported weekly alcohol consumption at the 2-month follow-up. The main hypothesis was that the intervention group would report a lower weekly alcohol consumption than the control group at follow-up. An unplanned sensitivity analysis was also conducted, which excluded three data points considered outliers post hoc. The objective of this study is to redo the primary and sensitivity analysis using a Bayesian framework and contrast the results with those of the original analysis.

Methods

Bayesian model

In the original analysis of the AMADEUS-2 trial, negative binomial regression was used to contrast grams of alcohol consumed per week between the intervention and control groups. The primary model was adjusted for baseline variables. The same model was used in the enclosed Bayesian analysis, with uniform priors for all model parameters. Negative binomial regression with uniform priors used to contrast grams of alcohol per week is expressed by Equation 1:

$$\text{g/week} \sim \text{NB}(r,p)$$

$$\log(r)=\theta_0 + \theta_1\text{GROUP} + \theta_2\text{SEX} + \theta_3\text{AGE} + \theta_4\text{UNIVERSITY} + \theta_5\text{HED}$$

$$\theta_{[0\text{-}5]}\sim\text{uniform}(-\infty, +\infty)$$

$$p\sim\text{uniform}(0, +\infty)$$

Equation 1 presents the full specification of the model, where HED represents the number of heavy episodes of drinking per week at baseline, that is, the initial screening question.

The primary interest was the regression coefficient θ_1 for the GROUP variable, that is, the expected difference in log count of grams of alcohol consumed between the intervention and control groups. By exponentiating this coefficient, we get the incidence rate ratio (IRR), which indicates by how much we should multiply the control group's consumption to get the intervention group's consumption. Thus, a value of exp (θ_1) lower than 1 would suggest that the grams per week consumed for the intervention group was lower than that for the control group at the time of follow-up. Informed by the original analysis, thresholds for which the marginal posterior distribution of exp (θ_1) should be inspected were chosen at 1, 0.96, and 0.92. The threshold of 1 was chosen to communicate whether offering the intervention was preferable to not doing so, and the thresholds 0.96 and 0.92 were chosen to indicate the magnitude of the difference between the two groups.

Inference

Hamiltonian Monte Carlo, a type of Markov chain Monte Carlo (MCMC) technique, was used for Bayesian inference. The model was coded using Stan (Textbox 1) and run in R with RStan version 2.16.2. The data were one-hot encoded before being passed to Stan. No transformations were made to the variables.

When using MCMC for inference, we aim to draw samples from the posterior distribution of all model parameters. These samples can then be used to calculate how probable different values of these parameters are. For each model in the enclosed analysis, 50,000 iterations were run with 25,000 warmup iterations in four chains.

Textbox 1. Stan code used for inference for the parameters of the negative binomial model described in Equation 1.

```
data {
int<lower=1> N; // Number of data items
int<lower=1> K; // Number of predictors
matrix[N,K] X;
int<lower=0> y[N]; // Response
}
parameters {
real<lower=0> phi; // Dispersion parameter
vector[K] beta;
}
model {
y ~ neg_binomial_2_log(X * beta, phi);
}
```

Ethical Approval

This study was approved by the Regional Ethical Committee in Linköping, Sweden (No. 2013/46-31).

Results

In total, 1605 eligible students agreed to take part in the trial, of which 825 were randomized to the intervention group and 780, to the control group. Two months after the initial invitation, 58% (931/1605) of trial participants completed the follow-up questionnaire.

Original Analysis: Null Hypothesis Framework

Part of the original analysis of the AMADEUS-2 trial is presented in Table 1. Null hypothesis tests were two-tailed and assessed at the .05 threshold. No statistically significant difference was found between the intervention and control groups with respect to grams of alcohol consumed per week at follow-up (*P*=.13). To clarify, if we hypothesize that the population IRR is exactly 1, then the data collected in this trial are not extraordinary, that is, the probability of seeing these data is greater than 5%. According to convention, this does not allows us to reject the hypothesis that the IRR is exactly 1. The CI identifies a span of hypotheses that cannot be rejected, given the available data. Since the span includes both hypotheses of effect and no effect, the evidence is inconclusive.

In an unplanned sensitivity analysis, data were graphically assessed for skewness (using Q-Q plots), and three potential outliers were identified (Figure 1): one in the intervention group (weekly consumption of 1044 g/week) and two in the control group (1128 g/week and 1524 g/week). These data suggest that the participants consumed over 80 standard drinks in a typical week. The difference between the groups was marginally statistically significant when these three outliers were excluded (*P* value=.049), with the intervention group on average reporting lower consumption than the control group.

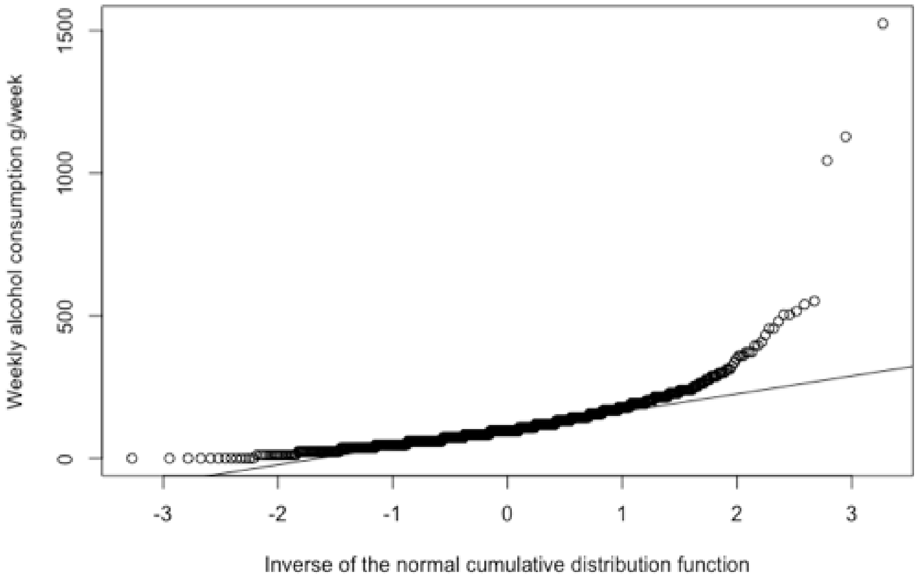
Table 1. Original analysis of grams of alcohol consumer per week at follow-up compared between the intervention and control groups. When removing three potential outliers, the difference was marginally statistically significant.

	Intervention group (n=402), mean (SD)[a]	Control group (n=529), mean (SD)[a]	Incidence rate ratio[b] (95% CI)	*P* value
Weekly alcohol consumption (g/wk)[b]	113.4 (81.1)	120.8 (86.4)	0.937 (0.861-1.019)	.13
Sensitivity analysis excluding three outliers	107.4 (73.4)	119.1 (81.3)	0.921 (0.848-1.000)	.049

[a] Mean and SD given by negative binomial regression.

[b] Incidence rate ratio given by negative binomial regression (adjusted for sex, age, university, and frequency of heavy episodic drinking at baseline).

Figure 1. Unplanned sensitivity analysis identifying three potential outliers with respect to weekly alcohol consumption.



Bayesian Analysis

We recall from our discussion in the Methods section that Equation 1 represents the coefficient for the GROUP variable, that is, the difference between the intervention and control group in terms of log count of grams of alcohol consumed per week. We get the IRR by exponentiating this coefficient. The control group’s consumption is multiplied with the IRR to get the intervention groups consumption, thus an IRR less than 1 implies that the intervention group consumed less than the control.

Histograms of the samples drawn from the posterior distribution of θ_1 during MCMC are shown in Figure 2 (exponentiated) and samples drawn when excluding the three potential outliers are depicted in Figure 3 (exponentiated). These histograms should be interpreted as visualizing how plausible different values of θ_1 are compared to one another. For instance, note how a strong majority of samples drawn were less than 1, indicating that it is more likely than not that the IRR is less than 1 when comparing the intervention and control groups. Thus, the model suggests that it is more likely than not, that the intervention group drank less than the control group.

For different IRR thresholds of interest, we can calculate the marginal posterior probability by simply counting the rate of samples that fall below or above a given threshold. In Table 2, we have calculated the marginal posterior probabilities for each of the predefined thresholds for the IRR. For instance, 17,875 samples were drawn below 0.96 when including the potential outliers (Figure 2), and we drew a total of 25,000 samples, resulting in a probability of 71.5% (17,875/25,000) that the IRR was less than 0.96.

No sampling issues during MCMC were found when inspecting trace plots (Multimedia Appendix 1).

Figure 2. Samples from the posterior distribution of θ_1 (exponentiated).

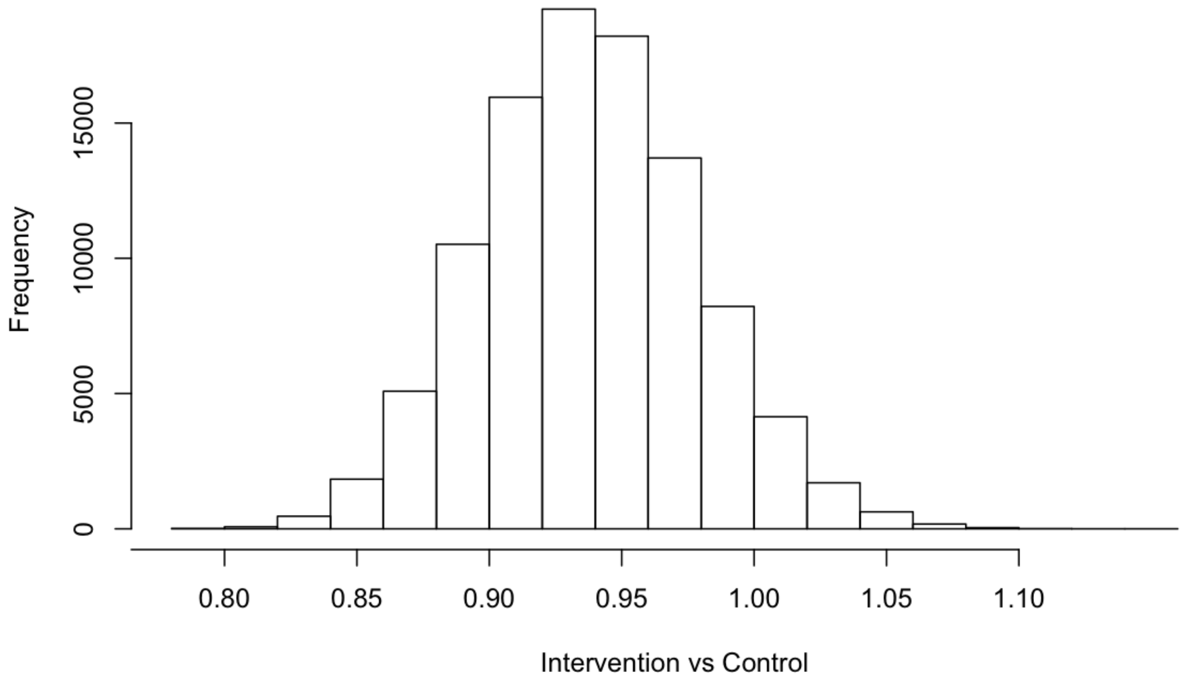


Figure 3. Samples from the posterior distribution of θ_1 (excluding three potential outliers, exponentiated).

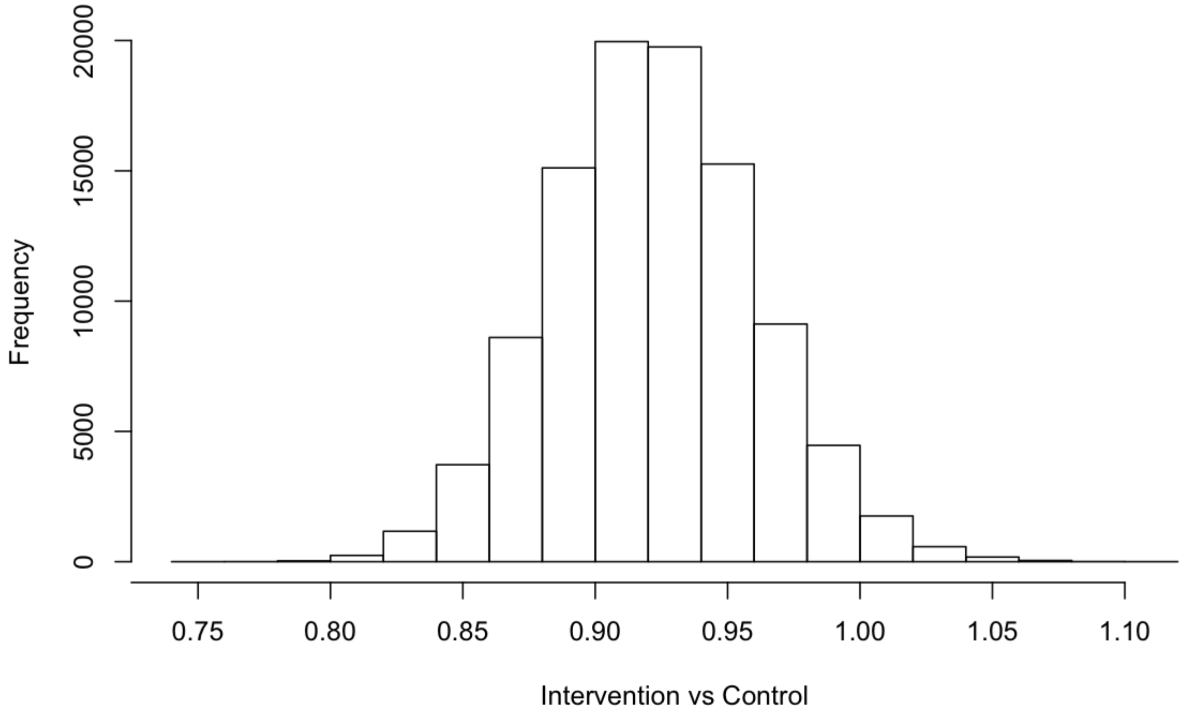


Table 2. Bayesian analysis of incidence rate ratios comparing the intervention and control groups at follow-up.

	Intervention (n=402), mean (SD)	Control (n=529), mean (SD)	Probability[a] (%)		
			Incidence rate ratio<1	Incidence rate ratio <0.96	Incidence rate ratio <0.92
Weekly alcohol consumption (g/wk)	113.4 (81.1)	120.8 (86.4)	93.6	71.5	33.9
Sensitivity analysis excluding three outliers	107.4 (73.4)	119.1 (81.3)	97.5	83.8	49.1

[a] Marginal posterior probabilities for incidence rate ratios comparing intervention and control groups, given by negative binomial regression (adjusted for sex, age university, and frequency of heavy episodic drinking at baseline, see Equation1).

Discussion

Null Hypothesis Testing

The original analysis of the AMADEUS-2 trial did not find a statistically significant difference between the intervention and control groups at follow-up (Table 2, *P* value=.13). A summary remark of the main analysis in the original publication was stated as follows [9]:

> *The study found no strong evidence of short-term effectiveness of the Swedish national system of proactive online alcohol intervention for university and college students. However, inspection of the confidence intervals for the primary outcome reveals that this study does not rule out an intervention effect of up to 13% reduction in total weekly alcohol consumption.*

Thus, dichotomization leads us into a state of uncertainty: We cannot rule out that the intervention had no effect, yet we cannot conclude that the intervention had an effect.

The unplanned sensitivity analysis excluding outliers identified a marginally statistically significant difference; however, such unspecified analyses should be viewed with skepticism. It is generally impossible to know which data points should be considered correct, which are data entry errors, and which are malicious entries.

Although not included in the original analysis, we calculated the *P* value when excluding only the most extreme potential outlier (1524 g/week) and found that the difference between groups was then statistically significant with a *P* value of .04 (down from .13). The null hypothesis testing framework, and, in particular, *P* values, rely on point estimates of difference, that is, single values that are supposed to summarize the data. Such point estimates can be highly sensitive to single data points. Considering that policy decisions might be made based on this type of trial, we should feel uneasy knowing that statistical significance in a data set of 931 entries may rely on a single or a few study participants alone.

Bayesian Analysis

The Bayesian analysis of the AMADEUS-2 trial (Figures 2 and 3, Table 2) suggests that that there is a 93.6% probability that the intervention group consumed less alcohol than the control group at follow-up in terms of the IRR. The data also suggest that the IRR was more likely than not to be less than 0.96. We may conclude that this difference is due to a positive effect of engaging in an eSBI, and this conclusion is licensed by the randomization component of the trial. However, the difference in point estimates of mean weekly alcohol consumption was approximately 7 grams between the intervention and control groups, suggesting that the eSBI had a lower mean effect than has been synthesized in meta-analyses [1-3].

When excluding the three entries with extreme levels of consumption, the probability of a difference increases. However, the difference is not extreme, partially because we are not relying on dichotomization, but mainly because in a Bayesian framework we look at the entire posterior distribution of parameters, rather than point estimates. The major benefit here is that we do not feel obligated to remove the potential outliers at all. Since analyses where outliers have been removed should be viewed with high skepticism, we can keep them in our data analysis while still obtaining similar results.

The posterior probabilities in Table 2 should be the basis for policy decision and be viewed in light of other factors, including alternative interventions and costs. The national system in Sweden used by the majority of student health care centers allows for eSBIs to reach tens of thousands of university students each year; however, the costs have been kept low by sharing a common platform. Given the high reach of the intervention and its low cost, there is a >90% probability of a positive effect in the trial, which may convince policy makers that the system should see continued use; however, this reasoning could not be established within the null hypothesis framework, since the evidence was found to be inconclusive.

Limitations

The AMADEUS-2 trial was not sufficiently powered to obtain the prespecified effect size considered worth investigation. Approximately one quarter of the target sample size was recruited, creating a limitation on the possibility of detecting significant effect sizes. This also creates a limit for the Bayesian analysis, as the width of the posterior distribution, in general, decreases as the number of samples increase, allowing for narrower posterior distributions.

All analyses were performed under the intention-to-treat principle with complete cases, which assumes that data are missing at random. Although attrition analyses in the original publication did not find evidence against data missing at random, there was a difference in follow-up rates between the intervention group (404/825, 49.0%) and the control group (529/780, 67.8%), which should temper any strong conclusions from the original analysis and this reanalysis.

Finally, subjective measures were used to collect data at baseline and follow-up, which requires participants to recall their alcohol consumption in a typical week. Although such measurements may be subject to several sources of bias, such as recall and social desirability bias, it is the norm in brief interventions to use subjective measures, as in most cases, it is infeasible to collect biomarker data.

Conclusions

The use of null hypothesis testing with *P* values has been the target for criticism for some time, not least due to the prevalent misinterpretation of *P* values and CIs [11,12,15-21]. Yet, the praxis stubbornly persists.

In the original publication of the AMADEUS-2 trial, it was acknowledged that it is challenging to reliably detect small effects and that the process may be subject to chance. Digital lifestyle interventions targeting large and sometimes non–treatment-seeking populations are generally expected to have a small-to-modest effect. Basing policy decisions on *P* values that may be highly sensitive to single data points may not be the most reliable way of deciding which evidence-based interventions should be recommended to the public.

Conflicts of Interest

MB owns a private company that develops and distributes evidence-based lifestyle interventions to be used in health care settings, including student health care centers. No other disclosures were reported.

Multimedia Appendix 1
Trace plots.
[DOCX File , 185 KB - jmir_v21i12e14420_app1.docx]

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Abbreviations

AMADEUS: Alcohol Email Assessment and Feedback Study Dismantling Effectiveness for University Students
eSBI: electronic screening and brief intervention
IRR: incidence rate ratio
MCMC: Markov chain Monte Carlo

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Corrigenda and Addenda

Correction: The Association Between Medication Adherence for Chronic Conditions and Digital Health Activity Tracking: Retrospective Analysis

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Related Article:

Correction of: https://www.jmir.org/2019/3/e11486/

(J Med Internet Res 2019;21(12):e17375) doi:10.2196/17375

In “The Association Between Medication Adherence for Chronic Conditions and Digital Health Activity Tracking: Retrospective Analysis” (J Med Internet Res 2019;21(3):e11486), a typesetting issue resulted in an error in Table 2 in the row “Comorbid conditions, n (%)”, subrow “Depression”.

The data was previously listed as follows:

- “Diabetes” column: 29,655 (9.35)
- “Dyslipidemia” column: 78,035 (11.59)
- “Hypertension” column: no data

However, the row was missing the value that should have been in the “Diabetes” column, so the two subsequent data points were misaligned into incorrect columns. The row now appears as follows:

- “Depression” column: 12,085 (10.26)
- “Dyslipidemia” column: 29,655 (9.35)
- “Hypertension” column: 78,035 (11.59)

The correction will appear in the online version of the paper on the JMIR website on December 10, 2019, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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