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Contents

Review

Original Papers

Review

The Use of the Personal Digital Assistant (PDA) Among Personnel and Students in Health Care: A Review

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Abstract

Background: Health care personnel need access to updated information anywhere and at any time, and a Personal Digital Assistant (PDA) has the potential to meet these requirements. A PDA is a mobile tool which has been employed widely for various purposes in health care practice, and the level of its use is expected to increase. Loaded with suitable functions and software applications, a PDA might qualify as the tool that personnel and students in health care need. In Sweden today, despite its leadership role in mobile technologies, PDAs are not commonly used, and there is a lack of suitable functions and software applications.

Objective: The aim of the present review was to obtain an overview of existing research on the use of PDAs among personnel and students in health care.

Methods: The literature search included original peer-reviewed research articles written in English and published from 1996 to 2008. All study designs were considered for inclusion. We excluded reviews and studies focusing on the use of PDAs in classroom situations. From March 2006 to the last update in May 2008, we searched PubMed, CINAHL, Cochrane, IngentaConnect, and a local search engine (ELIN@Kalmar). We conducted a content analysis, using Nielsen's Model of System Acceptability as a theoretical framework in structuring and presenting the results.

Results: From the 900 references initially screened, 172 articles were selected and critically assessed until 48 articles remained. The majority originated in North-America (USA: n=24, Canada: n=11). The categories which emerged from our content analysis coincided to a certain extent to Nielsen's Model of System Acceptability (social and practical acceptability), including usefulness (utility and usability) subcategories such as learnability, efficiency, errors, and satisfaction. The studies showed that health care personnel and students used PDAs in patient care with varied frequency. Most of the users were physicians. There is some evidence that the use of a PDA in health care settings might improve decision-making, reduce the numbers of medical errors, and enhance learning for both students and professionals, but the evidence is not strong, with most studies being descriptive, and only 6 randomized controlled trials. Several special software programs have been created and tested for PDAs, and a wide range of situations for their use have been reported for different patient groups. Drug and medical information were commonly accessed by PDA users, and the PDA was often viewed as the preferred tool when compared to paper-based documents. Some users regarded the PDA easy to operate, while others found it difficult in the beginning.

Conclusions: This overview of the use of PDAs revealed a positive attitude towards the PDA, which was regarded as a feasible and convenient tool. The possibility of immediate access to medical information has the potential to improve patient care. The PDA seems to be a valuable tool for personnel and students in health care, but there is a need for further intervention studies, randomized controlled trials, action research, and studies with various health care groups in order to identify its appropriate functions and software applications.

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KEYWORDS

Informatics; medical informatics; computers, handheld; health personnel; students, health occupations; personal digital assistant

Introduction

The use of modern technology in health care is exploding. Various technological tools are supposed to make health care more effective and secure, to provide appropriate information, and to make it available on a just-in-time basis. Patient security, quality of care, and accessibility to health care are supposed to be improved through the use of technology of various kinds [1]. Access to up-to-date information may be required anywhere and at any time [2], and Information Communication Technology (ICT) is supposed to facilitate decision-making by supporting health care personnel and students [3].

The potential to improve organizations and make them more effective by means of ICT stands in contrast to its limited use. As regards ICT development in Sweden, the National High-Level Group for e-Health [1] has come to an agreement on establishing cooperation nationwide. User-friendly ICT systems aim to provide more time for health care personnel to spend with patients. Today, ICT is used in all areas of health care for various purposes and in various ways, but even more efficient usability is needed. The use of ICT could be facilitated by making it more user-friendly and thus simplifying the daily routines of health care personnel, an objective that could be met by the PDA [1].

The PDA is a very small and portable, handheld computer, which has many more functions than a calculator, and the capacity to store information much like a Personal Computer (PC) [4]. Basic functionality available on most PDAs includes an address book, schedule, calendar, note pad, and e-mail [5]. The PDA is convenient to use in clinical and field situations for quick data management, and the information can be synchronized with a PC [4,6]. By means of a wireless network, information can be exchanged anytime from anywhere to and from a PDA [6], and the network will provide immediate access to all kinds of necessary clinical and administrative data [5]. “PDA” is used as a generic name for all handheld computers in our review.

Previous medical and health care reviews have summarized the research covering the use of PDAs [2,5], including adoption and barriers [7,8]. PDAs have been employed widely in health care practice, and the level of their use is expected to increase. The PDA is mainly a functional tool, but it is also associated with barriers like insufficient security and technical support [8]. Health care professionals need access to information several times a day, and the PDA has the potential to provide this. For the PDA, there are numerous documents and medical software applications available, with a wide variation in quality [5]. A large number of medical students take advantage of the PDA for educational purposes and patient care with great satisfaction [9]. If loaded with suitable functions and software applications, the PDA might meet the need for having access to up-to-date information on a just-in-time basis, thus making the PDA a qualified support tool for personnel and students in health care. In Sweden today, PDAs are not commonly used by personnel and students in health care, and there is a lack of suitable functionality and software applications designed for PDAs. The aim of the present review was to obtain an overview of existing research on the use of PDAs among personnel and students in health care.

Methods

A literature search was conducted from March to June 2006, followed by a second search in May 2007, and a third in May 2008, using the following search engines and databases: PubMed, CINAHL, Cochrane, IngentaConnect, and a local search engine named (ELIN@Kalmar). The search terms were similar but adapted according to the nomenclature of the specific databases/search engines (Table 1). Further articles were identified from reference lists in the retrieved articles. We included original, peer-reviewed research articles written in English and published from 1996 to 2008. Review articles and studies focusing the use of PDAs in classroom situations were excluded.

Table 1. Literature search—search terms and relevant reference titles

Literature search	Search terms	Relevant reference titles
PubMed	Search was done with Medical Subject Headings (MeSH) and with the text words computers handheld, PDA, personal digital assistant, microcomputers, handheld computers, computers, handheld, mini computers, pocket PC and palm pilot, single and combined with nurse, nursing, medicine, physicians, healthcare, healthcare personnel, health personnel or students	193
CINAHL	Search was done with Subject Headings computers-hand-held, computers-portable, microcomputers and health-personnel, nurses, physicians, students, interns-and-residents	163
Cochrane	Search was done with Medical Subject Headings (MeSH) minicomputers, microcomputers including computers-handheld and with the text words handheld-computer, PDA, microcomputer, minicomputer, mobile-device, health, care	56
(ELIN@Kalmar)	Search was done with the text words handheld-computer, mobile-device, minicomputer, microcomputer, PDA, health, care	49
IngentaConnect	Search was done with the text wFords handheld-computer, PD and, health-care	5
Reference lists		5
Total relevant references (before excluding duplicates)		**471**
./. Duplicates		**135**
Relevant references (after excluding duplicates) for abstract screening		**336**
Included references		**48**

The selection of articles was performed in several steps. The number of potentially relevant publications identified was over 900 of which 471 seemed relevant and, after excluding 135 duplicates, 336 remained. After reading available abstracts from those 336 references, 164 were excluded as not being relevant (ie, not original, peer-reviewed research articles or not meeting the aim and/or inclusion criteria), and 172 articles remained. After reading 172 full-text articles, 127 were then excluded as not meeting the aim and/or inclusion criteria and not meeting high or medium values in quality assessment (Table 2). The articles were reviewed independently by two of the authors (AL and PJ). Disagreements were resolved and a consensus was obtained. Of the 336 articles primarily found, 48 articles remained, the adequacy of which was checked by two of the authors (BIS and GN). The 48 articles were included in the present review, 43 from the database search and an additional 5 from the reference lists.

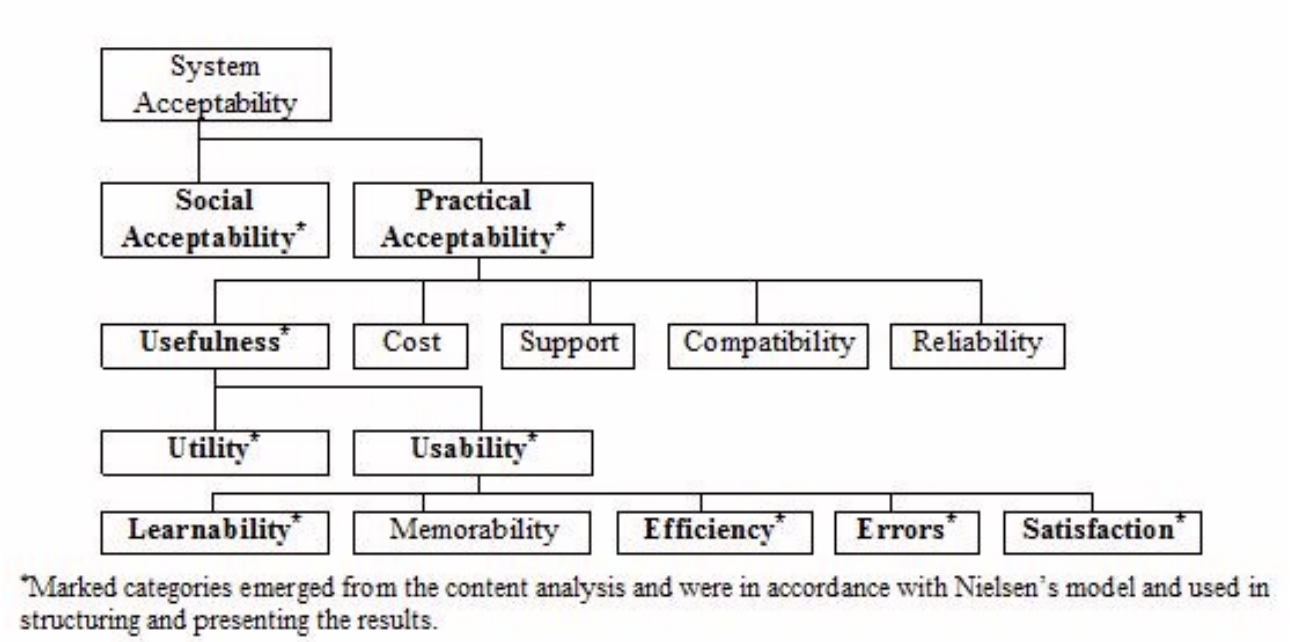
A content analysis inspired by Burnard [11] was performed and the categories which emerged were: social acceptability, practical acceptability, usefulness, utility, usability, learnability, efficiency, errors, and satisfaction. These categories coincided to a certain extent with Nielsen's Model of System Acceptability (see Figure 1). The model was used as a theoretical framework in providing a structure to present the results. The remaining categories in Nielsen's model: system acceptability, cost, support, compatibility, reliability, and memorability were not in agreement with our content analysis and, accordingly, were not used.

Table 2. Criteria for quality assessment, based on the criteria for quality assessment from the Swedish Council on Technology Assessment in Health Care (SBU) [10]

Design*	I=High	II=Medium	III=Low
RCT	Large and well accomplished multi-center study with sufficient descriptions of protocol, material, and methods. Enough sample size to answer the questions at issue.	neither high nor low	Sample size too small and/or too many interventions to give enough statistical power. Indistinctly described and high participant drop-out rate.
CCT	Well defined questions at issue, sufficient sample size and adequate statistics.	neither high nor low	Small sample size and questionable statistical methods.
DS	Large and well defined consecutive sample analyzed with adequate statistics, long follow-up.	neither high nor low	Small sample size, indistinctly described, follow-up too short, or inadequate statistics.
Q	Well defined questions at issue. Relevant and well described selection, data collection, and analysis. Logically and understandable interpretations and conclusions. Good communicability and conclusions.	neither high nor low	Insufficiently defined questions at issue, selection indistinctly described. Insufficiently described data collection, analysis, interpretations, and conclusions. Indistinct communicability and conclusions.

*RCT = randomized controlled trial, CCT=quasi controlled trial, DS=descriptive study, Q=qualitative study.

Figure 1. Model of System Acceptability (modified from Nielsen[12])



System acceptability is essentially the question of whether the system is good enough to satisfy all the needs and requirements of the users. The acceptability of a computer system is a combination of social and practical acceptability [12]. *Social acceptability* refers to how well a system complies with societal needs such as ethics and legality [12,13]. *Practical acceptability* is determined by usefulness and a number of more traditional attributes such as cost, reliability, and compatibility with existing systems. The *usefulness* category describes whether the system can be used to achieve the desired goals and is further divided into the categories of *utility* and *usability*. Utility refers to whether the functionality of the system can do what is needed, and usability applies to all aspects of a system with which a user may interact, being a question of how well a user can make use of its functionality. Usability has many components and is traditionally divided into 5 key attributes: *learnability*, *efficiency*, *memorability*, *errors*, and *satisfaction*. Learnability implies that the system should be easy to learn and that a user is rapidly able to begin working with the system. If it is efficient, the system should lead to the possibility of high productivity. Memorability in turn means that the system should be easy to remember. The system should have a low error rate and, finally, it should leave users with a feeling of satisfaction [12].

Results

Included Articles

The articles included (n=48, see Methods section) were published between 1999 and 2008. They originated from the United States (n=24), Canada (n=11), the United Kingdom (n=4), Hong Kong (n=3), Australia (n=1), Germany (n=1), Norway (n=1), South Korea (n=1), Sweden (n=1), and Taiwan (n=1). A variety of health care personnel and students participated in the studies, mostly physicians and medical students. The research methods varied, with most studies being descriptive and only a few (n = 6) involving randomized controlled trials. The number of participants in the articles varied from 3 to 1185, and the response rate ranged from 24 to 100% (Table 3).

Table 3. Articles included in present review (% = response rate)

Authors	Aim	Participants	Methods	Results/conclusions
Ammenwerth et al (2000) [14] Germany	Evaluate the prototype "a multi-functional mobile information and communication assistant".	Physicians n=19, nurses n=10, others n=2	One week simulation study, interviews and questionnaires	Participants found needs for mobile computer implementation in clinical routine.
Aziz et al (2005) [15] UK	Test if a PDA with built-in mobile telephone is more efficient in facilitating communication between health care providers than a hospital pager device.	Surgical physicians n=9	Intervention crossover pilot study, questionnaire	Physicians equipped with a PDA rather than a pager, responded more quickly to a call and had a lower of failure to respond rate.
Barrett et al (2004) [16] USA	Evaluate PDA use and what advantages and disadvantages a PDA have.	Residents n=88 (40%)	Descriptive study, questionnaire and follow-up interviews	Most residents use PDA daily. The use included commercial medical references and personal organization software.
Berglund et al (2007) [17] Sweden	Describe nurses and nurse students demands of functions and usability in a PDA	Nurses n=12, nurse students n=84 (75%)	Descriptive study, questionnaire and interviews	With a PDA, the nurses and nurse students expect access to information about the patients, knowledge resources and functions for their daily work.
Berner et al (2006) [18] UK	Evaluate the effectiveness of a PDA-based clinical decision support system (CDSS) on no steroidal anti-inflammatory drug (NSAID) prescribing safety.	Residents n=68	Randomized controlled trial	Participants provided with a PDA-based CDSS for NSAID prescribing made fewer unsafe treatment decisions than them without.
Bird & Lane (2006) [19] USA	Determine whether use of a PDA would improve emergency medicine documentation of procedures and patient resuscitations.	Emergency medicine residents (n=35)	PDA procedure were compared with paper-based	Sedation, thoracentesis, and ultrasound documentation significantly increased with PDA vs handwritings.
Bosma et al (2003) [20] Canada	Assess point-of-care use of PDA in patient consultation management for Intravenous Resource Nurse team (IVRN) consultant service.	Nurses n=5	Intervention study	Team members adopted the new technology with few problems and the service can now efficiently be analyzed.
Brilla & Wartenberg (2004) [21] USA	Examine the success of intervention of PDAs by comparing PDA use and user attitudes between residents of intervention group and residents in control group.	Neurology residents n=26	Intervention study with control group, structured interviews	Applications most often used were the address book and drug databases. Their use was higher in the intervention group.
Carroll & Christakis (2004) [22] USA	Determine the percentage of paediatricians using PDAs and computers, as well as the perceived strengths and weaknesses of PDAs.	Paediatricians n=1185 (63%)	Randomized selected descriptive study, questionnaire	35% currently used PDA in work. Most commonly used functions were drug reference, scheduling and medical calculations.
Chan et al (2004) [23] Hong Kong	Evaluate use of an electronic barcode system in PDA for patient identification during blood transfusion.	41,000 blood samplings	Retrospective study	No incidents of blood transfusion to wrong patients, or wrong labelling of blood samples occurred.
Chang et al (2004) [24] Taiwan	Develop PDA support systems for mass gatherings and evaluate ease of use and usefulness.	Nurses n=23, physicians n=6	5 simulated Patients' profiles were tested and evaluated, questionnaire	The PDA system included many information items and was easy to use and useful for mass gatherings.
Choi et al (2004) [25] South Korea	Evaluate the PDA system MobileNurse.	Nurses n=6	1 day caring for simulated patients was evaluated, questionnaire	Most nurses agreed that MobileNurse was helpful and convenient.
Criswell & Parchman (2002) [26] USA	Evaluate the uses of handheld computers in family practice residency programs in the United States.	Directors n=306 (50%)	Descriptive study, questionnaire	Two thirds of the education programs used PDAs in their residencies.
Dee et al (2005) [27] USA	Examined how frequent attending physicians and physicians in training used PDAs for patient care.	Physicians, physicians in training n=108	Descriptive study, questionnaire	87% reported PDA use for patient encounters 55% reported frequent, use for patient care.

Authors	Aim	Participants	Methods	Results/conclusions
De Groote & Doransk (2004) [28] USA	Determine PDA use on an academic health sciences campus to define the level of training and support the library can provide.	Faculty n=216, medical residents n=124, others n=12 (24%)	Descriptive study, questionnaire	61% of respondents used PDAs. Address book, date book, and calculator were the most commonly used.
Doran et al (2007) [29] Canada	Develop an electronic information gathering and dissemination system to support both nursing-sensitive outcomes data collection and evidence-based decision-making at the point-of care.	Nurses n=51	Cross-sectional study, work sampling, and focus group interviews	Most priorities were information concerning vital signs, drug information, and manuals of policies and procedures.
Farrell & Rose (2008) [30] Australia	Investigate whether the use of PDAs enhanced nursing students' pharmacological knowledge during clinical practice.	Nurse students n=76 (83%)	Quasi-experimental, questionnaire and focus group interviews	PDA users show a higher mean score compared to the control group. The PDA was easy to use and students perceived its use as beneficial to their clinical learning.
Fischer et al (2002) [31] Canada	Evaluate the feasibility of incorporating handheld computing technology in a surgical residency program.	Residents n=69	Intervention study, questionnaire	After a 5-month pilot period, 38% of surgical residents were using the procedure-logging program successfully.
Galt et al (2005) [32] USA	Compare drug information sources for PDAs, to minimize medication errors.	General practice physicians n=3	Questionnaire	Lexi-Drugs were found to be the most specific and complete PDA resource.
Gandsas et al (2004) [33] USA	Compare the ability of surgical residents to identify anatomical structures displayed on a standard monitor versus a PDA screen.	Surgical residents n=23	Randomized crossover study, questionnaire	The differences between what's displayed on a standard monitor vs a PDA screen were not significant.
Garrett & Jackson (2006) [34] Canada	Design, implement, and evaluate a PDA-based e-portfolio tool to support reflective learning in practice.	Nursing students n=6, medical students n=4	Intervention study, questionnaire and focus groups interview	There were positive attitudes to the use of PDA-based tool.
Goldsworthy et al (2006) [35] Canada	Examine the relationships between the use of PDA and self-efficiency.	Nursing students n=36	Randomized controlled trial	Findings showed a significant increase in self-efficacy in the groups with PDAs.
Greenfield (2007) [36] USA	Determine whether nursing medication errors could be reduced and nursing care provided more efficiently using PDA technology.	Nurse student n=87 (64%)	Non-randomized quasi-experimental study	Results for accuracy and speed were significantly higher in the PDA group than in the control group.
Greiver et al (2005) [37] Canada	Explore whether diagnostic software in the PDA would improve care for suspect angina.	Family physicians n=18	Randomized controlled pilot trial	A PDA-based software application can lead to improved care for patients with suspect angina.
Honeybourne et al (2006) [38] UK	Study impact of PDA on patient care to identify how often and which resources were used, as well as barriers to use in patient care.	Clinical and library staff phase I n=9, phase II n=12	Intervention study, questionnaire	Participants used PDA in clinical setting to support evidence-based practice and education.
Johnson et al (2004) [39] USA	Describe user acceptance of a suite of programs that deliver information to clinicians' PDAs.	Faculty, health care personnel n=16	Descriptive study, questionnaire	Most users reported that they learned about new medical developments sooner than they otherwise would have.
Johnstone et al (2004) [40] Hong Kong	Evaluate the usefulness and acceptability of PDAs loaded with clinical decision software.	Medical students n=169	Randomized controlled trial, questionnaire, and focus group interviews	The students found the PDA useful. They were less satisfied with the functional features.
Kneebone et al (2003) [41] UK	Describe the use of PDAs in scenario-based clinical procedural skills.	Nursing students, tutors and simulated patients n=25	Evaluation of a PDA-based rating form, observations, and focus group interviews	The PDA forms were easy to use. There were potentially significant advantages over paper-based versions.

Authors	Aim	Participants	Methods	Results/conclusions
Kushniruk et al (2005) [42] USA	Explore the relationship between system usability and medical errors.	Physicians n=10	Video and audio recorded PDA interactions	Certain types of usability problems were closely associated with the occurrence of specific types of errors in prescription of medications.
Lapinsky et al (2001) [43] Canada	Evaluate benefits and drawbacks associated with introducing PDA technology in an intensive-care unit.	ICU team with physicians n=20, paramedical staff n=6	Intervention study, scenario tests comparing PDA and paper textbook	PDAs were found to be convenient and functional, but more comprehensive training and improved searching capability were suggested.
Lau et al (2006) [44] Canada	Understand the current patterns of PDA use among physicians working in palliative medicine.	Physicians n=72	Descriptive study, questionnaire	The PDA was mostly used to organize a practice and look up medical references. Some used it in patient care.
Leung et al (2003) [45] Hong Kong	Test if a PDA could improve learning in evidence-based medicine.	Medical students n=169	Randomized controlled trial	The PDA improved participants' educational experience with evidence-based medicine benefiting the most.
Lu et al (2003) [46] USA	Identify the barriers that impede physicians' PDA use.	Physicians n=20	Descriptive study, interview	Four barriers were identified: organization, usability, inadequate technology support or access, and lack of need or motivation.
McAlearney et al (2004) [57] USA	Examine physician's perspectives about their experiences with PDAs in clinical practice.	Physicians n=54	Qualitative study, focus groups interview	Users seemed generally satisfied, the device helped them increase productivity and improve patient care.
McLeod et al (2003) [47] USA	Investigate PDA use in medical settings, use prevalence, user demo-graphic, and hardware preferences.	Physicians, medical students n=473 (55 %)	Descriptive study, questionnaire	Medical students reported more frequent PDA use in hospital settings and for direct patient care than physicians.
Mihailidis et al (2006) [48] Canada	Determine what assistive computing device features and functions nurses need.	Nurses n=20	Descriptive pilot study, questionnaire	Data analysis revealed a strong desire to facilitate information access and administer safe medication.
Morris et al (2007) [49] USA	Understand resident and faculty PDA use and training.	Physicians and n=410 (69%)	Multi-center, questionnaire	Use of PDAs was common. Common barriers were lack of time, knowledge, and formal education.
Murphy et al (2006) [50] Canada	Determine the frequency of use, usefulness, accessibility, and credibility of PDA, computer, and print drug information resources.	Nurses n=14, physicians n=13 (75%)	Descriptive study, questionnaire	The use of PDAs and computers remains limited. Education for users may facilitate future computer and PDA use.
Pattillo et al (2007) [51] USA	Identify nursing students' use of PDAs and compare and contrast the frequency of user resources with comparable text resources.	Nursing students n=90	Intervention study, with control group, questionnaire	The nursing students used their PDAs to look up words and unfamiliar terms, drugs, and the meaning of laboratory values.
Price (2005) [52] Canada	Examine whether using Palm Prevention improved adherence to 5 preventive measures in primary care.	General practitioners n=8	Randomized controlled trial (pilot study)	The guidelines in PDA increased screening.
Ranson et al (2007) [53] USA	Understand how physicians use PDAs in their clinical practice and describe how they use a PDA learning portfolio.	Physicians n=10	Literature review and a case study	Information for clinical decisions, patient education and teaching was used and the use was associated with the value of information.
Rothschild et al (2002) [54] USA	Evaluate the clinical contribution of a drug database, usage patterns, decision making etc.	Physicians n=703, medical students n=243 (32%)	Descriptive study, questionnaire	Physicians reported time saving during information retrieval and improves decision making.
Rudkin et al (2006) [55] USA	Assess feasibility of PDA.	Residents n=18, medicine attending n=12	Prospective cross-over time-motion study.	PDAs are feasible in emergency department and change management more often than texts.

Authors	Aim	Participants	Methods	Results/conclusions
Ruland (2002) [56] Norway	Evaluate nurses' use of CHOICE, a handheld, computer-based support system for preference-based care planning.	Nurses n=28, patients n=155	Intervention study, two control groups	Nurses' use of CHOICE made nursing care more consistent with patient preferences and improved patients' preference achievement.
Shiffman et al (1999) [58] USA	Evaluate physician's satisfaction and frustrations with the use of a PDA based program in asthma care.	Physicians in paediatrics n=9	Descriptive study, questionnaire	Three users gave strongly positive ratings while six users were neutral. Majority used documentation functions.
Stroud et al (2005) [59] USA	Describe the prevalence and patterns of PDA use among nurse practitioners, students, and faculty.	Nurse practitioner students, faculty n=227 (27 %)	Descriptive study, questionnaire	67% of the participants used PDAs. Use was higher among men. Most participants related that PDA use supported clinical decision making.
Teolis et al (2004) [60] USA	Determine what health professionals perceived as barriers to PDA use and how frequently participants used their PDAs for online searching.	Health care personnel n=97, others n=12	Descriptive study, questionnaire and interview	PDAs electronic information and software at point of care, users give users access to a wide variety of also experienced multiple barriers.
Yu et al (2007) [61] USA	Assess the breadth of and determine the patterns of clinical decision support (CDS) program and compare the difference in the recorded and reported PDA CDS utilization among physicians.	Physicians in training n=68 (82%)	A part of a larger study. An automatic tracking program in PDA, questionnaire	Physicians preferred to use certain PDA CDS tools in clinical settings. Drug references and medical calculator were commonly used.

Users and Situations of Use

The frequency of PDA use varied among different personnel and students in health care [16,21-23,26-28,44,47,59]. Most of the users were male [16,22,59,61], with some exceptions among students [36,47] and faculty [49]. Medical residents used PDAs more than physicians [22,31], but there were also reports of a similar frequency of use amongst the two categories [27], and some physicians used a PDA when teaching medical students [53].

Several special software programs have been created and tested for PDA use. Clinical Decision Support Software (CDSS) has been tested among medical students, and most students agreed that CDSS enhanced their learning, and they became especially fond of their access to Cochrane reviews, history, and physical examination functions [40]. The same decision tool was used by physicians when prescription of pharmaceuticals and safety were evaluated [18]. Physicians using the CDSS for prescription of non-steroidal anti-inflammatory drugs made fewer unsafe treatment decisions than those not using this software. In another study, nurses tested CHOICE, a PDA-based support system for preference-based care planning [56]. The system supported nurses in eliciting patient preferences for functional performance at bedside. Handling CHOICE made nursing care more consistent with patient preferences and improved patients' preference achievement.

A wide range of situations for use of the PDA have been reported for different patient groups. Guidelines for the management of childhood asthma exacerbations called AsthMonitor were implemented for PDAs and tested in a pilot study [58]. The program supports the documentation of clinical findings and provides guideline-based recommendations. The majority of the physicians in this study frequently applied the documentation functions and found most of the recommendations appropriate. Intelligent, triage-based, mass-gathering emergency medical service PDA support systems were tested among nurses and physicians [24]. The systems included a large number of information items. More than half of the participants perceived that the systems were useful and very easy to use. In another study, nurses used PDA software called MobileNurse which was comprised of 4 different components [25]. The first component was a medical order-checking module, which enables nurses to retrieve patient information, such as physicians' orders or test results, anywhere and at any time. The second component was a recording module, in which nursing processes at bedside could be recorded. The third component was a nursing unit care plan, and the fourth was a patient information management module by which it was possible to record patients' demographic information. The participants used the system for 1-day clinical trials, caring for simulated patients. Of those using MobileNurse, 5 of the 6 nurses regarded it to be generally helpful and convenient for checking medical orders and retrieving results of recent clinical tests at bedside [25]. In another pilot study, a software application was tested to help family physicians diagnose angina pectoris among patients with chest pain. This study found that the use of a PDA-based software application for cardiac stress-testing could lead to improved care [37]. For patient identification during a blood transfusion, the addition of an electronic barcode system was made to PDAs [23]. No incidents of blood transfusion to the wrong patients or of the wrong labelling of blood samples occurred with the 41,000 blood-sample procedure carried out during a 3-year period.

Access to Information

Access to medical reference information and databases is a widely appreciated function of PDA use. Drug and medical information were commonly retrieved by practising PDA users [14-16,19,21,22,24-26,28,30-32,34,35,38-40,43-47,49-51,53-57,59].

Nurses wanted access to drug information, medical references, patient information, medical lists, and test results on a PDA [17,29,48]. In a study of nurses, it was found that 40% of information written on "personal paper" at the point of care was later transcribed to the clinical record. Recording of vital signs and access to reference information about medications on a PDA were top priorities of nurses [29]. Medical students often used drug databases, especially for information about dosage, contraindications, and side effects, but less often for prices [21]. Faculty and health care personnel were presented with headlines about new books, guidelines, reviews, and medical literature on their PDAs [39]. They chose what they were interested in, and the information was delivered to their PDA by their next synchronization. The participants reported that they learned about new medical developments sooner than they otherwise would have and that, without the PDA, they would not have learned about them at all. One intensive-care unit installed a patient-management software program on PDAs, a program including medical reference information, schedules, and contact numbers [43]. Physicians and paramedical staff found the program convenient and functional, especially for patients who had long stays in hospital. An intravenous resource team with a consultant service introduced PDAs for statistical analysis and follow-up evaluation [20].

Social Acceptability

We identified different barriers to the PDA being socially accepted and to using a PDA at work. Nurses thought it would be a fashionable tool for those most interested in ICT. Some also believed that it would be hard to get acceptance for PDAs among older nurses and nurses that had worked for a long time in a hospital [17]. In another study, PDA use was reported to be a challenge for older physicians [53]. Other nursing students regarded the use of the PDA as rude and inconvenient [30], that the PDA was unnecessary, and that they contributed to a lack of motivation and bad experiences [46,53].

Practical Acceptability

We found that the PDA was accepted when it solved practical issues. When documents were implemented, the PDA often seemed to be a good tool, preferable to paper-based documents [15,19,41,43,55]. When logged, the PDA-based procedure was preferred and found to be more complete than the handwritten procedure [19]. Similar results were demonstrated when physicians compared electronic medical references [15]. Nursing students and faculty assessing simulated patients found the PDA easy to use when compared to paper work [41]. No difference was noted when text read on a PDA was compared to reading conventional text written on paper [43] and, likewise, when the ability for surgical physicians identifying anatomical structures displayed on a standard monitor was compared to a PDA screen [33]. However, contradictory results have also been reported. Physicians who had previously used a PDA but stopped using it reported reasons like complex and confusing software applications, lack of support, not being useful in practice, cost [44,49], and the inconvenience of carrying it [30,53].

Usefulness

In the Nielsen model [12], the category of "Usefulness" is divided into the subcategories "Utility" and "Usability" (Tables 4 and 5).

Utility

Utility refers to whether the functionality of the PDA can do what is needed [12]. In Table 4 and Table 5 under the subcategory "Utility", functions and software applications requested and used among personnel and students in health care are presented.

Usability

Usability applies to all aspects of a system with which a user may interact and is a question of how well a user can make use of the system's functionality [12]. In Table 4 and Table 5 under the subcategory "Usability", functions and software applications evaluated among personnel and students in health care are presented. "Usability" is further divided into the subcategories "learnability", "efficiency", "errors", and "satisfaction"; each of these subcategories are discussed in turn below.

Table 4. Reported usefulness as usability and utility for different functions and features of the PDA

	Utility		Usability	
Functions	Requested	Used	Evaluated	Comments
Address, phone book	[17,29]*	[14,16,21,26,28,43,44,58,59]	[14,16,21,26,28,43,44,58,59]	Valuable and commonly used
Calendar, scheduling	[29]	[16,22,26,28,34,40,43,44,46,47,49,53,57-59]	[16,22,26,28,34,40,43,44,47,49,57-59]	Commonly used
Memo pads, To Do list	[29]	[16,26,35,43,46,49,59]	[16,35,43,49,59]	Valuable
Internet access, email	[17,28,48]	[14,16,26,28,31,34,44,49,54,59]	[14,16,26,28,34,44,49,59]	Not often used
Phone	[48]	[14,15,26,34,44]	[14,15,34,44]	Improve access
Word processing	[28]	[28,30,40,45,58]	[28,30,40,45,58]	Not often used
Alarm	[17,29,48]	[46]	-	-
Camera	[17,48]	[34]	[34]	Useful
Video	[17]	[33]	[33]	Developable

*References refer to publications where the respective function was requested, used or evaluated

Table 5. Reported usefulness as usability and utility for software applications on the PDA

	Utility		Usability	
Software application	Requested	Used	Evaluated	Comments
Drug information	[17,28,29,39,48]*	[16,21,22,24,26,28,30-32,34,35,38,40,43-45,47,49-51,53-55,57,59,61]	[16,22,24,26,28,30,31,34,35,38,40,43-45,47,49-51,54,55,57,59,61]	Commonly used
Medical information	[17,28,29,39,48]	[3,14-16,19,24-26,28,30,31,34,35,38-40,44-46,49-51,53-55,59,61]	[14-16,24,26,28,30,31,34,35,38-40,44,45,49-51,54,55,59,61]	Commonly used
Guidelines	[16,29]	[37,52,53]	[37,52]	Improve care
Medical list/ orders	[17,29,48]	[25]	[25]	Helpful, reduce error
Medical calculator	[28,29,48]	[16,22,26,28,30,34,38,40,43-47,49,53,55,58,59,61]	[16,22,26,28,30,34,38,40,43,45,47,49,58,59,61]	Commonly used
Dictionaries	[17,48]	-	-	-
Patient information	[17,28,29,39,48]	[14,16,19,20,25,27,43,44,46,55,56,58]	[14,16,19,25,43,55]	Useful, convenient
Barcode identification	[48]	[23]	[23]	Reduce human errors
Test results	[17,29,48]	[14,25,51,55]	[14,25,51,55]	Convenient
Prescription	-	[18,19,22,26,40,42,45,47,57]	[18,22,26,40,42,45,47,57]	Increased safety
Billing	-	[22,26,44,46,47,53,57]	[22,26,47,57]	Not often used
Education	-	[19,26,31,35,38,40,41,45,51,53,57]	[35,38,40,41,45,51,53,57]	Preferable
Patient education	[16]	[53,57]	[53]	-
Anatomy atlas	-	[15]	-	
Statistical analysis	-	[20,31,57]	[20,31,57]	Valuable

*References refer to publications where the respective software application was requested, used or evaluated

Learnability

The PDA was associated with a fairly high degree of learnability. Practice and support could reduce problems when using a PDA. Some users regarded the tool as easy to understand, while others found it difficult in the beginning. Several technical problems were described, but after guided practice, explanations, and adequate time, many of the problems

were solved [20,22,24,31,34,38,41,46]. A majority of residents and faculty reported themselves as self-taught PDA users [49]. To optimize the technology and to overcome barriers, users of PDAs suggested that technical support should always be provided. The users requested that support be available constantly and were aware that there was more they could have accomplished with the PDA if they had sufficient knowledge [30,34,38,43,49,50,57]. There seemed to be a learning threshold at the introductory stage of PDA use. Physicians using a PDA mobile phone device preferred their traditional system, rather than having to learn how to operate a new device. However, after a 6-week trial they found the PDA mobile phone to be user-friendly and its operation easy to learn [15]. Nursing students found the PDA easy to use due to their experience and familiarity with other computers [30]. Many participants had difficulties handling the new and complex hardware and its software applications. They also had difficulty installing software applications and reported a lack of training and time to learn how to operate the PDA [14,49]. Thus, the combination of phone and PDA features may introduce a new degree of complexity for beginners [60].

Efficiency

The use of a PDA in health care settings can improve efficiency in many ways, including, for example, decision-making [27,52-55,59]. Its pocket size made the PDA easy to access, and it was considered to be a time-saving device, since it made it immediately possible to find needed information [43,51,57]. Wireless access to the Internet was also considered valuable, since users had a connection everywhere [34]. Second-year nursing students using a PDA loaded with medical software applications felt more confident and effective than peers who did not use a PDA [35]. The PDA can produce positive changes in patients' care plans [27,51,55], support physicians in medical decisions [53,54], and improve learning for medical students [45], as well as enhance learning for nursing students [51]. Evidence-based guidelines for screening were fast and easy to use at the point of care [52]. The software application of angina diagnosis in a PDA increased the use of cardiac stress-testing by family physicians [37]. Furthermore, having a handheld drug reference guide to find drug information was time-saving [54,57], and the possibility of an immediate search was useful in clinical knowledge deficits [38]. In a case study, participants using a PDA worked faster with a case than the control group [36]. Not everyone agreed that the PDA was time-saving [39,58], but it was believed that using it could lead to more efficient patient care [39]. In general, PDAs were considered to be a convenient tool; on the other hand, the PDA was not believed to decrease paperwork or improve patient health outcomes [50].

Errors

Using a PDA can reduce the number of medical errors in health care [18,22,32]. Some physicians felt that they were less likely to lose information when it was collected in their handheld tool, instead of written on paper-based index cards, guideline pamphlets, and calendars [16]. Introducing a barcode system to PDAs for patient identification during a blood transfusion was effective in reducing human errors related to bedside transfusion procedures [23]. Using a PDA-based decision support system in prescribing pharmaceuticals increased safety among PDA using physicians compared to the no-PDA control group [18]. In a case study, the accuracy was higher among nursing students using a PDA than for the control group [36].

Satisfaction

Both positive and negative attitudes toward the PDA were reported. The same aspects could be regarded as positive for some of the users and negative for others. The attitudes seemed situation-dependent. Physicians who had used a PDA found it very useful during night duty and in emergency situations, but in doctors' rounds it was found to be ineffective [14]. Its pocket size was regarded as convenient, as well as the screen size, which was large enough to be clear and easy to read [30,43,51,57]. The speed of getting information is one of its primary advantages [16]. In several studies, the small screen size was mentioned as a barrier to use [22,25,34,41,46,60], as well as its being inconvenient for viewing long documents [14,30,43] and its inability to add marginal notes [41,46].

Patient confidentiality when using a PDA was of no concern compared to using other technologies [50], and physicians had no concern about using the PDA in front of a patient [21]. Nurses and medical students who had used a PDA, both as a reference tool and multimedia technology medium, seemed to value the former in the PDA more than the built-in phone, e-mail, and camera, even though it was convenient to have them in the same tool [34]. The breadth and depth in specially created programs were not always satisfying [40,60]; information was not updated [53]; and a lack of programs was reported for health care specialities such as psychology, orthopaedic and plastic surgery, oncology, and otolaryngology [60]. Some physicians raised a concern about over-reliance on the tool [16,57]. Finally, limited memory and a short battery life were frequently mentioned barriers to use [23,38,40,46,53,57,60]. Nursing students did not find battery life to be a problem as long as they recharged the battery after each shift. To avoid a loss of data through loss of battery power, some students saved their documents to back up files rather than to the main memory [30].

Discussion

In the present study, we found the PDA to be a valuable tool for personnel and students in health care. The PDA allowed immediate and easy access to medical information that might improve patient care and the quality of health care. We found a number of areas where PDAs were used with different functions and software applications for personnel and students in health care. The main findings were that drug and medical information were accessed most often. We also identified functions that could be added and areas to be improved to take full advantage of the PDA. We hope that this overview of the use of PDAs will provide some direction for future research.

That we ended up with only 48 relevant publications after the quality assessment indicates that few original peer-reviewed research articles have been completed so far. In the articles reviewed, the research approach varied. Most studies were descriptive, and sample sizes and response rates varied. Since PDA intervention studies often entail a small sample size, due

to costs and available technical equipment, this might be accepted in our study. This includes one article with a response rate as low as 24% [28], which is a limitation; however, we chose to include that article due to its large sample size. Both the use and the research of PDAs in health care are expanding areas for study which we experienced through our updated literature searches.

The categories which emerged from our content analysis coincided to a certain extent with Nielsen's Model of System Acceptability [12]. The benefit of using Nielsen's model as a theoretical framework lies in providing a structure when presenting the results. A limitation of using Nielsen's model could be the risk of missing significant areas not fitting the model, and we did not cover all the existing categories of the model. However, the model seemed to cover all relevant aspects we found and has been used by others in health care research [62,63].

The various functions and software applications available on a PDA seem to ease the workload for health care personnel and students. Like Baumgart [5], we found that there are numerous medical software applications available for PDAs that can be used in order to improve health care. Since most hospitals are becoming more and more computerized, PDAs seem to be a good complement to stationary computers. It is our belief that to utilize fully its capabilities, the PDA needs to be integrated with hospital networks with access to, for example, patients' health care records, including patients' test results and internal memos.

The findings in the present study are not unanimous when it comes to whether or not using a PDA as a tool can save valuable time for personnel and students in health care. Some of the results from the present review are supported by Lu et al [8] who found that PDAs are time-saving for getting immediate access to drug information. Not all users think that a PDA saves time, but PDA users do believe it can deliver faster and more efficient patient care. Thus, an effective use of the tool might imply that more time can be devoted to patients.

The PDA seems to be a feasible and convenient tool, with one of its top advantages being the speed with which one can retrieve information on the spot. Accessibility to updated information can be improved when using a PDA, which provides an opportunity to check for the latest medical information in a convenient way. Access to drug and medical information might improve patient care and make it more effective and, hopefully, time-saving. In the present review, we found that PDAs improve decision-making and point toward positive changes in patient treatment, a conclusion in line with a previous review [5]. The possibility of checking medical orders and patient identification by using, for example, a PDA with a bar-code system, can reduce errors. We are convinced that there is a need for the PDA and that this is a tool for all professionals and students in health care.

Learnability concerns the ease with which one can learn to use a PDA. In the beginning, a PDA might seem to be complex and confusing hardware. To overcome barriers, the challenge is to provide the right support and to create suitable functions and software applications for various health care professionals in various specialities. In accordance with Lu et al [8], we identified several barriers and difficulties when starting to use a PDA. Most of these barriers seem to be more behavioral than technical in nature. To overcome these barriers, guided practice, explanations, and adequate training time are needed, and access to technical support is necessary. Other barriers, such as short battery life and small memory capacity, should be easily overcome by constantly expanding technology. The PDA can also improve learning for students in clinical practice and health care professionals. Participants stated in the Johnson et al study [39] that they learned about new medical developments sooner with a PDA than without one, in which case there might exist medical developments that they had not learned about at all. These important data confirm that a PDA is suitable for both students and professionals to improve learning.

It is difficult to draw definitive conclusions from the studies we reviewed. Altogether, the articles do not represent strong evidence for the benefits of using a PDA. We agree with Berglund et al [17] that a PDA has the potential to be accepted by personnel and students in health care, if the PDA meets their functional and software application needs and is user friendly. To implement fully PDAs in health care, we need more research into functions and software applications. References, mostly from the USA and including physicians and medical students, indicate that several professions are missing from PDA research, including nurses, physiotherapists, and others. Kho et al [9] confirmed that PDAs are appreciated among students, and this is important to explore in future research. Since we noticed similar findings in our own observations, and since students are increasingly requesting PDAs, it is important that functionality and software applications operate smoothly and securely when synchronized with a stationary computer; that the interface is easy to follow; and that patient data is secured. In agreement with Lu et al [8], we note that, to evaluate the effect PDAs have on the quality of medical practice, studies with larger sample sizes are needed. We argue for more research using intervention studies, randomized controlled trials, and action research. Finally, when introducing new technology in health care, there is a need for scientifically based evaluations that take into account not only the technology itself in relation to the individual, but also the organization, including context and costs.

Conflicts of Interest

None declared.

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Abbreviations

CDSS: clinical decision support software
ICT: information communication technology
PC: personal computer
PDA: personal digital assistant

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Original Paper

Development of Alive! (A Lifestyle Intervention Via Email), and Its Effect on Health-related Quality of Life, Presenteeism, and Other Behavioral Outcomes: Randomized Controlled Trial

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Abstract

Background: Cost-effective interventions to improve diet and physical activity are a public health priority. *Alive!* is an email-based intervention to increase physical activity, reduce saturated and trans fats and added sugars, and increase fruit and vegetable consumption. It was shown to improve these behaviors in a large randomized controlled trial.

Objective: (1) To describe the components and behavioral principles underlying *Alive!*, and (2) to report effects of the intervention on the secondary outcomes: health-related quality of life, presenteeism, self-efficacy, and stage of change.

Methods: The *Alive!* behavior change model is designed to elicit healthy behaviors and promote their maintenance. Behavioral strategies include assessments followed by individualized feedback, weekly goal-setting, individually tailored goals and tips, reminders, and promotion of social support. *Alive!* was tested among non-medical employees of Kaiser Permanente of Northern California, who were randomized to either the intervention group or the wait-list control group. After randomization, intervention group participants chose one topic to undertake for the intervention period: increasing physical activity, increasing fruits and vegetables, or decreasing saturated and trans fats and added sugars. Pre-post questionnaires assessed changes in SF-8 health-related quality of life, presenteeism, self-efficacy, and stage of change. Mixed effects multiple linear regression and ordinal logistic regression models were used, with department as a random effect factor. Analyses were by intention to treat: the 30% (238/787) who did not respond to the follow-up questionnaires were assigned change scores of zero.

Results: Participants were 19 to 65 years (mean 44.0 +/- 10.6), and 74.3% (585/787) were female. Mean SF-8 Physical quality of life score increased significantly more in the intervention group than in the control group, 1.84 (95% CI 0.96-2.72) vs 0.72 (95% CI -0.15-1.58) respectively, $P = .02$. SF8 Mental score also improved significantly more in the intervention group than in the control group ($P = .02$). The odds ratio for improvement in self-assessed health status was 1.57 (95% CI 1.21-2.04, $P < .001$) for the intervention group compared to the control group. The odds ratio for having a reduction in difficulty accomplishing work tasks because of physical or emotional problems, a measure of presenteeism, was 1.47 (95% CI 1.05-2.05, $P = .02$) for the intervention group compared to the control group. The odds of having an improvement in self-efficacy for changing diet was 2.05 (95% CI 1.44-2.93) for the intervention vs the control group ($P < .001$). Greater improvement in stage of change for physical activity ($P = .05$), fats ($P = .06$), and fruits/vegetables ($P = .006$) was seen in the intervention group compared to the control group. Significant effects on diet and physical activity behavior change are reported elsewhere.

Conclusions: Cost-effective methods that can reach large populations with science-based interventions are urgently needed. *Alive!* is a fully automated low-cost intervention shown to effect significant improvements in important health parameters.

Trial Registration: Clinicaltrials.gov NCT00607009; http://clinicaltrials.gov/ct2/show/NCT00607009 (Archived by WebCite at http://www.webcitation.org/5cLpCWcT6)

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KEYWORDS

Physical activity; diet; randomized controlled trial; evidence-based medicine; intervention studies; occupational health; community health services; employer health costs; health promotion; preventive health services

Introduction

The important role of diet and physical activity in reducing the burden of chronic disease and obesity is well-established [1]. Chronic diseases are responsible for 5 of the top 6 leading causes of death, as well as for decreases in quality of life. Much of the chronic disease burden is preventable [1]. Diets high in saturated and trans fats contribute substantially to coronary heart disease [2,3] and to cancers of the colon, breast, and prostate [4,5]. Low fruit and vegetable intake is associated with increased risk of 14 specific cancer types [4]. Physical inactivity is strongly associated with coronary heart disease [6,7], Type II diabetes [8,9], colon cancer, and possibly breast cancer [10,11]. Thus, improvements in dietary habits and physical activity can reduce the risk of obesity and of many chronic diseases.

Despite the substantial evidence linking these behaviors to health outcomes, the great majority of Americans do not meet dietary and physical activity guidelines [12-15]. More than half of US adults do not get enough physical activity to provide health benefits, including approximately one-fourth who are sedentary [1]. Similarly, only one-fourth of US adults consumes 5 or more fruits and vegetables per day [1].

Intervention programs can change these behaviors, and a number of on-site and face-to-face programs have been found to be effective, such as those described by Beresford et al [16] and Proper et al [17]. However, there is a large gap between the development of effective interventions and their extensive use in industry or public health practice [18,19]. While there are many barriers that impede translation of research into widespread practice, one significant obstacle has been the high cost and large time demands on both staff and participants [19]. As noted by Glasgow and Emmons [19], using lower cost intervention strategies, such as mail, phone, or computer-based approaches, may have the potential to overcome this limitation and make it possible to deliver effective behavior change interventions to large numbers of participants.

A number of research groups have developed effective mailed or computer-based and computer-tailored interventions, including Campbell et al [20], Gans et al [21], Marcus et al [22], and Brug et al [23]. Use of the Internet and email can greatly extend the reach of such programs. Significant improvements in diet and/or physical activity behaviors through use of Internet-based strategies compared with no-intervention controls have been shown by Oenema et al [24], Spittaels et al [25], Napolitano et al [26], Hurling et al [27] and others. Other interventions for physical activity have been reviewed by van den Berg et al [28]. Effective Internet-based programs to promote or maintain weight loss have also been developed [29,30]. The improvements in health and productivity resulting from some of these programs have even been shown to reduce employer costs [31].

Alive! (A Lifestyle Intervention Via Email) is an email-delivered, computer-tailored program to reach individuals on a large scale with an intervention which applies effective behavior-change principles. It is a modification of a previous program, WIN (Worksite Internet Nutrition), a computer-tailored, email-delivered program which was tested at a worksite and found to be effective in a pre-post analysis [32]. *Alive!* was developed in a collaboration between the Kaiser Permanente of Northern California Division of Research and NutritionQuest (formerly known as Block Dietary Data Systems). It is designed to achieve behavior change in physical activity and diet. In the dietary component, the targets are increases in fruits and vegetables and decreases in saturated and trans fats and added sugars. The development of *Alive!* and subsequent trial were funded by the Centers for Disease Control and Prevention (CDC) as part of the Health Protection Research Initiative emphasis on Worksite Health Promotion, which focused on interventions at worksites.

The primary outcomes of the randomized controlled trial were change in diet and physical activity. Those results are in preparation [33] and are summarized below. The decision to report the primary results of this trial in a different paper in a different journal was made because the content of the two papers was different, and because we wished to communicate our primary diet and physical activity behavior change results broadly to persons engaged in health promotion and preventive medicine. The trial was conducted among regional non-medical employees of Kaiser Permanente of Northern California. In comparison with change in the control group, the intervention group showed significant increases in minutes per week of moderate intensity activity, vigorous intensity activity, and walking; significant increases in fruits and vegetables; and significant decreases in saturated fat and trans fats. Decreases in added sugars in comparison with change in the control group approached statistical significance.

Here we describe the components and principles of the *Alive!* program, and report results of secondary outcomes of the *Alive!* trial, including health-related quality of life, self-assessed health status, presenteeism, self-efficacy, and stage of change. These are important outcomes in themselves, and the effect of presenteeism on productivity in particular is important in increasing the usage of wellness programs among employers.

Methods

Overview of Alive!

Alive! is designed to assist individuals in increasing their physical activity, increasing their fruit and vegetable intake, and decreasing their intake of saturated and trans fats and added sugars. *Alive!* is not a weight loss program; the focus is entirely on improving these nutritional and physical activity health behaviors. It is a completely automated system, in which all the

content and tailoring is contained in the computerized program, and is delivered entirely via email. No additional professional or technical expertise is required for the delivery. Potential participants may be invited to try *Alive!* through a batch email sent by the leaders of a business or organization to its employees or members. Completion of the initial step, health risk assessments on diet and physical activity, is encouraged by promising immediate feedback on their levels of those behaviors, regardless of whether or not they decide to participate further in *Alive!*. If they do decide to participate in the full program, participants choose an initial health-behavior module to work on for the subsequent 3 months, either to: (1) increase physical activity, (2) increase fruits and vegetables, or (3) decrease saturated and trans fats and added sugars. Participants then receive weekly messages offering tailored small-step goals to choose for the following week, tailored tips for achieving those goals, health information, and numerous opportunities for interaction and engagement. Information exchanged between client and server is encrypted by the industry standard security protocol, Secure Sockets Layer. Midweek messages remind the participants of the small-step goals they chose to work on for the week. A total of 25 personalized program-initiated email contacts occur over a single 3-month intervention period. In a non-research setting, participants may re-enroll in subsequent 3-month intervention periods, potentially covering all three topics over one year. The use of *Alive!* in the Kaiser trial differed slightly from the standard *Alive!* program, in that participants chose only a single topic, and the intervention lasted for a single 4-month period rather than 3 months, with messages sent weekly for the first 2 months and then every other week for the final 2 months.

Features of the Alive! Program

Baseline Assessments and Feedback

Diet and physical activity health risk assessments (HRAs), described in more detail below, are delivered via email and take approximately 15 minutes to complete.

Physical Activity

The physical activity questionnaire was adapted from the Cross-Cultural Activity Participation Study (CAPS) questionnaire [34]. It contains 34 specific activities, divided into domains that include walking, biking and other transportation, caregiving and household chores, conditioning exercises, dance and sports, and other leisure activities, such as watching TV or videos. Respondents are asked to indicate how many days a week and how many minutes a day they participate in each of the activities in a typical week in the past 4 months. Each activity is assigned a MET value (a measure of energy expenditure where 1 MET is equivalent to the energy required for sitting quietly) according to the Compendium of Physical Activities [35], multiplied by frequency and duration, and then summed over all relevant activities to create the summary variables. Five physical activity variables are estimated: total activity, in MET-minutes/week; moderate intensity and vigorous intensity physical activity, walking, and sedentary behavior, all in minutes/week. Four-month test-retest Spearman reliability (reproducibility) coefficient for minutes of moderate activity among the control group in the *Alive!* trial was 0.67.

Diet

The dietary questionnaire contains 35 items, asks about "usual" intake, and includes both frequency and portion size. Foods were identified for inclusion based on analyses of the National Health and Nutrition Examination Survey (NHANES) 1999-2004 [36], with separate analyses for African Americans, Whites, and Hispanics to ensure inclusion of foods appropriate for those ethnic groups. Foods were included if they were important contributors of saturated fat, trans fats, fruits and vegetables, or added sugars. Nutrient content was based on the US Department of Agriculture's Food and Nutrient Database for Dietary Studies [37] as well as on published data and label values. Nutrient estimates are calculated by multiplying frequency, portion size, and nutrient content and summing over all foods [38]. Additional questions on types of food consumed (eg, type of milk) permit more precise estimates of saturated and trans fats and sugars. The trans fat values are based only on hydrogenated products, and do not include trans fats from animal products. The database was developed and the randomized trial was conducted after the US Food and Drug Administration labeling regulations for trans fats went into effect [39]. Four-month test-retest reliability (reproducibility) of the dietary questionnaire ranged from 0.70 to 0.78, indicating good reliability. The questionnaire is a variant of widely-used Block questionnaires.

Tailoring/Lifestyle Questionnaire

A second questionnaire, again delivered via email, obtains demographic data, tailoring information, and information related to assessing secondary outcomes. Tailoring information includes presence of children at home, habits related to cooking and eating out, physical activity preferences such as structured, facility-based exercise or lifestyle physical activity, and stage of readiness for change [40] for physical activity. In addition, extensive tailoring is also based on specific foods and activities reported in the diet and physical activity questionnaires.

Barriers Questionnaire

In this questionnaire, participants identify barriers that may get in the way of achieving their health behavior goals. Subsequent messages provide tips for overcoming their reported barriers.

Feedback From the HRA

Feedback is provided immediately after the participant submits the HRA. Separate reports are made of the participant's intake of saturated fat, trans fats, added sugars, fruits and vegetables, and amount of physical activity, in relation to national and international guidelines [41-45]. Where improvement is needed, the feedback provides brief suggestions, including information on the participant's top three sources of problematic nutrients, and of sedentary behavior. This feedback also provides the participant with a basis on which to choose the health behavior to work on in the coming months. See Multimedia Appendix 1 for examples of the assessment and feedback.

After receiving the feedback, individuals may choose to participate in the full *Alive!* program. At that point they choose the overall health behavior objective to work on: Physical Activity, Fats and Sugars, or Fruits and vegetables.

Tailored Goal-setting

Tailored Goal-setting Is the Core of the Alive! Program

Each week, the participants receive an email suggesting four to six small-step goals which are tailored to the individual characteristics mentioned above (Figure 1).

Participants are asked to commit to one or two of these to work on for the following week. The purpose of the tailoring is to identify small-step goals that are relevant to the individual participant and that take into account his or her constraints and preferences. These are small achievable goals, such as "I will have a salad with lunch two days this week" or "I will walk 20 minutes at lunch time". Dietary goals are also suggested based on the individual's reported intake. For example, a person who eats doughnuts twice a week may receive a suggested goal to eat them only once a week, or to eat a smaller portion. Physical activity goals are also tailored to a combination of stage of change and initial level of activity: persons reporting precontemplation or low/no activity will initially be given goals that facilitate their getting started, such as easy walking or buying walking shoes. Table 1 contains examples of tailoring characteristics and associated goals.

In subsequent weeks, in the email delivering the next set of goals, the participant is also asked whether or not the previous week's goals were achieved. This is recorded in the Goal Tracker (see below).

Table 1. Illustrative tailoring characteristics and associated suggested goals

Characteristic of Participant	Sample Small-Step Goal
Physical Activity Path	
Early stage, prefers lifestyle activities, no children at home	I will make a date with a friend to go for a walk instead of for coffee or a drink.
Early stage, has children at home	I will go to the playground with my kids two days this week after school/work, and walk around the playground.
Action stage, prefers exercise activities, has children at home	I will get a family fitness video or DVD and do it with my kids at least one day this week.
Action stage, prefers lifestyle activities, no children at home	I will walk to do errands or window shop on my lunch hour rather than sitting in cafeteria or at my desk, at least two days this week.
Fats/Carbs Path	
Most dinners eaten at home, participant does the cooking	This week I will buy olive oil, and use it when I fry or stir-fry
Eats out frequently	I will look for opportunities to eat whole grain foods when I eat out this week.
Conditional (eats sweetened cereal)	This week when I shop, I will read the label on the box, and choose a cereal with less sugar.
Conditional (eats sweetened cereal) and has children at home	This week when I shop, I will show my children how to read the label, and choose a cereal with less sugar.
Fruits/Vegetables Path	
Eats out frequently	I will add vegetables to pizza or other carry-out this week.
Most dinners eaten at home, no children at home	I will try to eat one new fruit and one new vegetable this week (different from what I usually eat).
Most dinners eaten at home, children at home	I will have the kids participate in grocery shopping this week and choose one vegetable or fruit they are willing to eat.
Participant does the cooking	On two days this week, I will build vegetables into the main dish, like adding frozen green beans to stew.

Figure 1. Example of weekly email

Mid-week Reminders

A brief email mid-week reminds the participants of the goals they have chosen.

User's Home Page

Immediately after choosing a goal, the participant is taken to his or her "personal home page" containing tips for achieving the goal(s) they have chosen, tips regarding the barriers they mentioned, a goal tracker, an interactive simulation tool, health information, and links to sites for additional information, such as government and organizational websites. Thus, the act of choosing a goal in the email reader ensures that 100% of participants who choose a small-step goal for the week will also view the additional home page content described below; no additional initiative on the part of the participant is required. See Multimedia Appendix 2 for example of weekly email and home page.

Tips

Each week, participants receive tips on ways to achieve the specific small-step goals they have chosen that week; tips are also tailored to the factors above. They also receive tips on how to handle specific barriers that the participant has reported as constraints, such as time, money, or travel.

Goal-tracker

The program tracks which goals the participant has successfully achieved and categorizes them as to type of goal (eg, change in frequency vs change in amount). This is available on the participant's personal home page. This information was not used in the evaluation of the effectiveness of the program, but was provided as an aid to the participant in understanding what types of goals work for that individual.

Simulation Tool

The simulation tool is an interactive feature of the *Alive!* program that allows participants to see a graphic presentation of how much any specific change in diet or physical activity might move them closer toward the recommended level. The tool is linked to the participant's responses to the diet and physical activity questionnaires, and "remembers" both the individual's baseline score (eg, for saturated fat), the recommended level for that score, and the participant's baseline responses to each question. With it, the participant can experiment with changing aspects of his or her diet or physical activity and see a visual representation of how much such a change might move him or her toward the recommended level. Any of the 35 foods can be manipulated in terms of their frequency, portion size, or type. The 34 physical activity behaviors can be manipulated in terms of frequency and duration. For example, people who drink whole milk could change either the frequency, the portion size, or the type and see how much closer they would be to the saturated fat goal. Similarly, people who walk once a week for 15 minutes could see how much closer they would be to the physical activity recommendation if they walked three times a week for 20 minutes, and so forth.

Health Information

Each week, a different topic relevant to the selected intervention objective (ie, physical activity, fruits/vegetables, or carbs/fats) is discussed in a "Health Note". Topics include research on the relation of physical activity, fruits and vegetables, or saturated and trans fats to heart disease, healthy weight, various cancers, metabolic syndrome, mental health, and cognitive decline. Knowledge relevant to the particular intervention objective is also provided, such as the components of fitness, trends in physical activity, and different types of fats. A brief summary of the topic appears in each weekly email, and the full article is presented on the individual's personal home page.

Provisions for Social Support

Weekly suggested goals and tips promote building social support by suggestions such as walks with colleagues at lunch time. Equally important, *Alive!* encourages participants to invite family members to join *Alive!* to increase social support for behavior change. Finally, a chat room provides an opportunity for participants to discuss problems with each other and suggest solutions.

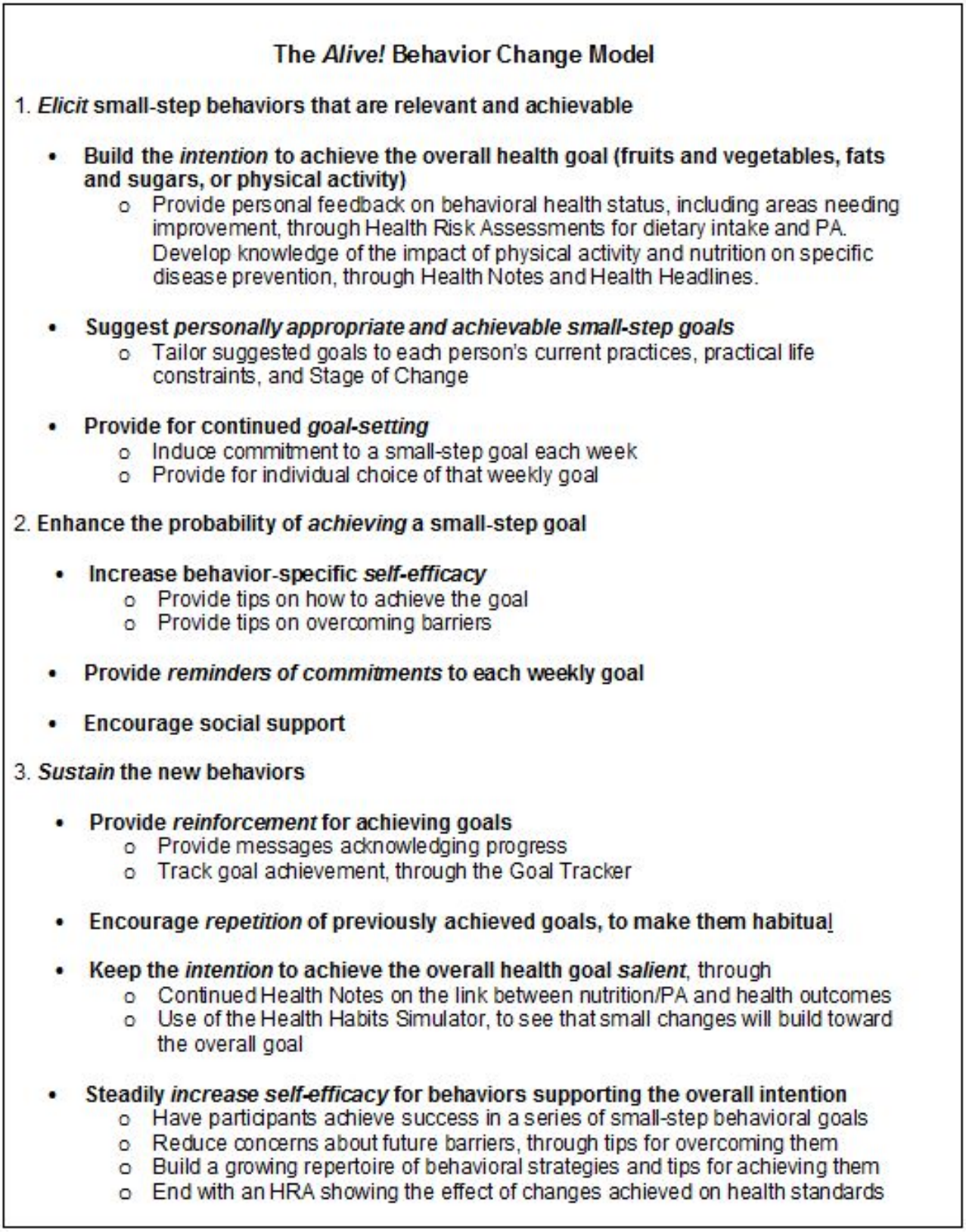
Principles Underlying the Alive! Program

The behavioral strategies underlying *Alive!* include certain of the principles from the health belief model [46], the theory of reasoned action [47], social cognitive/social learning theories [48], goal-setting theory [49], social marketing [50], and the transtheoretical model [51], all derived from behavioral and cognitive psychology. All of these theories suggest various concrete behavioral management strategies, such as setting goals, self-monitoring, anticipating barriers, rewarding accomplishments, and increasing knowledge and skills, as ways to elicit and reinforce the desired behavior. *Alive!* was not designed to test any particular model, but rather it incorporates elements from these various models which have been proven to be important in initiating and sustaining behavior change.

The Alive! Behavior Change Model

These behavioral strategies are applied in a basic structure of bringing forth a desirable behavior and providing the cues and repetition that help make the new behaviors habitual (Figure 2). Initially, *Alive!* promotes or reinforces the intention to change behaviors. It then moves to elicit specific behaviors by requesting commitment to small achievable weekly goals. It helps in achieving that commitment through tips and reminders, and it promotes sustaining the new behaviors through a variety of means as shown in Figure 2.

Figure 2. The Alive! behavior change model



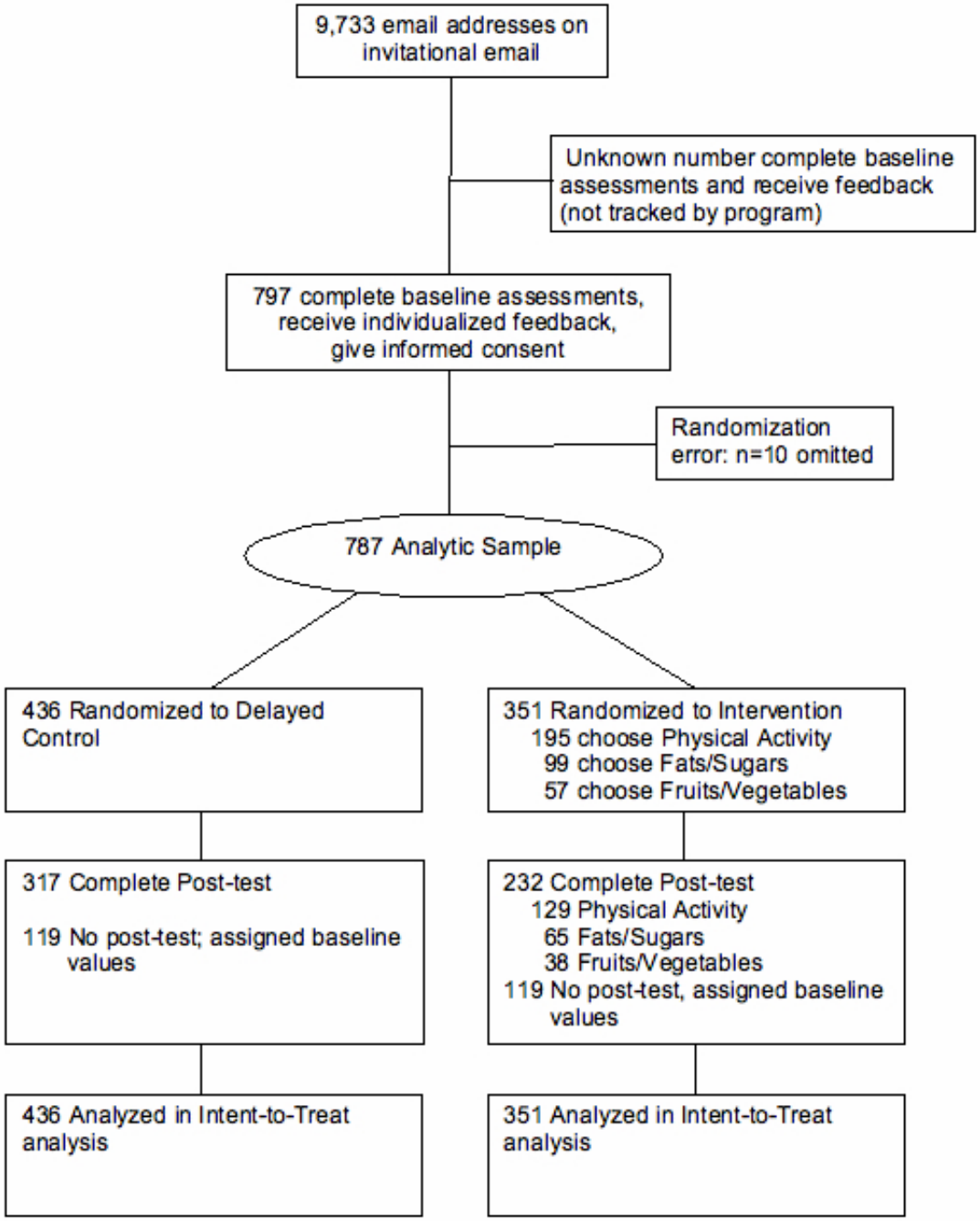
The Randomized Controlled Trial

Study Design and Sample

A randomized controlled trial was conducted among non-medical regional employees of Kaiser Permanente of Northern California (KP). Persons employed in the Kaiser Division of Research, of which Dr. Sternfeld is a member, were not eligible to participate. Recruitment began in July 2006 and was accomplished in approximately three weeks. The intervention and follow-up was completed in December 2006 (Figure 3). Procedures were approved by the Northern California Kaiser Permanente Institutional Review Board. The primary

objective was to test the effectiveness of *Alive!* in changing diet and physical activity. Those results will be reported elsewhere. Target sample size was based on the number and size of departments and 80% power to detect a difference in mean change scores in diet and physical activity across a reasonable range of probable intraclass correlations between baseline and follow-up. The primary hypotheses tested in the trial were that participation in *Alive!* would produce significantly greater improvement in physical activity and the targeted dietary behaviors in the intervention group in contrast with the control group. The prespecified secondary hypotheses were that participation in *Alive!* would produce significantly greater improvement in quality of life and presenteeism in the intervention group in contrast with the control group. We additionally examined treatment effects on stage of change and self-efficacy.

Figure 3. Randomized controlled trial intervention and follow-up



Employees were recruited through an invitational email sent from KP administrative offices, which included the diet and physical activity questionnaires described above. All employees were eligible. There was no monetary incentive to participate in the assessment or the subsequent randomized trial. The number who took the assessments and received individualized feedback but did not choose to join the randomized trial was not tracked.

Persons who agreed to participate in the randomized trial were automatically randomized by the program to either the intervention group or the control group. Randomization was by department (n = 192 departments) after stratification by

department size, using a random number table. The control group was a delayed control, and control group participants were offered the program 8 months after the initial randomization. Thus, participants were aware of their randomization group. The delivery of the intervention was completely automated and did not involve any investigator actions. Diet and physical activity questionnaires and questionnaires on secondary outcomes like health status were automatically administered by the program at baseline and at the conclusion of the intervention.

After randomization, participants in the intervention group chose the intervention path they wanted to pursue: Physical Activity (PA); Fruits and Vegetables (FV); Fats and Sugars (FS). Participants received intervention messages only for the chosen path. Neither participation in *Alive!* nor choice of an intervention topic was limited to persons with poor dietary or physical activity behaviors, and a substantial proportion had diet and physical activity behaviors within the recommended range at baseline.

Assessment of Study Outcomes

Data for secondary outcomes include self-assessed health status and health-related quality of life, using the SF-8 Health Survey questions [52]; presenteeism [53,54]; Stage of Change [40]; and self-efficacy [55] in physical activity and each of the dietary behaviors. Results were assessed by emailed questionnaire at baseline and after the 4-month intervention, administered automatically by the program.

The SF-8 Health Survey [52] is a set of quality-of-life measures, consisting of eight questions, representing eight domains of physical and mental health. The items are scored on a 5-point Likert scale, with the exception of self-assessed health status, which is scored on a 6-point scale from Excellent to Very Poor. Results were analyzed using the scoring algorithm provided for the instrument. This produces a standardized scoring permitting comparison with national data [56,57].

Presenteeism [53,54] is a concept that refers to reduced worker productivity resulting from mental and physical conditions, despite being present on the job, and has been shown to be a major contributor to the health-related costs of employers [58]. Presenteeism was assessed with three questions. Two questions asked about the number of hours in a typical 8-hour day that back pain or depression/anxiety interfered with accomplishing tasks at work. Response was provided in number of hours (0-8) and results were scored as decreased vs increased or stayed the same. The third was a question patterned after the SF-8 questions: “During the past 4 weeks, how much difficulty did you have concentrating at work and accomplishing work tasks because of physical or emotional problems?” The response pattern was a five-point scale ranging from “Not at all” to “Could not do my job work”.

Self-efficacy [55] was assessed with two questions: “How confident are you that you can make changes to be more physically active?” and “How confident are you that you can make changes to eat more fruits and vegetables and to reduce sweets, trans fat and saturated fat?”. In both cases the response categories were “Not at all”, “Somewhat”, and “Very confident”.

Stage of Readiness for Change [40] was assessed separately for change in fats, added sugar, fruits and vegetables, and physical activity.

Data Analyses

Results were analyzed by strict intention to treat, in which persons who did not respond to the follow-up questionnaire and therefore had missing data are included in the intention-to-treat analysis and assigned a change score of zero (119 of 436 in the control group, 27.3%; and 119 of 351 in the intervention group, 33.9%). Ordinal logistic regression models (Proc Genmod, SAS Institute, Cary, NC) were used for analyses of ordinal change variables. Multiple linear regression models (Proc Mixed, SAS Institute, Cary, NC) were used for analyses of the change in SF-8 quality of life. In all models, change in behavior was the dependent variable, randomization group was the primary fixed effect, department was a random effect factor, and all models were adjusted for age, gender, ethnicity, and baseline value of the dependent variable. Results are presented for the overall comparison of the intervention and control groups, although it should be noted that participants only received messages and goals relevant to the specific chosen path (Physical Activity, Fruits/vegetables, Fats/Sugars). Results presented as intention-to-treat probably represent an underestimate of effects, since they include all randomized participants including non-responders to the follow-up questionnaire (these were deemed to have a change score of zero, even though some of the non-responders may have experienced improvements in these behaviors).

Results

Participants

The trial includes 787 persons who gave informed consent to be randomized. A larger number completed the assessments and received feedback, but that number is not tracked by the system. Of the 787 participants in the trial, 351 (45%) were randomized to the intervention group and 436 (55%) to the control group. The mean age was 44 years (range 19-65 years), 202 (25.7%) were men, and 70% had a college degree or higher education (Table 2). The post-test questionnaire at the end of the 4-month intervention period was completed by 70.0% (549 of 787). Responders and non-responders to the post-test did not differ significantly in gender, education, or BMI category, but were significantly older (mean 44.8 vs 42.3 years) (data not shown).

Table 2. Demographic characteristics by treatment group and by intervention path (Alive! randomized trial, Oakland, CA 2006)

	Treatment Group			Intervention Path			
	Intervention	Control	*P* [a]	PA	Fruits/vegs	Fats/carbs	*P* [b]
n (%)	351 (45.0)	436 (55.0)	—	195 (55.6)	57 (16.2)	99 (28.2)	—
Age (yrs), mean (sd)	44.8 (10.0)	43.5 (11.0)	.09	45.3 (0.71)	42.7 (1.32)	44.9 (1.00)	.22
Age category, n (%)			.09				.05
< 35	63 (18.0)	106 (24.3)		32 (16.4)	10 (17.5)	21 (21.2)	
35-50	173 (49.3)	195 (44.7)		94 (48.2)	37 (64.9)	42 (42.4)	
> 50	115 (32.8)	135 (31.0)		69 (35.4)	10 (17.5)	36 (36.4)	
Gender, n (%)			.42				.16
Women	256 (72.9)	329 (75.5)		148 (75.9)	43 (75.4)	65 (65.7)	
Men	95 (27.1)	107 (24.5)		47 (24.1)	14 (24.6)	34 (34.3)	
Ethnicity, n (%)			.005				.80
African American	25 (7.1)	33 (7.6)		12 (6.2)	4 (7.0)	9 (9.1)	
Asian	28 (8.0)	39 (8.9)		19 (9.7)	3 (5.3)	6 (6.1)	
Latino	14 (4.0)	18 (4.3)		6 (3.1)	3 (5.3)	5 (5.1)	
White	111 (31.6)	188 (43.1)		62 (31.8)	21 (36.8)	28 (28.3)	
Mixed/Unknown	173 (49.3)	158 (47.7)		96 (49.2)	26 (45.6)	51 (51.5)	
Education, n (%)			.43				.29
High school or less/Some college	97 (27.6)	138 (31.7)		61 (31.3)	12 (21.1)	24 (24.2)	
College grad	119 (33.9)	145 (33.3)		59 (30.3)	20 (35.1)	40 (40.4)	
Graduate/ professional degree	135 (38.5)	153 (35.1)		75 (38.5)	25 (43.9)	35 (35.4)	
Children living at home, n (%)			.85				.78
Yes	153 (43.6)	193 (44.3)		88 (45.1)	23 (40.4)	42 (42.4)	
No	198 (56.4)	243 (55.7)		107 (54.9)	34 (59.7)	57 (57.6)	
Body mass index, mean (sd)	28.5 (6.8)	28.7 (7.5)	.74	30.0 (0.47)	25.7 (0.87)	27.3 (0.66)	< .001
BMI category, n (%)			.30				< .001
< 25	123 (35.0)	165 (37.8)		56 (28.7)	29 (50.9)	38 (38.4)	
25-29.9	117 (33.3)	123 (28.2)		59 (30.3)	21 (36.8)	37 (37.4)	
30-34.9	55 (15.7)	63 (14.5)		35 (18.0)	5 (8.8)	15 (15.2)	
35 and above	56 (16.0)	85 (19.5)		45 (23.1)	2 (3.5)	9 (9.1)	

[a]*P* values from *t* test for difference in means or chi-square test for differences in proportions between intervention and control groups.

[b]*P* values from ANOVA for differences among intervention paths.

Health-related Quality of Life (SF-8)

At baseline, the mean and standard deviation (SD) was 49.9 (7.9) and 48.0 (9.6) for the SF-8 Physical and SF-8 Mental summary scores respectively. The effect of treatment was significant for the two summary variables: change in these factors was significantly greater in the intervention group compared to the control group ($P = .02$) (Table 3). There was a significantly greater likelihood of having improvement in self-assessed health status in the intervention group vs the control (OR=1.57, 95% CI 1.21-2.04, $P < .001$). Several other components of the SF-8 were significant, including Role Physical, Bodily Pain, and Mental Health (data not shown).

Table 3. Effect of Alive! on SF-8 summary measures and self-assessed health status: change in the intervention group vs change in the control group

Variable	Adjusted Mean Change (MC)[a] or Odds Ratio (OR)[b] (95% Confidence Interval)[a]		*P*
	Intervention	Control	
SF-8 Physical[a]	MC 1.84 (0.96 -2.72)	MC 0.72 (-0.15 - +1.58)	.02
SF-8 Mental[a]	MC 0.69 (-0.28 - +1.67)	MC -0.29 (-1.22 - +0.65)	.02
Self-Assessed Health Status (SF8 "General health")[b]	OR 1.57 (1.21 - 2.04)		< .001

[a]Adjusted mean change and significance from mixed models with department as random effect factor and adjusted for baseline value, age, sex, and ethnicity. *P*-value represents significance of the difference between change in the intervention group and change in the control group. Intention-to-treat models, non-responders set to zero change.

[b]Odds ratio and significance, odds of having a reported improvement in general health, in the intervention group vs the control group. Model from ordinal logistic regression, with randomization group as primary fixed effect, department as random effect factor and adjusted for baseline value, age, sex, and ethnicity.

Presenteeism

The proportion of the sample reporting greater than zero hours for difficulty concentrating and accomplishing work tasks because of back pain or depression/anxiety at baseline was 22.5% (177/787) and 30.6% (241/787) respectively (data not shown). Decrease in number of hours of back pain and depression in the intervention group vs the control group approached significance, while differences in the third presenteeism measure were significant (Table 4). Persons in the intervention group were 1.47 times more likely to report improvement in the ability to concentrate and accomplish work tasks (*P* = .02) in comparison with changes in the control group.

Table 4. Effect of Alive! on presenteeism[a]: change in the intervention group vs change in the control group

Variable	Odds Ratio (95% CI)	*P*
Decreased hours of back pain at work[b]	1.66 (0.99 - 2.79)	.054
Decreased hours of depression at work[b]	1.74 (0.98 - 3.10)	.06
Change in Concentrate/accomplish[c]	1.47 (1.05 - 2.05)	.02

[a]Presenteeism refers to the situation in which the employee is present at work, but productivity is reduced as a result of physical or mental conditions. Intention to treat models, everyone included, non-responders set to zero change. Models from dichotomous or ordinal logistic regression with department as random effect factor and adjusted for baseline value, age, sex, and ethnicity.

[b]Odds ratio and significance, odds of having a decrease in pain or depression, in the intervention group vs the control group. Questions were asked in following format: "During a typical 8-hour workday, about how many hours does BACK PAIN interfere with concentrating on work and accomplishing work tasks?". Range of responses was 0-8. Change scored as 1 = hours decreased, 0 = hours stayed the same or increased.

[c]Odds of having improvement, intervention group vs. control group. Ordinal logistic regression with department as random effect factor, and adjusted for baseline. Question was asked in following format: "During the past 4 weeks, how much difficulty did you have concentrating at work and accomplishing work tasks because of physical or emotional problems?"

In Table 5 below, we examine change in efficacy for diet and physical activity in the entire intervention group, and we evaluate change in stage separately for fats, sugars, fruits/vegetables, and physical activity in the entire intervention group. However, it should be noted that participants in the intervention group received goals and interactions with regard to only one of the three intervention topics (physical activity, fruits/vegetables, or carbs/fats).

Self-efficacy

Persons in the intervention group had significantly greater improvement in confidence in ability to change their diet than did those in the control group (Table 5). For physical activity, confidence did not improve significantly in the intervention group compared to the control group, when all subjects are examined, including those "Very Confident" at baseline. However, it is notable that even there the direction of the effect is positive (odds ratio > 1.0), despite the fact that the only direction possible for those already "Very confident" was either no change or decrease. When change in confidence to improve physical activity is examined just in those in the Physical Activity path who were not already "Very confident", a significant improvement is seen (*P* = .037) (data not shown).

Stage of Readiness for Change

When all subjects are included, including those in Maintenance at baseline and thus with no room to improve, there was significant or almost significant forward movement in Stage in the intervention group in comparison with change in the control group for all domains except for change in sugar (Table 5). Among those needing improvement ("at risk"), significant forward movement was seen in all domains. The substantially greater effect on Stage of Change for sugar in the at-risk group is evidence of the large number of participants who were already

in Maintenance for reducing sugar intake at baseline. When only those in the relevant path are examined (eg, movement in Stage for physical activity among those in the Physical Activity path), there was significant movement in all domains (data not shown).

Table 5. Effect of Alive! on self-efficacy and stage of readiness for change: change in the intervention group vs change in the control group

	Intention-to-treat At-risk subjects[a] Odds Ratio (95% CI)[b]	*P* [c]	Intention-to-treat All subjects[a] Odds Ratio (95% CI)[b]	*P* [c]
Self-efficacy analyses				
Self-efficacy to change diet	2.68 (1.57 - 4.57)	< .001	2.05 (1.44 - 2.93)	< .001
Self-efficacy to change physical activity	1.42 (0.98 - 2.07)	.07	1.21 (0.87 - 1.67)	.26
Stage-of-change analyses				
Stage: Changing fat	1.32 (1.00 - 1.76)	.05	1.27 (0.99 - 1.63)	.06
Stage: Changing fruits/vegetables	1.76 (1.31 - 2.36)	< .001	1.62 (1.23 - 2.13)	.006
Stage: Changing added sugars	1.84 (1.31 - 2.58)	< .001	1.23 (0.92 - 1.64)	.17
Stage: Changing physical activity	1.42 (1.06 - 1.90)	.02	1.34 (1.00 - 1.80)	.05

[a]In intention-to-treat models, subjects who did not respond to the follow-up questionnaire have their change score set to zero. CI: 95% Confidence Interval. “All Subjects”: Subjects in Maintenance (for Stage analysis) or “Very confident” (for Self-efficacy analysis) at baseline are included. “At-risk Subjects”: Excludes those in Maintenance (or “Very confident”) at baseline.

[b]Odds ratio: Odds of having forward movement, intervention group vs control group.

[c]Significance of odds ratio for forward movement for intervention group vs control group from ordinal logistic regression models with department as random effect factor, adjusted for baseline value, age, sex, and ethnicity.

Process and Satisfaction

The personalized report on their diet and physical activity behaviors, which was provided to all 787 participants prior to randomization immediately after completion of the baseline questionnaires, appears to have benefited those subsequently randomized to the control group as well as those randomized to the intervention group. Of control group respondents to the follow-up questionnaires at the end of the 4-month period, 89.1% (271/304) reported they learned “Some” or “A lot” about their physical activity behaviors, and 88.5% (269/304) reported they had learned “Some” or “A lot” about their dietary behaviors (data not shown). Results were similar for the intervention group. Among members of the intervention group, 154 of 224 respondents to the follow-up questionnaires (68.8%) found the tailored tips “Somewhat” or “Very” relevant and helpful. The chat room was infrequently used. However, participation in the key element of the *Alive!* program, goal-setting, was high: 74% of those randomized to the intervention group (260/351) interacted with the program on 7 or more of the 12 weeks, as tracked automatically by the program. In addition, the program automatically tracks goals selected by each participant. The 351 participants in the intervention group selected 3836 goals over the 3-month intervention period, or an average of 10.9 goals per person.

Discussion

Principal Results

Alive! was developed to provide a low-cost intervention capable of reaching large numbers of people with an intervention grounded in established principles of behavior change. These analyses demonstrate that the *Alive!* program promoted significant improvements in SF-8 health-related quality of life, presenteeism, self-efficacy, and stage of change. The significant improvements in diet and physical activity will be reported elsewhere.

Quality of Life

The effects on SF-8 measures and self-reported general health suggest a potentially important beneficial effect of participation in the *Alive!* program on the population’s physical and mental health and quality of life. The SF-8 instrument used here is a reduced version of the SF-36, measuring the same eight constructs [56], which has been extensively validated [57]. *Alive!* produced significant improvements for the overall SF8-Physical and Mental scores, even in intention-to-treat analyses where non-responders are set to zero change. The single-item, self-assessed health status question has been shown to predict mortality among middle-aged and older persons, even after control for health, demographic, and social factors [59-61], and has been suggested to be even more reliable than biomedical measures [62]. Other researchers have found beneficial effects on related variables as a result of Web or email-based interventions. Christensen et al [63] and Clarke et al [64] found significant effects of a depression-oriented Web-based intervention. The only researchers of which we are aware to have found significant improvement in a depression score as a result of an Internet-based program to improve diet and physical activity, like *Alive!*, are Kerr et al [65].

Presenteeism

A recent large study demonstrated that health-related productivity losses cost employers more than four times as much as medical and pharmacy costs [58]. Measures of presenteeism

have been used in numerous studies that demonstrate the cost of such lost productivity [31,53,54]. Improvements in these sources of costs are of major interest to employers. Numerous studies have shown beneficial effects on absenteeism and presenteeism as a result of diet and physical activity interventions [31]. Our results suggest that *Alive!* can make a contribution to such improvements.

Self-efficacy

The improvements in self-efficacy shown here may have important implications for the longer-term impact of participation in *Alive!*, if they maximize the likelihood of sustaining the improved behaviors.

We believe that the demonstrated success of *Alive!* in achieving improvements in health-related quality of life, presenteeism, stage of change, and self efficacy, as well as diet and physical activity outcomes shown elsewhere, may be due, in part, to the nature of the tailoring variables. Rather than tailoring solely on psychosocial characteristics such as stage of change and self-efficacy, *Alive!*'s tailoring focused primarily on each individual's current dietary and PA practices, and on their practical life constraints, with small-step goals and tips that took such habits, constraints, and barriers into account.

The approach of *Alive!*, and in its predecessor, WIN, is consistent with the concept of "Stickiness" [66]. The "stickiness" concept suggests that ideas and intentions are likely to "stick" when they are particularly relevant to an individual and when they appear frequently in the mental or social environment. *Alive!* is designed to increase relevance and stickiness in numerous ways. These include the feedback from the diet and physical activity questionnaires; tailored goals and tips; the Health Notes, which may strike a chord in some people and increase relevance; and repeated reminders. Reminders not only increase continued commitment but also enhance the salience of other cues in the environment such as news reports. The 25 contacts over 3 months, all on aspects of the same overall behavior, both reinforce the overall behavior and provide repeated opportunities for the "motivational storm" that can generate deep and sustained change.

Reach and Engagement

In this study, the exact rate of participation in the randomized trial is not known, as there was no way to know how many of the 9733 email addresses were live nor how many of the invitational messages may have been spam-filtered. Our estimate is a participation rate of approximately 10%. This participation rate in the trial is reasonably consistent with other randomized trial experiences. As noted above, substantially more than 787 completed the assessments and received the feedback but did not choose to participate in the randomized trial. It is notable that there was no monetary incentive, and potential participants were told that they might not receive the intervention for 8 months if they were randomized to the control group. In addition, the participation rate was considerably higher than has been seen in some other Internet-based interventions. For example, Glasgow et al [67] found only a 2.4% participation rate among general non-diseased membership in an HMO, after a mailed letter of invitation.

Engagement in this intervention was substantial, with an average of 10.9 goals selected per person over the 12 intervention sessions, and with 74% of intervention group subjects interacting with the program on 7 or more of the 12 intervention sessions. This appears to be a substantially higher engagement than some researchers have seen in Internet-based programs for the general population. Glasgow et al [67] found that only 49% of the sample viewed at least one follow-up newsletter after the initial intervention message. Verheijden et al [68] found that only 9.6% used their Web-based health promotion site more than once.

Limitations

Some limitations of *Alive!* should be noted. The requirement for email and Internet access limits the applicability of *Alive!* to some segments of the population. However, as of 2006, 73% of American adults were Internet users, including 71% of persons 50-64 years of age [69]. While fewer low-income people have Internet access, 53% of adults living in households with less than $30,000 annual income go online, as of 2006 [69].

It is also acknowledged that effect sizes are small in this intention-to-treat analysis in which those with missing data are assigned change scores of zero. It is worth noting that the trial randomized subjects even if they had already met diet or physical activity goals or were already at the top of scales such as efficacy and stage. Thus, the study differs fundamentally from classic "clinical" trials in which only at-risk subjects are randomized. It is also worth noting that participants chose a goal only after being randomized to the intervention or control groups, and thus each person in the intervention group participated in only one of the three intervention topics. Consequently, the generalized effects on efficacy, stage, and quality of life suggest a generalized halo effect on healthy behaviors and characteristics beyond the direct topic in which they participated.

Another limitation is the fact that there are no objective measures of outcomes like self-efficacy, quality of life, sick days, or productivity. Potential conflict of interest of some of the authors may also be noted as a limitation, as NutritionQuest developed *Alive!* and has proprietary interests in it. However, the principal investigator of the randomized trial (BS) has no financial interest in *Alive!*, and all statistical analyses were either performed or confirmed by Kaiser statistical staff.

A notable strength of *Alive!* is its ability to reach very large numbers of people with a fully automated, quite intensive intervention grounded in effective behavior change principles. Marcus et al [70] note that "evidence supports individually tailored behavior-change-oriented programs at the workplace". Marcus et al also note that a major limitation of many studies is their failure to incorporate cognitive principles. In addition, many successful programs, although grounded in theory, fail to be effectively translated to the "real world" because they place too great a burden on organization and participant time and effort [19]. *Alive!* is immediately usable by organizations and businesses with little requirement for staff expertise and time commitment. Thus, *Alive!* provides the opportunity for widespread dietary and physical activity screening with

immediate individualized feedback, which can then be followed by *Alive!*'s research-based effective intervention.

Conclusions

In summary, these results show that participation in *Alive!* can result in significant improvements in important health parameters including physical and mental quality of life, self-assessed health status, self-efficacy for improving these health behaviors, and stage of adoption of change. Improvement in measures of presenteeism also suggests the possibility of economic benefits through improved productivity.

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Conflicts of Interest

GB, CB, and TB are co-owners of NutritionQuest, which holds the copyright on *Alive!* and which has a financial interest in *Alive!*. JN is a staff member of NutritionQuest. Barbara Sternfeld, Charles Quesenberry, Gail Husson, Heather Clancy, and Donald Hopkins have no potential conflicts of interest. Data analyses were performed by both Kaiser Permanente Division of Research and NutritionQuest, and all authors had full access to the data.

Multimedia Appendix 1

Examples of *Alive!* assessment and feedback

[PPT file (Microsoft Powerpoint File), 1.1 MB - jmir_v10i4e43_app1.ppt]

Multimedia Appendix 2

Examples of *Alive!* email and user's home page

[PNG file (Portable Network Graphics File), 576 KB - jmir_v10i4e43_app2.png]

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Abbreviations

Alive!: a lifestyle intervention via email
CAPS: cross-cultural activity participation study
CDC: Centers for Disease Control and Prevention
FS: fats and sugars
FV: fruits and vegetables
HMO: health maintenance organization
HRAs: health risk assessments
KP: Kaiser Permanente of Northern California
NHANES: National Health and Nutrition Examination Survey
PA: physical activity
WIN: worksite internet nutrition

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Original Paper

Predicting Successful Treatment Outcome of Web-Based Self-help for Problem Drinkers: Secondary Analysis From a Randomized Controlled Trial

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Abstract

Background: Web-based self-help interventions for problem drinking are coming of age. They have shown promising results in terms of cost-effectiveness, and they offer opportunities to reach out on a broad scale to problem drinkers. The question now is whether certain groups of problem drinkers benefit more from such Web-based interventions than others.

Objective: We sought to identify baseline, client-related predictors of the effectiveness of Drinking Less, a 24/7, free-access, interactive, Web-based self-help intervention without therapist guidance for problem drinkers who want to reduce their alcohol consumption. The intervention is based on cognitive-behavioral and self-control principles.

Methods: We conducted secondary analysis of data from a pragmatic randomized trial with follow-up at 6 and 12 months. Participants (N = 261) were adult problem drinkers in the Dutch general population with a weekly alcohol consumption above 210 g of ethanol for men or 140 g for women, or consumption of at least 60 g (men) or 40 g (women) one or more days a week over the past 3 months. Six baseline participant characteristics were designated as putative predictors of treatment response: (1) gender, (2) education, (3) Internet use competence (sociodemographics), (4) mean weekly alcohol consumption, (5) prior professional help for alcohol problems (level of problem drinking), and (6) participants' expectancies of Web-based interventions for problem drinking. Intention-to-treat (ITT) analyses, using last-observation-carried-forward (LOCF) data, and regression imputation (RI) were performed to deal with loss to follow-up. Statistical tests for interaction terms were conducted and linear regression analysis was performed to investigate whether the participants' characteristics as measured at baseline predicted positive treatment responses at 6- and 12-month follow-ups.

Results: At 6 months, prior help for alcohol problems predicted a small, marginally significant positive treatment outcome in the RI model only (beta = .18, P = .05, R^2 = .11). At 12 months, females displayed modest predictive power in both imputation models (LOCF: beta = .22, P = .045, R^2 = .02; regression: beta = .27, P = .01, R^2 = .03). Those with higher levels of education exhibited modest predictive power in the LOCF model only (beta = .33, P = .01, R^2 = .03).

Conclusions: Although female and more highly educated users appeared slightly more likely to derive benefit from the Drinking Less intervention, none of the baseline characteristics we studied persuasively predicted a favorable treatment outcome. The Web-based intervention therefore seems well suited for a heterogeneous group of problem drinkers and could hence be offered as a first-step treatment in a stepped-care approach directed at problem drinkers in the general population.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 47285230; http://www.controlled-trials.com/isrctn47285230 (Archived by WebCite at http://www.webcitation.org/5cSR2sMkp).

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KEYWORDS

Predictors; drinking; problem drinking; attribute-treatment interaction; Web-based intervention; self-help; pragmatic randomized trial; alcohol; general population

Introduction

Problematic alcohol use is not only a pervasive individual problem; it also imposes serious health and social burdens on the general population [1,2,3]. This makes it a major public health concern. Brief interventions offer the promise of easing these burdens, and their cost-effectiveness has been amply demonstrated in a number of studies and meta-analyses [4-9]. Yet in view of the small-to-medium treatment effects that have been reported by meta-analyses [4,6], it appears that not every problem drinker benefits equally from brief interventions. Web-based self-help interventions for problem drinking are the newest branch in the tree of brief interventions making it possible to reach out to problem drinkers on a broad scale at a relatively low cost. These Web-based interventions are clearly coming of age for a number of psychological disorders [10,11] and increasingly for alcohol problems as well [12,13]. As yet, however, the effect sizes found for brief Web-based interventions for problem drinking have not differed much from those for offline brief interventions [12,14]. The question therefore arises whether such Web-based interventions might work more effectively for some people than for others. The answer to this question could help to improve intervention development, treatment outcomes, and the matching of clients to treatment modalities, and is therefore of potential clinical, social, and economic interest [3,15].

It is well known that treatment response is not influenced by treatment alone [16]. A number of effect moderators of alcohol treatment outcomes have been identified [17]. These include clients' baseline sociodemographics, within-treatment variables such as treatment fidelity, and posttreatment factors like social support for curbing drinking activities [18]. Prediction studies have provided a limited number of consistently identified baseline predictors of treatment outcome, including readiness to change problematic alcohol use [19,20,21], self-efficacy [19,20,22], and severity of alcohol use [4,16]. The milestone study by Project MATCH [19] is the best known example. Most prediction studies, however, have focused on severely alcohol-dependent clinical populations, and far fewer have focused on brief interventions for clinical populations in primary care settings or on problem drinkers in the general population [16,19]. Research suggests that baseline characteristics are more likely to affect treatment outcomes for less severe problem drinkers than for more highly dependent clinical populations [23].

We therefore investigate here whether specific baseline characteristics can be identified as predictors of a positive treatment outcome for problem drinkers in the Dutch population who completed a Web-based self-help intervention called Drinking Less. On the basis of predictors already reported in the literature, we hypothesized that six putative baseline characteristics—(1) female gender, (2) higher education, (3) Internet competence, (4) a moderate level of problem drinking, (5) prior professional help for problem drinking, and (6) high expectancy for positive results from a Web-based intervention—would interact with Drinking Less to predict a more favorable treatment outcome at follow-up. We conducted a secondary analysis of our Drinking Less trial data [14] to examine attribute-treatment interaction (ATI)—the interplay between the baseline characteristics (attributes) of problem drinkers and the intervention itself—and the influence such interaction might have on treatment response [24]. Drinking Less has been shown effective for problem drinkers who want to reduce their alcohol intake, yielding a medium effect size at 6-month follow-up (d = 0.40, 95% CI 5.86 - 18.10; P < .001). At 12 months, the difference between the groups had faded (d = 0.01, 95% CI -2.63 ~ 9.20, P = .21), mainly due to a further decrease in alcohol consumption in the control group. Results of this pragmatic randomized trial have been reported elsewhere [14].

To the best of our knowledge, this is the first article that uses randomized trial data to assess predictors of short- and longer-term outcomes in Web-based self-help for problem drinkers in the general population.

Methods

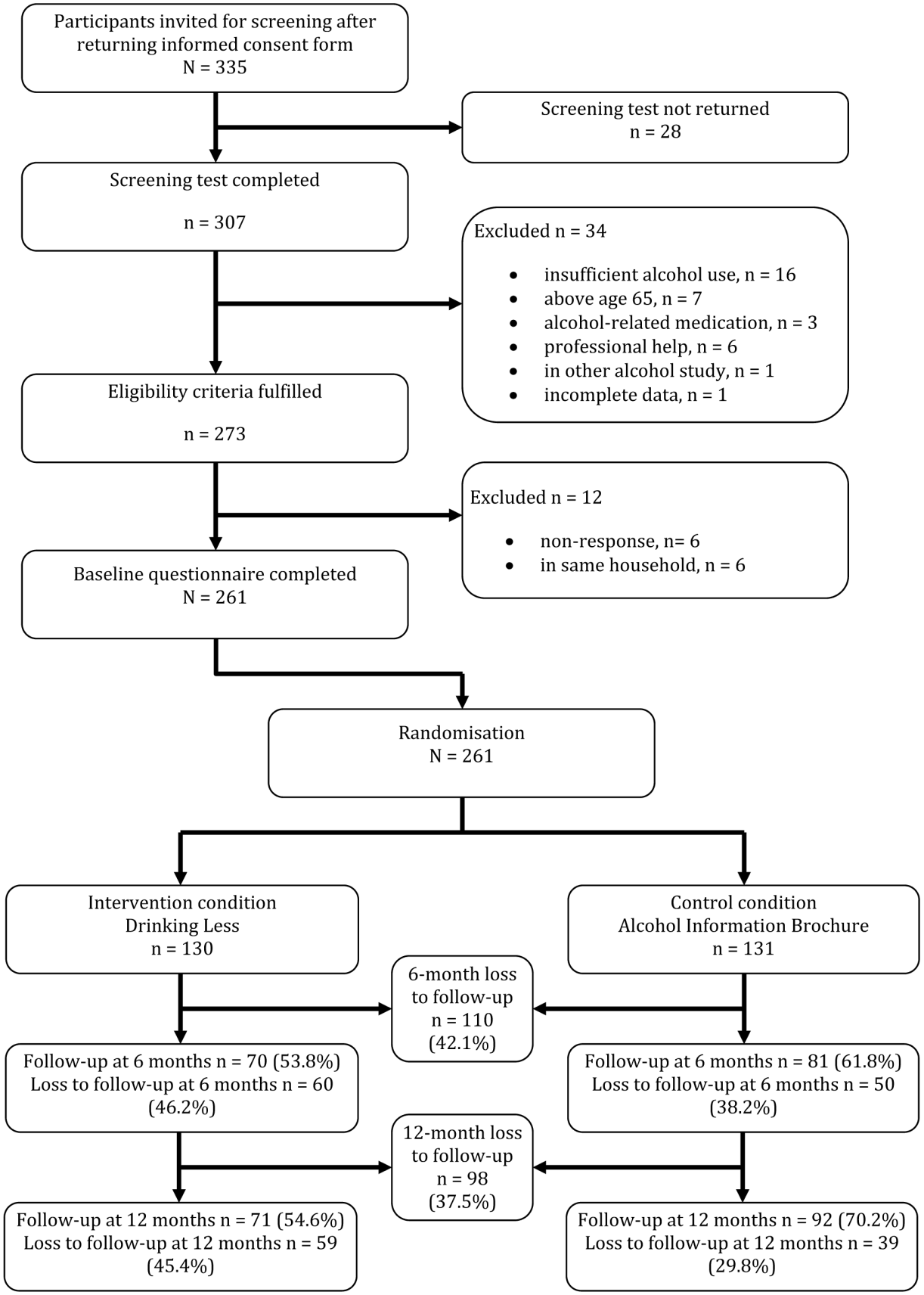
Participants and Procedure

Data were retrieved from a pragmatic randomized trial with two parallel groups using block randomization stratified for gender, with follow-up at 6- and 12 months [14]. In brief, we recruited adult participants from the general population through advertisements in national newspapers and health-related websites. The study and intervention were conducted entirely via the Internet, with the exception of the informed consent form which had to be signed and returned by post. In the inclusion criteria, we applied different cut-off points for problem-drinking men and women. Men were selected who were drinking either more than 21 standard units per week (excessive drinking) or 6 or more units at least 1 day per week for the past 3 months (hazardous drinking). Women were included if they drank over 14 units a week or 4 or more units at least 1 day a week for the past 3 months. One standard unit represents 10 g of ethanol. Additional inclusion criteria were: age 18-65, access to the Internet, and no previous professional help for problem drinking at the start of the study.

We kept our exclusion criteria to a minimum to facilitate a low-threshold inclusion strategy consistent with the nature of

self-help interventions without therapeutic guidance. We therefore did not conduct diagnostic interviews. After screening and baseline assessment, participants were randomly assigned to the experimental condition (the Drinking Less intervention) or to the control condition (an online psychoeducational brochure on alcohol use that could be read in 10 minutes) [25]. We selected a total of 261 adult problem drinkers. Figure 1 shows the flow of participants through the trial.

Figure 1. Flow of participants through the trial



Intervention

Participants in the experimental condition received access to the Drinking Less intervention [26]. Drinking Less is a free-access, Web-based self-help intervention without therapist guidance for problem drinkers who want to reduce their alcohol consumption, preferably to within the recommended Dutch limits for low-risk drinking [27]. The intervention is based on cognitive-behavioral and self-control principles [28,29] which are suitable for Web-based implementation due to their standardized nature and systematic approach. Drinking Less consists of a home page giving information on alcohol and treatment services and offering access to the self-help program via an automated sign-up procedure with a description indicating for whom the intervention is suitable (Figure 2). The program proceeds in four successive stages: (1) preparing for action; (2) goal setting; (3) behavioral change; and (4) maintenance of gains and relapse prevention. These stages contain elements known to be effective, such as goal setting and analysis of drinking behavior [29,30]. The self-help program also includes access to a moderated peer-to-peer discussion forum. The recommended treatment period is 6 weeks, which should give a reduction in alcohol consumption enough time to take hold [31]. Trial participants were allowed to use the intervention as long as they felt necessary. Access to Drinking Less proceeded through a unique log-in and security identification code and was available on a 24-hours-a-day, 7-days-a-week basis.

Figure 2. Drinking Less home page [26]

Predictive Variables

Our choice of baseline participant characteristics as putative predictors was based on theoretical assumptions and results from previous prediction studies [16-22]. We selected six characteristics: (1) gender, (2) education, (3) Internet use competence (sociodemographic factors), (4) mean weekly alcohol consumption, (5) prior professional help for alcohol problems (level of problem drinking), and (6) participants' expectancies of Web-based intervention as helpful for overcoming problem drinking.

Outcome Measure

The outcome measure was defined as the individual differences between baseline (T0) mean weekly alcohol consumption and the mean level of consumption at posttreatment (6 months, T1) and at follow-up (12 months, T2) in the total group. Alcohol consumption was assessed with the Dutch version of Weekly Recall (WR) [32,33]. It records the number of units consumed in the 7 days preceding the assessment.

Statistical Analyses

We first used *t*-tests, chi-square tests, and logistic regression to assess whether the randomization had resulted in two comparable groups at baseline and whether any differential loss to follow-up had occurred. We then performed intention-to-treat

(ITT) analysis, using last-observation-carried-forward (LOCF) data and regression imputation (RI) to deal with loss to follow-up. Overall loss to follow-up was high (Figure 1), and we wanted to avoid overestimating the impact of the intervention [34]. ITT analysis enabled us to maintain sufficient power and the integrity of randomization. The LOCF imputation procedure assumes that outcome assessments of participants not reached for follow-up would equal their last available assessment [34]. Missing WR data at 6 months and 12 months were also estimated by RI, using the significant predictors for the missing outcomes and for dropout [34]. At 6 months those predictors were condition, baseline partner status, and baseline weekly alcohol units according to WR; at 12 months they were condition, gender, weekly alcohol units according to WR at 6 months (imputed), and baseline alcohol units as measured by the Dutch version of the Quantity-Frequency Variability Index (QFV) [35].

In the third step, we created dichotomous measures for the continuous and categorical baseline variables, alongside the already dichotomous variable of gender (female gender: yes/no). Values on the WR scale were transformed into a variable distinguishing moderate problem drinking (14 - 35 mean weekly alcohol units for women, 21 - 50 for men) from severe problem drinking (> 35 or > 50 units women/men). Categorical variables with more than two categories were recoded into two meaningful categories: (1) education: high/low (university and professional degrees versus the rest); (2) Internet competence: experienced/beginner; (3) prior professional help for alcohol problems: yes/no; and (4) expectancies of Web-based intervention: high/low. We then applied regression analyses to ascertain whether these particular groups benefited more from the intervention than others. We assessed the interactions between the above-baseline attributes and the Drinking Less intervention modality, and then the effects of those interactions on treatment outcome. In this model, the standardized individual change scores (pre- to post-intervention effect sizes) served as the dependent or outcome variable. The interaction terms of each participant characteristic with the intervention dummy (Drinking Less experimental condition = 1, control condition = 0) served as independent predictor variables, along with their constituent main effects.

We next calculated the product of the intervention dummy and each of the dummy variables describing the participants' characteristics [36,37]. The interaction terms were entered together with the corresponding main effects into the linear regression model and tested at $P < .05$. Independent-samples *t*-tests were used to analyze differences between the conditions in terms of problem drinking outcome at T1 and T2. This technique permitted us to test for the differential effects of the predictors in interaction with the Drinking Less treatment. It also enhanced the power to detect effects. If neither of these interaction terms proved significant, then the effect of the predictor was deemed not to be modified by Drinking Less. That is, the effect of Drinking Less on drinking outcome could not be explained by the predictor's modifying effect on the relationship between treatment and outcome.

We subsequently repeated this procedure in completers-only analyses on those participants who completed the follow-up questionnaire at 6 months (n = 151) or at 12 months (n = 163) to verify whether the results of the two ITT analyses would be sustained. Finally, we used descriptive statistics to illustrate the changes in alcohol consumption over time in terms of the identified predictors. The sample size provided 24 participants per variable at 6 months and 26 per variable at 12 months [38]. All analyses were conducted with SPSS version 15 and were carried out independently by two researchers to cross-check outcomes.

Results

Sample Characteristics

The demographic and clinical characteristics of participants at baseline are shown in Table 1. No differences were found between the experimental and control groups on any of these variables at baseline (even when tested conservatively at $P < .10$ to ensure against marginal differences that could affect results). This indicated that the randomization was successful. At baseline, all 261 participants (100%) were exceeding the mean number of weekly alcohol units set by the Dutch guideline for sensible drinking for healthy adults. Mean weekly alcohol intake was 43.6 standard units (SD = 21.6). More than half the sample belonged to the category of moderate, as opposed to severe, problem drinkers (n = 148, 57.7%). The female-to-male ratio was almost 1:1. Two-thirds of participants had high educational backgrounds (n = 182, 69.7%). Most participants considered themselves experienced Internet users (n = 204, 78.1%). Almost half had positive expectations of the intervention (n = 127, 48.2%). The large majority of participants (n = 231, 88.5%) were in the contemplation stage of change, meaning that they wanted to reduce their alcohol consumption in the near future [39,40]. Most (n = 243, 93.1%) aimed for moderation rather than abstinence. Few (n = 33, 12.6%) had ever received professional help for their problem drinking.

Table 1. Baseline characteristics of the 261 participants (values are numbers and percentages of participants, unless otherwise indicated)

	Condition[a]	
	Experimental n = 130	Control n = 131
Female gender[b]	64 (49.2)	64 (48.9)
Education[b]		
Low	41 (31.5)	38 (29.0)
High (academic/professional)[b]	89 (68.5)	93 (71.0)
High Internet competence[b]	104 (80.0)	100 (76.3)
High treatment expectancy[b]	61 (46.9)	66 (49.6)
Weekly alcohol intake in standard units[c] (mean, SD)	43.7 (21.0)	43.5 (22.3)
Moderate problem drinking[b] 14-35 units per week (women) 21-50 units per week (men)	74 (56.9)	74 (56.5)
Severe problem drinking > 35 (women) and > 50 (men) units[c] per week	56 (43.1)	57 (43.5)
Prior professional help for problem drinking[b]	18 (13.8)	15 (11.5)
Contemplation stage[d]	116 (89.2)	115 (87.8)
Alcohol moderation as goal	120 (92.3)	123 (93.9)
Age (mean, SD)	45.9 (8.9)	46.2 (9.2)
Living with a partner	75 (57.7)	71 (54.2)
Paid employment	94 (72.3)	96 (73.3)

[a]All differences between conditions were non-significant (tested at $P < .10$).

[b]Indicates putative predictor of favorable treatment response.

[c]A standard unit contains 10 g of ethanol.

[d]Assessed with validated Dutch version of Readiness to Change Questionnaire [39].

Predictors of Loss to Follow-up

Participants who did not return the questionnaire 6 months after baseline did not differ from posttreatment responders in terms of the characteristics assessed at baseline ($P > .10$; Table 1 for characteristics). Loss to follow-up at 6 months was 42.1% (n = 110) and was distributed rather evenly across the two conditions (n = 60 in the experimental and n = 50 in the control condition; $\chi^2_1 = 1.71$, $P = .19$). At 12 months, loss to follow-up was 37% (n = 98) and was greater in the experimental condition (n = 59, 45%) than in the control condition (n = 39, 30%; $\chi^2_1 = 5.56$, $P = .02$). Non-responders at 12 months had a higher baseline mean weekly alcohol intake as measured by WR (46.9 units, SD = 24.3) than non-responders (41.7 units, SD = 19.7; $t_{259} = 1.91$, $P = .06$).

Predictors of Successful Outcome: Mean Weekly Alcohol Consumption at 6 and 12 Months

Analyses of predictor-by-treatment interaction effects in terms of a successful reduction of mean weekly alcohol use at 6 and 12 months showed similar results for the last-observation-carried-forward (LOCF) and the completers-only model. We therefore present here only the intention-to-treat models. Results of the completers-only analysis are available from the first author.

Analyses of predictor-by-treatment interaction effects in terms of a successful reduction of mean weekly alcohol use found no significant effects for the putative predictors at 6 months (Table 2 and Table 3), with the exception of prior professional help for problem drinking, which emerged only after regression imputation (RI; Table 3). Its predictive power with regard to treatment response was only marginally significant and the explained variance was small (N = 261, beta .18, $P = .05$, $R^2 = .11$). At 12 months, female gender predicted successful alcohol reduction in both analysis models (Table 2 and Table 3). RI indicated a significant but small impact and explained variance (N = 261, beta = .27, $P = .01$, $R^2 = .03$), while the LOCF model showed a less strongly significant impact and a lesser amount of explained variance (N = 261, beta = .22, $P = .045$, $R^2 = .02$). High education level was identified as an additional predictor of successful outcome at 12 months. The LOCF analysis (N =

261, beta = .33, P = .01, R^2 = .03) showed a significant but modest effect and accounted for a small fraction of the variance in treatment outcome, but the effects in the RI model were not significant.

Table 2. Predictor-by-treatment interaction regressed individually using last-observation-carried-forward (LOCF) imputation at 6- and 12-month follow-up

Interaction term: participant characteristic by condition (Drinking Less = 1)	Effect on mean weekly alcohol consumption[a] at 6 months (N = 261)			Effect on mean weekly alcohol consumption[a] at 12 months (N = 261)		
	beta[b]	*P*	R^2 [c]	Beta[b]	*P*	R^2 [c]
Female	.003	.98	.03	.22	.045	.02
High educational level	.17	.17	.03	.33	.01	.03
High Internet competence	.13	.39	.03	.11	.44	.00
High treatment expectancy	.09	.37	.03	.09	.37	.00
Moderate problem drinking (female/male 14-35 or 21-50 units a week[a])	-.02	.86	.03	.04	.70	.06
Prior help for drinking	.07	.48	.03	-.05	.60	.00

[a]measured in standard units containing 10 g of ethanol

[b]beta: standardized regression coefficient

[c]R^2: amount of variance in treatment response explained by the model

Table 3. Predictor-by-treatment interaction regressed individually using regression imputation (RI) at 6- and 12-month follow-up

Interaction term: participant characteristic by condition (Drinking Less = 1)	Effect on mean weekly alcohol consumption[a] at 6 months (N = 261)			Effect on mean weekly alcohol consumption[a] at 12 months (N = 261)		
	beta[b]	*P*	R^2 [c]	beta[b]	P	R^2 [c]
Female	.06	.53	.12	.27	.01	.03
High educational level	.11	.37	.10	.21	.10	.03
High Internet competence	.002	.99	.10	.06	.97	.01
High treatment expectancy	.15	.14	.11	.04	.74	.00
Moderate problem drinking (female/male 14-35 or 21-50 units a week[a]	-.08	.46	.16	-.09	.39	.17
Prior help for drinking	.18	.05	.11	.02	.79	.01

[a]measured in standard units containing 10 g of ethanol

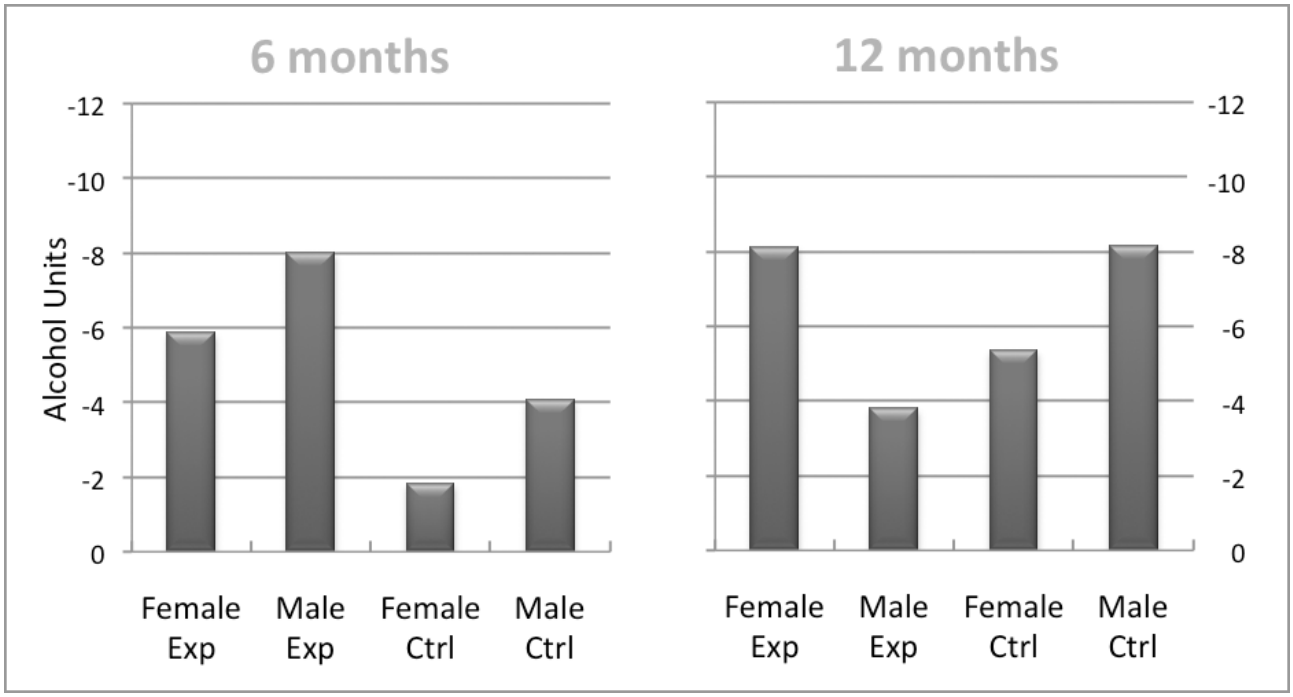
[b]beta: standardized regression coefficient

[c]R^2: amount of variance in treatment response explained by the model

We compared the mean weekly alcohol consumption at 6 and 12 months for the two conditions as shown by the intention-to-treat and completers-only analyses. The last-observation-carried-forward (LOCF) model appeared to be the most conservative estimation method for the total group, as it returned the highest alcohol intake in both conditions—thus suggesting less improvement. We therefore chose these more cautious LOCF results to report outcomes for the two main predictors identified in our analysis. Detailed information about the other two models can be obtained from the first author.

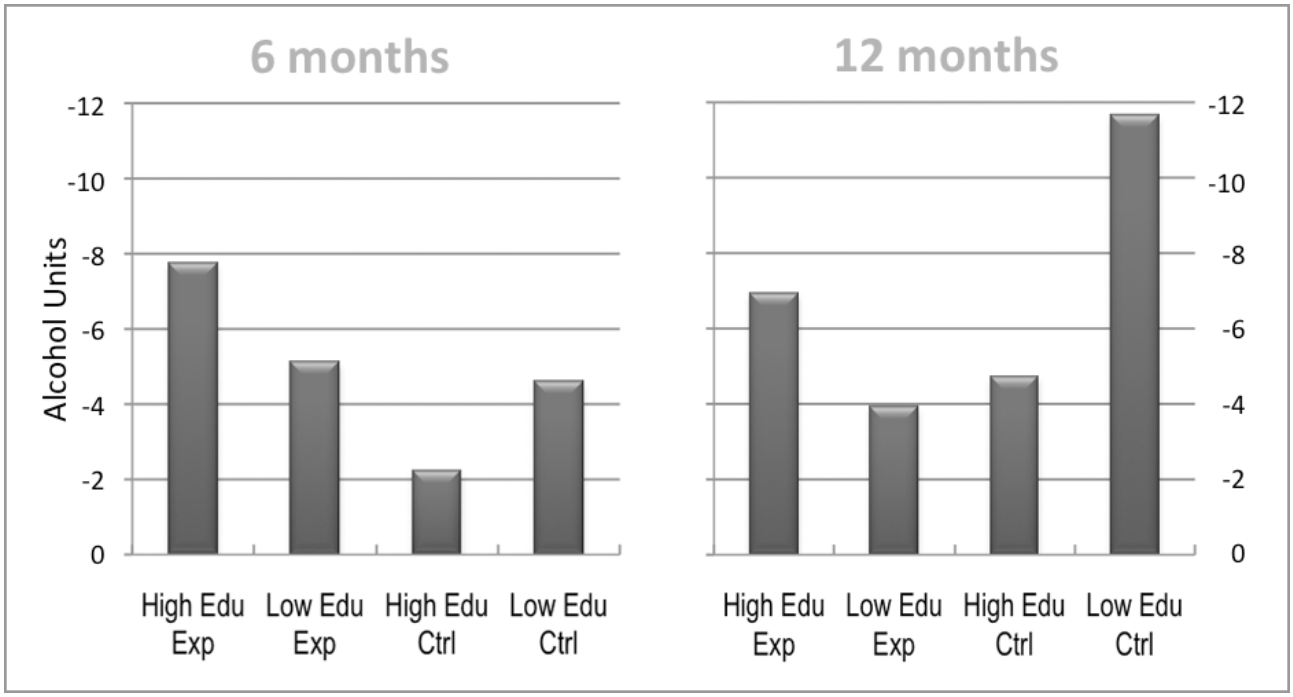
Figure 3 shows that women in the Drinking Less condition had not reduced their mean weekly alcohol consumption at 6 months to a greater degree than their male counterparts either in absolute terms (-5.86 vs -8.01 units) or in relative terms (-14.6% vs -16.9%). At 12 months, in contrast, women in the Drinking Less condition had reduced their intake (-8.13 units, -20.3% as compared to baseline) substantially more in both absolute and relative terms than female controls (-5.36 units, -15.3%) or than males in the experimental condition (-3.8 units, -8.0%). Interestingly, men in the control condition had decreased their intake at 12 months by a larger amount in absolute and relative terms (-8.16 units, -15.5%) than men who had completed the Drinking Less intervention (-3.8 units, -8.0%).

Figure 3. Reductions in mean weekly alcohol consumption (in mean weekly units containing 10 g of ethanol) in experimental and control groups 6 and 12 months after baseline, by gender (LOCF)



At 6 months, the more highly educated Drinking Less (experimental) participants had achieved the greatest reduction in both absolute and relative terms (-7.74 units, -19.0%) as compared to other categories (Figure 4). Although at 12 months their reduction had diminished by nearly one unit (0.80), they were still drinking less (-6.94 units, -17.1%) than at baseline, and their reduction remained greater than that of the lesser educated experimental participants (-3.93 units, -7.8%) and the more highly educated controls (-4.73, -11.6%). Interestingly, though, the lesser educated controls achieved the greatest reduction of all (-11.65 units, -23.1%) at 12 months.

Figure 4. Reductions in mean weekly alcohol consumption (in mean weekly units containing 10 g of ethanol) in experimental and control groups 6 and 12 months after baseline, by high and low education (LOCF)



Discussion

The aim of this study was to determine whether some groups would benefit more than other groups from Drinking Less, a Web-based self-help intervention for problem drinkers, when assessed at 6 and 12 months. We investigated six characteristics of the participants at baseline as putative predictors of treatment response: (1) female gender, (2) high level of education, (3)

high Internet experience, (4) moderate as opposed to severe level of problem drinking, (5) prior professional help for alcohol-related problems, and (6) high expectancies for Web-based intervention.

At the 6-month follow-up, we could not convincingly establish predictive value for any of these putative predictors, with the possible exception of prior help for alcohol problems, which was only marginally significant under the regression imputation model. Some other studies have likewise identified prior professional help as a predictor of positive client-by-treatment interaction leading to successful outcomes [23]. An explanation might be that reducing problem drinking requires multiple efforts over time (perhaps with a cumulative facilitating effect), and that help seeking is one such effort.

At 12 months, we found a modest prognostic value for female gender and for higher education; both variables were associated with better treatment response to the Drinking Less self-help intervention. Women who completed the intervention were found to have reduced their alcohol consumption to a significantly greater extent than men or than control group participants. Comparable results for female gender as a predictor of a successful brief intervention outcome in general population samples were reported by Sanchez-Craig and colleagues [31] and, to a lesser extent, for general practice patients by Reinhardt [41]. By contrast, several meta-analyses have found similar effectiveness of brief interventions for men and women in primary care populations [5,42] or even far stronger effects for men in general practice populations [9,43]. Women's favorable results in our Web-based course for problem drinking are, however, in line with findings that e-health in general is of particular interest to women [44].

Higher levels of education also had modest predictive power and explained a small amount of variance at 12 months in combination with Drinking Less. This finding is consistent with results from other studies that identified high education as interacting with treatment interventions to produce favorable outcomes [18,45]. Like female gender, high education is also reportedly associated with a greater use of the Internet for health-related issues [46]. Interestingly, the added benefit of high education in the Drinking Less treatment outcome at 12 months coincided with a remarkable decrease in alcohol consumption by lesser educated male control group participants. On the basis of our data we can only hint at possible explanations, such as that our online psychoeducational information may have had a delayed but more effective long-term impact on men with lower levels of education. This issue needs further research.

The other characteristics investigated were not found to act as predictors in our study. A moderate baseline level of problem drinking (in terms of mean weekly alcohol consumption) did not predict better outcomes than a severe level. This contrasts with the many studies that assume brief interventions to be better suited to moderate problem drinkers [4]. One explanation could be the high level of motivation and readiness to change that we found in both moderate and severe drinkers in our self-referred study sample (Table 1). Another explanation could be that baseline severity of drinking is less relevant to treatment outcome for problem drinkers in the general population than for the more severely alcohol-dependent clinical samples that form the basis of many studies. The former group may be experiencing a range of incipient problems, such that their treatment response may be influenced by a wider range of factors, whereas the health and social problems of severely dependent drinkers may have already crystallized into more specific forms [23].

We did not find any predictive value for the two remaining putative predictors, Internet experience and positive expectancies of treatment efficacy, in contrast to some other studies that did [47,48]. Explanations might be that Drinking Less is equally suitable for both experienced and beginning Internet users and that positive expectations were what prompted both the experimental and control participants in our self-referred sample to take part in the first place.

Limitations and Strengths

This study has several limitations that are important to acknowledge. We conducted secondary analysis of data from our pragmatic randomized trial [14].The overall loss to follow-up in that trial was substantial at both follow-up assessments (Figure 1). High dropout rates are common in self-help interventions for problem drinking without therapist guidance, whether Web-based or otherwise [49,50], but attrition rates appear to be especially high for those delivered over the Internet, as easy accessibility may also mean easy dropout.High loss to follow-up is therefore a potential concern in all Web-based self-help interventions [51,52].In the present study, we dealt with attrition data analytically as rigorously as possible by conducting intention-to-treat analyses, using last-observation-carried-forward and regression imputation. Nevertheless, the high loss to follow-up may still have biased our results by obscuring meaningful predictors.

Secondly, we conducted a prespecified subgroup analysis and hence cannot rule out false-positive or false-negative predictors resulting from multiple testing [53,54]. Given that we found only a marginally significant predictor (prior help) at 6 months and two further predictors (female gender and high educational level) at 12 months, this might well have been the case. On the other hand, we kept the number of putative predictors to a minimum and also appropriate in relation to our sample size [38]. The fact that we detected different predictors at 6- and 12-month follow-up could also mean that different factors operate at different points during the post-intervention period [16].

We were also limited by the data in the number of predictors we could investigate. That prevented us from studying self-efficacy, a potentially important predictor [21]. Nor could we investigate another key predictor, readiness to change [55], as most participants by far (n = 231, 88.5%; Table 1) were at the contemplation stage [39]. A final limitation is that our findings are generalisable only to self-referred problem drinkers in the general population who are motivated to take part in a Web-based self-help intervention.

Our study has a number of strengths as well. The study on which the analysis is based was one of the first pragmatic randomized

trials on the effectiveness of Web-based self-help interventions without therapeutic guidance for problem drinkers in the general population. The data also enabled us to examine short- and longer-term relationships. Because we had anticipated a high overall loss to follow-up when we first selected the trial sample, we included enough participants to ensure the statistical power to detect differences between the experimental and control conditions and between subgroups [14].

Conclusion

Female gender and a high level of education were found to have interacted with the Drinking Less self-help intervention to predict a somewhat better treatment response one year after the start of the intervention. This suggests that Web-based self-help without therapeutic guidance may hold a special attraction for problem drinkers with greater fears of stigmatization, including women or more highly educated people—population segments that might otherwise be difficult to reach with face-to-face brief interventions [56]. The non-stigmatizing approach to problem drinking in Web-based self-help and the lack of a need to interact with a therapist may form part of the appeal to these groups [44, 57].

At the same time, the effects of the predictors identified here offer only a very partial explanation for how client characteristics interact with treatment to affect outcome. Other baseline attributes such as self-efficacy may also play a role [21]. In addition, non-baseline predictors, including treatment progress factors (such as dose-response interaction stemming from variable treatment compliance) and posttreatment factors (such as social support), may prove to have stronger influences on client-by-treatment interaction and therapeutic outcomes, as has indeed been reported in clinical treatment samples [16,58].

Implications for Public Health Strategies

Our findings could enhance public health strategies that use stepped-care approaches to curb problem drinking in the general population. Since none of the groups we identified stood out conspicuously against others as deriving benefit from Drinking Less, we would argue that Web-based self-help is well suited to a broad, heterogeneous group of problem drinkers. It may therefore serve well as an initial intervention in a stepped-care model, suitable for matching to a large and varied group of problem drinkers in the general population and not just at more individual levels [58,59]. The 24/7 free access to Drinking Less guarantees swift entry to the help program, and such ready access is known to facilitate positive outcomes as well as additional help-seeking behavior, if needed [60,61]. To sustain treatment progress, booster sessions might be needed 6 months after the intervention, in particular to support male participants.

Future Studies

Our results add to the knowledge already gained from prediction studies in that we tested the role played by individual baseline attributes in the effectiveness of Web-based self-help for problem drinkers in the general population. The scope of future prediction research now needs to be extended to include the contributions of within-treatment progress variables, such as dose-response relationships and the time required to initiate positive behavioral change, and of posttreatment variables like social support. Replication of our study is needed in view of the novelty of Web-based interventions for problem drinkers and the related prediction research.

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Conflicts of Interest

None declared.

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Abbreviations

ATI: attribute treatment interaction
ITT: intention to treat
LOCF: last observation carried forward
QFV: quantity-frequency variability index
RI: regression imputation
WR: weekly recall

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Original Paper

Internet-Based Treatment for Adults with Depressive Symptoms: Randomized Controlled Trial

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Abstract

Background: Many depressed people do not receive help for their symptoms, and there are various barriers that impede help-seeking. The Internet may offer interesting alternatives for reaching and helping people with depression. Depression can be treated effectively with Internet-based cognitive behavioral therapy (CBT), but a short intervention based on problem solving therapy (PST) could constitute a worthwhile alternative to CBT.

Objective: In this study we evaluated the effectiveness of Internet-based CBT and Internet-based PST in comparison to a waiting list control group (WL), and we determined the differences between the two treatments.

Methods: We conducted a 3-arm randomized controlled trial to compare CBT, PST, and WL. The main inclusion criterion was presence of depressive symptoms (≥ 16 on the Center for Epidemiological Studies Depression scale). CBT and PST consisted of eight and five weekly lessons respectively. Participants were supported by email. Self-report measures of depression, anxiety, and quality of life were completed at pretest and after 5, 8, and 12 weeks.

Results: A total of 263 participants were randomized to the three conditions (CBT: n=88; PST: n=88; WL: n=87). Of the 263 participants, 184 (70%) completed questionnaires after 5 weeks, 173 (66%) after 8 weeks, and 151 (57%) after 12 weeks. Between-group effect sizes for depressive symptoms were 0.54 for CBT after 8 weeks (95% confidence interval (CI): 0.25 - 0.84) and 0.47 for PST after 5 weeks (95% CI: 0.17 - 0.77). These effects were further improved at 12 weeks (CBT: 0.69, 95% CI: 0.41 - 0.98; PST: 0.65, 95% CI: 0.36 - 0.95). For anxiety, effect sizes were also at a medium level. Effect sizes for quality of life were low. The number of participants showing clinically significant change at 12 weeks was significantly higher for CBT (n = 34, 38.6%) and PST (n = 30, 34.1%), compared to WL (n = 0).

Conclusions: Both Internet-based treatments are effective in reducing depressive symptoms, although the effect of PST is realized more quickly.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 16823487; http://www.controlled-trials.com/ISRCTN16823487/16823487 (Archived by WebCite at http://www.webcitation.org/5cQsOj7xf).

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KEYWORDS

Internet; depression; self-help; cognitive therapy; problem solving; randomized trial

Introduction

Depression is known to be one of the most prevalent mental disorders in the world [1] and is expected to be the disorder with the highest disease burden in high-income countries by 2030 [2]. Several trials have shown that there are effective self-help treatments for depression, including Internet-based self-help [3,4]. Still, many depressed people do not seek treatment [5]. Barriers to receiving adequate treatment include a shortage of skilled therapists, costs, and long waiting lists. More personal barriers to talking to a professional therapist include the idea that "talking" does not help, lack of willingness to talk to a stranger about personal problems, and fear of stigma [6].Thus, a major challenge lies in increasing the applicability and accessibility of Internet-based psychological treatments for a broad population with clinically relevant depressive symptoms and simultaneously minimizing contact with a professional therapist.

Most self-help therapies are based on cognitive behavioral therapy (CBT) because of its effectiveness with depression [4,7] and its structured format which makes it very suitable for self-help purposes. It is unknown whether other self-help formats are also effective. Problem-solving therapy (PST) is effective in reducing depression and several other mental health problems [8,9]. As far as we know, there is no study which evaluates Internet-based PST for depression. Recently, a new, generic, PST-based intervention for multiple mental health problems that could be applied through the Internet was developed [10]. As a general framework for the intervention, the model of Bowman and colleagues [11], which is called self-examination therapy, was used. The general idea of self-examination therapy is that subjects learn to regain control over their problems and lives by (1) determining what really matters to them, (2) investing energy only in those problems that are related to what matters, (3) thinking less negatively about the problems that are unrelated, and (4) accepting those situations that cannot be changed. Self-examination therapy was exclusively designed to be a self-administered treatment and has been found to be effective in several studies in the United States [11-14]. In these studies, self-examination therapy was offered in book format, and it is not known whether it also works when given via the Internet.

Our PST-intervention is a Dutch adaptation of self-examination therapy. After adjusting PST for the Internet, the effectiveness of this intervention was shown in patients with different mental health symptoms [10]. A characteristic of this intervention is its short duration of only 5 weeks. It would be interesting to know whether this short, Internet-based intervention works equally well as an 8-week Internet-based CBT intervention, thereby possibly making it a worthwhile alternative.

The current study evaluated two Internet-based interventions with support for adults with elevated depressive symptoms. The goal of this study is twofold. First, we wanted to evaluate the effectiveness of Internet-based CBT and Internet-based PST compared to a waiting list control group. Second, we wanted to determine the differences between the two treatments regarding their effectiveness.

Method

Design

This study is a randomized controlled trial with three groups: two Internet-based self-help interventions (CBT and PST) and a waiting list control group (WL). The study was designed to compare the efficacy of each of the two interventions with the WL. The sample size was based on the expected difference in the primary outcome variable (ie, depressive symptoms, between one of the intervention groups and the waiting list control group at post-test). Based on a power of 0.80 in a one-tailed test, an alpha of 0.05, we needed 100 subjects in each condition to show an effect size of 0.40. Therefore, the total sample size was determined at 300.

Participants

Participants were recruited through advertisements in daily and weekly newspapers and through banners on general websites such as Google and on websites relating to mental health problems. Recruitment took place during two periods, in August/September 2006 and in January/February 2007. Application took place via a website. After application, subjects received a brochure about this study and an informed consent form by post. After giving informed consent, participants received the baseline questionnaire by email. The study protocol was approved by the Medical Ethics Committee of the VU University Medical Center.

All adults aged 18 years and older with depressive symptoms who were willing to participate in a self-help course, were eligible for this study. The main inclusion criterion was a score of 16 or more on the Center of Epidemiologic Studies Depression—scale (CES-D) [15]. Participants with more severe symptoms of depression (indicated by a CES-D score of 32 or higher) were advised to consult their general practitioner but could participate in the study. Other inclusion criteria were: sufficient knowledge of the Dutch language, access to Internet, and having an email address. No exclusion criteria were defined for this study.

Randomization

Randomization took place at an individual level after the baseline measurement and one week before the start of the interventions. Received baseline questionnaires were numbered in order of arrival. Subjects were randomized into three groups, two intervention groups and a waiting list control group. We used block randomization, with each block containing 9 allocations. An independent researcher made the allocation schedule with a computerized random number generator. Immediately after randomization, subjects were informed about the randomization outcome by email.

Interventions

Problem Solving Therapy (PST)

Our PST-based intervention is a Dutch adaptation of SET from Bowman [11]. We added more information, examples, exercises, and forms. PST consisted of three steps. First, the subjects described what really matters to them. Second, they wrote down their current worries and problems. They divided these problems

into three categories: (a) unimportant problems (problems unrelated to the things that matter to them), (b) solvable problems, and (c) problems which cannot be solved (eg, the loss of a loved one). For each of these three types of problems a different strategy is proposed to solve the problems or to learn to cope with the unimportant and unsolvable ones. The core element of PST is to address the solvable problems by the following six-step procedure: describing the problem, brain-storming, choosing the best solution, making a plan for carrying out the solution, actually carrying out the solution, and evaluation. During the third and last step, the subjects made a plan for the future in which they described how they would try to accomplish those things that matter most to them. The course took 5 weeks and consisted of one lesson a week. The intervention made use of information, exercises, examples of people applying the principles of PST, and a built-in feedback system. There were no audio-visual aids. See Multimedia Appendix 1 for a screenshot of the PST intervention.

Cognitive Behavioral Therapy (CBT)

The CBT intervention was developed by the Trimbos Institute—The Netherlands Institute of Mental Health and Addiction. This intervention is based on the "Coping with Depression" course (CWD) [16], Dutch version [17].CWD is a highly structured psycho-educational form of cognitive behavior therapy for depression. Theoretically, this course is based on the social learning theory according to which depression is associated with a decrease in pleasant and an increase in unpleasant person-environment interactions. People's problems are viewed as behavioral and cognitive patterns which can be unlearned or relearned.

Like CWD, CBT in this study included psycho-education and focused on skills such as relaxation, cognitive restructuring (including worrying), social skills, and how to increase the number of pleasant events. CBT consisted of eight lessons, one lesson a week. The ninth lesson took place 12 weeks later. See Multimedia Appendix 1 for a screenshot of the CBT intervention. The intervention made use of information, exercises, and audio-visual aids with instructions during the lessons and examples of people applying the principles of CBT. This Web-based intervention has been found to be effective in older adults with sub-threshold depression, both in the short-term [18] and at one-year follow-up [19] and was found to be superior to a group intervention.

Support

Subjects in both intervention groups received support during the intervention period by email from Master-level students of clinical psychology. Students underwent training of 6 hours in total. This training was given by the first author of this article. Support was directed at helping the participant to work through the intervention, and not at developing a therapeutic relationship or giving direct or individual advice on how to cope with depressive symptoms or other problems. The content of the feedback consisted of three aspects: showing empathy by letting participants know that the coach had read the assignments, being positive by giving compliments on what the participant had done, and giving suggestions on how to continue with the course.

Every week, a standardized email was sent to the participants. This email communicated the lesson of that week and the date on which the assignments were to be sent to their coach. Participants received feedback within three working days. All feedback was checked by the first author and if necessary comments were added before it was sent to the participants. The average time spent on each participant by a therapist to provide feedback and answer questions via email is estimated to be 20 minutes per week, resulting in approximately 100 minutes for PST and 160 minutes for CBT.

Outcome Measures

All participants were contacted for outcome assessments at 5, 8, and 12 weeks after the start of the interventions. All questionnaires were administered on the Internet. Participants received an email with a link to the questionnaire.

Depressive Symptoms

The Center for Epidemiological Studies Depression scale (CES-D, Dutch version) [15] was the primary outcome measure for depressive symptoms. The CES-D is widely used for identifying people with depressive symptomatology. Scores of 16 and higher represent a clinically significant level of depressive symptoms. The validity of the CES-D has been tested in different populations [20-22]. The CES-D consists of 20 items and the total score varies between 0 and 60 with higher scores indicating more depression [15].

Anxiety

The anxiety subscale of the Hospital Anxiety and Depression Scale (HADS) was used for the measurement of anxiety symptoms [23]. The anxiety subscale consists of 7 items. Scores range from 0 to 21 with higher scores indicating more anxiety. The HADS showed good homogeneity and reliability, with Cronbach's alpha ranging from .81 to .84 in various normal and clinical Dutch samples [23].

Quality of Life

Quality of life was assessed with the EuroQol Questionnaire (EQ5D) [24], which is a validated tool for measuring general health-related quality of life. It consists of 5 items (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), each of which is rated as causing "no problems", "some problems", or "extreme problems". The EQ5D thus distinguishes 486 unique health states. Each unique health state has a utility score which ranges from 0 (poor health) to 1 (perfect health). We used this single EQ5D summary index score.

Statistical Analyses

Missing Values

All analyses were performed on the intention-to-treat sample. The Linear Mixed Modeling (LMM) procedure was used for all analyses to estimate missing values. LMM includes incomplete cases in the analysis and employs restricted maximum likelihood estimation to calculate parameter estimates. LMM assumes that missing data are missing at random.

Baseline Differences and Attrition

Baseline differences in demographic and clinical characteristics were investigated using Chi-square tests, *t*-tests, and analysis of variance (ANOVA). Attrition was defined as completing none or one of the three post-treatment measures.

Treatment Differences

LMM was used to investigate treatment differences. As we were interested in the differences between groups at each time period, we treated time as a categorical variable. Treatment condition was treated as a fixed effect. The intercept was included as a random effect.

Effect Sizes

Between-group effect sizes were calculated according to Cohen's d. Effect sizes of 0.8 can be assumed to be large, while effect sizes of 0.5 are moderate, and effect sizes of 0.2 are small [25]. Estimated data from the LMM procedure were used to calculate effect sizes.

Clinically Significant Change

Clinical significant change was determined with norms for the outcome measure and with the Reliable Change Index [15,26]. We used the cut-off score of 16 on the CES-D as an indication of recovery. RC was used as an index for improvement. Results were analyzed for the intention-to-treat sample as they were for the sample who completed questionnaires.

Completion Status

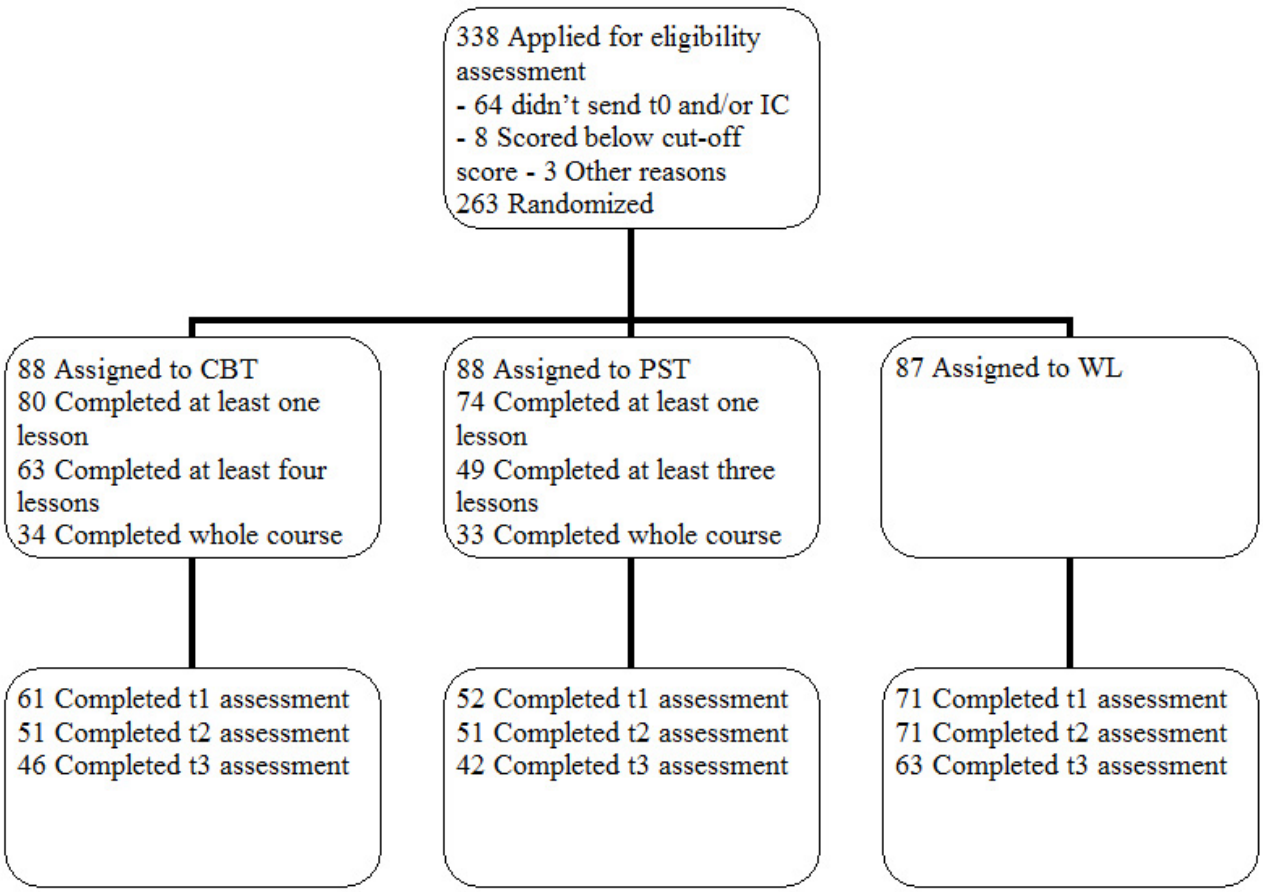
LMM was used to investigate differences in development of depressive symptoms between treatment completers, non-completers, and WL. Time was treated as a continuous covariate. Completers were defined as subjects who completed all lessons.

Results

Participants

Figure 1 shows the progress of participants through the trial. Of the 338 individuals who were potentially interested in participating, 64 did not send back the baseline questionnaire or did not give informed consent. From 274 subjects we received baseline questionnaires and written informed consent. Of these, 8 did not score above the cut-off of 16 on the CES-D and 3 subjects decided not to participate for other reasons. The remaining 263 participants were randomized to one of the three conditions. Table 1 presents demographic characteristics. Participants were mainly female (71%, n = 187). The mean age was 45 years (SD: 12.1). Almost all subjects came from the Netherlands (92%, n = 243). A majority of the participants (64%, n = 168) had completed higher vocational education or university. The mean score of the 263 participants on the CES-D at baseline was 31.7 (SD: 7.5, median: 31.0). There were no statistically significant differences between the groups at baseline with respect to demographics or symptoms (Table 1 and Table 2).

Figure 1. Participant flow



Attrition

Attrition rates for the full sample were 30% (n = 79) at the 5-week assessment, 34% (n = 90) at 8 weeks, and 43% at 12 weeks (n = 112). Reasons for the high level of attrition were unknown. Some participants dropped out because of, for example, other treatment, feeling better, lack of time, and problems understanding the computer program, but the majority did not specify any reason. There were significant differences in attrition rates between the three conditions. Attrition rates were lower in the control group than in both intervention groups at all assessments (5wk WL: 18%, n = 16, 5wk CBT: 31%, n = 27, 5wk PST: 41%, n = 36, $\chi^2_{2,263} = 10.58$, $P = .01$; 8wk WL: 18%, n = 16, 8wk CBT: 42%, n = 37, 8wk PST: 42%, n=37, $\chi^2_{2,263} = 14.47$, $P = .001$; 12wk WL: 28%, n = 24, 12wk CBT: 48%, n = 42, 12wk PST: 52%, n = 46, $\chi^2_{2,263} = 12.33$, $P = .002$).

Some statistically significant differences at baseline were detected between participants who completed post-treatment measures and those who did not. Participants who completed post-treatment measures were more likely to have been born in the Netherlands (95%, n = 161) than participants who didn't (87%, n = 82, $\chi^2_{1,263} = 5.55$, $P = .02$), and they were also older (46.6 and 41.9 years respectively, $t_{259} = -2.91$, $P = .004$).

Table 1. Demographic characteristics at baseline

	All (n = 263)	CBT (n = 88)	PST (n = 88)	WL (n = 87)	Statistic
Age (years)	45.0	45.7	45.1	44.1	$F_{2,258} = 0.40$, $P = .67$
Female	187 (71.1)	61 (69.3)	57 (64.8)	69 (79.3)	$\chi^2_2 = 4.71$, $P = .10$
Country of birth					$\chi^2_2 = .12$, $P = .94$
The Netherlands	243 (92.4)	81 (92.0)	82 (93.2)	80 (92.0)	
Education[a]					$\chi^2_4 = 5.96$, $P = .20$
lower	23 (8.7)	9 (10.2)	5 (5.7)	9 (10.3)	
middle	72 (27.4)	26 (29.5)	18 (20.5)	28 (32.2)	
higher	168 (63.9)	53 (60.2)	65 (73.9)	50 (57.5)	
Paid job	135 (53.8)	43 (52.4)	43 (50.6)	49 (58.3)	$\chi^2_2 = 1.12$, $P = .58$

Note: Data are presented as n (%) of participants unless otherwise indicated.

[a]lower = primary education or lower general secondary education, middle = intermediate vocational education or high school, high = higher vocational education or university

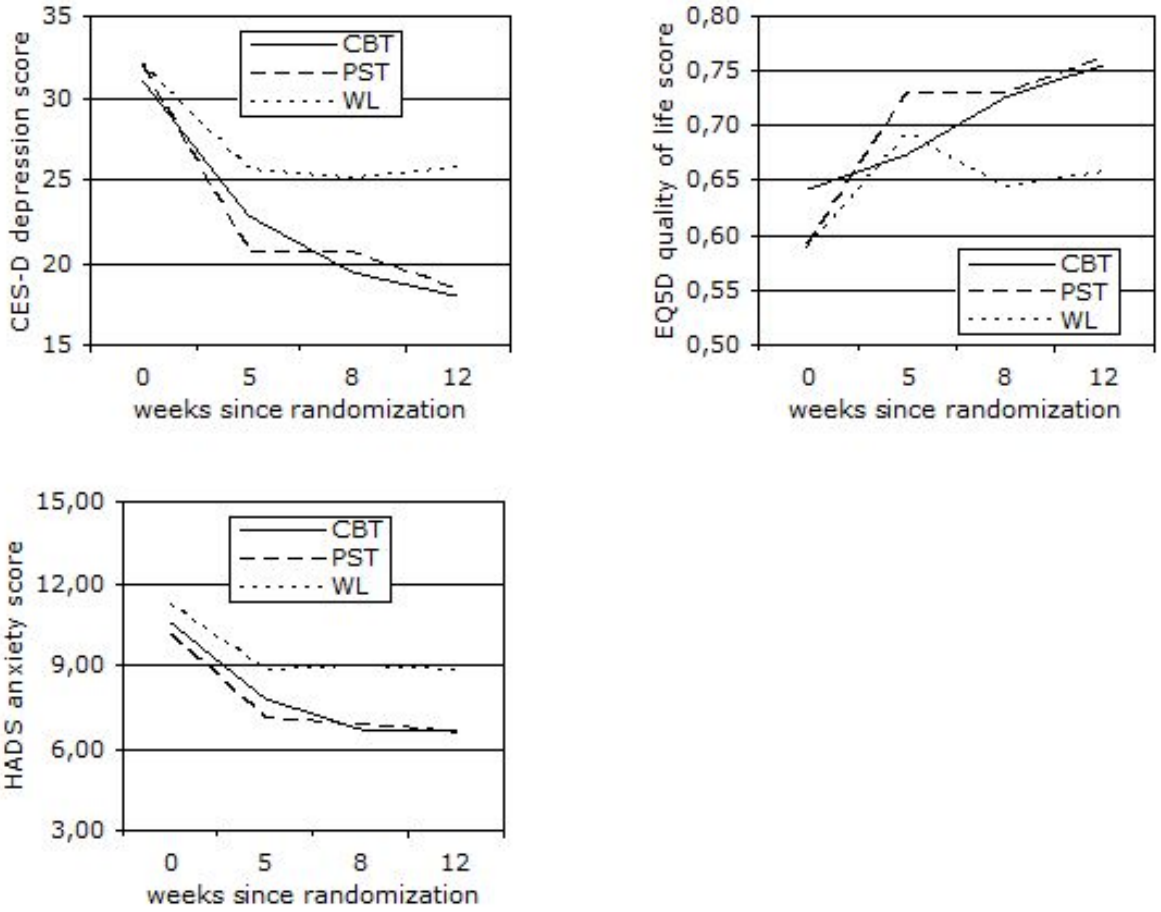
Effects of the Interventions

Table 2 reports the estimated means and standard deviations as produced by the linear mixed model procedure, using the intention-to-treat sample. These means are used to produce the estimated trajectories in Figure 2. There was significant overall improvement over time for all groups on the CES-D, $F_{3,543} = 124.57$, $P < .001$. In addition, results revealed significant group x time interaction effects on the CES-D, $F_{6,543} = 5.61$, $P < .001$. As shown in Figure 2, mean depression scores after 5 weeks were significantly lower in PST than in WL, $t_{592} = -3.01$, $P = .002$. After 8 weeks, both CBT and PST showed significantly lower depression scores than WL (CBT: $t_{598} = -3.64$, $P < .001$, PST: $t_{596} = -2.89$, $P = .004$). Also after 12 weeks, CBT and PST showed significantly lower depression scores than WL (CBT: $t_{635} = -4.73$, $P < .001$, PST: $t_{650} = -4.34$, $P < .001$). No differences were found in depression scores between CBT and PST at each assessment.

Regarding anxiety scores, significant overall improvement over time was found for all groups on the HADS, $F_{3,538} = 81.74$, $P < .001$ (Figure 2). After 5 weeks, PST showed significantly lower mean anxiety scores than WL, $t_{582} = -2.78$, $P = .006$. After 8 weeks, both CBT and PST showed significantly lower anxiety scores than WL (CBT: $t_{588} = -3.63$, $P < .001$, PST: $t_{586} = -3.34$, $P = .001$). Also after 12 weeks, CBT and PST showed significantly lower anxiety scores than WL (CBT: $t_{627} = -3.51$, $P < .001$, PST: $t_{642} = -3.35$, $P = .001$). No differences were found in anxiety scores between CBT and PST at each assessment.

As shown in Figure 2, there was significant overall improvement over time for all groups on the EQ5D, $F_{3,502} = 23.25$, $P < .001$. Furthermore, results showed significant group x time interaction effects on the EQ5D, $F_{6,501} = 2.97$, $P = .007$. No differences were found between each of the treatments and WL after 5 weeks. After 8 weeks, both CBT and PST showed significantly higher quality of life scores than WL (CBT: $t_{560} = 2.11$, $P = .04$, PST: $t_{564} = 2.20$, $P = .03$). After 12 weeks, CBT and PST indicated significantly higher quality of life scores than WL as well (CBT: $t_{588} = 2.41$, $P = .02$, PST: $t_{613} = 2.52$, $P = .01$). No differences were found in quality of life scores between CBT and PST at each assessment.

Figure 2. Estimated trajectories of improvement in depression, anxiety and quality of life scores by treatment assignment



All effect sizes are presented in Table 3. Effect sizes were based on the intention-to-treat sample, using the estimated data from Table 2. The between-group effect sizes were around a medium level for depression and anxiety. Low effect sizes were found for quality of life. The highest values were found for depression after a 12-week follow-up: CBT: 0.69 (95% CI: 0.41 - 0.98), PST: 0.65 (95% CI: 0.36 - 0.95). The lowest value was found for PST on quality of life scores, d = 0.14, which was non-significant.

Table 2. Estimated outcomes of CBT and PST on depression, anxiety, and quality of life

Measure and treatment condition	Baseline M (SD)	5 weeks M (SD)	8 weeks M (SD)	12 weeks M (SD)
CES-D				
CBT	31.2 (9.3)	22.9 (10.6)	19.4 (11.3)	17.9 (11.7)
PST	31.9 (9.3)	20.6 (11.2)	20.6 (11.3)	18.4 (12.1)
WL	32.1 (9.3)	25.6 (9.9)	25.2 (9.9)	25.8 (10.4)
HADS				
CBT	10.6 (3.6)	7.8 (4.1)	6.7 (4.4)	6.6 (4.5)
PST	10.2 (3.6)	7.1 (4.3)	6.9 (4.4)	6.6 (4.7)
WL	11.3 (3.6)	8.9 (3.9)	9.0 (3.8)	8.9 (4.0)
EQ5D				
CBT	0.64 (0.18)	0.68 (0.27)	0.73 (0.27)	0.76 (0.27)
PST	0.59 (0.18)	0.73 (0.27)	0.73 (0.27)	0.76 (0.27)
WL	0.59 (0.18)	0.69 (0.27)	0.65 (0.27)	0.66 (0.27)

Table 3. Effect sizes (95% CI)

Measure and treatment condition		5 weeks	8 weeks	12 weeks
CES-D	CBT		0.54 (0.25 - 0.84)	0.69 (0.41 - 0.98)
	PST	0.47 (0.17 - 0.77)		0.65 (0.36 - 0.95)
HADS	CBT		0.54 (0.25 - 0.83)	0.52 (0.23 - 0.81)
	PST	0.42 (0.12 - 0.72)		0.50 (0.21 - 0.80)
EQ5D	CBT		0.30 (0.02 - 0.59)	0.36 (0.07 - 0.65)
	PST	0.14 (-0.14 - 0.42)		0.38 (0.09 - 0.68)

Clinically Significant Change

Data on clinically significant change are presented in Table 4. Rates are reported for participants who were randomly assigned to the conditions (estimated) as well as for participants who completed questionnaires (observed).

Estimated results showed significant between-group differences in terms of clinically significant change on the CES-D. Improvement and recovery after 5 weeks more often occurred in PST (n = 18) than in CBT and in WL, $\chi^2_{2,263} = 38.43$, $P < .001$. After 8 and 12 weeks, both CBT and PST showed more improvement and recovery than WL (8 weeks: $\chi^2_{2,263} = 28.73$, $P < .001$, 12 weeks: $\chi^2_{2,263} = 42.31$, $P < .001$). The number of participants showing clinically significant change at 12 weeks was n = 34 for CBT, n = 30 for PST, and n = 0 for WL. Observed results also showed significant between-group differences at each assessment (5 weeks: $\chi^2_{2,184} = 9.63$, $P = .008$, 8 weeks: $\chi^2_{2,173} = 7.0$, $P = .03$, 12 weeks: $\chi^2_{2,151} = 11.57$, $P = .003$).

Table 4. Proportions of participants reaching the criteria of clinically significant change on the CES-D as defined by Jacobson and Truax (1991)

	5 weeks, No. (%)		8 weeks, No. (%)		12 weeks, No. (%)	
Treatment Condition	Estimated	Observed	Estimated	Observed	Estimated	Observed
CBT	0 (0.0)	11 (18.0)	26 (29.5)	21 (41.2)	34 (38.6)	18 (39.1)
PST	18 (20.5)	19 (36.5)	18 (20.5)	20 (39.2)	30 (34.1)	17 (40.5)
WL	0 (0.0)	10 (14.1)	0 (0.0)	15 (21.1)	0 (0.0)	9 (14.3)

Treatment Completers Versus Non-completers

Many participants failed to complete the whole course. Of those participants assigned to CBT and PST, 8 (9.1%) versus 14 (15.9%) completed no lesson at all. Of those assigned to CBT, 63 (71.6%) participants completed at least four lessons and 34 (38.6%) completed all eight. Of those assigned to PST, 49 (55.7%) participants completed three or more sessions and 33 (37.5%) finished the whole course. More completers had received higher education in contrast to the non-completers (75% vs 60.4%),$\chi^2_{1,178} = 4.1$, $P = .04$. Regarding clinical characteristics, completers showed significantly lower depression scores at baseline than non-completers (29.8 vs 32.8), $t_{176} = 2.69$, $P = .008$. In addition, quality of life scores were significantly higher among completers (0.68 vs 0.57), $t_{165} = -3.38$, $P = .001$.

We investigated differences in development of depression scores between treatment completers, non-completers, and WL, using the intention-to-treat sample. The interaction between completion status and time was significant $F_{2,578} = 12.58$, $P < .001$. Both completers and non-completers showed lower depression scores over time than WL (completers: beta = -2.15, $t_{537} = -4.11$, $P < .001$, non-completers: beta = -2.56, $t_{608} = -4.33$, $P < .001$). No differences were found in improvement of depressive symptoms between completers and non-completers (beta = .41, $t_{596} = 0.68$, $P = .50$). Table 5 presents the observed outcomes on depression for participants who completed questionnaires.

Table 5. Descriptive statistics of treatment completers, non-completers, and waiting list (WL) on depression

Completion status	N	Baseline M (SD)	N	5 weeks M (SD)	N	8 weeks M (SD)	N	12 weeks M (SD)
completers	72	29.8 (6.8)	67	20.0 (9.2)	65	17.9 (9.2)	62	16.5 (10.5)
non-completers	106	32.8 (7.9)	48	23.4 (10.4)	39	22.5 (10.5)	28	18.9 (9.9)
WL	85	32.0 (7.5)	69	25.1 (9.2)	69	24.9 (11.5)	61	26.2 (10.9)

Discussion

Principal Results

The results from the present study show that Internet-based CBT and Internet-based PST are both effective in reducing depressive symptoms in comparison to a waiting list control group. These results were visible directly after treatment and 12 weeks after baseline. There is no indication that one is more effective than the other, although the effects are realized faster by PST than by CBT. Both Internet-based treatments had medium effect sizes for depression after treatment (CBT: d = 0.54, PST: d = 0.47), and these effects were further improved at 12 weeks (CBT: d = 0.72, PST: d = 0.66). Furthermore, 34 participants of CBT (38.6%) and 30 of PST (34.1%) were improved and recovered to a clinically significant degree at follow-up. The secondary outcomes (symptoms of anxiety and quality of life) also showed significant gains over time for both treatment groups, but again, no differences could be demonstrated between them.

Comparison with Prior Work

Both treatments showed a fast improvement during the first 5 weeks. Rapid improvement at the beginning of treatment is a common finding [27]. Nevertheless, the fast improvement during PST is striking. Perhaps the focus at the beginning of the treatment (activity scheduling for CBT and problem-solving for PST) affects speed of improvement, although both activity scheduling and problem-solving are effective cognitive behavioral strategies [8,28]. More plausible is the role of non-specific factors like expectations. For example, the expectation that symptoms reduce within 5 weeks, could lead to more rapid improvement in PST. It would be worthwhile to shorten the CBT intervention to see if the same effects could be reached as with an 8-week intervention.

The effect sizes we found for depression are somewhat larger than the effect sizes for a subgroup of studies about Internet-based treatment for depression reported in a recent meta-analysis [4]. The interventions in this subgroup of studies had no support, which could be a reason for the difference in effect size. Only one study about depression treatment including support showed a high effect size [29]. With regard to clinical change, the proportion of improved and recovered participants is roughly in line with some other studies [10,18,30]. It is, however, not often that clinically significant change is reported, making it difficult to say which proportions are commonly found.

A crucial problem of self-help is the amount of treatment participants receive. The level of completers in our study (38%) is relatively low in comparison to other trials about Internet-based self-help for depression [29,31,32]. The benefits of these interventions, when taking into consideration the population as a whole, however, could be huge. At a relatively low cost, it's possible to reach and treat many people with Internet-based therapies, as compared to traditional therapies. It should be noted that we used a strict criterion to define completion. To increase completion rates, telephonic support could be considered in addition to, or instead of, email support [33]. The pace of one lesson per week may have been too rapid, and giving an extra two weeks, for example, could have led to higher completion rates.

Non-completers had lower levels of education and more clinical symptoms at baseline than completers. In fact, our whole sample had a higher education level in comparison to the general population. This raises the question about the suitability of these interventions for people with lower levels of education or more severe symptoms. The importance of completing the whole treatment is unclear. We found that non-completers improved more than those on the waiting list, and no differences were found between participants who completed all lessons and participants who completed fewer lessons.

Limitations

A number of limitations should be noted. First, we were faced with a high attrition rate, which is a general problem in Internet interventions [34]. Attrition in the control group was significantly lower than that of both treatment groups. We could find no indications for selection bias since we could not demonstrate clear baseline differences between participants who completed questionnaires and participants who did not (except for age and country of birth). The bias that still might have been introduced was accounted for by estimating all missing data (based on restricted maximum likelihood) and performing intention-to-treat analyses. Nevertheless, estimating data and using "imputed" values might have led to unreliable estimates.

It's also possible that our methods for recruiting people could have led to selection-bias. Therefore, the results may not apply to all depressed people (eg, clinical populations), but we do think that the depression scores of the participants in this study (31.7) are well above the normal range scores and represent clinical forms of depression. A sample of self-referred elders with depressive symptoms and two psychiatric patient samples showed mean CES-D scores of respectively 25.9, 24.4, and 39.1 [21,35].

Another limitation concerns the (lack of) diagnosis. Self-report was used to include participants. However, one of the potential benefits of internet-delivered treatments is that people can stay at home. Requiring participants to come in for a clinical assessment would therefore introduce a limitation. From an economic perspective, the idea of Internet-based self-help without therapist contact is attractive because costs are saved which could be allocated to patients with more extensive care needs.

A methodological issue concerns the comparison of interventions with a different duration. We remedied this obstacle by reporting the effect size, a standardized measure, which makes it possible to compare the effect of CBT at 8 weeks with PST at 5 weeks. In addition, participants were not blind to their condition, which is inherent to studies of psychotherapy in general, and could introduce some bias. Furthermore, our study was limited by a short follow-up period of 12 weeks.

Future Research and Implications

Future research on Internet-based treatment for depression would benefit from evaluations in other populations. Besides the fact that the effective mechanisms of treatment are still unclear, the

cost-effectiveness of Internet-based treatments also needs to be investigated.

Clinical implications of the results in this study are twofold. First of all, this study shows promising results for a short term PST-based intervention. It gives some insight into the necessary length of a treatment to reach a significant reduction of depressive symptoms. Short interventions reduce costs in terms of time and effort, for the depressed participant as well as for the supporting therapists. The second implication concerns the possibility of fitting a short, generic intervention, like the Internet-based PST in this study, within a stepped-care path. The generic nature of PST makes it suitable to address different kinds of symptoms. This is of practical use because of the large co-morbidity of diverse psychological symptoms.

Conclusions

In summary, the results of this study provide support for the use of a short Internet-based problem solving therapy with depressive symptoms. The results seem to be as good as other, longer, Internet-based therapies.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshots of the PST and CBT interventions

[PDF file (Adobe PDF), 496 KB - jmir_v10i4e44_app1.pdf]

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Abbreviations

CBT: Internet-based cognitive behavioral therapy
CES-D: Center for Epidemiological Studies Depression scale
CI: confidence interval
CWD: Coping with Depression course
EQ5D: EuroQol questionnaire
HADS: Hospital Anxiety and Depression Scale

LMM: linear mixed modeling
PST: Internet-based problem solving therapy
RC: reliable change index
SET: self-examination therapy
WL: waiting list control group

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Original Paper

Patient Accessible Electronic Health Records: Exploring Recommendations for Successful Implementation Strategies

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Abstract

Background: Providing patients with access to their electronic health records offers great promise to improve patient health and satisfaction with their care, as well to improve professional and organizational approaches to health care. Although many benefits have been identified, there are many questions about best practices for the implementation of patient accessible Electronic Health Records (EHRs).

Objectives: To develop recommendations to assist health care organizations in providing patients with access to EHRs in a meaningful, responsible, and responsive manner.

Methods: A Patient Accessible Electronic Health Record (PAEHR) Workshop was held with nationally and internationally renowned experts to explore issues related to providing patient access to the EHR and managing institutional change.

Results: The PAEHR Workshop was attended by 45 participants who discussed recommendations for the implementation of patient accessible EHRs. Recommendations were discussed under four subject domains: (1) providing patient access to the EHR, (2) maintaining privacy and confidentiality related to the PAEHR, (3) patient education and navigation of the PAEHR, and (4) strategies for managing institutional change. The discussion focused on the need for national infrastructure, clear definitions for privacy, security and confidentiality, flexible, interoperable solutions, and patient and professional education. In addition, there was a strong call for research into all domains of patient accessible EHRs to ensure the adoption of evidence-based practices.

Conclusions: Patient access to personal health information is a fundamental issue for patient engagement and empowerment. Health care professionals and organizations should consider the potential benefits and risks of patient access when developing EHR strategies. Flexible, standardized, and interoperable solutions must be integrated with outcomes-based research to activate effectively patients as partners in their health care.

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KEYWORDS

Electronic Health Record (EHR); Personal Health Record (PHR); medical records; recommendations; health planning guidelines; access; access to information

Introduction

There has been a growing interest in, and demand for, harnessing the power of electronic health records (EHRs) beyond just the delivery of care. The demand has arisen in part from the trend toward consumerism in health care. Patients and the public are no longer satisfied with the status quo and a growing wave of public and patient expectation is mounting [1-6]. Health care organizations are also realizing the need for patient accessible health records (PAEHRs) on a number of different levels including improving the patient experience, supporting patients with chronic conditions, improving transparency, increasing referral rates, and ensuring the continuity of care beyond the hospital walls. In addition, there is the growing global trend of adopting legislation to ensure that patients are able to access, review, and amend their medical record [7-18]. The coupling of these social and professional trends with new technologies that provide ubiquitous access to health information offers tremendous opportunity to transform the delivery of care.

A white paper from the American Association of Medical Informatics outlined the potential barriers to and benefits for the adoption of personal health records (PHRs) not only for patients, but also for health care organizations. There are a number of barriers to overcome, including privacy and security issues, change management issues, and the lack of basic infrastructure such as EHRs [19]. At the same time, potential benefits for patients include better access to health information, increased ability to self-manage chronic health conditions, increased medication tracking and safer prescription renewals, etc., and improved connections for patients and providers [19,20]. Potential benefits for organizations and health professionals include increased patient satisfaction, continuity of care, and improved standardization of care as organizations streamline processes and information to address this change in clinical practice [19,20].

In recognition of the potential benefits, many strategies and approaches have been developed to record electronically health and medical information and allow for electronic access to this information, most commonly through the Internet [21-25] and portable solutions such as CD-ROMs, mobile phones, and USB devices [26]. In addition, several pilot studies have demonstrated that many patients would review and interact with their medical record on an ongoing basis if the record was made available to them [2,5,6,16,27]. Many researchers and health care organizations have begun to implement pilot projects to test the concept of PAEHRs, but, with some notable exceptions [2], very few have been able to overcome all of the operational barriers to integration with clinical practice [21]. A few organizations, such as the Markle Foundation, have begun to establish basic principles for patient access to the EHRs [28,29], but there are very few standards, guidelines, and roadmaps for both the IT and clinical adoption of PAEHRs [20].

Mechanisms, in the form of policies and procedures, are therefore necessary to ensure success in moving towards a system that supports wide-scale use of PAEHRs. In an attempt to meet this need, the Canadian Committee for Patient Accessible Electronic Health Records (CCPAEHR) undertook a two-part project with the intent of (1) scanning the country to determine hospital readiness for the implementation and use of PAEHRs [30] and (2) assembling a PAEHR Workshop of key stakeholders in the field of the EHR and PAEHRs. The CCPAEHR is a group of Canadian researchers, clinicians, information specialists, and educators working together to promote patient access to and involvement with electronic health records. This paper presents the findings of the PAEHR Workshop. The results from the national survey have been published separately [31].

Methods

PAEHR Workshop

In response to the need for recommendations around the implementation of patient accessible electronic health records, a PAEHR Workshop was held in Toronto, Canada in October 2006 with nationally and internationally renowned experts. This workshop was designed to explore issues related to providing patient access to the EHR and managing the requisite institutional change. The objective was to develop draft recommendations that would assist health care organizations in providing patients with access to EHRs in a meaningful, responsible, and responsive manner.

The PAEHR Workshop involved the following steps: (1) a working group from an expert body, the CCPAEHRs, was established; (2) a national survey was conducted; (3) based on the published literature and the survey [2,5,32], a framework for patient access was developed; (4) four subject domains were identified; (5) subject briefs were created by experts in the working group; (6) the briefs were then provided to the entire CCPAEHR group for content validation; (7) national and international experts were identified through literature reviews and professional networks and invited to participate; (8) invited experts were sent copies of the subject briefs for their review and input; (9) the briefs were circulated prior to the workshop and participants were asked to review the materials and identify their area(s) of expertise; (10) presentations were delivered by experts in each of the domains and then participants broke out into working groups co-facilitated by the invited experts and CCPAEHR members to develop recommendations in their domain (proceedings were recorded by two transcribers per session); (11) the recommendations were presented to the larger group and discussed; (12) the CCPAEHR working group then analysed and summarized the discussion and drafted the initial report; (13) the report was sent to all participants for content validation; (14) two members of the research team then analyzed the recommendations and workshop notes for emergent themes.

Terms and Definitions

For the purposes of the workshop, the definition of terms was intended to be as broad and as inclusive as possible, while maintaining the focus on patients accessing EHRs. EHR was defined as "a computerized record of a person's health and/or medical history. This record may contain a person's full health and medical record, or can be used for certain records, such as lab results, in conjunction with a more traditional paper-based patient chart" [19].

The concept of a PAEHR partly overlaps with the concept of a Personal Health Record (PHR), although there are some important differences. While there is no universally accepted definition of a PHR, it is important to delineate where the concepts overlap and where they diverge. The definition of PHR itself is controversial. In some concepts, the PHR includes the patient's interface to a health care provider's EHR while, in others, PHRs are thought of as being any consumer/patient-managed health record. A report from the National Committee on Vital and Health Statistics has noted, "This lack of consensus makes collaboration, coordination and policymaking difficult. It is quite possible now for people to talk about PHRs without realizing that their respective notions of them may be quite different" [33].

The *Connecting for Health* Personal Health Working Group sponsored by the Markle Foundation defines PHRs as follows:

> *The Personal Health Record (PHR) is an Internet-based set of tools that allows people to access and coordinate their lifelong health information and make appropriate parts of it available to those who need it. PHRs offer an integrated and comprehensive view of health information, including information people generate themselves such as symptoms and medication use, information from doctors such as diagnoses and test results, and information from their pharmacies and insurance companies [29].*

The definition promoted by the American Health Information Management Association (AHIMA) is similar, but it stresses that the PHR is not simply a patient view on EHR data:

> *The personal health record (PHR) is an electronic, universally available, lifelong resource of health information needed by individuals to make health decisions. Individuals own and manage the information in the PHR, which comes from the health care provider and the individual. The PHR is maintained in a secure and private environment, with the individual determining the rights of access. The PHR is separate from and does not replace the legal record of the provider [34].*

Tang and colleagues defined personal health records more broadly:

> *An electronic application through which individuals can access, manage, and share their health information and that of others for whom they are authorized, in a private, secure and confidential environment [19].*

In the same article, the authors distinguished a "tethered" PHR (bound to a certain organization) from a "stand-alone" PHR and the ideal "interconnected" PHR.

PHRs, according to many definitions, do not have to be linked or integrated, either directly or indirectly, with clinical systems such as EHRs (they can be "stand-alone" PHRs), which is where the concept of PAEHR differs from the PHR concept.

For the purposes of the PAEHR Workshop, the definition of PAEHRs was narrowed to focus on patient access to provider-held, electronic records (in full or in part), regardless of the type of application that is used to provide access. As such, PAEHRs partly overlap with some PHR definitions (particularly "tethered" PHRs as defined by Tang and colleagues [19]).

Workshop Participants

The issues related to PAEHRs traverse a number of areas of expertise. For this reason, a small group of experts in PAEHRs, as well as experts in other domains such as clinical practice, privacy, health care administration and policy, research, eHealth, information technology, consumerism, and patient advocacy were invited to participate in the workshop. Participants were sought from as many provinces as possible, and several international participants were invited in order to have heterogeneous viewpoints on a wide range of issues. To facilitate the process of inviting international experts, the workshop was held as a satellite event to a major international conference on Internet in medicine (Mednet 2006). Experts were identified through published literature, as well as nominated through the CCPAEHR committee. Experts were selected by reviewing their experience in various domains, their knowledge of the subject domains, their participation in related national and international initiatives, and their publication records (Table 1). Despite the attempt to have geographic, academic, and clinical diversity amongst workshop participants, many of the identified experts came from a few regions and organizations in the country where active work in the field was being undertaken. In addition, many of the clinical experts identified were working in the area of oncology. Attempts were made to broaden representation from medical disciplines and international experts were identified and invited to ensure a broader representation from across disciplines and specialties.

Table 1. PAEHR Workshop participants inclusion/exclusion criteria

Inclusion/Exclusion Criteria	
1.	Identified as a domain expert by a Member of the Canadian Committee for Patient Accessible Health Records (CCPAEHR).
2.	Researcher actively addressing issues related to patient accessible EHRs.
3.	Participant in a clinical implementation of patient accessible EHRs.
4.	Experts working in closely related issues such as patient education and privacy.
5.	Researchers addressing patient empowerment or patient advocacy issues.
6.	Clinical staff with an active interest in patient access to their health information

Members of the lay public did not participate in the PAEHR Workshop, because the workshop was intended as a first step in the identification of issues and potential recommendations. Obtaining patient involvement and public engagement was determined to be part of subsequent phases of this ongoing initiative.

Four Subject Domains

The working group identified four major subject domains for PAEHRs through literature reviews and discussions with the CCPAEHR committee: (1) providing patient access to the EHR, (2) maintaining privacy and confidentiality related to the PAEHR, (3) patient education and navigation of the PAEHR, and (4) strategies for managing institutional change. For each subject domain, a briefing note was created based on the issues articulated in Leonard's *A Prescription for Patience: A Guide to Improving Our Healthcare System* [35]. Each briefing note contained a general summary, a list of topics of interest, a reference list, as well as draft recommendations for each subject domain (Multimedia Appendix 1: Briefing Documents).

Results

The PAEHR Workshop was attended by 45 participants and renowned experts from the United States, Canada, Spain, Iceland, and the Netherlands. Participants contributed to the development of recommendations through moderated breakout and discussion sessions. The discussions for each subject domain, summarized by the research team and validated by the participants themselves, were as follows:

Patient Access to the EHR

Most participants agreed that access to the EHR is a fundamental patient right and that the implementation of PAEHRs should not be delayed. However, there was little agreement on exactly how access should be provided. There were two general but opposing approaches which emerged. The first was to provide access to only the "relevant" content in the EHR. Ideally, this clinical information should be coupled with tailored educational materials to help people meet their information needs. However, there were some participants who thought patient access to these results should only be provided after being vetted by a physician, or viewed only in the presence of a health care professional, as an approach to managing the anxiety that may transpire from accessing results perceived as "bad news". The second approach was to provide open access to all information contained within the EHR and allow the patient or their proxy to decipher what information they feel to be relevant. In this approach, educational information could also be linked to a fully accessible PAEHR; however, the tailoring of information with a broad release of results was perceived to be an enormous barrier to adoption of this approach.

With reference to the EHR, there was general agreement that access should include the ability to make entries into the EHR. Patients should be both receivers and contributors of information. Allowing for this type of patient annotation could result in a feeling of "ownership" on the part of the patient. However, there were concerns about who would be responsible for reviewing or monitoring patient entered data and the potential for professional liability if patient entered data was not addressed in a timely manner.

Privacy and Confidentiality

There was agreement among participants regarding the necessity to adopt and support one standard with respect to ownership and/or custodianship of the EHR and its content. Traditionally, the patient record has existed under the control of the provider or treating institution/organization. As patient access continues to increase, this would ultimately result in a culture shift related to the control of health information. Mechanisms need to be in place to help manage the potential conflicts resulting from territorialism and protect providers of health information from the risks of sharing ownership of information with their clients. In the short run, providers may be reluctant to give up what has traditionally existed in their domain.

Regular and ongoing access by patients to the EHR demands the development of policies and procedures related to record management. Patient records should be audited regularly to ensure the accuracy, integrity, and quality in the record, especially in situations in which patient entries are permitted and incorporated into the record. Furthermore, policies need to be in place regarding the retention of information. The emergence of patient portals and the ability to customize patient views may result in a unique set of challenges. In addition, clear statements of where the institutionally-based EHR ends, and the patient portal begins will need to be articulated.

Patient Education & Navigation

With respect to EHRs and PAEHRs, it was agreed that patient education can be understood as either a means of educating patients on how better to understand and use EHR data, or it can be understood as the information necessary to educate people on what the EHR is, what it contains, individual rights regarding the EHR, and the potential benefits of accessing the EHR. It was agreed that the provision of education within the

EHR should not be used in lieu of information provided by health care providers, but rather as a supplemental source.

When providing access to the EHR, the provision of educational support should be available to all, but presented so that individuals who do not need the resources are not inundated by them. This could be accomplished by embedding links to credible educational sites. It was agreed that the standardized educational materials in relation to elements of the EHR should be adopted.

Institutional Strategies for Change

In order to succeed in wide-scale adoption and implementation of PAEHRs, systems need to be in place to help health care providers, primarily clinicians, feel less threatened by the introduction of this new technology. The benefit of the innovation needs to be demonstrated through research and the development of evidence-based protocols.

Accepting the cost of change was highlighted as another step towards successful change management. Unless institutions are willing to cover the financial costs associated with the adoption of these new technologies, it is unlikely that they will succeed. There needs to be the acknowledgement that workload may increase in the short run. There needs to be continuous organizational reassurance that the increased burden will not continue in the long run and that support will be provided.

The success of institutional change is also dependent on the specific drivers for change. The importance of a physician champion clearly emerged. However, a culture shift is required recognizing that access to medical records is a fundamental right of every patient. In an institution committed to patient-centered care, making patients the drivers of change may help to guarantee success. Unlike clients in other industries, patients have traditionally experienced a power imbalance in health care. Now that patients are becoming more empowered, health care systems need to develop means of meeting the consumers' demands and needs—providing PAEHRs would be an important first step.

Recommendations for PAEHR Implementation

From the discussions and briefing notes, each workshop group developed a set of draft recommendations. These recommendations were presented to the group for discussion and approval and then they were reviewed a second time once the final report was completed. The recommendations outline priority areas for each of the subject domains (Multimedia Appendix 2: Subject Domain Recommendations). Although the recommendations were developed for each of the subject domains, there was, in fact, a great deal of overlap, and several important themes that transcend the domains were identified by the research team:

1. *National Infrastructure*: There is a need for national standards and guidelines that will ensure that patient-centered care is delivered nationally. The infrastructure will include not only the required IT networks, but also the infrastructure to support the development and dissemination of policies, procedures, security protocols, and educational standards. In addition, the infrastructure should engage the public, raise awareness, and promote knowledge sharing and patient advocacy.
2. *Security and Confidentiality*: Security and confidentiality must be protected according to national standards, but at the same time, a paradigm shift is required so that health care organizations create a culture of custodianship, rather than ownership, of patient data. This shift will be achieved by creating models of shared control between health care professionals, patients, and the public. Health care organizations need to be confident they can manage the additional risk exposure in sharing electronic patient information with their users. Patients should have the ability to control the flow of their clinical data and to delegate access to the data.
3. *Flexible, Interoperable Solutions*: No one solution will fit all of the diverse health care settings; therefore, flexibility is required at all levels of the implementation of PAEHRs, including: (1) flexibility for diverse clinical practices; (2) flexibility for diverse organizational cultures and approaches to clinical care; (3) flexibility for diverse patient groups; (4) flexibility to accommodate patient choice and promote a patient-centered model of care; and (5) interoperable solutions to ensure the continuous flow of personal health information.
4. *Education*: Education is required at all levels. Education materials should be developed to support clinicians through the paradigm shifts and cultural changes that are required for patient-centered care models. Public education is required to raise awareness of fundamental rights to access health data. Patient education is also required to help patients understand the nature of the health record itself, including methods of reporting results and tests, and, at the same time, education is required to help patients understand what their clinical data means to them and how they can manage their care to ensure the best possible health outcomes. Health care administrators need to be educated on how to deliver and manage PAEHR systems and the costs associated with such practice.
5. *Research and Evidence-Based Practice*: Little is known about the potential risks and benefits of PAEHRs. Research should be a fundamental component of implementing PAEHRs and should focus not only on evaluation research to ensure that the best possible systems are put in place, but also on outcomes research to measure the health benefits in order to identify the real risks and the true benefits.

Discussion

Participants of the PAEHR Workshop did support the concept of patient access to electronic health records; however, many important issues and concerns were expressed. The themes emerging from this PAEHR Workshop were, on a high level, similar to themes articulated for PHRs in general: the focus on the need for interoperable solutions for information exchange to avoid building "information islands" [19], the need for education at all levels [19], the need for research, and the need to build systems that respond to audiences with diverse needs to eliminate barriers to patient use [36]. However, within the specific context of patient access to the EHR, there were some

important shifts in focus and concerns about national infrastructure and security, privacy, and confidentiality that emerged. This PAEHR Workshop also made a substantial contribution in creating a draft framework consisting of 22 specific and practical recommendations. Although there is a great deal of work to do in terms of validating the recommendations from many different perspectives, including that of the patient and the public, this workshop represented an important step towards the widespread implementation of PAEHRs.

It was clear from the PAEHR Workshop that there are many issues surrounding PAEHRs for which there was still little agreement or great uncertainty. There was a lack of agreement around fundamental issues such as how much of the EHR should be provided. Many participants thought that patients do not need access to certain results, despite the fact that several studies have illustrated that patients would like full access to all elements of their EHR [6]. In the Canadian context, the Supreme Court ruling in 1992 on McInerney vs MacDonald states that, while not an absolute right, patients have a right to access their personal health information in all but a few circumstances based on the fiduciary relationship of the patient and doctor [37]. In other countries such as the UK, the argument of patient access based on the fiduciary relationship has not been upheld, but laws have been put in place to ensure that patients have appropriate access [37]. Even within Canada, there are very few standards in the practice of providing access to personal health information [31]. The McInerney vs MacDonald ruling came before the widespread use of EHRs, and therefore the courts have not clarified many issues that have become pertinent because of the use of new technologies. The discussion of the PAEHR Workshop reflected the complexity of the issues and the diverse approaches and attitudes toward providing patients with access to their own personal health information.

There was also an important discussion and debate about when results should be provided—in real-time, after physician approval, or after a specified time delay. A balance must be struck between making the information available to patients in a timely fashion that supports self-managed care and patient safety so that patients are not unduly stressed by complex and ambiguous information. However, it is evident that the health care community is currently divided on this issue.

It is clear from the recommendations that emerged from this workshop that flexible solutions will be required to meet diverse organizational structures and patient populations. In addition, research that extends beyond the evaluation of delivery systems is desperately needed to provide some cornerstones that will support future developments. Research is required in every domain of PAEHRs. Although a great deal of work has been completed in testing the efficacy of the idea and the usability of certain applications [2,16,24,38], little research has been completed that demonstrates the benefits or potential risks of EHRs.

Infrastructure is required if PAEHRs are going to be successfully implemented into the health care system. Although PHRs can be a combination of data that is both entered by patients and pulled from existing clinical systems, PAEHRs must be incorporated in the clinical roadmaps that include the development of EHRs. The IT infrastructure, however, is only one barrier to adoption. The need for policies, procedures, and clinical infrastructure that support PAEHRs is evident. In addition, changes in clinical practice may be required to reap the full potential from PAEHRs. As has been pointed out, implementing a “disruptive” technology will take time [20], and technology adoption models clearly predict increases in resource utilization before the benefits of new technologies are realized [35].

Finally, it is clear from this workshop that a national—perhaps embedded into an international—debate is required regarding the relative risks and the potential benefits of PAEHRs. The introduction of PAEHRs will require the allocation of resources and major changes in clinical practice. At the same time, there are potential risks that are not yet well understood. There are privacy, confidentiality, and security issues that must be managed. Levels of security, for example, could become so tight that PAEHRs could become virtually unusable, and thus the ratio of acceptable risk versus potential benefits must be established. Public education is required, and awareness of patients’ rights and responsibilities in changing health care models must be raised. The public and consumer demand for PAEHRs will be a major determinant of how clinicians and health care organizations respond [4], and without patient advocacy and clinician champions, the numerous barriers to adoption may continue to stand in the way of widespread adoption.

There were a number of key limitations in the design of the workshop. Although many of the findings relate to key principles, the discussion focused primarily on the realities of the Canadian health care system and, in particular, to a few organizations focused on developing patient accessible electronic health records. This was not unexpected as a recent Canadian survey indicated that very few organizations were ready to provide online access to the EHR [31]. Furthermore, while patient advocacy viewpoints were expressed, patient viewpoints were not well represented as part of this consensus building process. Thus the opinions emerging from this workshop represent those primarily from representatives of the health care sector and academic fields. Since the development of patient accessible EHRs is still quite new in this context, developing recommendations was an ambitious goal for the PAEHR Workshop. The development of a framework and preliminary recommendations, while an important step forward, still need to be tested within multiple practice settings and validated through a public and patient engagement process.

Conclusions

Patient access to EHRs is a fundamental patient right, and health care professionals and organizations must move in a responsive and responsible manner to provide this access. There are many issues that need to be addressed, and in the absence of research and generalizeable evidence, organizations are faced will a cadre of difficult and complex operational issues. Targeted research is essential, and at the same time, coordinated, national efforts are required to provide the necessary infrastructure for PAEHRs. Flexible, standardized, and interoperable solutions are essential

for ensuring that PAEHRs support integrated, comprehensive care. Providing access to EHRs is a vital next step in activating patients in their care and improving the health system on a profound scale. The challenge remains for organizations, policy makers, clinicians, and patients to respond to this need and put these recommendations into practice.

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Conflicts of Interest

GE is editor of the Journal of Medical Internet Research (JMIR). Because of his involvement in the conduct of this research and writing of this paper, assessment and peer review have been carried out entirely by an associate editor (Khaled El Emam). KE and the peer-reviewers were blinded about the co-authorship of GE. GE has not been involved in making the decision on the paper.

Multimedia Appendix 1

Briefing documents

[PDF (Adobe PDF), 74 KB - jmir_v10i4e34_app1.pdf]

Multimedia Appendix 2

Subject domain recommendations

[PDF file (Adobe PDF), 27 KB - jmir_v10i4e34_app2.pdf]

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Abbreviations

AHIMA: American Health Information Management Association
CCPAEHR: Canadian Committee for Patient Accessible Electronic Health Records
CHI: Canadian Health Infoway
CIHR: Canadian Institute for Health Research
EHR: electronic health record
PAEHR: patient accessible electronic health record
PHR: personal health record

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Original Paper

Individuals Appreciate Having Their Medication Record on the Web: A Survey of Attitudes to a National Pharmacy Register

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Abstract

Background: Many patients receive health care in different settings. Thus, a limitation of clinical care may be inaccurate medication lists, since data exchange between settings is often lacking and patients do not regularly self-report on changes in their medication. Health care professionals and patients are both interested in utilizing electronic health information. However, opinion is divided as to who should take responsibility for maintaining personal health records. In Sweden, the government has passed a law to enforce and fund a national register of dispensed medications. The register comprises all individuals with dispensed medications (6.4 million individuals, September 2006) and can be accessed by the individual online via "My dispensed medications". The individual has the right to restrict the accessibility of the information in health care settings.

Objective: The aim of the present study was to evaluate the users' attitudes towards their access to "My dispensed medications" as part of a new interactive Internet service on prescribed medications.

Method: A password-protected Web survey was conducted among a first group of users of "My dispensed medications". Data was anonymously collected and analyzed with regard to the usefulness and design of the Web site, the respondents' willingness to discuss their "My dispensed medications" with others, their reasons for access, and their source of information about the service.

Results: During the study period (January-March, 2007), all 7860 unique site visitors were invited to answer the survey. Invitations were accepted by 2663 individuals, and 1716 responded to the online survey yielding a view rate of 21.8% (1716/7860) and a completion rate of 64.4% (1716/2663). The completeness rate for each question was in the range of 94.9% (1629/1716) to 99.5% (1707/1716). In general, the respondents' expectations of the usefulness of "My dispensed medications" were high (total median grade 5; Inter Quartile Range [IQR] 3, on a scale 1-6). They were also positive about the design of the Web site (total median grade 5; IQR 1, on a scale 1-6). The high grades were not dependent on age or number of drugs. A majority of the respondents, 60.4% (1037/1716), had learned about "My dispensed medications" from pharmacies. 70.4% (1208/1716) of all respondents said they visited "My dispensed medications" to get control or an overview of their drugs. Getting control was a more common ($P < .001$) answer for the elderly (age 75 or above), whereas curiosity was more common ($P < .001$) for the younger age group (18-44 years).

Conclusion: We found that users of the provider-based personal medication record "My dispensed medications" appreciated the access to their record. Since we found that the respondents liked the design of the Web site and perceived that the information was easy to understand, the study provided no reason for system changes. However, a need for more information about the register, and to extend its use, was recognized.

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KEYWORDS

Medical informatics; drug information services; patient access to records; pharmacy; confidentiality; informed consent; Internet; Sweden

Introduction

The development of Information and Communication Technology (ICT) is expected to have the potential to improve safety, quality, and efficiency in health care [1]. Since the first article on a computerized medical record in use almost 40 years ago [2,3], the clinical use, along with research [3], of Electronic Health Records (EHRs) has increased considerably. EHRs include longitudinal collection of health information which can be electronically accessed by authorized users. The records vary regarding the extent and kind of information displayed. Some include virtually all patient data, while others are restricted to certain types of data, such as a medication list or lab results [1,4].

Medication lists are one of the most important types of information to be included in an EHR, since they are used for filling refill requests, assessing quality, performing research, and informing computerized clinical decision support [5]. The intention of an EHR is to make important patient information available at the time and site of need. However, many patients receive health care in different settings, while most EHRs comprise information from specific settings only [1]. Thus, a limitation of clinical care may be inaccurate medication lists, since data exchange between settings is often lacking, and patients do not regularly self-report on changes in their medication [5,6].

Individuals are increasingly becoming more engaged in their health care and are interested in reading their medical records [4,7,8], and they also find it valuable to access their medical records via the Internet [9]. Individuals are expected to be important users of their own electronic health information [1]. Current and past medication information is one type of information requested by patients [4] because they regard one of the advantages of an electronic patient record (EPR) to be the ability to become better informed about their medication [10]. Though both health care professionals and patients are interested in electronic health information, opinions differ about who should take responsibility for the maintenance of the EPRs, including their accuracy, security, and accessibility.

In Sweden, the government has passed a law to enforce and fund a national register of dispensed medications. Since July 2005, all dispensed prescriptions from all pharmacies are automatically recorded in a mandatory national pharmacy register, independent of different care settings or prescribers and whether or not the individual is reimbursed for the medication. Thus, the register provides complete information on medications dispensed to the individual, with the exception of over-the-counter drugs, herbal remedies, and drugs dispensed for inpatients at hospitals [11]. The dispensed medication register is thought to suffer less from inaccuracy than a prescribed medication register, as dispensed drugs are closer to the true exposure of consumed drugs than are prescribed drugs. The record is mandatory, but the individual decides if and how he or she will use the information. The information cannot be modified by the individual. The register can be accessed by the individual online via “My dispensed medications”. We considered it important to assess a first group of users of the Web site, to suggest improvements of the service.

The aim of the present study was to evaluate the users’ attitudes towards their access to “My dispensed medications” as part of a new, interactive Internet service on prescribed medications.

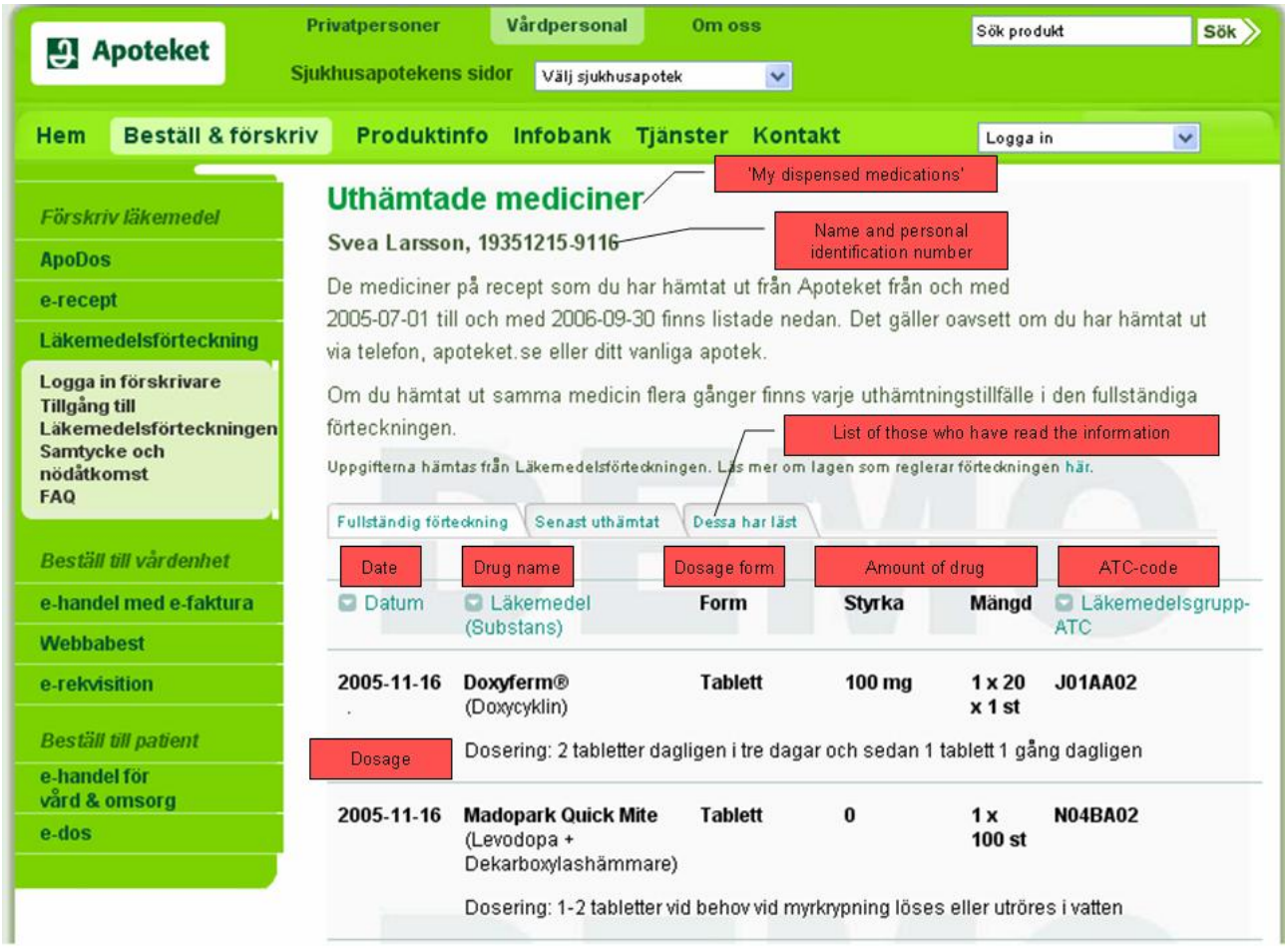
Methods

We conducted a Web survey among users of the Web-based service “My dispensed medications”. The questionnaire was developed for the purpose of this survey by two of the authors and validated by an experienced evaluator. The researchers did not have any access to the respondents’ medication records. The study was not subject to Institutional Review Board approval. All data in this study were given by the survey respondents. The respondents’ opinions were anonymously collected and analyzed with regard to the usefulness and design of the Web site, the respondents’ willingness to discuss their “My dispensed medications” with others, their reasons for access, and their source of information. The study period of 34 days ran from January 31 to March 6, 2007.

“My dispensed medications”

“My dispensed medications” is a Web-based service where individuals can access their list of dispensed drugs recorded in the Swedish national pharmacy register (Figure 1). Prescribers and pharmacists can only access the register with an individual’s consent, with an exception being made for physicians in case of emergency. The register is individual-based, including all dispensed prescription drugs to a person, independent of different prescribers, or whether or not the individual is reimbursed for the medication. The information is stored in the register for 15 months and thereafter cleared. In Sweden, iterations of prescriptions are filled every third month. In September 2006, 6.4 million individuals were registered in the Swedish national pharmacy register, representing 71% (6,424,487/9,047,752) of the Swedish population [11]. “My dispensed medications” is located on the Web site of Apoteket AB, The National Corporation of Swedish Pharmacies [12].

Figure 1. Screenshot of a demo of the web-based service "My dispensed medications" (English explanations in red boxes)



The Web survey was closed and password-protected, due to the requirement for a secure digital signature when logging on to "My dispensed medications". The secure digital signatures are issued by Swedish banks, stored on computers, and used by the individual in combination with a personal code, and they are in general use in Sweden by several authorities and private companies for personal identification in online contacts. All Swedish citizens at the age of 18 and above can easily apply for a secure digital signature over the Internet from all major banks. In February 2007, there were about 1 million unique individuals with secure digital signatures in Sweden (personal communication, BankID, Sweden).

Survey Design

All registered individuals using the register online to view their "My dispensed medications" during the study period were sent an invitation two seconds after they had logged on asking them to answer the survey. The registered individuals were notified that their responses would be used to improve the service "My dispensed medications" and that the survey would take less than five minutes to answer. The invitation request was not hindered by pop-up blockers. A cookie was set on the page "My dispensed medications", preventing the invitation from being sent to the same computer twice during the study period. A unique site visitor was determined based on the use of their secure digital signature. The Web survey was not announced or advertised prior to the invitation. It was a voluntary survey. Individuals could reject the invitation or simply close the invitation screen. No incentives were offered for answering the survey.

When the visitor had approved the survey, 12 statements and 3 questions followed about their attitudes towards "My dispensed medications", as well as 4 questions on their demographics (Tables 1, 2, and 3, and Multimedia Appendix 1). The first 7 statements were intended to answer the extent to which the respondents agreed with the purposes of the law restricting the use of the Swedish national pharmacy register [11]. The statements were displayed on two screens and the 7 questions on one screen each, yielding 11 screens in total, including the invitation screen and a final confirmation screen. By using the "back" button, respondents could review and change their answers. The respondents were allowed to skip a survey question. Checks for completeness were made after submission. All submitted surveys were analyzed. Skipped questions were reported as "no response" (Tables 1, 2, and 3).

The respondents agreed/disagreed with statements 1-12 graded on a scale ranging from 1 (do not agree at all) to 6 (fully agree) (Table 1). For the questions, the first one could only be answered with 1 of 6 alternatives, whereas questions 2 and 3 could be answered with several of the 5 alternatives (Table 2). For demographic questions, only one alternative could be chosen (Table 3). The respondents were able to provide free-text feedback to all statements and all questions on their attitudes.

Statistics

The survey was distributed and collected with the software Easyresearch (Easyresearch Scandinavia AB, Stockholm, Sweden). Collected survey answers were analyzed using Excel (ver. 2003; Microsoft, Seattle, WA). Statistical analysis was performed using SPSS (ver. 15.0 for Windows; SPSS Inc, Chicago, IL) and Statistix 8 (Analytical Software, FL). Rate Ratio (RR) with a 95% confidence interval (95% CI) was calculated using Episheet.

The non-parametric Kruskal-Wallis test was performed to analyze the differences of sample medians and Wilcoxon rank test to analyze differences of sample medians from total median. As a measure of variability, the Inter Quartile Range (IQR) was calculated (the upper quartile – the lower quartile). χ^2-test was used to test for association between different response alternatives and age. The rate ration [RR] with 95% CI was calculated as (negative statement $_{\text{yes to question}}$ /negative statement $_{\text{all answers}}$) / (positive statement $_{\text{yes to question}}$ /positive statement $_{\text{all answers}}$), statements graded 1-3 were considered negative and 4-6 positive. $P < .05$ was regarded significant.

Results

During the study period 7860 unique site visitors (approximately 0.8% (7860/1,000,000) of individuals with a secure digital signature) accessed “My dispensed medications” 10,192 times. Of the 7860 unique site visitors, 2663 individuals accepted the invitation and 1716 responded to the online survey, resulting in a view rate of 0.218 (1716 survey visitors/7860 site visitors) and a completion rate of 0.644 (1716 finished survey/2663 agreed to participate) [13].

The time to answer the survey was automatically measured and lasted an average of 2.8 (median 2, IQR 2) minutes; 1% (18/1716) of the respondents submitted the survey in less than 1 minute.

The completeness rate [13] (number of responses to each question/1716 completed surveys) was between 0.995 (1707/1716) for the first screen and 0.949 (1629/1716) for the last, decreasing for every screen displayed with statements and questions on their attitudes.

Usefulness

In general, the respondents’ opinions of the usefulness of “My dispensed medications” were high, with a total median grade of 5 (IQR 3), when asked to agree/disagree on a scale of 1 to 6 with statements on how “My dispensed medications” may be used (Table 1, “a. By means of...”). The statements “the pharmacist’s dispensing of my drugs may be safer” ($P < .001$) and “my physician may have a better decision basis for my medication” ($P < .001$) were graded above the total average. “My drug utilization may be improved” ($P = .68$) and “the information in my medical record may be improved” ($P = .07$) were in line with the total average. “I may receive better health care and treatment”($P < .001$), “I may to a greater extent comply with my physician’s ordination” ($P < .001$), and “I may be more involved in the decisions regarding my medication” ($P < .001$) were graded under the total average. However, the differences were small, with statement medians ranging from 4 to 5.

More respondents considered “My dispensed medications” to be of greater use for the pharmacists than for the physicians ($P< .001$), when the statement “the pharmacist’s dispensing of my drugs may be safer” was compared with the statement “my physician may have a better decision basis for my medication”.

Table 1. Number (n) and percentage (%) of the respondents' grading of statements (n = 1716)*

Survey statement		1	2	3	4	5	6	Completeness rate	No response	Grade median	IQR
a. By means of "My dispensed medications"...											
my physician may have a better decision basis for my medication	n	119	62	176	356	406	575		22	5	2
	%	6.9	3.6	10.3	20.7	23.7	33.5	0.987			
I may receive better health care and treatment	n	120	85	246	457	352	420		36	4	3
	%	7.0	5.0	14.3	26.6	20.5	24.5	0.979			
the information in my medical record may be improved	n	113	66	212	362	402	524		37	5	2
	%	6.6	3.8	12.4	21.1	23.4	30.5	0.978			
the pharmacist's dispensing of my drugs may be safer	n	75	43	142	312	494	617		33	5	2
	%	4.4	2.5	8.3	18.2	28.8	36.0	0.981			
my drug utilization may be improved	n	122	83	205	379	389	510		28	5	2
	%	7.1	4.8	11.9	22.1	22.7	29.7	0.978			
I may be more involved in the decisions regarding my medication	n	152	119	288	383	313	423		38	4	3
	%	8.9	6.9	16.8	22.3	18.2	24.7	0.980			
I may to a greater extent comply with my physician's ordination	n	162	116	262	338	335	469		34	4	3
	%	9.4	6.8	15.3	19.7	19.5	27.3	0.980			
Total median										5	3
b. My opinion of "My dispensed medications" is that...											
log on is easy	n	44	61	115	212	449	783		52	5	2
	%	2.6	3.6	6.7	12.4	26.2	45.6	0.970			
the information is easy to understand	n	18	53	132	257	523	672		61	5	2
	%	1.0	3.1	7.7	15.0	30.5	39.2	0.964			
I get a good overview of my drugs	n	23	13	42	153	417	1004		64	6	1
	%	1.3	0.8	2.4	8.9	24.3	58.5	0.963			
the information is valuable to me	n	16	24	87	211	487	820		71	5	1
	%	0.9	1.4	5.1	12.3	28.4	47.8	0.959			
the appearance of the Web page is good	n	33	45	112	304	546	611		65	5	2
	%	1.9	2.6	6.5	17.7	31.8	35.6	0.962			
Total median										5	1

* The statements were graded on a scale of 1 to 6 according to extent of agreement, with grade 1 being "do not agree at all" and grade 6 being "fully agree". IQR, Inter Quartile Range, is calculated as upper quartile – lower quartile.

Design

Asked about their opinion on the design of the Web site "My dispensed medications" (Table 1, "b. My opinion of..."), respondents were generally positive, returning a total median grade of 5 (IQR 1). The statements "I get a good overview of my drugs" followed by "the information is valuable to me" were graded above the total median ($P < .001$ and $P = .01$ respectively). "Log on is easy" was in line with the total median ($P = .19$). "The information is easy to understand" and "the appearance of the Web page is good" were graded high, although below the total average ($P < .001$ and $P < .001$ respectively) (Table 1). The high grades for the statements (P-values given in the same order as the statements in Table 1 under "b. My opinion of 'My dispensed medications' is that...") were not dependent on age ($P = .24$, $P = .91$, $P = .55$, $P = .92$, and $P = .52$ respectively) or number of drugs stated, except for the statement "the information is valuable to me" ($P = .71$, $P = .62$, $P = .75$, $P = .03$, and $P = .12$ respectively).

Source of Information

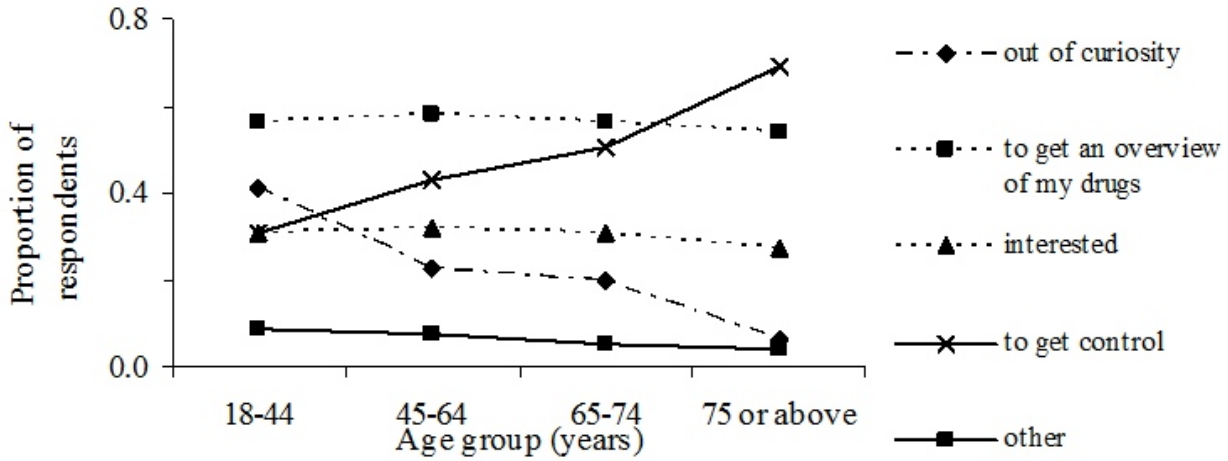
A majority of the respondents, 60% (1037/1716), had learned about "My dispensed medications" from pharmacies (Table 2). In general, the respondents included free-text comments in the

range of 3-13% (49/1716; 231/1716) for different statements and questions. Comments to at least one statement or question were submitted with 27% (464/1716) of the surveys. When the free-text comments on the respondent's source of information were analyzed, 102 respondents could be added to the category "from pharmacies", yielding the fact that 66% ((1037+102)/1716) of the respondents had learned about "My dispensed medications" from pharmacies. Many of these comments indicated that the visitor had learned about the service not only at local pharmacies but also at the pharmacies' shared Web site.

Reasons for Access

The respondents visited "My dispensed medications" primarily to get an overview of their drugs and to get control, with 24% (414/1716) of the respondents acknowledging both motives and 70% (1208/1716) acknowledging either overview or control, or both, as reasons for their access. Accessing the Web site out of interest and curiosity were less common reasons, with 45% (771/1716) answering one or both ($P < .001$) (Table 2). To get control was a more common ($P < .001$) answer for the elderly (75 or above), whereas curiosity was more common ($P < .001$) for the younger age group (18-44) (Figure 2). Those who did not identify with any of the four response alternatives numbered 5% (91/1716), only answering "other".

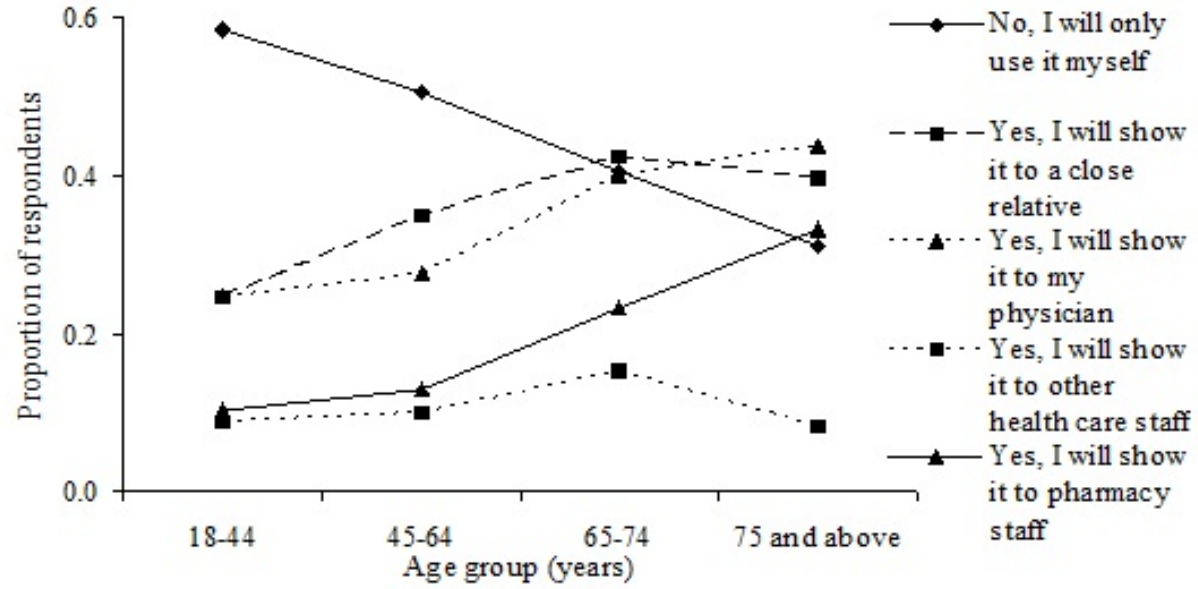
Figure 2. Frequency distribution of respondents' answers to the question, " Why did you take a look at 'My dispensed medications'?"



Willingness to Share "My dispensed medications"

Respondents were keener to share their record with a close relative or their physician than with the pharmacy and other health care staff ($P < .001$) (Table 2). Respondents' willingness to share "My dispensed medications" increased with age, except for sharing with other health care staff, which was low for all age groups (Figure 3).

Figure 3. Frequency distribution of respondents' answers to the question, "In the future, will you show or discuss your 'My dispensed medications' with another person?"



Giving high grade to the statement "my physician may have a better decision basis for my medication" was well in accordance with answering yes to the question "In the future, I will show "My dispensed medications" to my physician" (RR = 0.56, 95% CI 0.44-0.71). The same relationship was found between "the pharmacist's dispensing of my drugs may be safer" and "In the future, I will show "My dispensed medications" to the pharmacy staff" (RR = 0.48, 95% CI 0.30-0.76).

Table 2. Number (n) and percentage (%) of respondents for different response alternatives to 3 questions

	Total (n = 1716)		Age 18-44 (n = 614)		Age 45-64 (n = 810)		Age 65-74 (n = 177)		Age 75 or above (n = 48)		No response (n = 67)	
	n	%	n	%	n	%	n	%	n	%	n	%
How did you get to know about "My dispensed medications"?*												
by a physician	35	2.0	7	1.1	21	2.6	7	4.0	-	-	-	-
by a health care staff	11	0.6	2	0.3	8	1.0	-	-	-	-	1	2
by the pharmacy	1037	60.4	374	60.9	497	61.4	117	66.1	34	71	15	22
via papers/television	113	6.6	36	5.9	60	7.4	12	6.8	3	6	2	3
via a closely related	45	2.6	19	3.1	21	2.6	3	1.7	2	4	-	-
other	404	23.5	171	27.9	186	23.0	36	20.3	7	15	4	6
no response	71	4.1	5	0.8	17	2.1	2	1.1	2	4	45	67
Why did you take a look at "My dispensed medications"?†												
out of curiosity	475	27.7	251	40.9	181	22.3	35	19.8	3	6	5	8
to get an overview of my drugs	958	55.8	347	56.5	471	58.1	100	56.5	26	54	14	21
interested	521	30.4	190	30.9	260	32.1	54	30.5	13	27	4	6
to get control	664	38.7	189	30.8	347	42.8	89	50.3	33	69	6	9
other	132	7.7	54	8.8	63	7.8	9	5.1	2	4	4	6
no response	60	3.5	3	0.5	6	0.7	4	2.3	1	2	46	69
In the future, will you show or discuss your "My dispensed medications" with another‡												
I will only use it myself	862	50.2	360	58.6	409	50.5	72	40.7	15	31	5	8
Yes, I will show it to a closely related	534	31.1	152	24.8	284	35.1	75	42.4	19	40	4	6
Yes, I will show it to my physician	472	27.5	152	24.8	223	27.5	71	40.1	21	44	5	8
Yes, I will show it to other health care staff	171	10.0	55	9.0	81	10.0	27	15.3	4	8	4	6
Yes, I will show it to the pharmacy staff	232	13.5	64	10.4	105	13.0	41	23.2	16	33	6	9
no response	70	4.1	9	1.5	9	1.1	-	-	2	4	50	75

*Only one of the options could be chosen. Completeness rate 0.973.

†Several options could be chosen. Completeness rate 0.965.

‡Several options could be chosen. Completeness rate 0.959.

Demographics

Demographics showed that 28% (488/1716) of the respondents resided in one of the three major Swedish cities of Stockholm, Göteborg, or Malmö, 40% (686/1716) in other cities, and 27% (469/1716) in the countryside (Table 3). The respondents seem geographically representative, since the respondents' residences corresponded with the Swedish population as a whole with 76% (6,897,691/9,047,752) living in cities and 24% (2,150,061/9,047,752) in the countryside [14].

Table 3. Demographics in number (n) and percentage (%) of respondents (n = 1716)*

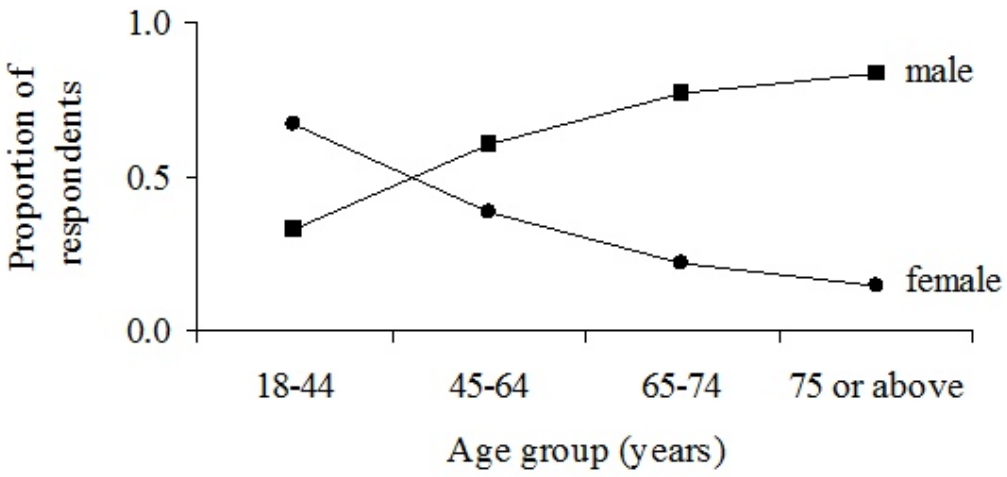
	Total		Men		Women		No response	
	n = 1716	%	n = 873	%	n = 771	%	n = 72	%
Age†								
18-44 years	614	35.8	201	32.7	410	66.8	3	0.5
45-64 years	810	47.2	494	61.0	315	38.9	1	0.1
65-74 years	177	10.3	137	77.4	39	22.0	1	0.6
75 years and above	48	2.8	40	83.3	7	14.6	1	2
no response	67	3.9	1	1.5	-	-	66	99
Number of dispensed prescriptions								
0	33	1.9	19	57.6	14	42.4	-	-
1-5	500	29.1	262	52.4	236	47.2	2	0.4
6-10	364	21.2	203	55.8	160	44.0	1	0.3
11-15	186	10.8	86	46.2	100	53.8	-	-
more than 15	509	29.7	280	55.0	227	44.6	2	0.4
no response	124	7.2	23	18.5	34	27.4	67	54
Place of residence								
Stockholm/Göteborg/Malmö	488	28.4	280	57.4	206	42.2	2	0.4
an other city	686	40.0	347	50.6	336	49.0	3	0.4
the countryside	469	27.3	242	51.6	225	48.0	2	0.4
no response	73	4.3	4	5.5	4	5.5	65	89

*Completeness rate 0.961 for age, 0.985 for gender, 0.949 for number of dispensed prescriptions and 0.957 for place of residence.

†Individuals younger than 18 years old were not eligible to participate in the study, since they are not allowed a secure digital signature and thereby not able to get online access to “My dispensed medications”.

In the age group 18-44 years, more women, 66.8% (410/614), than men responded to the survey, in contrast to the older age groups 45-64 years, 65-74 years, and 75 years and above, in which more men than women responded, at rates of 61.0% (494/810), 77.4% (137/177), and 83.3% (40/48) respectively (Figure 4).

Figure 4. Frequency distribution of respondents’ per gender and age groups



Discussion

We found that the first group of users of "My dispensed medications" appreciated having their medication record on the Web, and that they had a generally positive attitude towards the Web-based service. The respondents found the information valuable and easy to understand. They primarily visited the Web site to get control and see an overview of their drugs.

Representativeness

The generalizability of Web surveys may be limited by selection bias due to the non-representative nature of the Internet population, as well as the volunteer-effect of self-selected participants [15]. The respondents in the present study comprise individuals using the Web-based service "My dispensed medications", and thus the generalization of results to non-users should be done with care. The results of the present study are assumed to be representative for individuals who are registered in the Swedish national pharmacy register holding a secure digital signature and who have chosen to use the service "My dispensed medications". The individuals with a secure digital signature were 18 years and older, presumably interested in ICT and health, representing the first group of users. An overestimation of positive attitudes might occur due to the nature of the early adopters [16]. However, due to restrictions in the Swedish legislation and relatively few visitors to the Web site "My dispensed medications", we were not able to contact potential survey respondents in ways which may have generated a more representative sample. Nor could we categorize the non-respondents to assess the difference between those who chose to answer the survey and those who did not. Due to the anonymous nature of the survey, there were no means to validate the survey answers given by the respondents, by comparing them with other sources of information.

Early Adopters

In spite of the potential value of, and positive response to, the present study, relatively few of the registered individuals in the Swedish national pharmacy register have accessed "My dispensed medications". Although about two thirds of the respondents stated that their main source of information about the service was the pharmacies, the marketing seems to be insufficient. Also, the moderate penetration of the secure digital signature is a restriction to widespread access. Thus, we expect that only the early adopters [16] have started to use the service, about one year after its introduction on the Web.

Usefulness

The respondents' perception of the usefulness of "My dispensed medication" was in good accordance with the aims stated in the law (ie, to achieve a better decision basis for medications, provide the registered individual with care or treatment, supplement the individual's health care record, assist the dispensing pharmacist, and facilitate the registered individual's drug utilization) [11]. However, the similarly positive responses to these different statements indicated that the respondents might have had difficulties distinguishing between the different aims.

Personal Access

The information in the national pharmacy register is available for registered individuals online via the service "My dispensed medications" and at the pharmacy counter. We found that the main reason respondents visited "My dispensed medications" was to get an overview and to get control of their drugs, followed by their interest and curiosity (Figure 2). That to get an overview and to get control were more common reasons than interest and curiosity indicates that the register is of genuine value to the respondents. For the elderly, to get control was the most common reason, whereas it was curiosity for the younger age groups. Few respondents used the response alternative "other", indicating that the suggested response alternatives well described the respondents' reasons for visiting "My dispensed medications". That the service in fact gave the respondents a good overview of dispensed drugs and valuable information favors the view that patients appreciate access to their own data. Others have reported that patients want access to their EPR to be better informed about their health care and medication [10], to enhance their understanding of their medical condition, and also to facilitate their care at home [4]. For the latter, medication information, along with lab results and medical history, are most likely requested [4].

From the individual's point of view, the safe access to his or her medication record must be easy with regard to Web site design. It seems that access to the pharmacy register is adequate, since we found that the respondents considered that logging on to "My dispensed medications" was easy. However, this might not be true for a larger population, as the Web survey was only conducted among those who had successfully logged on to the Web site. It seems that the respondents considered the Web site "My dispensed medication" to have a logical and well-structured design, since there were high grades of agreement for "the appearance of the Web page is good", "the information is easy to understand", and "I get a good overview of my drugs". The high grade was not dependent on age or number of drugs, indicating that the service provided a clear overview with a high level of understandability, even for those with many drugs listed.

Access After Conditioned Consent

There is a need to reduce overconsumption of pharmaceuticals, since excessive prescriptions might result in uncontrolled side effects and extra costs. "My dispensed medications" could be described as a provider-based personal health record [17] for dispensed medications, where the individual has the right to restrict the accessibility of the information to specific individual health care professionals, with full disclosure of those who have accessed the information. We found that the respondents were keener to share their record with a close relative or their physician than with pharmacy staff.

The finding that respondents considered "My dispensed medications" to be of great use to both pharmacists and physicians suggests that the respondents might suppose that pharmacists and physicians already have access to their medication records. However, pharmacists and physicians are dependent on the individual's consent to view a patient's medication record, with an exception made for physicians in the case of an emergency. Since willingness to share "My

dispensed medications" increased with age, the benefits from the national pharmacy register might first be apparent for elderly persons (Figure 3). However, this might not depend on age per se, but rather an elderly person's greater need of health care or, perhaps, a greater trust in health care professionals.

It seems reasonable that all medications should be screened at the point of care. Since the individual might visit several physicians, sometimes involving different, non-communicating EHRs, the physician might not be informed about medications prescribed by others. In Sweden, the national pharmacy register provides a complete, individually dispensed medication record, which would help when a person is visiting several physicians. Our study revealed that only about one third of the respondents were willing to show their physician their "My dispensed medications". In the context of uncontrolled side effects with increased health care costs, one third might seem to be a small proportion; however, the same respondents agreed to a large extent with the statement that "my physician may have a better decision basis for my medication". This indicates that the respondents who had realized that "My dispensed medications" may help their physician were also willing to share their medication record with their physician. Also, free-text comments indicated that some of the respondents had not understood that their "My dispensed medications" was not available to their physician and pharmacy staff without their consent. This implies that more information is needed about the clinical advantages for individuals when sharing their medication records with prescribers and pharmacists.

A Nation-Wide Dispensed Medication Record

For privacy reasons, personal control over who can access the information is pivotal to deploy successfully a mandatory, nation-wide register. Individuals expect EHRs to be safe and their privacy to be respected [18], and they wish to be able to decide for themselves who else can access their record [10]. How to balance these personal confidentiality aspects with the demand for safe prescribing is a subject for continued debate. Internationally, two models for making personal health records available have been presented: the opt in model and the opt out model [5, 19-21]. Denmark and Sweden have chosen an alternative model with a legally enforced, mandatory collection of dispensed prescriptions, in combination with personal access and control. The Scandinavian approach seems to be well-balanced with public support, as there have been remarkably few public concerns raised so far.

Internet Use and Gender Differences

The increasing use of the Internet still seems to indicate some gender differences. Internet use in Sweden is high, with a majority of the Swedish population (16-74 years of age) using the Internet. The number of men using the Internet is somewhat higher in the older age groups, relative to the number of women [14]. This is also reflected in our study in which men were the predominant respondents aged 45 years and above (Figure 4). However, the Internet use of health information has been reported to be dominated by women [22], especially young and middle-aged women [23]. This might explain the dissimilar numbers of men versus women of different age groups in our study (Figure 4). The deciding factor for the younger age group (18-44) may not be about technological experience and enthusiasm, but rather an interest in health-related issues.

Potential Use

If used more extensively, the register might convey several advantages for users, as well as for health care generally. By using the register, the individual might have a better overview and control, helping to consume pharmaceuticals more accurately. Physicians might have better grounds for their future prescribing and pharmacists for future counseling. Whether an extended use of the register will improve drug utilization, making it more cost effective, remains to be studied. First, efforts must be made to extend the use of the register. Our study reveals that there seem to be few obstacles to the use of the register itself; rather, the limiting factor is insufficient knowledge about the register.

Conclusion

We found that users of the provider-based personal medication record "My dispensed medications" appreciated access to their record. Keeping in mind the limitations of a Web survey, we considered it important to assess a first group of users of the Web service to be able to suggest improvements to the service. Since we found that the respondents liked the design of the Web site and perceived that the information was easy to understand, the survey provided no reason for changes. However, a need for more information about the register, to extend its use, was recognized.

Acknowledgments

We are indebted to Andrea Gruvmalm, Apoteket AB, for assisting with the Web survey.

Conflicts of Interest

The study was supported financially by Apoteket AB, including support to the e-Health institute.

Multimedia Appendix 1

Survey questions translated into English

[PDF file (Adobe PDF File), 20 KB - jmir_v10i4e35_app1.pdf]

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Abbreviations

CI: confidence interval
EHR: electronic health record
EPR: electronic patient record
ICT: information and communication technology

IQR: inter quartile range
RR: rate ratio

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Original Paper

Evaluation of an Internet-Based Hearing Test—Comparison with Established Methods for Detection of Hearing Loss

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Abstract

Background: Hearing impairment is most accurately measured by a clinical pure-tone audiogram. This method is not suitable for large-scale, population-based epidemiological studies as it requires that study participants visit a clinic with trained personnel. An alternative approach to measuring hearing ability is self-estimation through questionnaires, but the correlation to clinical audiometric tests varies.

Objective: To evaluate an Internet-based hearing test pilot compared to a question about self-estimated hearing and the feasibility of using an Internet-based hearing test and an Internet-based questionnaire in a population of 560 members of the Swedish Hunters' Association in the age group 20-60 years.

Methods: An invitation was mailed to the participants in March 2007 together with the URL to the study Web site, a personal username, and a password. The Web site included the questionnaire, the hearing test, and instructions for participating in the study. The hearing test resembles a clinical audiogram presenting 6 tones between 500 and 8000 Hz. Tones are presented between 0 and 60 dB, and the participant responds to the tones by pressing the space bar. The hearing test requires headphones and is based on JAVA programming. Before the participant can start the hearing test, it has to be calibrated against a reference person with good hearing between 15 and 35 years of age.

Results: After 5 months, 162 out of 560 (29%) had answered the questionnaire, out of which 88 (16%) had completed the hearing test. Those who actively declined participation numbered 230 out of 560 (41%). After removing duplicates and hearing tests calibrated by unreliable reference data, 61 hearing tests remained for analysis. The prevalence of hearing impairment from the Internet-based hearing test was 20% (12 out of 61), compared to 52% (32 out of 61) from the self-estimated question. Those who completed the hearing test were older than the non-participants, and more had headphones (P = .003) and the correct version of the JAVA program (P = .007) than those who only answered the questionnaire.

Conclusions: Though an Internet-based hearing test cannot replace a clinical pure-tone audiogram conducted by a trained audiologist, it is a valid and useful screening tool for hearing ability in a large population carried out at a low cost.

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KEYWORDS

Hearing tests; audiometry, pure-tone; Internet; questionnaires; epidemiology; cohort study

Introduction

Hearing loss is one of the most common physical impairments in the western world and is an increasing problem among younger age groups [1]. The gold standard for estimating hearing impairment is a clinical pure-tone audiogram [2]. This method is not suitable for large-scale, population-based epidemiological studies as it demands access to equipment and trained personnel and is demanding for the participants in terms of travel to a clinic. An alternative approach for estimating hearing in epidemiological studies is self-estimation from a set of questions [3,4]. However, the sensitivity of these self-estimated hearing approaches varies, and their correlation to pure-tone audiograms is arguable [4-10]. Though self-estimated hearing approaches might be efficient in measuring a patient's reactions and the social impact of hearing loss [11], they cannot replace audiometric hearing tests [4].

Digital technologies provide the possibility of developing computer-based programs for measurement of physical impairment. A number of commercial programs resembling clinical audiograms for measuring hearing are available online [12,13]. Various Internet-based and computerized audiology systems for measuring hearing thresholds of patients have been developed and tested in different studies [14-17]. The systems are developed to evaluate patients with a suspected hearing impairment at remote sites where access to trained audiologists and clinical pure-tone audiograms is limited. These systems are connected to a conventional audiometer and controlled via the Internet, or they require specific sound cards and modules. Trained personnel are still required, and the systems cannot be used for self-screening of hearing in large-scale epidemiological studies.

We have developed an Internet-based hearing test resembling a clinical pure-tone audiogram. The hearing test aims at measuring real-time hearing ability in large-scale epidemiological and clinical studies in the participant's home environment, using headphones and a home computer. The Internet-based hearing test has been validated against a pure-tone audiogram at the Karolinska University Hospital [18]. Out of 72 individuals, 20 individuals were diagnosed with a moderate or severe hearing loss (greater than 40 dB) according to the pure-tone audiogram.The Pearson's correlation coefficient between the two tests was 0.94 (P-value < .001) for the right ear and 0.93 (P-value = .001) for the left, and the Internet-based hearing test had a 75% sensitivity and a specificity of 96% compared to the clinical audiogram. The Internet-based hearing test is not a substitute for pure-tone audiometry for diagnosis of hearing loss, but rather should be used to screen for hearing ability in longitudinal, large-scale, population-based studies. Therefore, the sensitivity is sufficient.

This paper evaluates the pilot study testing the feasibility of collecting epidemiological data on hearing ability using an Internet-based hearing test together with an extensive questionnaire including questions about self-estimated hearing prior to the test. The study is also evaluated in terms of willingness to participate and possible reasons for non-participation, including technical obstacles.

Methods

Study Method

A pilot study was designed to test the feasibility of conducting a large-scale cohort study among more than 200,000 hunters and marksmen from the Swedish population. The larger study aims at studying the relationship between noise-induced hearing loss, exposure to heavy gun shots, and the use of hearing protection.

The participants enter the study through a Web site that includes a Web-based questionnaire and an Internet-based hearing test. To enter the Web page, the participant enters a personal username and password. The participants cannot access the hearing test before filling in the questionnaire. The questionnaire includes 12 sections with, in total, approximately 100 questions regarding background, hunting, self-estimated hearing, occupation, military service, problems with hearing, medications, and recreational activities. The question about self-estimated hearing was stated as, "How is your hearing?", and the optional answers were "good", "minor hearing loss", "moderate hearing loss", or "severe hearing loss".

The hearing test is based on JAVA 5.0, and before the participants can start the hearing test, they are instructed to verify whether or not the computer has the correct version of the JAVA program. If not, the JAVA program can be downloaded free of charge. Before the participants can start the hearing test, the sound levels are calibrated against a reference person to compensate for variations in different headphones and noise interference from the computer and surroundings. Prior to the calibration test, the participant and the reference person are instructed to follow guidelines on how to set correct volume settings on the computer as well as using the headphones. In the following calibration phase, the reference person enters age (preferably between 14 and 35 years) and gender. The reference person is presented with a volume slider having a fine-tuned scale ranging over 30 dB. The reference person is instructed to move the slide head to a barely audible position, which is the reference hearing level (RefHL) for the frequency, and then request the program to present the next tone. The tone is a frequency-modulated sinus tone—a slightly vibrating tone which can be heard on headphones having "dead points" at certain pure frequencies. This tone is presented to both ears to get the lowest hearing threshold for each ear. The procedure starts from 500 Hz and is repeated for 1000 Hz, 2000 Hz, 4000 Hz, 6000 Hz, and 8000 Hz.

Quality check of the calibration of the RefHL data is performed on the finalized data. It is limited to a maximum check of a 15 dB difference over the frequencies, along with a check of whether the reference person has moved the volume slider for each frequency.

During the hearing test, intensity levels are presented between 0 (from reference calibration) and 60 dB sound pressure level (dBSPL). The hearing test starts by presenting the 500 Hz tone to the left ear for 1 second at 30 dBRefHL, which is 30 dB higher than the hearing threshold set by the reference person for that frequency. The tone is followed by a shorter pause of

random length to discourage the participant from guessing. The participant presses the space bar on the computer keyboard to register that a tone is heard. The key press is accepted as registering a threshold if the key is pressed within the presented tone timeframe, adjusted for the human reaction time. If the space bar is pressed half a second after the accepted timeframe, it is registered as too late and considered "imagined". This is not accepted as a threshold measure. When a tone is registered as heard, the test presents the same frequency at a 6 dB lower intensity level. When a tone is not heard, the test instead presents a tone at a 6 dB higher intensity level. The test proceeds for both left and right ears to settle the hearing levels for each frequency. This test procedure is a Web adaptation of established clinical audiometric testing and follows the guidelines for clinical audiometric testing [19].

After completing the test, the participant is shown an audiogram presenting the hearing levels for both ears at each measured frequency.

Recruitment

In March 2007, an invitation letter was sent to 560 members of the Swedish Hunters' Association. Subjects were selected proportionally to the distribution among the members in terms of gender (men = 500, women = 60) and age (in the age group 20-60). The mailed invitation included a description of the study and a personal username and password. The invitation also included a prepaid return letter which the participants could use to decline participation. This letter included a voluntary question about their reason for non-participation. The data collection was closed in August 2007. During the study, 2 paper reminders were sent, followed by a telephone reminder. The first reminder was sent 3 weeks after the initial invitation, followed by a second reminder after an additional 3 weeks and a telephone reminder 3 weeks after the second paper reminder. During the telephone reminder, those who declined participation were asked about the reason for their non-participation. Reminders were sent to subjects who had not yet completed the questionnaire and hearing test without declining participation, and to those who had answered the questionnaire but not completed the hearing test.

Statistical Analysis

The audiometric data from the hearing test was classified according to the definition by WHO for normal hearing, minor hearing loss, moderate hearing loss, and severe hearing loss [20]. Normal hearing was set as between 0 and 25 dB on all frequencies. The cut-off level for minor hearing loss was 1 or more frequency-values in the range 26-40 dB; for moderate hearing loss 1 or more frequency-values in the range 41-60 dB; and for severe hearing loss 1 or more frequency-values higher than 60 dB on either frequency. The result of the hearing test was compared to the self-estimated hearing question from the questionnaire prior to the hearing test and graded on the above scale (no hearing loss to severe hearing loss). The analysis is based on the audiometric data from the best ear in the hearing test. The 2 hearing tests (Internet-based hearing test and self-estimating question) were compared by using a contingency table presenting individuals categorized with normal hearing, minor hearing loss, moderate hearing loss, and severe hearing loss.

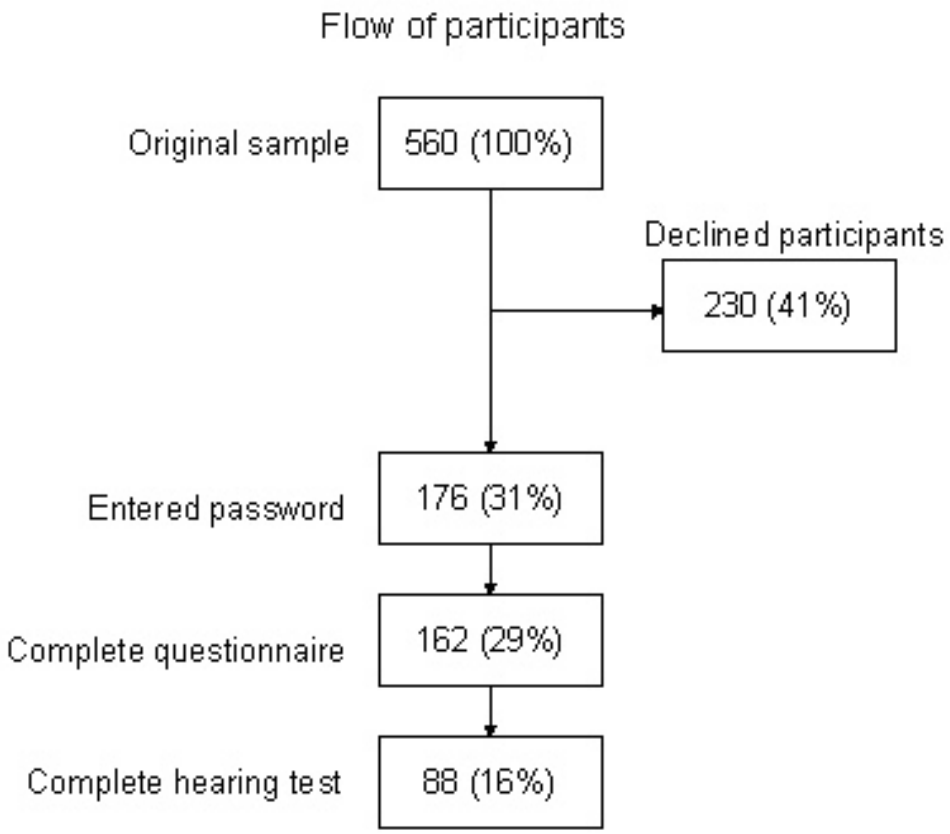
The study procedure is described with respect to the compliance and dropout at different checkpoints throughout the study (Table 1). Background data on age and gender were provided from the Swedish Hunters' Association for comparison of non-respondents, participants who declined, and respondents. Full respondents were compared with participants who had answered the questionnaire but had not completed the hearing test (questionnaire respondents) on the basis of different background variables including age, gender, level of education, and number of individuals in household. To evaluate the different technical steps, the full respondents were also compared with the questionnaire respondents as to whether or not they had headphones in their home prior to the test, if they had the correct version of JAVA installed on their computers, and their willingness to provide their e-mail addresses for future contact. The Pearson Chi-Square test was calculated to test if the distribution of subjects across demographic variables between full compliers and questionnaire completers was equal (Table 2). All tests of the statistical hypothesis were made on the two-sided 5% level of significance. To calculate the agreement between the hearing test and the self-estimated hearing, a simple kappa coefficient was used where agreement was corrected for chance [21]. All presentations and data evaluations were made utilizing the SAS 9.1.3 software. The regional ethical committee approved the study in October 2006.

Results

Response Rate

After 3 reminders, 162 out of 560 (29%) had completed the questionnaire (questionnaire respondents), of which 88 (16%) had completed the hearing test (full respondents). After reminders 1 and 2, 146 had actively declined participation, and an additional 84 declined participation during the telephone reminder (total 230, 41% of the total sample). There were 154 individuals who could not be reached or did not contact the study center for non-participation, and 14 participants entered the password without completing the study. A flowchart of the participation scheme is presented in Figure 1.

Figure 1. Flowchart of participation in the pilot study for evaluating an Internet-based hearing test among 560 members of the Swedish Hunters' Association



Hearing Test

In total, 126 hearing tests were carried out by 88 unique participants. Among the duplicates, the test with the best (eg, smallest degree of hearing loss) result was used in the analysis. After removal of those hearing tests with an incorrect reference, 61 hearing tests remained for which the mean age was 45 years. Results of the hearing test in comparison to the self-estimated hearing question are shown in Table 1.

On the self-estimated hearing question, 32 out of 61 (52%) reported hearing loss; 12 of those 61 (20%) showed hearing loss on the Internet-based hearing test. The Chi-Square test shows this difference to be statistically significant ($P < .001$). Only one who had a higher degree of hearing loss had a documented ear injury. Among those who had a hearing impairment according to the Internet-based hearing test, 6 out of 12 (50%) had classified their hearing differently in the self-estimated question. After excluding severe hearing loss, the simple kappa coefficient was calculated to 0.18 (95% confidence interval 0.005-0.359), indicating a slight agreement between the two measurements.

Table 1. Correlation of hearing test to the self-estimated hearing question (61 individuals)

		Self-estimated hearing loss, 1 question				
		No	Minor	Moderate	Severe	
Hearing test	No	27 (55%) (93%)	21 (43%) (84%)	1 (2%) (14%)	-	49 (80%)
	Minor	2 (29%) (7%)	3 (43%) (12%)	2 (29%) (29%)	-	7 (11%)
	Moderate	-	1 (25%) (4%)	3 (75%) (43%)	-	4 (7%)
	Severe	-	-	1 (100%) (14%)	-	1 (2%)
		29 (48%)	25 (41%)	7 (11%)	-	61

Sociodemographic Distribution

The distribution of gender was similar in all groups of respondents, the original sample, declined participants, and non-respondents (Table 2). The full respondents were older than the non-respondents and questionnaire respondents. Statistically, the full respondents were not significantly different from the questionnaire respondents in terms of sociodemographic characteristics or self-estimated hearing prior to the test (Table 3). When looking at the technical attributes, full respondents were more likely to have headphones at home (P = .003) and the correct JAVA version on their computers (P = .007) compared to questionnaire respondents (Table 2).

Common reasons for declining participation were lack of time (17%), lack of interest in the study (35%), lack of headphones (13%) (which reflects a difference between questionnaire respondents and full respondents), having no experience of gunshots or hunting, or already experiencing hearing loss and therefore considering themselves to be inappropriate for the study (Table 4).

Table 2. Distribution of age and gender among all participants in the pilot study for evaluating an Internet-based hearing test among 560 members of the Swedish Hunters' Association

	Non-respondents n = 154 (28%)	Declined study n = 230 (41%)	Drop outs/ Lurkers n = 14 (3%)	Answered questionnaire only (Questionnaire respondents) n = 74 (13%)	Hearing test and questionnaire (Full Respondents) n = 88 (16%)	Total n = 560 (100%)
Gender						
Men	138 (90%)	200 (87%)	13 (93%)	68 (92%)	81 (92%)	500 (89%)
Women	16 (10%)	30 (13%)	1 (7%)	6 (8%)	7 (8%)	60 (11%)
Age category						
20-34	51 (33%)	57 (25%)	3 (21%)	17 (23%)	17 (19%)	145 (26%)
35-49	63 (41%)	110 (48%)	7 (50%)	35 (47%)	39 (44%)	254 (45%)
50-60	40 (26%)	63 (27%)	4 (29%)	22 (30%)	32 (36%)	161 (29%)

Table 3. Sociodemographic characteristics among questionnaire respondents and full respondents for evaluating an Internet-based hearing test among questionnaire and full responders

	Answered questionnaire only (Questionnaire respondents) n = 74 (%)	Hearing test and questionnaire (Full respondents) n = 88 (%)	Pearson's Chi-Square	*P*-value
Gender				
Men	68 (92%)	81 (92%)	0.001	0.97
Women	6 (8%)	7 (8%)		
Age category				
20-34	17 (23%)	17 (19%)	0.86	0.65
35-49	35 (47%)	39 (44%)		
50-60	22 (30%)	32 (36%)		
Household Members				
1	12 (16%)	6 (7%)	5.20	0.16
2	26 (35%)	27 (31%)		
3-4	31 (42%)	43 (54%)		
5-6	5 (7%)	11 (69%)		
Missing		1 (1%)		
Education				
Preschool	9 (12%)	9 (10%)	1.03	0.80
High School	30 (41%)	34 (39%)		
College/ University	35 (47%)	43 (49%)		
Missing		2 (2%)		
Environment				
Large city	10 (13%)	8 (10%)	2.50	0.64
Suburb	11 (15%)	9 (10%)		
Medium-sized city	10 (14%)	14 (16%)		
Small town	14 (19%)	23 (26%)		
Countryside	29 (39%)	33 (38%)		
Missing		1 (1%)		
Java				
Yes	23 (31%)	44 (50%)	7.31	0.007
No	51 (69%)	40 (45%)		
Missing		4 (5%)		
Reported email				
Yes	73 (99%)	86 (98%)	0.19	0.66
No	1 (1%)	2 (3%)		
Have headphones at home prior to test				
Yes	48 (39%)	74 (60%)	8.88	0.003
No	26 (61%)	13 (30%)		
Missing		1 (1%)		
Self-estimated hearing prior test				

	Answered questionnaire only (Questionnaire respondents) n = 74 (%)	Hearing test and questionnaire (Full respondents) n = 88 (%)	Pearson's Chi-Square	*P*-value
No loss	44 (59%)	39 (44%)	7.35	0.06
Minor loss	18 (24%)	35 (40%)		
Moderate loss	8 (24%)	12 (14%)		
Severe loss	4 (5%)	1 (1%)		
Missing		1 (1%)		

Table 4. Reasons for declining participation in the pilot study for evaluating an Internet-based hearing test among 560 members of the Swedish Hunters' Association

Non-participation Reason	After paper reminders 1 and 2 n = 146	After telephone reminder n = 84	Total n = 230
Have hearing loss prior study	5 (3%)	1 (1%)	6 (3%)
Have no computer	7 (5%)	10 (12%)	17 (7%)
Have no headphones	27 (18%)	4 (5%)	31 (13%)
Have no reference	3 (2%)	1 (1%)	4 (2%)
Don't trust technique	3 (2%)	-	3 (1%)
Not interested	62 (42%)	19 (23%)	81 (35%)
Have no time	13 (9%)	26 (31%)	39 (17%)
No experience of hunting	17 (12%)	15 (18%)	32 (14%)
Computer problem	5 (3%)	8 (10%)	13 (7%)
Other	4 (3%)	-	4 (2%)

Discussion

This study evaluates an Internet-based hearing test in terms of its agreement to self-estimated hearing assessed by a question in a questionnaire and willingness to participate. Statistically, the results from the hearing test and the self-estimated hearing were significantly different ($P < .001$). The Internet-based hearing test indicated hearing loss in 20% of the tested individuals, compared to 52% in the self-estimated question. These results could indicate an underestimation of self-estimated hearing ability and display the difficulty of evaluating a self-estimated hearing impairment. The high degree of underestimation could be a result of the difficulties in the calibration procedure of the Internet-based hearing test, resulting in minor hearing loss not being detected. But, as this study population is relatively young (20-60 years), 52% seems to be a high prevalence of hearing impairment, even though the study includes a population with high exposure to impulse noise. In 2005, 14.3% of the Swedish population had a hearing impairment, out of which 63% were still of working age (16-64 years) [22]. This figure is more comparable to the Internet-based hearing test than to the self-estimated hearing. Many of the validated questionnaires and questions measuring self-estimated hearing ability have been evaluated on older populations with a high prevalence of hearing loss [2,4,5,8,9,10] and are, therefore, difficult to use on a younger population with a low prevalence of hearing loss. Self-estimated questionnaires cannot measure noise-induced hearing loss in terms of changes in frequency-specific impairments and can, therefore, not replace a clinical audiogram [4]. This strengthens the need for a more objective tool for measuring hearing ability in larger samples. The high prevalence of self-estimated hearing loss among the full respondents could, however, be biased by the fact that it was answered predominantly by people with hearing loss while people with no hearing loss refrained from participating.

The study also aims at evaluating the willingness to take part in a study including a Web-based questionnaire and an Internet-based hearing test. Our study had a response rate of 29% to the questionnaire and 16% to the hearing test, which is low for an epidemiological study. Full respondents were slightly older than the average non-participant, which might indicate that the older age group had a keener interest in the study. This was expected, as hearing decreases with age.

There were no differences between questionnaire respondents and full respondents in terms of sociodemographic characteristics and self-estimated hearing, where the full respondents were a representative sample of the total respondents. The full respondents had, however, greater access to headphones and already possessed the correct version of JAVA prior to the test more often than did the questionnaire respondents. The low response rate might therefore be due to the technique and the many steps prior to the test (including the need for acquiring headphones, JAVA, and a reference person),

rather than personal characteristics. One concern prior to the study was computer and Internet knowledge among the study participants, but Internet use in Sweden is among the highest in the world. In Sweden, 96% of the population can access the Internet from their homes [23], and an increasing number of households have broadband with a high-speed connection [24]. Therefore, the Swedish population is a suitable target group for this kind of study. When looking at non-respondents, the primary reason for non-participation is probably lack of interest. Of the non-respondents, 14% said that they had no experience of firing during hunting and therefore felt they were not the correct target group for the study. According to the Swedish Hunters' Association, 5% of the members do not hunt, but many of the members are involved in hunting without firing. In the invitation letter, the relationship between heavy gun shots and hearing impairment during hunting was mentioned, thus this group of non-participants might have misunderstood the invitation. To raise the response rate in the large-scale study, the information in the invitation letter should be enhanced and possibilities for subvention of headphones should be investigated. The large-scale study aims at recruiting 50,000 individuals.

One of the major problems of this study was the calibration and especially the quality of the reference data, as many of the respondents seemed to use a reference person with unreliable hearing. The ability to test the hearing of the reference person is limited. Other Internet-based hearing tests have used a reference tone or a specific program for calibrating the zero level [12,15]. This is problematic, however, as noise levels of computers and the surrounding environments, as well as the quality of headphones, vary for each individual and setting. In a small pre-study, different headphones were evaluated in terms of sound-levels on different frequencies, and differences between the different headphones and frequencies were found. Many of the headphones had "dead points" where the tone had reduced intensity or was distorted at specific frequencies. This problem was reduced by using a frequency modulated sinus tone that is a slightly vibrating tone instead of a pure sinus tone. The individuals in the study were instructed to calibrate the system and perform the test in an environment as silent as possible. This is no guarantee for excluding environmental noise. However, the validation study performed parallel to this study showed surprisingly small differences between the Internet-based test and the pure-tone audiogram in the lower frequencies (500 Hz and 1000 Hz), indicating that these frequencies were not badly affected by environmental noise. Nor were other frequencies effected, and the highest mean difference between the two tests was 5 dB [18].

For the large-scale study, the calibration technique will be redesigned to measure the reference threshold twice in order to get more reliable values and to better judge that a reference is suitable (hearing loss estimated to be less than 15 dB). Also, the reference person will be asked to answer a couple of questions regarding hunting experience and perceived hearing in order to detect potential bias.

Hearing impairment is a growing problem and can occur at all ages. Causes include repetitive exposure to loud sounds, or other external noises [25]. Hearing loss is a social handicap and can often lead to a decrease in quality of life and premature retirement [3,26]. As hearing ability decreases naturally with age, a minor hearing loss caused by noise at a younger age can become a greater problem later in life [27,28]. A major challenge in treating hearing loss is early identification. If hearing ability is decreased in one ear at a young age, it is often compensated for by the better ear. When hearing ability is decreased naturally with age, the acquired hearing loss increases the problem. Prospective longitudinal epidemiological studies can increase the knowledge about the development of hearing loss and preventive measures. The Internet-based hearing test in this study has been validated against a clinical pure-tone audiogram and provides the benefit of an objective and cost effective alternative to screening hearing ability on 6 different frequencies. It can also detect changes in hearing impairment over time when used in longitudinal epidemiological studies.

Though the Internet-based hearing test cannot replace an audiogram from a clinical pure-tone audiometer conducted by a trained audiologist, it is a more useful and objective tool for screening hearing in a large population than a self-estimated hearing questionnaire.

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Conflicts of Interest

None declared.

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Abbreviations

JAVA: Java technology was created as a computer programming tool at Sun Microsystems in 1991

dB: decibel
dBRefHL: dB reference hearing level
dBSPL: dB sound pressure level
Hz: Hertz
URL: Uniform Resource Locator
WHO: World Health Organization

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Original Paper

Response Audit of an Internet Survey of Health Care Providers and Administrators: Implications for Determination of Response Rates

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Abstract

Background: Internet survey modalities often compare unfavorably with traditional survey modalities, particularly with respect to response rates. Response to Internet surveys can be affected by the distribution options and response/collection features employed as well as the existence of automated (out-of-office) replies, automated forwarding, server rejection, and organizational or personal spam filters. However, Internet surveys also provide unparalleled opportunities to track study subjects and examine many of the factors influencing the determination of response rates. Tracking data available for Internet surveys provide detailed information and immediate feedback on a significant component of response that other survey modalities cannot match. This paper presents a response audit of a large Internet survey of more than 5000 cancer care providers and administrators in Ontario, Canada.

Objective: Building upon the CHEcklist for Reporting Results of Internet E-Surveys (CHERRIES), the main objectives of the paper are to (a) assess the impact of a range of factors on the determination of response rates for Internet surveys and (b) recommend steps for improving published descriptions of Internet survey methods.

Methods: We audited the survey response data, analyzing the factors that affected the numerator and denominator in the ultimate determination of response. We also conducted a sensitivity analysis to account for the inherent uncertainty associated with the impact of some of the factors on the response rates.

Results: The survey was initially sent out to 5636 health care providers and administrators. The determination of the numerator was influenced by duplicate/unattached responses and response completeness. The numerator varied from a maximum of 2031 crude (unadjusted) responses to 1849 unique views, 1769 participants, and 1616 complete responses. The determination of the denominator was influenced by forwarding of the invitation email to unknown individuals, server rejections, automated replies, spam filters, and ‘opt out’ options. Based on these factors, the denominator varied from a minimum of 5106 to a maximum of

5922. Considering the different assumptions for the numerator and the denominator, the sensitivity analysis resulted in a 12.5% variation in the response rate (from minimum of 27.3% to maximum of 39.8%) with a best estimate of 32.8%.

Conclusions: Depending on how the numerator and denominator are chosen, the resulting response rates can vary widely. The CHERRIES statement was an important advance in identifying key characteristics of Internet surveys that can influence response rates. This response audit suggests the need to further clarify some of these factors when reporting on Internet surveys for health care providers and administrators, particularly when using commercially available Internet survey packages for specified, rather than convenience, samples.

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KEYWORDS

Health care surveys; Internet; survey methodology

Introduction

There has been perceptible growth in the popularity of Internet surveys over the last decade. However, Internet survey modalities often compare unfavorably with traditional survey modalities, particularly with respect to response rates [1-7]. Response to Internet surveys can be affected by the distribution options and response/collection features employed as well as the existence of automated (out-of-office) replies, automated forwarding, server rejection, and organizational or personal spam filters. However, Internet surveys also provide unparalleled opportunities to track study subjects and examine many of the factors influencing the determination of response rates. Tracking data available for Internet surveys provides detailed information and immediate feedback on a significant component of response that other survey modalities cannot match [9]. This information generates questions about the appropriateness of traditional methods for determining response rates that may affect the comparability of results between Internet and mail/telephone surveys. This paper presents a response audit of a large Internet survey of more than 5000 cancer care providers and administrators in Ontario, Canada. Building upon the CHEcklist for Reporting Results of Internet E-Surveys (CHERRIES) [10], which is similar to other checklists for reporting on research such as CONSORT (for randomized trials) or QUORUM (for systematic reviews), the main objectives of the paper are to (a) assess the impact of a range of factors that influence response rates for Internet surveys and (b) recommend steps for improving published descriptions of Internet survey methods.

Methods

As part of a study to measure the coordination and integration of cancer services, we developed the Cancer Services Integration (CSI) Survey [11]. The intent was to administer the survey to over 5000 physicians, other clinicians and a range of managers and administrators based at comprehensive cancer centers, teaching hospitals, community hospitals, and community care access centers across Ontario involved in the organization and/or delivery of cancer services.

After considering the relative impact on cost, response rates, and survey design [1,3,5-8,12-15], the decision was made to administer the CSI Survey via the Internet. A plethora of vendors provide 'canned' Web-based survey tools for administering Internet surveys [16]. While some features do vary, as do the fixed and variable rates charged for the service, the basic design options available are similar across Internet survey vendors. Therefore, based primarily on cost considerations, SurveyMonkey.com was selected as the vendor through which we would conduct the Internet survey.

Internet Survey Options

The key Internet survey options that influence the determination of response rates can be categorized into 2 main groups: (a) distribution/list management options and (b) response/collection options.

Distribution/List Management Options

Internet surveys can be distributed in many different ways, with the most typical involving email invitations to a specified sample or Web-based pop-up invitations to a convenience sample [8,17,18]. For this survey, we planned to distribute the survey to a specified sample of study subjects via an email invitation that included a link to a Web-based survey. Internet survey vendors, such as SurveyMonkey.com, usually provide two main options for distributing Internet surveys via email. The first and most basic option involves the creation of a generic survey Web link that can be copied and inserted into any email message. The email message with the generic survey Web link can then be sent to study subjects for which email addresses are available. When invited study subjects click on the link, they are taken to the Web-based survey where they can complete the survey based on the response/collection settings discussed below. While this option ensures confidentiality for participants, from a research perspective, the key limitation is that no information on individual response status is collected (eg, you cannot determine whether a specific study subject initiated a response, completed the survey or declined to participate). Furthermore, the email with the generic survey Web link can be forwarded to an infinite number of other email addresses, allowing other individuals to complete the survey with researchers unable to determine which respondents were part of the original sample and which were not (eg, it is possible to have more responses than intended study subjects).

The second option addresses most of these limitations by using a list management feature. For SurveyMonkey.com, this involves importing a list of email addresses into a secure, online database and then using the list management feature to automatically distribute a customizable email that contains an individual-specific survey Web link to all study subjects in the list. This list management option provides constantly updated

information on the response status (eg, responded, no response, declined to participate, etc.) of each individual in the list. This option allows automated reminder messages to be generated and directed to specific subsets of the sample (eg, only to non-responders). There are a couple of limitations to the list management feature, however. We found the response status was usually, but not always, accurate (eg, in some cases, the response status indicated that specific individuals had not responded when in fact they had done so). Also, information on incomplete responses is not particularly useful for sending out reminder messages as no distinction is made between a respondent who completes a very small portion of the survey (eg, one question) and another respondent who completes a large portion of the survey (eg, all but the last question). Despite these limitations, we selected the list management feature, which from a research perspective, is preferable for distributing an Internet survey to a specified sample.

Response/Collection Options

In addition to distribution/list management options, there are several response/collection options that enable or limit a respondent's access to an Internet survey. These options can (a) affect the number of responses that can be entered by an individual respondent (eg, when a respondent clicks on the survey Web link, they can be taken to a blank survey, or, if they have already initiated their response, can be taken to the last question they responded to), (b) affect the number of sittings upon which the survey can be completed (eg, require that the survey must be completed in one sitting vs multiple sittings), (c) affect the ability to move backwards and forwards though the survey to edit/change responses, and (d) affect the ability to have multiple respondents respond from the same computer. For example, at the time of our survey launch (February 2007) SurveyMonkey.com had four main response/collection options when using the list management option, described on the vendor's website as follows:

1. *One Response per Respondent* – After completing the survey, respondents will be prevented from entering additional responses. Respondents that return to a survey later will be able to edit their existing answers. Respondents that return to an incomplete survey will be taken to the point that they left off.
2. *One Response per Respondent (Forward Only)* – After completing the survey, respondents will be prevented from entering additional responses. In addition, respondents are prevented from backing up to edit their existing answers. Respondents that return to an incomplete survey will be taken to the point that they left off.
3. *Multiple Responses per Respondent* – After completing the survey, respondents will be allowed to enter an additional response. Respondents that return to an incomplete survey will be taken to the point that they left off.
4. *Multiple Responses per Respondent (Shared Computer)* – After completing or exiting the survey, respondents will be allowed to enter additional responses. Once respondents leave the survey, their answers are considered finished and cannot be edited. Useful for computer labs and tradeshow kiosks.

These response/collection options are critical as they affect the prevalence of duplicate and/or incomplete responses in the final data set. As a significant portion of our sample, particularly clinic nurses and radiation therapists, often share access to computers with Internet access at work, the response/collection option needed to accommodate multiple respondents per computer. We conducted extensive pre-testing of the four SurveyMonkey.com options combined with the list management feature to determine the impact on respondents' access to partially complete responses, response confidentiality, and data capture. This testing revealed several issues. Of particular concern, options (1), (2), and (3) did not consistently protect response confidentiality. These options, which each allowed a respondent to return to the last question completed, also allowed other individuals, if they had been forwarded the original email invitation, to see the original respondent's responses in some situations. Options (1)) and (2) did not allow duplicate responses; however our testing revealed situations where original, but not fully complete, responses could be overwritten by subsequent responses, whether by the same individual or another individual forwarded the email invitation. Ultimately, option (4) was selected as it was the only option that consistently protected response confidentiality in shared computer contexts and did not allow initial responses to be overwritten.

The main concern with option (4) was that it allowed multiple responses per unique email address. While the invitation email with survey Web link could be forwarded to other email addresses, based on option (4), all individuals who accessed the survey through that individual-specific Web link would have their responses linked to the original individual-specific email address. This creates uncertainty regarding whether a duplicate response originated from the intended study subject or from other unintended individuals. Also, option (4) did not allow respondents to access prior incomplete responses (rather a blank survey was accessed every time the Web link was selected), therefore we instructed study subjects to make every attempt to complete the entire survey in one sitting (approximately 10-15 minutes).

Survey Distribution and Response Audit

Using the list management feature and response/collection option (4) allowing multiple responses per respondent from a shared computer, we imported 5636 email addresses into the SurveyMonkey.com list management database and created custom email invitations for each regional cancer program in Ontario. The initial automated invitation email was sent to all individuals in the list management database on 26 February 2007 with 3 automated reminder emails sent out to all individuals in the list management database with a response status of 'no response'. To reduce the impact of forwarding of the invitation email to unidentified individuals, the first question on the survey asked the respondent how they accessed the survey. Those individuals who indicated that they did not receive the invitation email from csi.survey@cancercare.on.ca were asked to contact the study's research coordinator who would send out an original invitation email if the individual fit the sampling criteria.

After each invitation or reminder email sent out, error messages were collected and dealt with where possible. This included documenting the number of server rejections and automated replies, as well as the response status of the study subjects. The survey was 'closed' (ie, no further responses accepted) on 16 March 2007. Following the close of the survey, we audited the response data, analyzing the factors that affected the numerator and denominator in the ultimate determination of response. We also conducted a sensitivity analysis to account for the inherent uncertainty associated with the impact of some of the factors on the response rates. Ethics approval for the survey was provided by the University of Toronto's Research Ethics Board.

Results

The determination of the response rate requires both a numerator and a denominator. The numerous factors affecting the determination of both are described below.

The Numerator

The response rate's numerator varies and can represent the number of study subjects who viewed, participated, or completed the survey. There were two main factors which influenced the determination of the numerator: duplicate/unattached responses and response completeness.

Duplicate/Unattached Responses

With the list management feature and the distribution/collection options used, the potential for duplicate responses was high. A duplicate response could occur if the intended study subject accessed the survey through the individual-specific Web link more than once (eg, each click on the Web link resulted in a separate response). A duplicate response could also occur if the intended study subject forwarded the invitation or reminder emails to another individual who then accessed the survey through the same individual-specific Web link. In either case, a new response associated with the original study subject's email address would be automatically captured and added to the data set. While a duplicate response may often reflect benign intentions (eg, not having time to complete the survey in one sitting or sending the email invitation from a work email address to a personal email address), researchers need to be aware of attempts to influence the results by essentially 'stuffing the ballot box'.

Of the 2031 responses captured in the database, 1699 were associated with a single email address representing an intended study subject from the original sample. There were 321 responses captured of which two or more were associated with the same study subject's email address. Another 11 responses captured were not associated with any study subject's email address which, based on the list management and response/collection options used, should not have been possible.

For the numerator, criteria for what to do with duplicate and unattached responses need to be established. The unattached responses, while raising some lingering questions regarding the accuracy of the list management feature, represented a very small proportion of the sample. Therefore, the 11 responses not associated with a study subject were excluded. Criteria for exclusion of duplicate responses represent a more challenging problem that includes inherent uncertainty and requires judgement. For the 321 duplicate responses, 171 were ultimately excluded based on the exclusion criteria set out in Table 1. Overall, there were 1849 responses associated with a unique email address.

Table 1. Duplicate/unattached response exclusion criteria

Exclusion criteria	Responses excluded (N)
(i) When a response is not associated with a study subject (ie, no email address), the response is excluded.	11
(ii) When only 1 of 2 or more responses associated with the same study subject (ie, a unique email address) indicate in the first question of the survey that the invitation email was received directly from csi.survey@cancercare.on.ca, the other responses are excluded.	33
(iii) When 2 or more responses associated with the same study subject (ie, a unique email address) are 'identical', the initial response is included and all subsequent responses are excluded.	12
(iv) When 2 or more responses associated with the same study subject (ie, a unique email address) are 'identical' up until a certain question, after which 1 response continues on and the other responses are incomplete, the less complete responses are excluded.	112
(v) When 2 or more responses associated with the same study subject (ie, a unique email address) are clearly different (eg, responses indicate different sex, position, location of work, etc.), the most unlikely responses (eg, based on comparison to available demographic/position information for the study sample) are excluded.	4
(vi) When none of the above criteria apply, multiple responses associated with the same study subject (ie, a unique email address) were randomly selected to exclude all but 1 response per study subject.	10
Total responses excluded	**182**

Response Completeness

Response completeness reflects varying response patterns and reporting options that can influence the determination of the numerator [10]. Simply clicking on the survey Web link in the invitation email is defined as a response by SurveyMonkey.com. For this survey, the crude number of responses captured was 2031, with 1849 unique respondents 'viewing' the survey after adjusting for duplicate responses. The number of views,

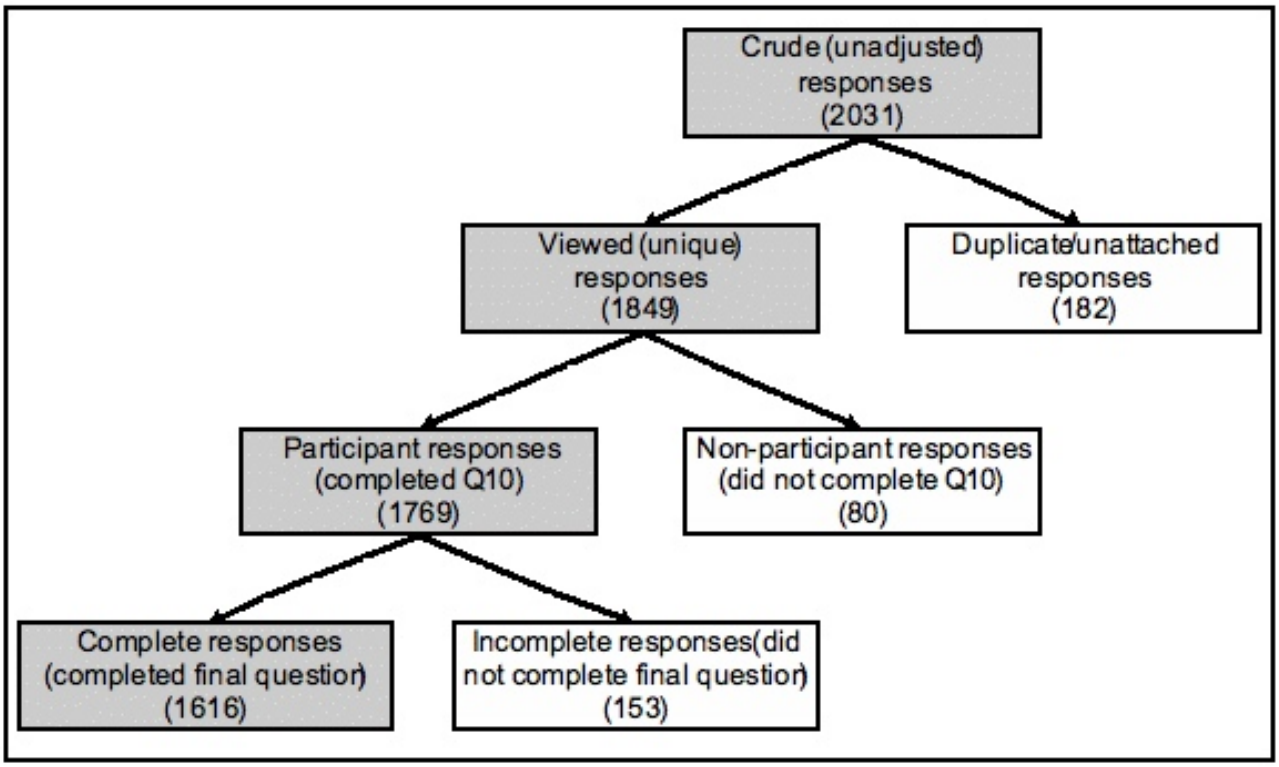
however, does not necessarily reflect participation, as no questions need to be answered.

A more conservative measure of response completeness links 'participation' to an actual response to a specific question. In this survey, the tenth question on the survey asked the respondent to identify the regional cancer program most relevant to their clinical/professional work. As this question was the base for the conditional logic that directed the respondent to region-specific survey sections, a response to this question was required before the respondent could move on to subsequent sections of the survey. For this survey, adjusted for duplicate responses, 1769 unique respondents participated in the survey by answering the tenth question.

As not all 'participants' completed the remaining 54 Likert scale items in the survey, another measure of response completeness reflects the number of respondents who 'complete' the final question on the survey. In this survey, adjusted for duplicate responses, 1616 respondents completed the final survey question (although it should be noted that only 722 respondents completed all survey questions).

Therefore, the response data collected for this survey provide four plausible numerators that could be reported (Figure 1). If we exclude the crude number of responses that is not adjusted for duplicate/unattached responses, there are still considerable differences between the number of respondents who viewed (n = 1849), participated (n = 1769) or completed (n = 1616) the survey.

Figure 1. Estimating the numerator



The Denominator

The response rate's denominator varies and can represent the number of individuals who received, or were intended to receive, an invitation to participate in the survey. There are a number of factors impacting on the denominator that require consideration including forwarding of the invitation email to unknown individuals, server rejections, automated replies, spam filters, and 'opt in/out' options. These factors are elaborated in turn below.

Forwarding Email Invitation to Unknown Individuals

Forwarding of invitation emails affects the number of individuals who actually receive the invitation. While the list management and response/collection options provide greater certainty with respect to the impact of forwarding on the numerator, it is much more difficult to assess the impact on the denominator.

For this survey, there were many indications that forwarding was occurring. For example, when responding to the first question of the survey, 47 individuals indicated they did not receive the invitation email directly from csi.survey@cancercare.on.ca, but rather received the message from another individual (eg, colleague/friend). The many duplicate responses associated with the same study subject also suggested that invitation/reminder emails were being forwarded to other email addresses. While email forwarding leads to an increase in the denominator, there is no clear mechanism to determine how many invitation emails were actually forwarded to unintended recipients. Unfortunately, there is little guidance on how the denominator should be adjusted, if at all, to acknowledge the impact of forwarding. There are two main options which include (a) not adjusting the denominator but rather adjusting the numerator (ie, remove duplicate responses that are due to email forwarding) to maximize the likeliness that a response was from an intended study subject or (b) adjust

the denominator based on an estimate of the number of email invitations that were forwarded to other individuals. Therefore, as part of our sensitivity analysis, we considered the impact on the denominator if 1% (56/5636), 5% (282/5636), or 10% (564/5636) of original email invitations were forwarded to other individuals.

Server Rejection (Bounce-Back)

Server rejections usually represent an email that does not reach the intended recipient and normally result in a bounce-back email to the original sender which provides information on the reason for the rejection. Server rejections were monitored after the initial email invitation and after each of the 3 subsequent reminder emails. Some server rejections were due to incorrect or dormant email addresses, while other rejections were due to temporary (eg, communications failure, message delays, disabled mailbox, etc.) and permanent (eg, no such recipient, syntax/format error, etc.) delivery failures. For the invitation and 3 reminder emails, 346 study subjects (ie, a unique email address) had at least 1 server rejection.

Incorrect email addresses were updated and invitation emails resent where possible. We confirmed that 171 of these study subjects were no longer in their positions. However, there was little guidance for how to deal with other temporary or permanent server rejections. Examining each server rejection individually, we noted that for 54 study subjects, all attempts to send the invitation and reminder emails were rejected by the server. For another 19 study subjects, 3 of the 4 attempts were rejected by the server, while for 25 study subjects, 2 of the 4 attempts were rejected, and for 77 study subjects, 1 of the 4 attempts was rejected (Table 2).

In the case where all invitation/reminder emails to a study subject are rejected by the server, should that study subject be removed from the sample, thereby reducing the denominator? Complicating this issue, our response audit showed that for 2 of the 54 study subjects who had all 4 invitation/reminder emails rejected by the server, a response had been captured. Ultimately, we excluded those study subjects that did not receive a single invitation or reminder email (ie, all email invitation/reminders were rejected by the server), adjusted for those where a response was still captured.

Table 2. Server rejection and automated reply patterns

Server rejection patterns (unadjusted)	Responses (N)	Automated reply patterns (unadjusted)	Responses (N)
Total invitation emails sent out*	5640	Total invitation emails sent out*	5640
No server rejections (0/4)	5294	No automated replies (0/4)	5344
Server rejection to 1/4 launch/reminder emails	77	Automated reply to 1/4 launch/reminder emails	198
Server rejection to 2/4 launch/reminder emails	25	Automated reply to 2/4 launch/reminder emails	63
Server rejection to 3/4 launch/reminder emails	19	Automated reply to 3/4 launch/reminder emails	12
Server rejection to 4/4 launch/reminder emails	54	Automated reply to 4/4 launch/reminder emails	2
Server rejection – confirmed no longer at organization	171	Automated reply – extended leave	21

*Includes 4 additional invitations sent out after initial survey launch

Automated Reply (Out-of-Office)

Automated reply options available in most email software programs (eg, Microsoft Outlook) allow an individual to set up a message that is automatically sent in reply to all received email messages over a specified period of time. A key distinction between server rejections and automated replies is that server rejections normally indicate that the email did not reach its intended target, while automated replies normally indicate that the email was received, but that the intended recipient may not have had the opportunity to read and/or respond to the message.

The most common example of an automated reply is the out-of-office reply. Whether an out-of-office reply is received by the original sender is affected by a range of settings, with some providing an automated reply only to the first email received from a unique address within a specified period and others restricting to whom automated replies will be sent (eg, only to emails originating from within the individual's organization or from specified 'safe' domains). Therefore, it is likely that not all out-of-office replies are received by the survey sender. Fortunately, for those out-of-office replies that are received, they usually indicate the duration of an individual's absence.

For this survey, one or more automated replies to the invitation/reminder emails were received from 296 study subjects (Table 2). Of these, 23 indicated that the study subject would be out-of-office for the duration of the survey (ie, either an automated reply indicating an extended leave for the period of the survey or automated replies to each of the 4 invitation/reminder emails). This type of information is not usually available to researchers when using traditional survey modalities. Therefore, in terms of determining response, there is limited guidance on how to use it. Should those individuals who clearly indicate that they will be away for the duration of the survey be excluded from the denominator? Again complicating the issue, our response audit revealed that a response was captured for 3 of the 23 study subjects whose automated replies indicated they would be out-of-office for the duration of the survey. Ultimately, we excluded those study subjects where an out-of-office reply was received for each

email invitation/reminder or indicated in the automated reply that they would be away for the duration of the survey, adjusted for those where a response was still captured.

Spam Filters (Junk Mail)

Spam filters present another degree of uncertainty in terms of determining the denominator. There are two main approaches to dealing with spam. The first involves preventing potentially unwanted emails from reaching the email server, and the second involves automated marking of potentially unwanted emails as spam and allowing individuals to review and filter them accordingly.

The former approach, often used by large organizations such as hospitals and universities, involves commercially available services. However, while these filters do a reasonably good job of detecting spam, they also potentially filter out emails that are not spam, which therefore never reach the intended individual. Some of the commercially available spam filter services guarantee false positive rates of 1 in 10,000 or better (eg, MessageLabs claims a false positive rate of 1 in 333,333 [19]), which for our survey would suggest that it would be unlikely that the invitation or reminder emails would be filtered as spam. Furthermore, SurveyMonkey.com's list management feature allowed us to designate the email address from which the invitation and reminder emails would be sent. Therefore, we used the provincial cancer agency's domain (ie, 'cancercare.on.ca') for the invitation email, which, as a recognizable domain within the Ontario health care system, should have reduced the possibility that the invitation/reminder emails would have been filtered as spam. Although, we did not have information on the specific commercial spam filter services used by the study subjects' organizations, when at least one response was received from an organization's email domain, we could deduce that the specific organization's spam filter did not automatically filter out the email invitations sent to study subjects with the same organization's email domain.

The impact of the latter spam filtering approach is less clear. Most email providers and software programs provide some type of spam filter control for the individual user. This includes a number of filtering levels that range from blocking all emails from an email address not designated in a safe list to allowing almost all but the most obvious spam to the inbox. There are also customizable filtering options, where user-defined keywords can be filtered out automatically. For example, if an individual sets their filter to exclude any emails with the word 'survey' in the message, our invitation email would not be received.

In contrast to email forwarding, where the concern is that more individuals receive the invitation email than intended, the concern with spam filters is that not all study subjects receive the invitation email. Unfortunately, it is very difficult to determine the extent to which spam filters affect the number of study subjects who actually receive the invitation. Ultimately, for our best estimate, we did not adjust the denominator to account for the impact of spam filters. However, similar to our assessment of the impact of email forwarding, we did consider the impact on the denominator if 1% (56/5636), 5% (282/5636), or 10% (564/5636) of invitation emails were filtered from the intended recipients, as part of the sensitivity analysis.

'Opting Out' and 'Opting In'

When using the list management feature, Surveymonkey.com requires that an 'opt out' Web link be included in the invitation email message. In part to prevent use of the list management feature for distributing spam, the opt out option allows those individuals sent the invitation email to click on the specified opt out link which removes that individual's email address from the list and prevents further emails from being sent to that individual. It should be noted that when an individual decides to opt out, it may not be possible to send an email to their email address for an extended period of time (eg, at least 1 year in our most recent experience with SurveyMonkey.com's list management feature).

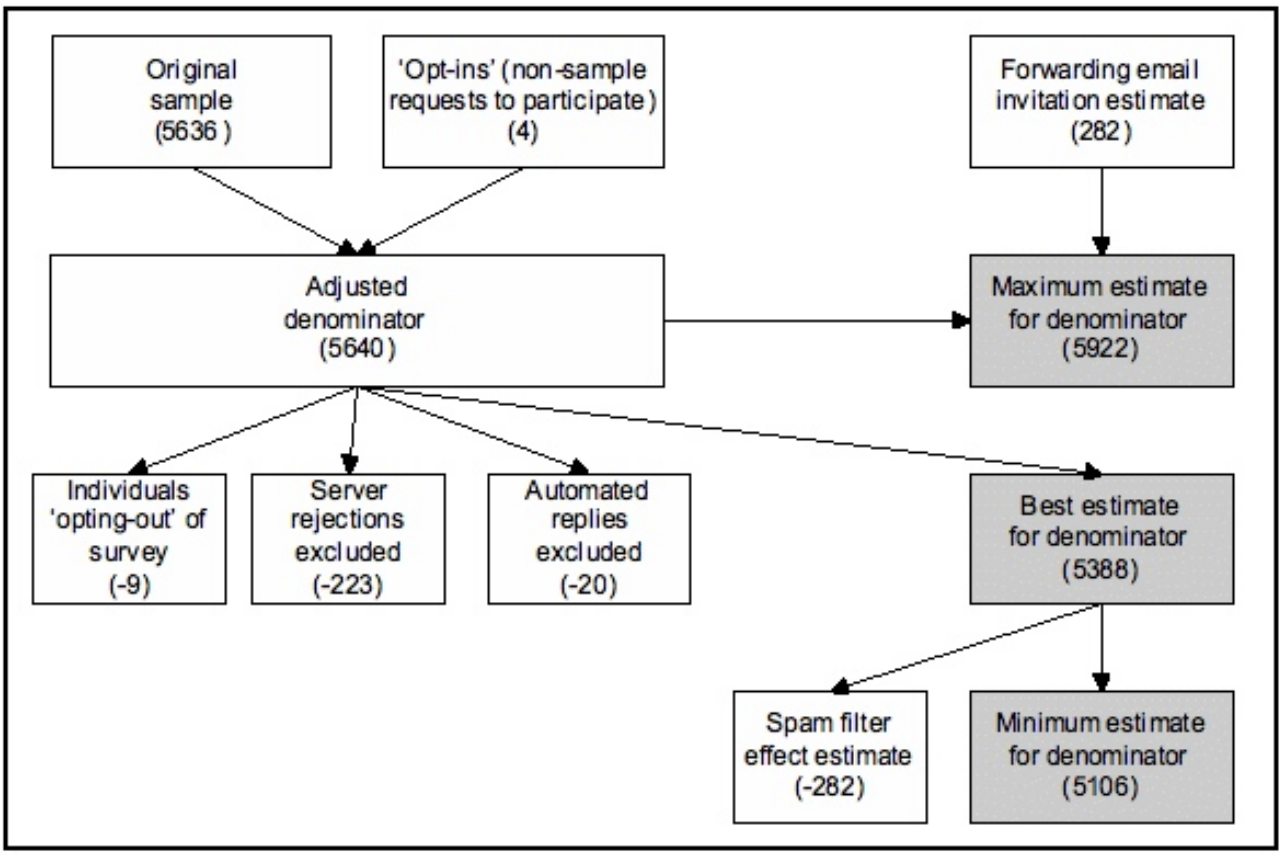
For this survey, we had 126 individuals actively opt out using the provided Web link. Another 18 individuals contacted the study's research coordinator to indicate that they should not have been included in the sample. A reasonable explanation for why they should not be included in the survey was provided by 11 of these individuals (eg, no longer a cancer care provider). From the denominator, 9 were removed while 2, having already initiated their response, were included. The remaining 7 individuals were considered eligible recipients and were therefore also included in the denominator.

There were also 4 individual requests to be added to our sample. The case for each individual was reviewed and accepted, with an invitation email then sent to each to allow direct access to the survey. This reflects an 'opt in' option, which thereby increased the denominator.

Estimating the Denominator

Considering the factors described above, there is considerable uncertainty inherent in any estimate of the denominator for an Internet survey. Most factors, such as server rejections, automated replies, and spam filters, tend to reduce the number of individuals receiving the invitation email, while other factors, such as email forwarding, tend to increase the number of individuals receiving the invitation email. Figure 2 presents the impact of various factors for estimating the denominator.

Figure 2. Estimating the denominator



Response Rate Estimates and Sensitivity Analysis

While established protocols for determining response rates for mail/telephone surveys exist [8], these survey modalities lack the type of tracking data immediately available for Internet surveys. Therefore, one needs to ask whether response rates should be calculated differently for Internet surveys. Based on our response audit, Table 3 sets out a maximum, minimum, and best estimate for both the numerator and denominator. From these estimates, a sensitivity analysis was conducted that examines the impact of the various assumptions on the overall response rate. Based on our best estimates, the response rate was 32.8%. However, under more or less conservative assumptions for the numerator and denominator, the sensitivity analysis suggests that the response rate could have varied by more than 12% (27.3% to 39.8%). This is based on a 5% estimate for the email forwarding and spam filter effect. When considering the impact of lower (1%) or higher (10%) estimates for the email forwarding and spam filter effects, the sensitivity analysis suggests that the response rate could have varied by more than 9% (28.4% to 38.1%) with a lower (1%) estimate of effect, or by more than 16% (26.0% to 42.1%) with a higher (10%) estimate of effect.

Table 3. Response rate estimates and sensitivity analysis

	Maximum estimate	Best estimate	Minimum estimate
Numerator			
Crude	2031	2031	2031
Duplicate/unattached	0	-182	-182
Response completeness (view – participate)	0	-80	-80
Response completeness (participate – complete)	0	0	-153
Numerator Estimate	**2031**	**1769**	**1616**
Denominator			
Crude	5636	5636	5636
Opt in	+4	+4	+4
Forwarding impact*	+282	0	0
Opt out	0	-9	-9
Server rejection	0	-223	-223
Automated reply	0	-20	-20
Spam filter effect*	0	0	-282
Denominator Estimate	**5922**	**5388**	**5106**

Numerator	**Crude**	**Max**	**Max**	**Max**	**Best**	**Best**	**Best**	**Min**	**Min**	**Min**
	2031	2031	2031	2031	1769	1769	1769	1616	1616	1616
Denominator	**Crude**	**Max**	**Best**	**Min**	**Max**	**Best**	**Min**	**Max**	**Best**	**Min**
	5640	5922	5388	5106	5922	5388	5106	5922	5388	5106
Response rate	36.0%	34.3%	37.7%	39.8%	29.9%	32.8%	34.6%	27.3%	30.0%	31.6%

*based on 5% (282/5636) estimate of effect; max = maximum estimate; best = best estimate; min = minimum estimate

Discussion

Surveying a specified sample of health care providers and administrators, we intended to use an Internet survey to replicate, to the extent possible, traditional survey modalities (eg, mail/telephone). However, given the range of design, distribution, and response/collection options available, Internet surveys present unique features that affect the determination of response rates. This response audit raises important questions for researchers regarding the appropriateness of traditional rules/protocols used for determining and reporting on the response of health care providers and administrators to Internet surveys.

We concur with the CHERRIES statement recommending more complete and detailed descriptions of the conduct of Internet surveys [10]. While much of the CHERRIES checklist is relevant to all Internet surveys, there is less emphasis on the use of commercially available canned software programs, such as SurveyMonkey.com, targeted to specified (vs convenience) samples. Our response audit suggests there is an equally strong need for detailed information on how Internet surveys directed to specified samples using commercially available software programs are administered, how response rates are calculated, and how multiple responses from the same individual are prevented. The distribution/list management and response/collection options available from these Internet survey vendors should be clearly identified and the particular options selected should be justified. It would be helpful if Internet survey vendors provided more detailed information on the effects of the various options on respondent access, privacy, and confidentiality as well as data capture, but without this, researchers should provide details of any pre-testing of the distribution/list management and response/collection options available. Reports of Internet surveys should also include discussion of assumptions used in determining response rates, including the impact of email forwarding, server rejections, automated replies, and spam filters.

Some limitations to this work should be noted. First, this response audit was based on a survey conducted through a widely available Internet survey vendor (SurveyMonkey.com) in February 2007. However, SurveyMonkey.com has since modified its response/collection options, highlighting the evolving nature of this field. Further, while Internet survey options may be similar across the many competing vendors,

standards for distribution/list management and response/collection options, as well as the type of response status data collected, differ. While the underlying factors that impact on response rates for Internet surveys are the same, there is a need to further standardize and categorize the necessary descriptive information that should be reported for any Internet survey. Second, it should be noted that a defining characteristic of a subset of our target population was the need to respond from a shared computer. This influenced our choice of the response/collection option selected, which allowed more duplicate responses than would otherwise have been the case. Third, our sensitivity analysis of the effects of email forwarding and spam filters were based on rough estimates. While our intent was to use fairly conservative estimates to highlight the potential impact of these factors, there is a need for more work in this area to accurately measure the effect of email forwarding and spam filters on response rates. Fourth, although not unusual for surveys of clinicians [20], the overall response rate to our survey (however determined) was low. However, for the purposes of the response audit, our large sample of over 5000 study subjects provided sufficient data from which to examine the factors that influence response rates. Lastly, this response audit focuses on technical factors relevant to Internet surveys that impact on response rates. We acknowledge that other factors such as respondent characteristics may also influence response; however, this does not preclude the need to accurately describe how Internet surveys are conducted and response rates calculated.

While it has been questioned whether Internet surveys will ever become part of mainstream research [17], it seems clear that Internet surveys are here to stay. Therefore, there is a growing need to improve the documentation and reporting of Internet survey design features, distribution, and response/collection options employed. As Internet survey options continue to evolve, further consideration of the way survey research is conducted and reported is needed. The CHERRIES statement is an important starting point [10]; however, further emphasis on the use of commercially available Internet survey products for specified, rather than convenience samples, is needed. We hope this paper advances development in this important methodological area.

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Conflicts of Interest

None declared.

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Original Paper

eHealth Trends in Europe 2005-2007: A Population-Based Survey

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Abstract

Background: In the last decade, the number of Internet users worldwide has dramatically increased. People are using the Internet for various health-related purposes. It is important to monitor such use as it may have an impact on the individual's health and behavior, patient-practitioner roles, and on general health care provision.

Objectives: This study investigates trends and patterns of European health-related Internet use over a period of 18 months. The main study objective was to estimate the change in the proportion of the population using the Internet for health purposes, and the importance of the Internet as a source of health information compared to more traditional sources.

Methods: The survey data were collected through computer-assisted telephone interviews. A representative sample (N = 14,956) from seven European countries has been used: Denmark, Germany, Greece, Latvia, Norway, Poland, and Portugal. The European eHealth Consumer Trends Survey was first conducted in October-November 2005 and repeated in April-May 2007. In addition to providing background information, respondents were asked to rate the importance of various sources of health information. They were also queried as to the frequency of different online activities related to health and illness and the effects of such use on their disposition.

Results: The percentage of the population that has used the Internet for health purposes increased from an estimated 42.3% (95% CI [Confidence Interval] 41.3 - 43.3) in 2005 to an estimated 52.2% (95% CI 51.3 - 53.2) in 2007. Significant growth in the use of the Internet for health purposes was found in all the seven countries. Young women are the most active Internet health users. The importance of the Internet as a source of health information has increased. In 2007, the Internet was perceived as an important source of health information by an estimated 46.8% (95% CI 45.7 - 47.9) of the population, a significant increase of 6.5 % (95% CI 4.9 - 8.1) from 2005. The importance of all the traditional health information channels has either decreased or remained the same. An estimated 22.7% (95% CI 21.7 - 23.6) are using it for more interactive services than just reading health information.

Conclusion: The Internet is increasingly being used as a source of health information by the European population, and its perceived importance is rising. Use of the Internet for health purposes is growing in all age groups and for both men and women, with especially strong growth among young women. We see that experienced Internet health users are also using the Internet as an active communication channel, both for reaching health professionals and for communicating with peers.

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KEYWORDS

Internet; patient-provider communication; Internet health communication; electronic mail; information services, trends, and utilization; medical informatics; health services; demography; data collection; health care surveys

Introduction

In recent years, the number of Internet users has increased considerably and the Internet is being used for various health purposes [1-5]. Health professionals, patient organizations, and the pharmaceutical industry are using the Internet as a medium for communicating health information [6-9]. For patients the most obvious use is as a source of health information. Nevertheless, we also see that they use it for accessing and managing their own personal health record [10-13], for purchasing health products and services, and for communicating with peers and health professionals [14,15].

However, most of the literature on this issue comes from the United States. Studies on the use of Internet-based technologies for health purposes within Europe are still rare [16,17]. To chart the European status of this development, a survey in Denmark, Germany, Greece, Latvia, Norway, Poland, and Portugal was conducted in 2005 as the first phase of the WHO eHealth Consumer Trends Survey funded by the European Commission. This baseline study showed that even if there were considerable regional differences, a significant proportion of citizens in all the countries studied were using Internet for health purposes [18-20].

To study the pace and direction of the European citizens' appraisal of eHealth services, we repeated the survey in 2007. In addition to studying trends in the general population, the study also focuses on whether the type and frequency of health-related activities on the Internet change as the medium matures and Internet users become more experienced. In doing so, we hope to shed some light on the future of Internet-based services for health and illness.

Methods

Participants and Procedure

The first survey was conducted in the period from October to November 2005. Random digit dialling in strata was used to ensure a randomized representative sample of the seven participating countries. Sampling continued until we had approximately 1000 completed interviews per country, except for Portugal where the limit was increased to 2000 complete interviews, as health-related Internet use was expected to be low.

The second survey took place in April and May 2007. Experiences from the first survey showed that the sample was skewed for some age groups. In 2007, quotas were therefore constructed based on census data for age and gender to make sure the data were more representative in this regard. This ensured that the sample had the same distribution age (six groups) and gender as the census. As described below, weighting were used on the 2005 data to adjust them accordingly. The target sample size was set to 1000 for all countries in 2007.

Mobile phone numbers were included in Norway, Denmark, and Latvia. In the other countries only landline telephones were included since it was difficult to get a reliable sample based on mobile phones in these countries in 2005. In the countries where mobile phones were included, the telephone penetration was close to 100% for Norway and Denmark, while it was around 93% in Latvia. In the countries where only landline telephones were used, the telephone penetration was estimated for 2005/2007 to be 87/82% in Greece, 63/64% in Poland, and 65/60% in Portugal. In Germany is was close to 100%.

To get a response rate for telephone interviews comparable to ordinary interviews can be challenging. In 2005, we were not able to get comparable numbers from all countries allowing us to give an exact response rate. This procedure was improved for 2007. Problems reaching the target person can be divided into two groups. The first is "no contact", including incorrect numbers, disconnected numbers, and answering machines. When we are doing stratified sampling with no additional details about the person we are calling, this group also contains people not in the target group. This group was on average 58% of the total numbers called (min: 36% in Germany, max: 76% in Denmark). If we want a response rate comparable to ordinary interviews, it is reasonable to exclude this group. We should then calculate the response rate of the people that actually had a chance to participate.

The second group is "non-responses", including people not wanting to participate in interviews, people not having time to participate, language problems, interrupted interviews, and people being too sick to participate. Using this number for calculation, we get an average response rate of 36% (min: 17% in Greece, max: 60% in Latvia).

National ethics committees in all the participating countries were informed and had no objections to the study. The data was analysed using the SPSS software version 15.0 and R version 2.5.1.

Measures

The questionnaire used in the study was designed for computer-assisted telephone interviews (CATI). The questionnaire was first designed in English. A dual-focus approach was then used for translating it into the languages of the seven European countries participating in the survey: Denmark, Germany, Greece, Latvia, Norway, Poland, and Portugal. The dual-focus approach strives for conceptual equivalence rather than wording and grammar, and is a modification of the back-translation method [21]. After the translation, the questionnaire was piloted with 100 individuals in Norway.

Internet use for health purposes was measured with the question, "How often do you use the Internet to get information about health or illness?". The response alternatives were: "Every day", "Every week", "Every month", "Every six months", "Every year", "Less than once a year", and "Never". All not answering

"Never" were coded as having used the Internet for health purposes. To measure the importance of different health information channels, the respondents were asked to rate their importance on a scale going from 1 "not important" to 5 "important".

Data Analyses

Mainly the analyses compare change in proportion from 2005 to 2007. Secondly, differences in proportions by demographic variables such as age and gender are assessed. Significant change is judged by non-overlapping confidence intervals (CI). All reported CI's are 95%. The CIs are derived by Gaussian approximations of the distribution of the sum of strata frequencies or sum of ratios of strata frequencies. *P*-values of two sided tests are not given. Significant test results are reported when the null is not inside the 95% interval.

The 2005 data were weighted based on the 2007 distribution regarding age and gender. The reason for weighting the data was to distinguish real effects from minor changes in the demographics of the samples. The weighting also corrected for differing sample sizes, mainly Portugal in 2005. Unfortunately, the weighting means that it would be confusing to state absolute numbers of respondents to each question for 2005.

All countries contribute equally to the grand total, but numbers weighted for population size are also stated in Table 1.

Logistic regression analysis was calculated using employment status, year, gender, and age as dependent variables for the independent variables Internet user, Internet health users, and users of interactive Internet health services. For each variable, we report odds ratios and 95% confidence intervals of the odds ratios.

Results

General Trends

On average, the percentage of the population that had used the Internet for health purposes increased from 42.3% (41.3 - 43.3)in 2005 to 52.2% (51.3 - 53.2) in 2007 (Table 1). There were regional differences. The lowest 2007 use was registered in Greece at 32.1% (29.5 - 34.7) and Portugal at 38.3% (35.6 - 41.0). The highest use was recorded in Denmark at 71.6% (69.1 - 74.1) and Norway at 66.8% (64.2 - 69.5) [22].

Significant growth in the use of Internet for health purposes was found in all the seven countries participating in the survey, with an average growth of 9.9% (8.5 - 11.3). Highest growth was noted in Germany (12.2%), Poland (11.8%), and Latvia (11.3%), whereas the lowest growth was noted in Portugal (9.1%), Greece (8.9%), and Norway (6.6%).

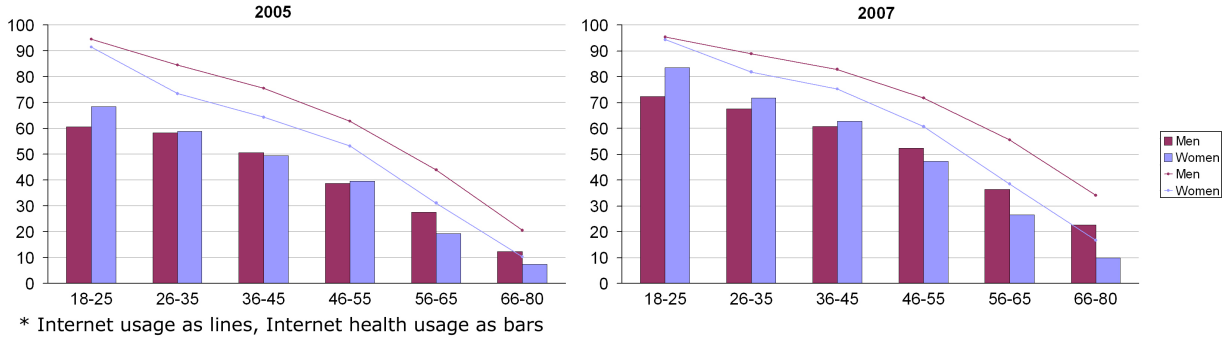
Table 1. Internet health users in the seven European countries—trends 2005 and 2007 (an expanded version that also includes Internet users is available as Multimedia Appendix 1)

			Internet health users		
	Pop. Weight	2005/2007	2005	2007	Growth
Country		Count (N)	% (CI)	% (CI)	% (CI)
Denmark	3,5	960/1021	61.8 (59.0 - 64.7)	71.6 (69.1 - 74.1)	9.8 (6.0 - 13.6)
Germany	53,4	974/1000	44.4 (41.4 - 47.5)	56.6 (53.9 - 59.3)	12.2 (8.1 - 16.2)
Greece	7,2	1000/1000	23.2 (20.7 - 25.7)	32.1 (29.5 - 34.7)	8.9 (5.3 - 12.5)
Latvia	1,5	1000/1000	35.7 (33.2 - 38.2)	47.0 (44.4 - 49.6)	11.3 (7.7 - 14.9)
Norway	3,0	972/1001	60.3 (57.4 - 63.1)	66.8 (64.2 - 69.5)	6.6 (2.7 - 10.4)
Poland	24,7	1027/1000	41.5 (38.8 - 44.2)	53.3 (50.6 - 56.0)	11.8 (8.0 - 15.6)
Portugal	6,8	2001/1000	29.2 (27.4 - 31.1)	38.3 (35.6 - 41.0)	9.1 (5.8 - 12.3)
Average			42.3 (41.3 - 43.3)	52.2 (51.3 - 53.2)	9.9 (8.5 - 11.3)
Average (weighted for population size) (See note under Methods)			42.1 (40.3 - 43.9)	53.5 (51.9 - 55.1)	11.4 (9.0 - 13.7)

Demographics

In 2005, there were significantly more men using the Internet in all age groups. This difference seems to have diminished and was no longer significant in 2007 for the youngest age group (15 - 25 years). Of women aged 15 - 25 years, 83.5% used the Internet for health purposes in 2007. The corresponding proportion for men was 72.4%. At the other end of the age scale (66 - 80 years), we saw the opposite effect, where 22.6% of men and 9.9% of women used the Internet for health purposes (Figure 1, Multimedia Appendix 3). The same effect was visible in 2005, but it was not so clear.

Figure 1. Internet and Internet health usage in 2005 and 2007, by age and gender (numbers are available in Multimedia Appendices 2 and 3)



The Internet as a Source of Health Information

The participants rated the importance of various sources of health information on a scale from 1 to 5. The top two alternatives (4 = important and 5 = very important) were recoded as "important" in Table 2. The Internet had a 6.5% (5.0 - 8.1) increase, and in 2007 was characterized as important by 46.8% (45.7 - 47.9) of the population. Direct contact with health professionals, although decreasing from 2005, was still perceived as the most important source of health information with 73.8% (72.8 - 74.8) describing it as important. It was followed by "family, friends, and colleagues" at 63.8% (62.8 - 64.9). The sharpest decline was observed in newspapers and magazines, which had a 5.1% (3.5 - 6.7) decrease to 48.2% (47.0 - 49.3).

Table 2. Importance of various sources for health information

	2005 N = 7934 Mean % (CI)[a]	2007 N = 7022 Frequency Mean % (CI)	Change Mean Difference % (CI)
Health professionals	77.5 (76.5 - 78.5)	5180 73.8 (72.8 - 74.8)	-3.7 (-5.1 - -2.3)
Family, friends, and colleagues	63.6 (62.5 - 64.7)	4480 63.8 (62.8 - 64.9)	+0.3 (-1.3 - 1.8)
TV/radio	57.1 (56.0 - 58.2)	3763 53.6 (52.5 - 54.8)	-3.5 (-5.1 - -1.9)
Pharmacies	55.4 (54.3 - 56.5)	3646 52 (50.8 - 53.1)	-3.4 (-5.0 - -1.8)
Newspapers and magazines	53.3 (52.2 - 54.4)	3380 48.2 (47.0 - 49.3)	-5.1 (-6.7 - -3.5)
Books	51.6 (50.5 - 52.7)	3353 47.8 (46.7 - 48.9)	-3.8 (-5.3 - -2.2)
Internet	40.3 (39.2 - 41.4)	3288 46.8 (45.7 - 47.9)	+6.5 (5.0 - 8.1)
Courses and lectures	32.9 (31.8 - 33.9)	2249 32.1 (31.0 - 33.1)	-0.8 (-2.3 - 0.7)

[a] 2005 data were weighted based on the 2007 distribution regarding age and gender. Absolute numbers are therefore not reported

There is considerable variation in the importance placed on the Internet as a source of health information within the seven European countries studied. In Denmark currently, the Internet is already considered the second most important source, preceded only by "health professionals". At the other end of the scale, in Greece, the Internet is considered the least important source of information about health and health-related problems (Multimedia Appendix 4). All countries do, however, show significant growth in the importance placed on the Internet, with the exception of Germany where the increase is not significant.

Usage Patterns

The percentage of consumers using the Internet for health purposes in other, more interactive, ways did increase from 15.3% (14.5 - 16.1) in 2005 to 22.7% (21.7 - 23.6) in 2007 (Table 3). In 2007 a total of 9.9% (9.2 - 10.6) have participated in health related forums or self-help activities more than once a year. The study also shows that 8.5% (7.8 - 9.1) order medical health products online, 11.1% (10.4 - 11.8) have online communication with health professionals whom they have not previously met, and 6.9% (6.3 - 7.4) have used the Internet to

interact with known health professionals. The use of all interactive, health-related online services increased significantly. Multimedia Appendix 5 also includes the numbers for the subsamples of Internet users and Internet health users.

Table 3. Percentage of consumers who are using interactive Internet health services at least once a year (Multimedia Appendix 5 shows the percentages for Internet users and Internet health users)

	2005 Mean % (CI)[a]	2007 Frequency (n) Mean % (CI)	Change Mean % (CI)
Self-help activities	7.0 (6.4 - 7.6)	694 9.9 (9.2 - 10.6)	2.9 (2.0 - 3.8)
Order medicine or other health products	5.5 (4.9 - 6.0)	596 8.5 (7.8 - 9.1)	3.0 (2.2 - 3.9)
Interact with Web doctor/health professional you have not met	8.2 (7.6 - 8.8)	780 11.1 (10.4 - 11.8)	2.9 (2.0 - 3.9)
Approach family doctor or other known health professional	3.6 (3.2 - 4.1)	484 6.9 (6.3 - 7.4)	3.2 (2.5 - 4.0)
Using at least one of the interactive services above	15.3 (14.5 - 16.1)	1593 22.7 (21.7 - 23.6)	7.4 (6.2 - 8.6)

[a] 2005 data were weighted based on the 2007 distribution regarding age and gender. Absolute numbers are therefore not reported

From a country-specific point of view (Multimedia Appendix 6), we observed large increases in specific interactive activities in Denmark and Germany. In Denmark the percentage of Internet users who approach a family doctor or other known health professional online has increased by 12.2% (9.1 - 15.2) to 20.1% (17.6 - 22.6) in 2007. In Germany the percentage of Internet users ordering medicine or other health products has increased by 6.2% (3.1 - 9.3) to 17.7% (15.3 - 20.1) in 2007.

Using logistic regression models (Table 4), we analysed trends from 2005 to 2007, looking at age, gender, and employment status and their effect on the use of the Internet, Internet health information, and interactive health services. The logistic analysis shows no significant effect of gender on the use of the Internet. There is, however, a significant interaction effect between gender and age, where the proportion of men is largest in the highest age groups. Employment status is also a significant factor, since a very large proportion of students are using the Internet.

For the Internet health user, the gender difference is much clearer, since women are using the Internet significantly more (OR = 2.92, 95% CI 2.36 - 3.62). Age seems to have less effect in predicting numbers of Internet health users than in predicting Internet users. There has been significant growth in the number of Internet users, Internet health users, and people using interactive Internet health services. There seems to be significant growth in the number of men using interactive health services as well.

Table 4. Factors affecting Internet usage, Internet health usage, and the use of interactive health services. Sample is based on all respondents in all seven countries (N = 14,955).

		Internet user	Internet health user	Interactive health user
		Odds ratio (95% CI), *P*	Odds ratio (95% CI), *P*	Odds ratio (95% CI), *P*
Age	10 year intervals[a]	0.61 (0.58 - 0.64), < .001	0.77 (0.74 - 0.81), < .001	0.80 (0.76 - 0.85), < .001
Year	2005	1	1	1
	2007	1.49 (1.10 - 2.01), .01	2.06 (1.66 - 2.57), < .001	1.77 (1.39 - 2.27), < .001
Gender	Male	1	1	1
	Female	1.15 (0.86 - 1.52), .35	2.92 (2.36 - 3.62), < .001	2.54 (1.99 - 3.23), < .001
Employment	Unemployed	1	1	1
	Work	3.51 (3.21 - 3.84), < .001	2.68 (2.46 - 2.92), < .001	1.67 (1.49 - 1.87), < .001
	Student	10.57 (7.913 - 14.12), < .001	2.83 (2.42 - 3.31), < .001	1.49 (1.26 - 1.77), < .001
Interactions				
	Age * Gender	0.90 (0.85 - 0.95), < .001	0.80 (0.76 - 0.83), < .001	0.835 (0.790 - 0.882), < .001
	Age * Year	1.04 (0.98 - 1.10), .18	0.97 (0.92 - 1.01), .14	1.04 (0.98 - 1.10), .21
	Gender * Year	0.93 (0.79 - 1.10), .39	1.02 (0.89 - 1.19), .75	0.82 (0.67 - 0.99), .03

[a]Odds Ratio (OR) is estimated for every 10 year difference

Discussion

A majority of our European study population now uses the Internet for health purposes. We have seen a significant increase in all countries (Table 1).To a great extent this increase in use can be explained by improved Internet access.

In Denmark, Germany, Greece, and Portugal, we see that growth in the number of Internet health users is larger relatively speaking than growth in the number of Internet users. This might indicate that new Internet services for health users have been launched in these countries. In Denmark and Germany, our results also show a significant increase in one of the interactive health services. The relatively large increase in Internet users buying medicines online in Germany is matched by the growing eCommerce market for medicine since new legislation was introduced in 2004 [23,24]. In Denmark, we observe an increase in online communication with known health professionals as more and more GPs offer services to meet the expectations of their patients and to implement these services before January 2009, when it will become mandatory for GPs to offer online services [25].

Demographics

There is still a majority of men representing Internet users in the seven countries studied. However, the difference between men and women is diminishing in younger age groups, and the 2007 survey did not show any significant difference between male and female Internet users for respondents aged between 15 and 25. Nearly all in this age group do have access to the Internet. It is therefore logical that it is among the oldest users that we have the largest growth potential.

The gender differences in Internet health use should be seen in the context of overall Internet use. Elderly people and women are traditionally overrepresented as health care receivers. This notion stands in contrast to the characteristics of the average Internet user. Internet health users are a combination of these factors. Looking at the youngest age group, we saw in 2005 that there were more women than men using Internet health services. The difference was 7.6% (4.6 - 10.7). In 2007, this difference increased to 11.1% (8.3 - 13.9). In other words, young women were already overrepresented as Internet health users in 2005, and it seems like this tendency increased in 2007.

In the logistic regression in Table 4, some interesting interaction effects can also be observed. While we can see an overall growth in Internet health usage among women, this does not apply to the oldest age group. Here the growth is largest among men, and it is not growth that can be explained by growth in general Internet usage. It is difficult to say why this is happening. One explanation might be that it is due to specific Internet services that target elderly men. Another might be that using the Internet for specific purposes like health is of greater interest to users in older age groups. The first adopters of the Internet in these groups were men, and perhaps they are now among those who use it for health purposes.

The Internet as a Source of Health Information

The importance of the Internet as a source of health information is growing. The absolute numbers for this kind of Internet use in every country seem to rely on how the scale for ranging the importance of health information channels is interpreted. It seems more reliable to focus on the relative importance of the Internet as a health information source (compared to the traditional ones) in a specific country and on the change within that country from 2005 to 2007. From this perspective, it is interesting to notice that the greatest change in the importance of the Internet actually occurs in the countries that already had a high Internet health usage in 2005.

In Denmark for instance, the Internet was the second most important source of health information in 2007—outranked only by information from health professionals. Both in Norway

and in Denmark, the Internet is now considered more important as a source of health information than television and radio. The aggregated results for all the countries show that, even if the Internet is at the bottom of the list, there is just a small, non-significant difference between the Internet and more traditional media such as books, newspapers, and magazines. As the latter media decrease in importance and the Internet increases, it is legitimate to predict that the Internet might surpass them over the next few years.

Interactive Use of the Internet for Health Purposes

More in-depth analysis of the actual eHealth activities performed by the Internet health users in our two surveys reveals a tendency toward more "advanced" and more interactive use of the Internet for health purposes. Rather than using the Internet to search for and read health information, people are increasingly taking part in online communication with peers, unknown professionals, and their family doctors. In addition, the Internet is being used by more people for ordering medical health products.

Beckjord [5] estimates that 7% of US Internet users communicated online with a health care provider in 2003, and this increased to 10% in 2005. Since our study distinguishes between known health professionals and medical personnel whom patients meet only online, and since the study period is different, it is hard to make a direct comparison. Multimedia Appendix 5 extends Table 3 to give numbers for the Internet users only. This shows that interaction with Web doctors and other health professionals whom patients have not personally met did increase from 13.2% to 16.8% from 2005 to 2007. Communication with family doctors or other known health professionals increased from 5.0% to 9.7%. Even if the studies are not directly comparable, they give an indication that the average use in our seven European countries is not falling behind the average for the US.

However, both in the US and in Europe, it does seem that the overall trend is moving toward an increase in communication with health personnel over the Internet. The main factor driving this trend is patient demand for such services. In general it appears that patients are considerably more positive in their attitudes toward online communication than physicians are [26]. Other factors influencing this development are legislation, tariffs, and technical limitations. We see that the legislators are starting to take the consequences of this trend into account in Denmark, where all general practitioners will be obligated to offer eHealth-services to patients in 2009 [25].

We can, therefore, see a general growth in the use of the Internet for health purposes which parallels an increase in more interactive use. Even if our study does not follow the same individuals over time, it seems logical to assume that simply browsing for health information is the starting point. It seems that, when Internet users become more experienced and comfortable with opportunities provided by the Web, they also start to use it for two-way communication, either with peers in forums or with health professionals. This could be called the second generation of Internet health users, and the trend which we detect in Web use for health purposes parallels the current movement in general Internet use toward more interactive usage of the so-called Web 2.0.

Nevertheless, the Internet is still a relatively young medium, and its widespread use in some countries at present might still be limited by bandwidth and technical difficulties. We therefore expect that the proportion of more interactive Internet health use will grow significantly in the years to come. Additionally, health services which today still seem to be in a more or less premature phase, or are only recognized by a minority of the population, such as online access to one's medical record from a health care provider or even managing one's own personal health record, will gain in importance in the coming years.

With the current movement of mass software providers such as Microsoft and Google into the health care market [27], we will probably see a tendency among Internet health users to demand a more equitable role in their health care process. As stated by Ball and Lillis in 2001, new eHealth technologies provide opportunities for more empowered patients, and physicians need to be prepared for the likelihood that patients will start acting more as consumers [28] and challenge the current asymmetry of knowledge [29] in order to achieve a much fuller participation in health care decision-making processes.

Limitations

The WHO eHealth consumer trends survey is based on previous surveys carried out in Norway as well as in Europe. Particular attention was devoted to the questionnaire addressing cultural differences with the dual-focus method and pilot surveys. Some variables turned out to be difficult to include in this comparison. One of them was education. There are seven independent educational systems in the countries studied. We used ISCED codes [30] in order to compare education across countries. The codes are fairly complicated to use, and we detected variations in how they were interpreted over the course of two years. We therefore decided to drop this variable in the analysis.

Another useful variable in the analysis would have been household income. In several of the countries in the study it would, however, have been inappropriate to ask about this in a telephone interview. Even if the question were included in the first Norwegian study, we would have had to drop it in the international questionnaire.

There was an interval of 18 months between the surveys. This is a fairly short time period, and many of the effects studied may not have been significant in such a short time span.

Another limitation of the study is the use of CATI and the sizable percentage of the population which cannot be reached using landline phones. The lack of public mobile-phone directories in several of the countries studied made it hard drawing representative samples. We used strata in compensation for this in 2007. Our main focus in this article is changes between 2005 and 2007. We were therefore especially concerned that such differences could be caused by demographic variation in the samples and chose to use weighting of the 2005 data, as described in Methods. This is not ideal, but we are confident that, in our situation, this did improve the quality of the analysis.

Conclusion

The perceived importance of the Internet as a health information source is increasing. There is relative growth in all age groups

and for both men and women in Internet use for health purposes, with especially strong growth among young women. Along with this growth, we also see that the second generation of Internet health users is using the Internet for more than just reading information. They are using the Internet as a channel, for direct communication with health professionals as well as with peers.

Our research has now been able to detect small trends over a two-year period. It will be important to follow up on this research in upcoming years and evaluate whether this trend in second-generation Internet health users continues. Physicians need to be aware of their patients' use of such new technologies, since this might lead to much better informed patients and requests from patients for more interactive, Internet-based communication pathways.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Internet users and Internet health users in the seven European countries—Trends 2005 and 2007

[PDF file (Adobe PDF), 129 KB - jmir_v10i4e42_app1.pdf]

Multimedia Appendix 2

Internet users by age and gender

[PDF (Adobe PDF), 105 KB - jmir_v10i4e42_app2.pdf]

Multimedia Appendix 3

Internet health users by age and gender

[PDF (Adobe PDF), 105 KB - jmir_v10i4e42_app3.pdf]

Multimedia Appendix 4

Importance of the Internet in various countries

[PDF file (Adobe PDF), 92 KB - jmir_v10i4e42_app4.pdf]

Multimedia Appendix 5

Expanded version of Table 3—percentage of consumers who are using interactive Internet health services at least once a year

[PDF file (Adobe PDF), 107 KB - jmir_v10i4e42_app5.pdf]

Multimedia Appendix 6

Total and estimated relative frequency of Internet health users and Internet users who are using at least one of the interactive services at least once a year

[PDF file (Adobe PDF), 139 KB - jmir_v10i4e42_app6.pdf]

Multimedia Appendix 7

Questionnaire in English (used as basis for translation in 2007)

[PDF file (Adobe PDF), 326 KB - jmir_v10i4e42_app7.pdf]

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Abbreviations

CATI: computer-assisted telephone interviews
GP: general practitioner
ISCED: International Standard Classification of Education
WHO: World Health Organization

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Original Paper

Answers to Questions Posed During Daily Patient Care Are More Likely to Be Answered by UpToDate Than PubMed

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Abstract

Background: UpToDate and PubMed are popular sources for medical information. Data regarding the efficiency of PubMed and UpToDate in daily medical care are lacking.

Objective: The purpose of this observational study was to describe the percentage of answers retrieved by these information sources, comparing search results with regard to different medical topics and the time spent searching for an answer.

Methods: A total of 40 residents and 30 internists in internal medicine working in an academic medical center searched PubMed and UpToDate using an observation portal during daily medical care. The information source used for searching and the time needed to find an answer to the question were recorded by the portal. Information was provided by searchers regarding the topic of the question, the situation that triggered the question, and whether an answer was found.

Results: We analyzed 1305 patient-related questions sent to PubMed and/or UpToDate between October 1, 2005 and March 31, 2007 using our portal. A complete answer was found in 594/1125 (53%) questions sent to PubMed or UpToDate. A partial or full answer was obtained in 729/883 (83%) UpToDate searches and 152/242 (63%) PubMed searches ($P < .001$). UpToDate answered more questions than PubMed on all major medical topics, but a significant difference was detected only when the question was related to etiology ($P < .001$) or therapy ($P = .002$). Time to answer was 241 seconds (SD 24) for UpToDate and 291 seconds (SD 7) for PubMed.

Conclusions: Specialists and residents in internal medicine generally use less than 5 minutes to answer patient-related questions in daily care. More questions are answered using UpToDate than PubMed on all major medical topics.

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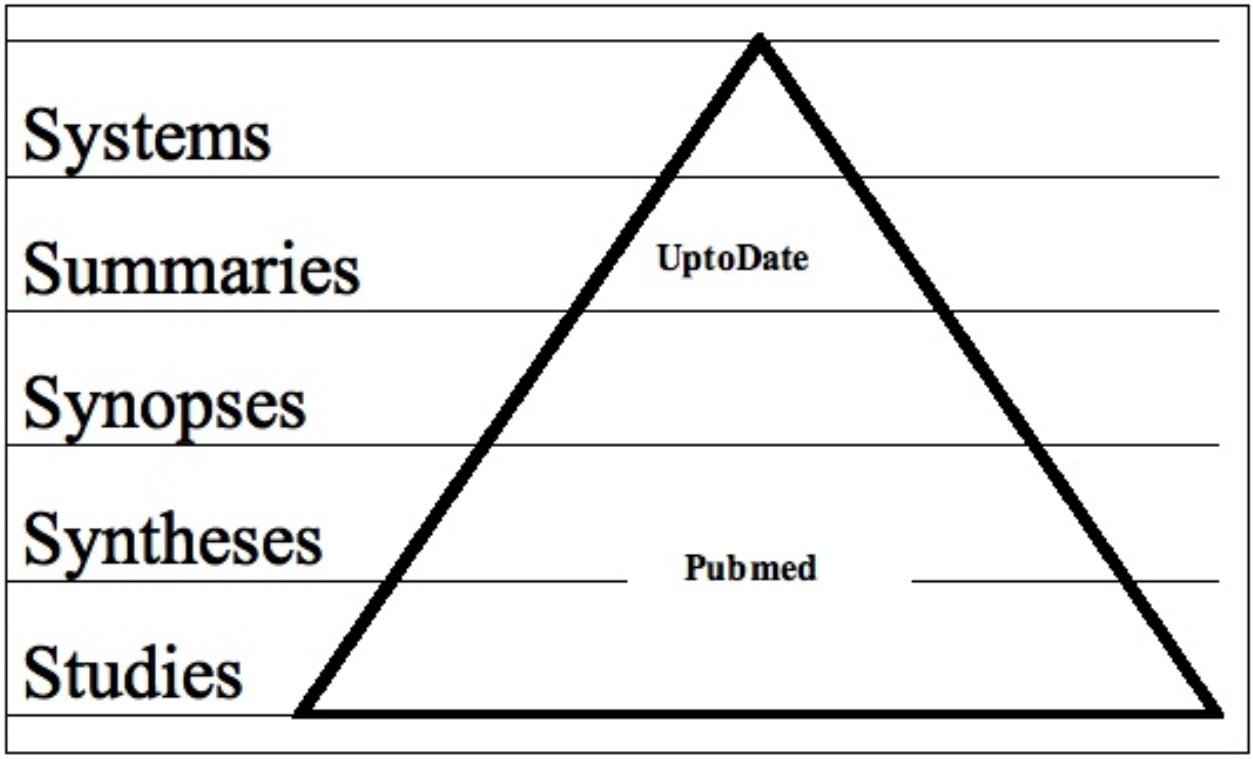
KEYWORDS

PubMed; information storage and retrieval; evidence-based medicine; medical informatics; information services; Internet; hospitalists

Introduction

The use of Internet information sources for answering patient-related questions is taking an ever more important place in the daily practice of a physician. There are numerous sources available on the Internet. These sources can roughly be divided into five categories, as described by Haynes [1]. These five categories are arranged in a pyramid in the following top-down order, as depicted in Figure 1: systems (computerized, decision-support systems), summaries (evidence-based textbooks), synopses (evidence-based journal abstracts), syntheses (systematic reviews), and studies (original journal articles).

Figure 1. The "5S" levels of organization of evidence from health care research and the position of the studied information sources within the pyramid (after Haynes [1])



UpToDate is an evidence-based, peer-reviewed information resource designed to provide information at the point of care [2]. PubMed is a search engine offering access to the Medline database [3].

From top to bottom, the information sources are less rigorously evaluated for evidence and take more time to evaluate for scientific rigor. On the other hand, it takes more time to establish the evidence. The sources at the top are therefore less up-to-date than sources at the bottom. Furthermore, the sources at the bottom are more abundant, being able to answer more questions. One should start searching preferably at the top, going from level to level when the source used did not provide the solution to the problem. From an evidence-based view, this is the best solution. As physicians usually spend less than 10 minutes to answer questions, this method would take too much time in the majority of cases [4-6]. When going down the pyramid of evidence takes too much time, it may be important to know at which level it is best to enter the pyramid. There may be certain topics (etiology, prognosis) that are difficult to find at a certain level and require a search that starts at a lower level. Furthermore, when certain topics are poorly addressed in information sources, this may give developers clues for enhancement of the information source. As there are links from our electronic patient record system to two major evidence-based information sources (PubMed and UpToDate), we conducted an observational study to determine how both sources are used in daily routine practice for answering patient-related questions. Our second target was the amount of time spent searching by hospital physicians.

Methods

Population and Measuring Tool

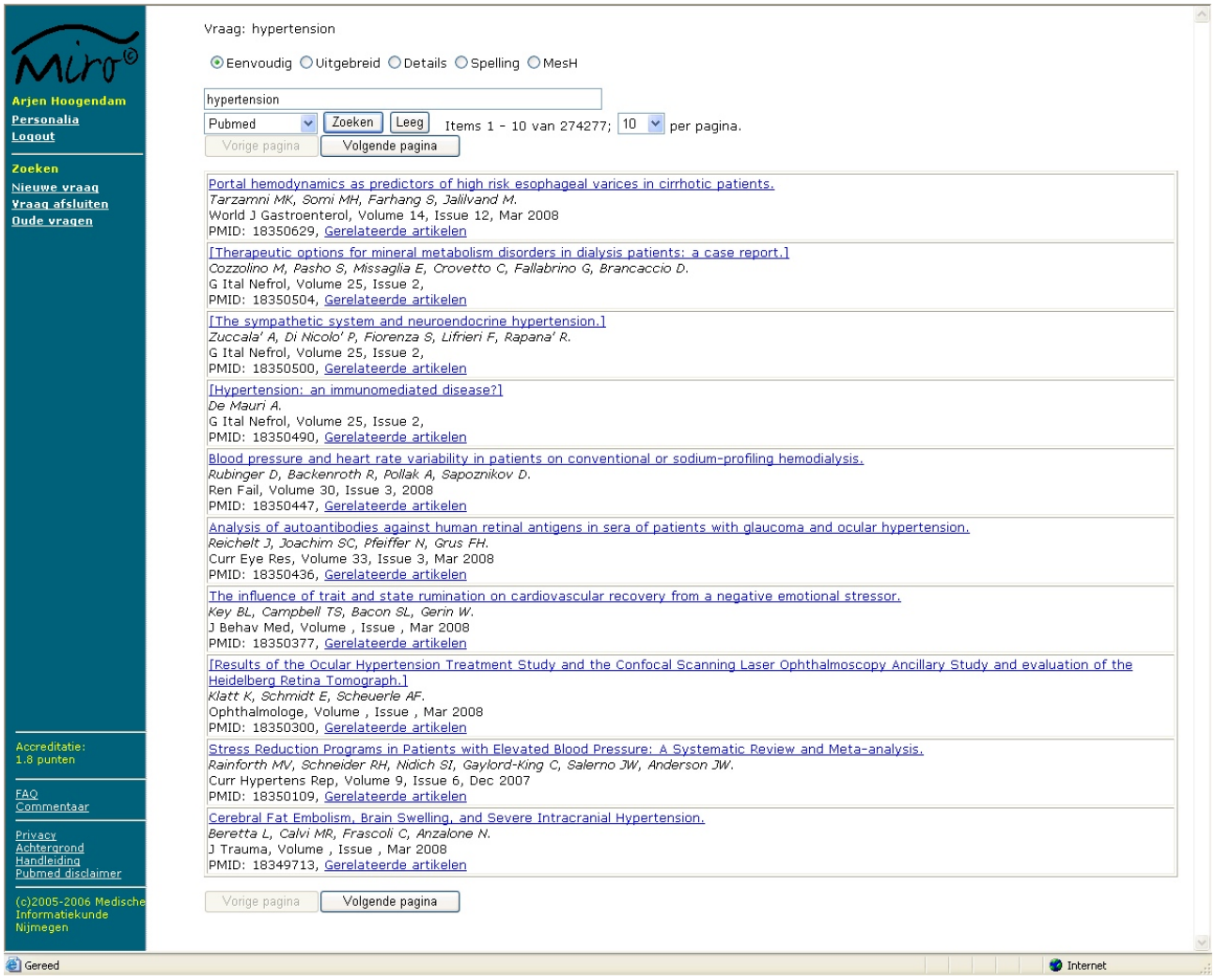
As part of an ongoing observation of medical information sources used to retrieve information, we developed a Web portal. This portal gives access to PubMed, UpToDate, Harrison's Online, and a Dutch pharmacotherapy database. All residents and specialists in internal medicine selecting PubMed or UpToDate from our hospital information system were automatically linked to our portal.

PubMed Interface

To enable the registration of all aspects regarding the use of PubMed, we built our own PubMed interface for accessing PubMed through e-utils [7]. E-utils gives access to full PubMed functionality. Query handling conducted by PubMed is identical to the original PubMed website, but e-utils delivers the data in XML to permit recording of the data in a database. The XML data need to be translated into Web pages to be readable for users. To mimic the functionality of PubMed, most of the special search options relevant for patient-related searches were copied in our interface: MeSH database, details, a selection of limits (publication date, publication type, human or animal, and age), and spelling. As shown in Figure 2, on the left of the page, the participant can choose to start searching for a new question, close the question, or re-open older questions (Nieuwe vraag, Vraag afsluiten, Oude vragen). There are links to background information (Achtergrond) and the manual (Handleiding). Search options are simple, advanced, details, check spelling, and MeSH database (Eenvoudig, Uitgebreid, Details, Spelling, and MeSH).

All queries were recorded as well as the use of the different search options, the articles that were selected for abstract reading, and the articles that were selected for full-text reading.

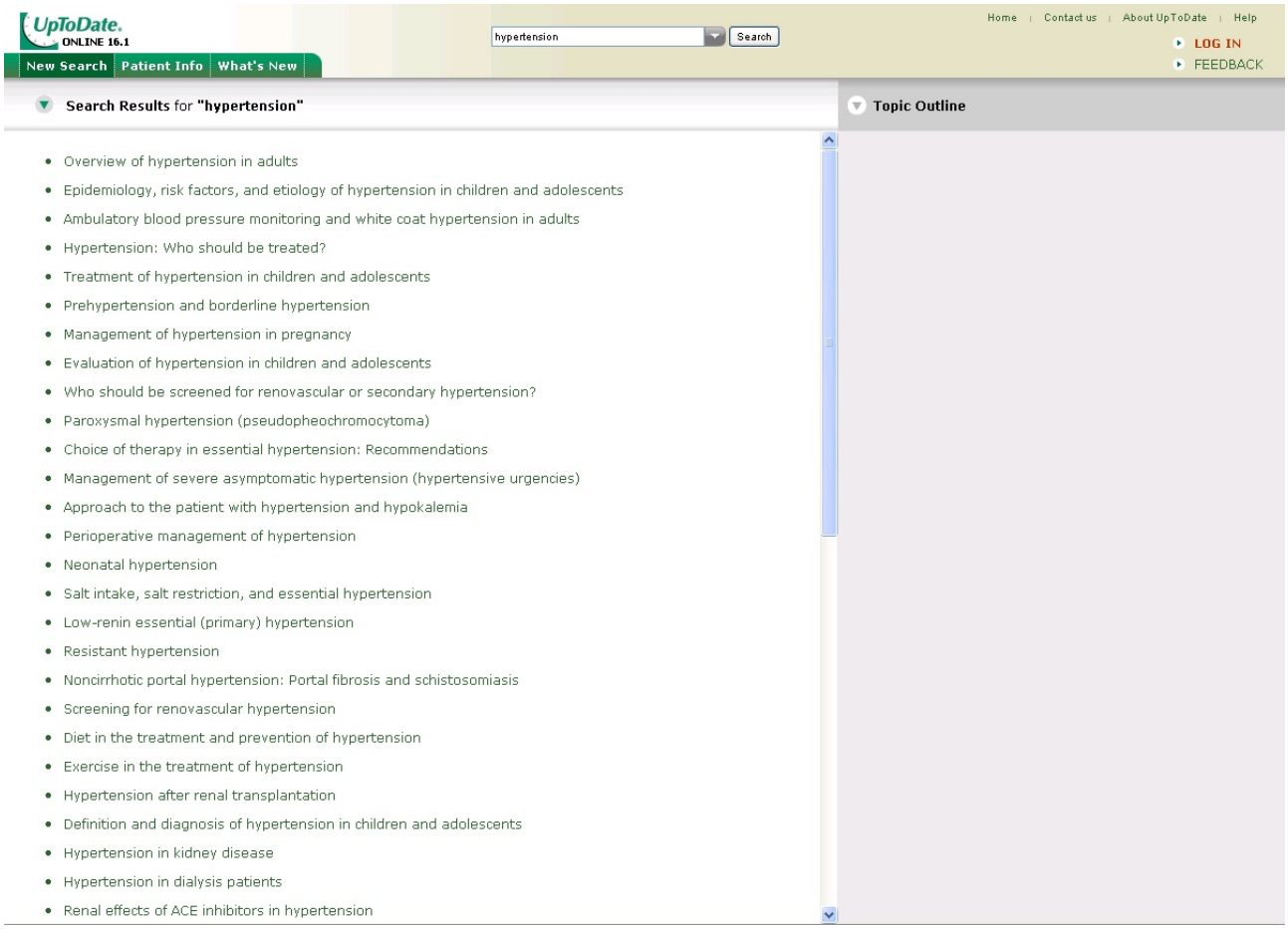
Figure 2. Screenshot of the portal: PubMed search result for “hypertension”



Other Online Information Sources

As the other online sources do not permit direct access to their database, we linked directly to their website. The interface of UpToDate, therefore, was presented unaltered to the physician (Figure 3). After reading the information at the website, searchers returned to our own portal to answer questions regarding their search.

Figure 3. Screenshot of the UpToDate interface (Reproduced with permission from UpToDate, Rose BD, editor, UpToDate, Waltham, MA, 2008. Copyright 2008 UpToDate, Inc. [2])



Testing and Introduction

The portal was tested by direct observation using several user groups. After the testing phase, the program was introduced and tested by a select group of users during a period of 2 months. Starting October 2005, the portal was made publicly available. A manual is available from all screens in the portal. During the first year, all new users were asked if they needed help with the use of the portal. Participants received regular emails reminding them that help was available within the portal or that they could receive direct coaching.

First Access

Upon accessing the database for the first time, the physician was asked to give informed consent to the observation of the search process. The physician was also presented with background information regarding our study and was urged to read the manual, which is available from every screen of the portal.

Search Process

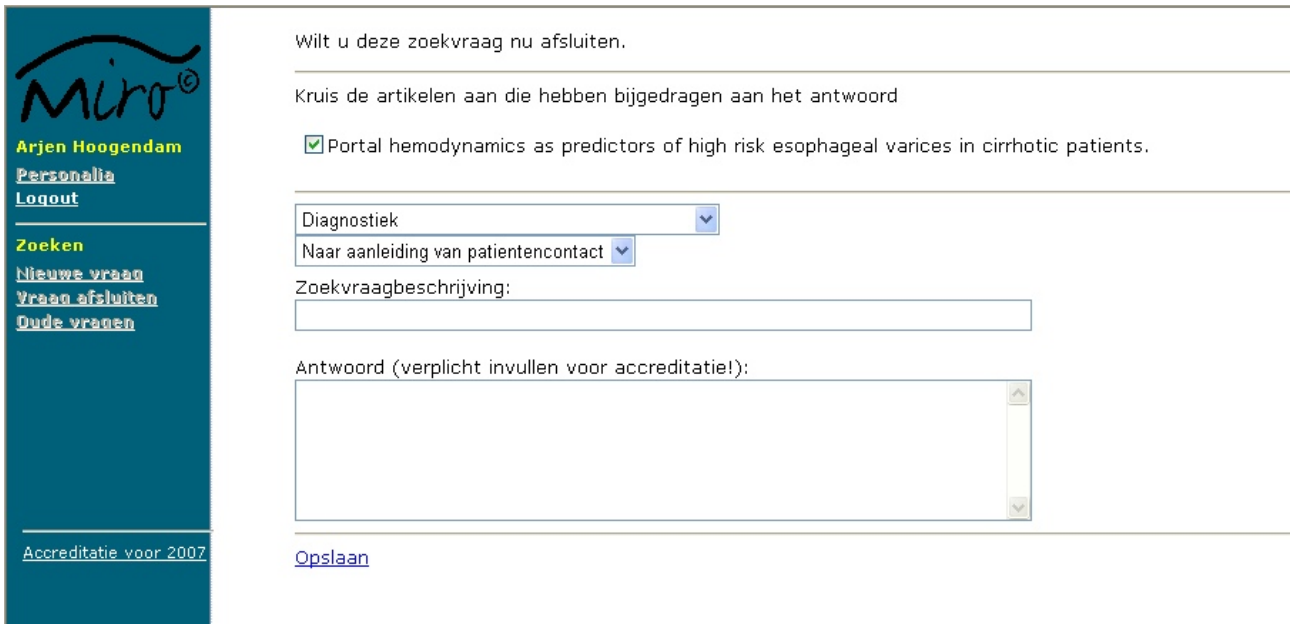
Every search was started by entering a query and selecting an information source. Search time was recorded by the monitoring program. Sending of the first query regarding a problem was marked as the start of the search. While searching, all queries were recorded by the portal. After completing the search, participants were asked whether they found no answer, a partial answer, or a full answer to their question; answering this question marked the end of the search (Figure 4).

Figure 4. Screenshot of the page were participants could mark whether they were disturbed while searching, could select whether a complete, partial, or no answer was found, and could return to the problem

They were also asked to select the situation that led to the search (direct patient contact, patient rounds, scientific research, review/study, preparing talks, or not specified) and to place the topic into categories used by Hersh and Hickam and Haynes et al in previous studies (diagnosis, etiology, prognosis, therapy, side effects, complications, overview/review, mechanism, or unclear) [8,9]. Participants were given the option to provide additional data, including the question, the answer to the question, and whether articles selected for further reading contained information relevant to the question (Figure 5). The subject and the situation triggering the search could also be provided.

As multiple persons can access a single computer, sessions were automatically closed after 15 minutes of inactivity.

Figure 5. Screenshot of the page where details regarding the search could be provided



Nonresponse

We intended to maximize the use of our computer portal. Physicians were encouraged to use the program as much as possible. At regular intervals, the database was checked to identify participants who infrequently provided details after searching. These participants were approached to determine the reason for nonresponse and were encouraged to improve their response. Nonresponse could be related to the participant but also to the monitoring system. We expected that physicians searching during daily medical care would not always be prepared to answer our questions directly after searching. Full-text articles and UpToDate were always opened in a separate pop-up window as most sites do not permit the opening of their Web pages within another frame. The Web page containing the questionnaire was available directly behind the pop-up windows. Forgetting to close the pop-up window after searching (and before closing the connection to the database) would lead to nonresponse. As both sources of nonresponse could lead to bias, we performed an additional check during the first year of our study. If participants did not fill in the questionnaire after searching, the questionnaire was repeated before the next search. As details regarding a former search are likely to become less reliable after some time, we intended to use the details provided within 24 hours after searching for a nonresponse bias analysis. After one year of monitoring, we

had enough data to exclude nonresponse bias and removed the questionnaire before searching as it led to avoidance of the website.

Selection of Queries

Only problems triggered by visit rounds or related to patient contact were included in our analysis. There were four different categories of searches: (1) searches that were completed with search-related details provided in one session, (2) searches with search-related details provided during a second session within 24 hours, (3) searches with search-related details provided during a second session after 24 hours, and (4) searches with no additional information provided. To minimize the risk of recall bias, only searches of the first category were included in our study. Searches of the second category were used for nonresponse bias analysis. The last two categories were excluded. The Dutch pharmaceutical database and Harrison's Online cannot be considered as online evidence-based information sources because they do not link the text directly to literature references. Queries sent to these databases were therefore excluded from this study.

Analysis

Whether an answer is partial or complete is a subjective qualification. We therefore combined partial and full answers when determining significance of our findings. Determining statistical significance was performed by the chi-square statistic. Statistical analysis was performed using SPSS 14.0 (SPSS Inc, Chicago, IL, USA).

Results

Participants used our portal for 2986 patient-related questions. These questions were sent by 40 residents and 30 specialists in internal medicine from October 1, 2005 to March 31, 2007. There were 1305 searches selected for analysis, according to the inclusion criteria (Figure 6).

Aspects of searches conducted in a single database are shown in Table 1. UpToDate was the most popular database with 883/1125 (78%) questions. The most popular topics were diagnosis, etiology, and therapy, with 924/1125 (82%) questions. Full answers were provided to 594/1125 (53%) questions. A partial or full answer was obtained in 729/883 (83%) UpToDate searches and 152/242 (63%) PubMed searches ($P < .001$).

Analysis of searches answered during a second session within 24 hours found partial or full answers obtained by 260/300 (87%) UpToDate searches and 115/179 (64%) PubMed searches, showing that there was no negative response bias.

The average time spent searching online medical sources was 252 seconds. Time to answer was 291 seconds (SD 24) for searches conducted in PubMed and 241 seconds (SD 7) for searches conducted in UpToDate.

Data concerning questions sent to both databases compared with questions sent to a single database are shown in Table 2. Consultation of UpToDate occurred frequently after searching in PubMed, in 119/361 (33%) searches, and resulted in more partial and full answers than the consultation of PubMed alone. Searching PubMed after consulting UpToDate occurred in 61/944 (6%) searches, but did not result in more partial or full answers than the consultation of UpToDate alone.

The relationship between search topic and answers found is shown in Table 3. Queries sent to UpToDate resulted in a higher percentage of answers compared with PubMed, regardless of the subject. This difference was significant in queries concerning etiology and therapy.

The use of information sources by residents and specialists is shown in Table 4. Residents used UpToDate for 579/669 (87%) questions, in contrast to specialists, who used UpToDate for 304/456 (67%) questions. PubMed searches were equally successful for both specialists, but UpToDate provided relatively more answers to residents.

Figure 6. Selection of problems for analysis

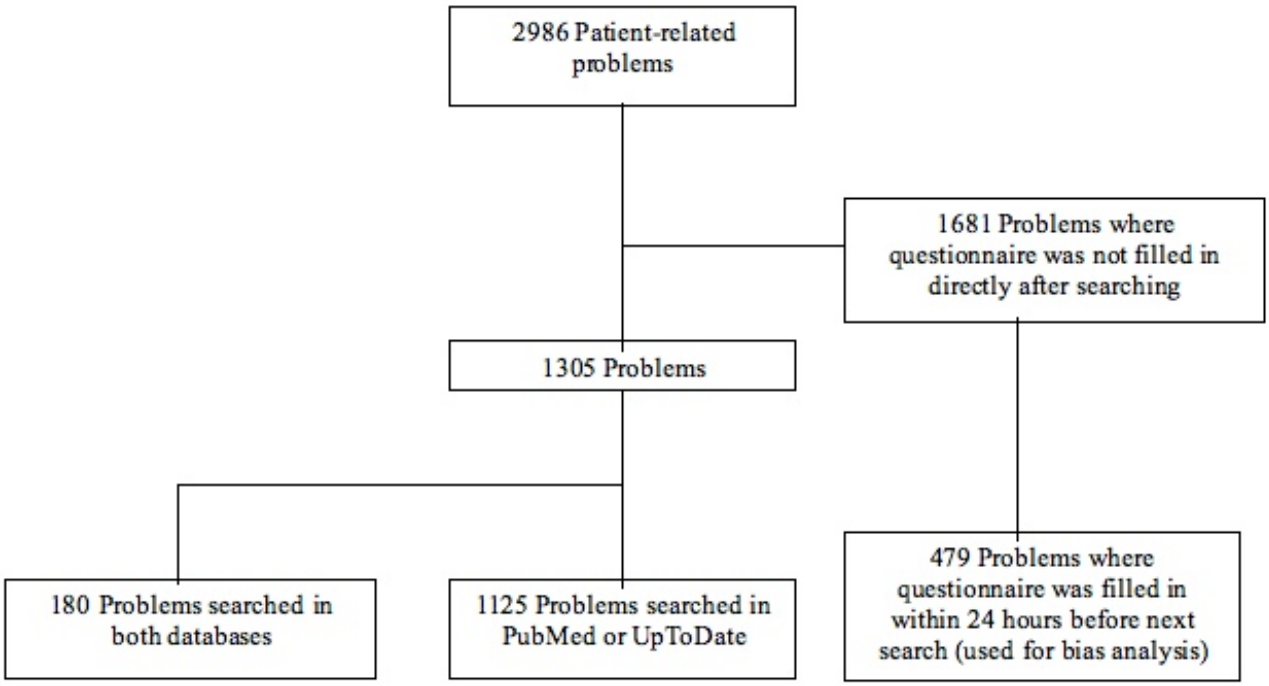


Table 1. Aspects of questions that were sent to only one of the two databases (N = 1125)

	PubMed (N = 242) No. (%)*	UpToDate (N = 883) No. (%)*	χ^{2} †	*P*
Answer			54	< .001
No answer found	90 (37)	154 (17)		
Partially answered	68 (28)	219 (25)		
Fully answered	84 (35)	510 (58)		
Subject				
Diagnosis	51 (21)	400 (45)	46.41	< .001
Etiology	70 (29)	219 (25)	1.69	.19
Prognosis	3 (1)	8 (1)	0.01	.92
Therapy	41 (17)	143 (16)	0.08	.78
Side effects	14 (6)	12 (1)	16.48	< .001
Complications	17 (7)	33 (4)	4.83	.03
Overview/Review	40 (17)	61 (7)	21.51	< .001
Mechanism	5 (2)	3 (0.3)	5.76	.02
Unclear	1 (0.4)	4 (0.4)	0.21	.64

*Percentages may not add to 100% due to rounding.

†Chi-square of difference between UpToDate and PubMed.

Table 2. Comparison of answers to questions sent to a single database and to both databases (N = 1305)

Primary Information Source	Secondary Information Source	Answer*		
		None Found	Partially Answered	Fully Answered
		n/N (%)	n/N (%)	n/N (%)
PubMed	None	90/242 (37)	68/242 (28)	84/242 (35)
PubMed	UpToDate	20/119 (17)	47/119 (40)	52/119 (44)
UpToDate	None	154/883 (17)	219/883 (25)	510/883 (58)
UpToDate	PubMed	20/61 (33)	26/61 (43)	15/61 (25)

*Percentages may not add to 100% due to rounding.

Table 3. Number and percentage of partial or full answers found to questions sent to only one of the two databases, by subject (N = 1125)

Subject	PubMed	UpToDate	χ^2_1*	*P*
	n/N (%)	n/N (%)		
Diagnosis	38/51 (75)	339/400 (85)	3.46	.06
Etiology	38/70 (54)	175/219 (80)	17.97	< .001
Prognosis	2/3 (67)	7/8 (88)	0.01	.94
Therapy	24/41 (59)	117/143 (82)	9.64	.002
Complications and side effects	22/31 (71)	37/45 (82)	1.34	.25
Other†	28/46 (61)	54/68 (79)	4.67	.03

*Chi-square of difference between PubMed and UpToDate in partial and full answers found.

†Mechanism, unclear, and overview/review combined.

Table 4. Number and percentage of partial or full answers found by specialists and residents to questions sent to only one of the two databases

	Resident	Specialist	χ^2_1*	*P*
	n/N (%)	n/N (%)		
PubMed	57/90 (63)	95/152 (63)	0.02	.90
UpToDate	488/579 (84)	241/304 (79)	3.47	.06

*Chi-square of difference between residents and specialists in partial and full answers found in PubMed and UpToDate.

Discussion

This is an observational study that delivers valuable data regarding the actual use of PubMed and UpToDate during daily medical practice. Our study shows that participants were able to find full answers to 53% of their questions using our portal, which is comparable to results found in other studies [5,10].

Physicians spend less than 5 minutes on average searching for online information. Previous studies have pointed out that the use of evidence at the point of care is closely related to the time needed to answer the question. Most of the questions generated by physicians can be answered, but it is time consuming and expensive to do so [11,12]. The time used for searching online information sources was shorter than that found in other studies [5,6,13,14] in which conditions did not always reflect daily care, but comparable to the study by van Duppen et al performed during daily patient visits [15].

Participants preferentially used UpToDate and succeeded in answering more patient-related questions during daily medical care using UpToDate than using PubMed. This is comparable to previous research in which UpToDate is the preferred information source over PubMed and is perceived as equally or more useful for answering patient-related questions [16-19].

Schilling et al suggested that PubMed and UpToDate are used by residents as complementary sources [17]. UpToDate would be more suitable for general questions about well established evidence, and PubMed would be more suitable for specific questions. However, physicians interviewed by Ely et al stated that common conditions are not searched because the answers are already known [18]. But, it is just as likely that common conditions trigger complex questions and rare conditions trigger general questions. We did not rate the complexity of the questions or motivations for selecting a particular database, but clinical experience and conducting searches in both databases are likely to be related to question complexity. When both databases were used, the consultation of UpToDate after PubMed occurred more frequently and resulted in more partial or full answers in comparison to consultation of UpToDate followed by PubMed and PubMed alone. This would not be the case if PubMed was used primarily for complex questions with answers that were not likely to be found in UpToDate. Our

findings show that starting the search with UpToDate, followed by consultation of PubMed if the answer is not satisfactory, is a sensible strategy. This is consistent with the advice given by Haynes [1]. If the complexity of questions plays a crucial role in the choice of an information source, the choice is influenced by experience. As it is likely that specialists have more detailed knowledge than residents, we used professional status as an indicator of question complexity. Our data show that there was no difference in PubMed search results between residents and specialists. Residents were able to answer more questions using UpToDate; however, this difference is not significant and too small to be of concern in daily practice. PubMed was used relatively more frequently by specialists than by residents. Professional status is likely to play a role in the choice of an information source, but it is not reflected in a substantial difference in search results. Professional status, therefore, is no argument for choosing a particular information source.

Our data show that questions sent to UpToDate retrieved more answers than questions sent to PubMed regardless of major medical topic. This difference was only significant in etiology and therapy, but sample size is insufficient to detect significance in other medical topics. Based on our data, there is no reason to start searching on a lower level of the evidence-based pyramid for any major medical topic, but it is sensible to use UpToDate as the primary information source.

Ely et al identified 59 obstacles when searching for evidence-based answers to doctors' questions [20]. Among the most salient were failure of the resource to address the topic, inadequate time to search for information, and inadequate synthesis of multiple bits of evidence into a clinically useful statement. Online textbooks provide information that is synthesized and displayed in a text that can be scanned within a couple of minutes, but failure to address the topic is the limiting factor. Search time and scattering of evidence over multiple articles are the limiting factors for PubMed. This, combined with the fact that physicians spend less than 5 minutes to find an answer during daily medical care, makes PubMed an unsuitable information source to use. Conducting a thorough search takes nearly 30 minutes [21]. This is the most likely explanation why UpToDate is the primary information source and performs better at the point of care in our study and other studies [16-19]. Improvements in PubMed must therefore be aimed at trying to create search methods that are targeted to a maximum search time of 5 minutes, including time needed for evaluation of the literature. Improvements in search methods that are aimed at significantly reducing search time are likely to increase the effectiveness of PubMed for patient-related questions during daily medical care.

Limitations

This study was performed in a single hospital where specialists and residents are accustomed to accessing PubMed and UpToDate as primary information sources. There are many more evidence-based information sources available on the Internet. For our observation, we chose to use the information sources that our population was familiar with, limiting the generalizability of our results.

Optimal testing of the performance of medical information sources requires taking the physician out of daily practice as physicians will not be prepared to look up answers in several databases and answer additional questionnaires during working hours. Most studies, therefore, resort to observation in laboratory situations or questionnaires without direct observation [22]. As PubMed is likely to answer most of the questions if the search time is unlimited, testing PubMed out of daily practice without time constraint is meaningless for daily care use. We used a novel approach that combined observation with post-search questionnaires. We consider PubMed and UpToDate as reliable information sources, but there is limited information that compares their usefulness in daily use. Physicians working at our hospital are very familiar with these sources; PubMed and UpToDate are therefore ideal for an observational study regarding their everyday use. There are several limitations to an observational study that apply to our study as well. We could not influence the information source approached or check whether the answer would be found in a second database in all questions. This makes a direct comparison of the information sources impossible.

We rebuilt most of the functionality of PubMed in our interface. However, exact mimicry of the website was not allowed by legal and ethical issues. Users could provide comments to the portal but did not report that the use of our interface was more difficult than the original PubMed interface.

The fact that physicians report that they have found an answer is not a guarantee that the answer really has been found. Physicians tend to overestimate the quality of the information retrieved through searching. Previous studies have shown that correct answers before searching can be incorrectly altered by searching online information sources [14,23]. Whether a partial or full answer is found is a subjective interpretation. The qualification should, however, reflect satisfaction of the participant with the obtained answer.

In many questions, the questionnaire was not filled in after searching. The major reason is opening of multiple Web pages on the screen, causing the monitoring program to disappear in the background. This, in turn, resulted in participants forgetting to answer the required information after the search within the time limit of 15 minutes. We also suspected that physicians would be reluctant to spend additional time answering search-related questions during daily care. It is likely that more complex questions leading to no answer after extensive searching will result in nonresponse. To detect whether this noncompliance would lead to a nonresponse bias, we performed a secondary analysis regarding queries answered during a second session within 24 hours. The results were comparable, showing that question complexity itself was not a reason for nonresponse.

PubMed is our default database for searching, so the use of PubMed might be overestimated. We asked whether participants were interrupted while searching, but we did not exclude these searches because we consider disturbances part of one's daily routine. As we did not ask what database gave the answer to the question, it is impossible to identify which database contributed most to the answer when multiple sources were used. For this study, we assumed that the intention for consulting

a second database was to improve the answer found in the first information source.

Conclusions

Our study makes a contribution in observing hospital physicians in their daily routine solving patient-related questions. We have shown that answers to questions posed during daily medical care are more likely to be answered by UpToDate than PubMed, regardless of the topic of the search. Physicians trying to answer patient-related questions use less than 5 minutes to search for an answer during daily medical care. Improving medical information sources should be aimed at delivering an answer within 5 minutes as this is the average time a hospital specialist spends finding an answer at the point of care. Future research should be aimed at comparing more information sources at different levels of the evidence pyramid. Question complexity may play a role in the choice of where to enter the hierarchy of evidence-based sources. Analysis of query content and the search process should reveal more information to improve PubMed as a search tool for daily medical care.

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Authors' Contributions

Hoogendam has had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Hoogendam, Stalenhoef, de Vries Robbé, Overbeke; acquisition of data: Hoogendam; analysis and interpretation of data: Hoogendam; drafting of the manuscript: Hoogendam; critical revision of the manuscript for important intellectual content: Hoogendam, Stalenhoef, de Vries Robbé, Overbeke; statistical analysis: Hoogendam; administrative, technical, or material support: Hoogendam, de Vries Robbé, Overbeke; study supervision: Hoogendam, Stalenhoef, de Vries Robbé, Overbeke.

Conflicts of Interest

None declared.

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Original Paper

The ALFA (Activity Log Files Aggregation) Toolkit: A Method for Precise Observation of the Consultation

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Abstract

Background: There is a lack of tools to evaluate and compare Electronic patient record (EPR) systems to inform a rational choice or development agenda.

Objective: To develop a tool kit to measure the impact of different EPR system features on the consultation.

Methods: We first developed a specification to overcome the limitations of existing methods. We divided this into work packages: (1) developing a method to display multichannel video of the consultation; (2) code and measure activities, including computer use and verbal interactions; (3) automate the capture of nonverbal interactions; (4) aggregate multiple observations into a single navigable output; and (5) produce an output interpretable by software developers. We piloted this method by filming live consultations (n = 22) by 4 general practitioners (GPs) using different EPR systems. We compared the time taken and variations during coded data entry, prescribing, and blood pressure (BP) recording. We used nonparametric tests to make statistical comparisons. We contrasted methods of BP recording using Unified Modeling Language (UML) sequence diagrams.

Results: We found that 4 channels of video were optimal. We identified an existing application for manual coding of video output. We developed in-house tools for capturing use of keyboard and mouse and to time stamp speech. The transcript is then typed within this time stamp. Although we managed to capture body language using pattern recognition software, we were unable to use this data quantitatively. We loaded these observational outputs into our aggregation tool, which allows simultaneous navigation and viewing of multiple files. This also creates a single exportable file in XML format, which we used to develop UML sequence diagrams. In our pilot, the GP using the EMIS LV (Egton Medical Information Systems Limited, Leeds, UK) system took the longest time to code data (mean 11.5 s, 95% CI 8.7-14.2). Nonparametric comparison of EMIS LV with the other systems showed a significant difference, with EMIS PCS (Egton Medical Information Systems Limited, Leeds, UK) (P = .007), iSoft Synergy (iSOFT, Banbury, UK) (P = .014), and INPS Vision (INPS, London, UK) (P = .006) facilitating faster coding. In contrast, prescribing was fastest with EMIS LV (mean 23.7 s, 95% CI 20.5-26.8), but nonparametric comparison showed no statistically significant difference. UML sequence diagrams showed that the simplest BP recording interface was not the easiest to use, as users spent longer navigating or looking up previous blood pressures separately. Complex interfaces with free-text boxes left clinicians unsure of what to add.

Conclusions: The ALFA method allows the precise observation of the clinical consultation. It enables rigorous comparison of core elements of EPR systems. Pilot data suggests its capacity to demonstrate differences between systems. Its outputs could provide the evidence base for making more objective choices between systems.

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KEYWORDS

Video recordings; process assessment; observation; attitude to computer; professional-patient relations; general practice; family practice; decision modeling; process assessment; medical informatics; computers; medical records systems, computerized; electronic patient record (EPR); electronic medical record (EMR); evaluation methodologies; usability

Introduction

Electronic Patient Record (EPR) Systems Vary, and These Differences Provide Opportunities to Make Comparisons

Information and communications technology is ever more widely used in health care [1,2]; however, most EPR systems have grown organically, rather than being based on development specifications. Most countries have started with multiple small vendors developing EPR systems to meet the needs of the GP customers. Subsequently, commercial and regulatory pressures have reduced that number over time [3]; however, even within the same health system, the interfaces and functionalities clinicians use vary [4], as is the way they integrate the computer into the consultation [5]. Health systems are moving toward introducing new enterprise-wide information systems, which provide the opportunity for improved efficiency and patient safety through data sharing across the health system, so-called systemic interoperability [6]. The implementation of these new systems provides an opportunity to improve the interface and functionality, or, at the very least, have a rational reason for adopting the best design features of the existing systems.

Using Video to Record the Impact of the EPR on the Clinical Consultation

For nearly a decade, we have been developing a video-based method to measure the influence of technology on the clinical consultation. We started with a single channel video, but found that, without simultaneously displaying the clinical system screen and closely questioning the clinician about their objectives behind interactions, it was impossible to interpret the video [7]. Trying to measure the precise length of interactions was also challenging.

We recognized that analogue video (which did not have an accurate time stamp), and using a stopwatch to time events in the consultation, had major limitations. Our next development was to record 3 channels of video: (1) wide-angle view of the consultation, (2) view of clinician's head and upper body, and (3) screen capture. We used professional video recording tools to do this, as we needed an accurate time stamp to synchronize the videos. Although we produced useful output, the expense and the setup meant that this was not going to be a readily deployable technique [8].

Therefore, we set out to develop a recording method that would enable precise and objective measurement of consultation activities. The system would have to meet the following objectives: (1) can be readily set up in real consulting rooms or clinics in less than an hour; (2) be reliable and could be readily set up by others in a range of settings; (3) provide objective time stamps of activities within the consultation, allowing the synchronization and subsequent simultaneous viewing of multiple measures; and (4) produce an output that could be used by computer software engineers to develop better systems.

Lack of Readily Available Applications to Compare EPR Applications

We initially reviewed existing applications that we could use to meet these specifications but found none. We looked at applications widely used for (1) qualitative research, (2) transcription and analysis of audio or video recordings, (3) usability testing, and (4) screen casting for demonstrations or training materials. Their shortcomings, compared with our requirements, are shown in Table 1.

There are well established applications used in qualitative research, such as ATLAS.ti (ATLAS.ti Scientific Software Development GmbH, Berlin, Germany) and QSR NVIVO (QSR International Pty Ltd, Melbourne, Australia) which allow detailed analysis and coding of text and multimedia data. They are not designed, however, to incorporate the precise monitoring of computer use that we require or to produce an output that can be exported into a package to develop UML diagrams. Transana (Wisconsin Center for Education Research, University of Wisconsin-Madison, Madison, WI, USA) provides facilities to perform a greater level of analysis by incorporating transcriptions; however its main analysis approach (which is based on the use of keyword, annotations, or their groupings) is not suitable to classify and measure doctor-computer interactions, which often include series of small durations or overlaps with patient interactions.

Widely used usability tools, such as Morae (TechSmith Corporation, Okemos, MI, USA), record observational data about computer use from multiple aspects. Due to the merged outputs they produce, they cannot be flexibly adopted according to research needs and are less helpful to obtain separate quantifiable measures for different combinations of interactions. Camtasia (TechSmith Corporation, Okemos, MI, USA), Adobe Captivate (Adobe Systems Incorporated, San Jose, CA, USA), and BB Flash Back (Blueberry Consultants Ltd, Birmingham, UK) are examples of screen-casting applications. While providing greater details about computer use, they are not optimized to classify interactions in a meaningful way. Focus of their outputs is too narrow to identify the effect of computer use on the overall consultation.

Table 1. Existing applications investigated

Expected features	Qualitative research		Transcription and analysis	Usability testing	Screen casting		
	ATLAS.ti	NVivo	Transana	Morae	Camtasia	Adobe Captivate	BB FlashBack
Handles input from 3 cameras or combined video	1 video file. Limited view	1 video file. Limited view	1 video file. Limited view	1 webcam	No	No	1 webcam
Computer screen capture	No	No	No	Yes	Yes	Yes	Yes
Fast setup for recording and data export	No recording element	No recording element	No recording element	Complex set-up	Moderate set-up, large data file	Moderate set-up, large data file	Moderate set-up, large data file
Coding and measuring of interactions	Codes segments. Manually measure.	Codes segments. Manually measure.	Codes video clip. No measure.	Codes video frame. Manually measure.	No coding. No measure.	No coding. No measure.	No coding. Manually measure.
Simultaneous viewing of multiple observations	Limited view. All in one channel	Limited view. Multiple channels	Limited view. All in one channel	Limited view. All in one channel	No	No	3 observations only
Easy to compare observational data	Using network diagrams	Using nodes or networks	Using codes, collections	Using tables, graphs	No	No	No
Standard output for UML diagrams	No	Need processing	No	Need processing	No	No	Only computer interactions

Rationale for This Development

In the absence of any suitable off-the-shelf application, we commenced our own development process to produce a set of applications that would enable researchers to capture the complexity of the computer-mediated consultation.

Methods

Developing a Specification

We developed a specification for our development program based on our objectives and on our experiential learning about the limitations of existing techniques. We recognized that our technique should be extendible, to combine a number of monitoring methods which, at that time, we would not be able to define. At the time, we identified: (1) an indeterminate number of video channels; (2) a transcript of the consultation, captured with a precise time stamp, possibly using voice recognition software; (3) output from pattern recognition software [9] and other change recognition technologies [10]; (4) aggregate log files from observation techniques that we could not anticipate, as elements of our specification.

Developing Separate Work Packages

We converted this work schedule into small work packages, which we developed separately on a largely opportunistic basis, as we had not received any consistent funding. The elements of this were:

1. To determine the optimal number of video channels and a low-cost way of recording. This should have time stamps to allow synchronization with other video channels and methods of data collection.

2. To find a reliable way to code the video footage, so we could navigate directly to particular activities in the consultation and measure their durations.

3. To automate the capture of body language and eye contact, using pattern recognition and gaze detection direction technologies.

4. To aggregate all these elements into a single navigable analysis output.

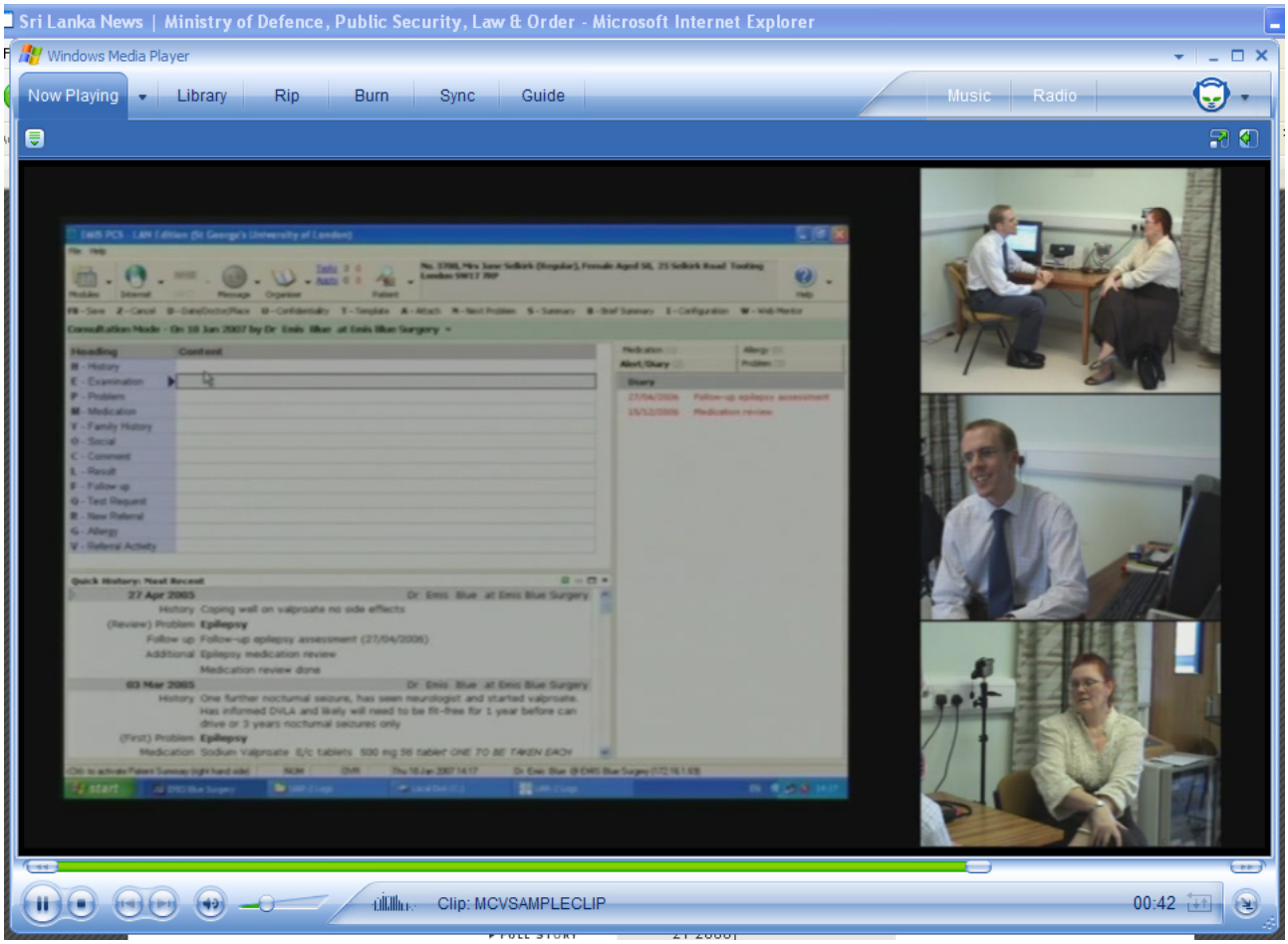
5. To introduce the ability to export data in a format that could readily be utilized by software engineers to improve systems.

Multichannel Video

We explored using 3, 4, and 5 channels of video, mixed onto a single screen, as well as a 4-channel version where clicking on a screen would enlarge that window to full screen (Figure 1). The additional channels experimented with since the 3-channel stage are the cameras focused on the patient's upper body and the clinician's facial view. We showed example consultations to experienced educationalists and academics accustomed to assessing video consultations, and we conducted semi-structured interviews to elicit their opinions [11].

We also needed to identify low-cost methods of filming the consultation, ideally using unobtrusive tools, which recorded sound and video with a digital time signal so that precise synchronization was possible [12].

Figure 1. The multichannel video output, combined recordings of clinical computer system screen and 3 views of consultation



Capturing and Coding Consultation Activity

We needed to be able to code interactions in the consultation so that we could readily navigate to a particular activity (eg, prescribing) and also identify its duration. We selected a flexible software called "ObsWin" (Antam Ltd, London, UK) to do this [13] (Figure 2). We conducted reliability tests of our manual coding method using multiple observers coding simulated blood pressure management follow-up consultations. We used intra-class correlation coefficient as an index of reliability [14]. Subsequently, we compared the manual coding time for prescribing activities with frame-by-frame analysis of the video to further assess the reliability of our approach.

Wherever possible, we set out to automate the time stamps for the start and end of activities in the consultation. We developed a User Action Recording (UAR) application to measure the precise time stamp of keyboard use (each key depression is recorded and time stamped), as well as all mouse clicks and coordinates. We also produced a Voice Activity Recorder (VAR), which detects and time stamps the start and end of speech (Figure 3).

Figure 2. Observational data capture using ObsWin, rating interface and outputs with summary statistics

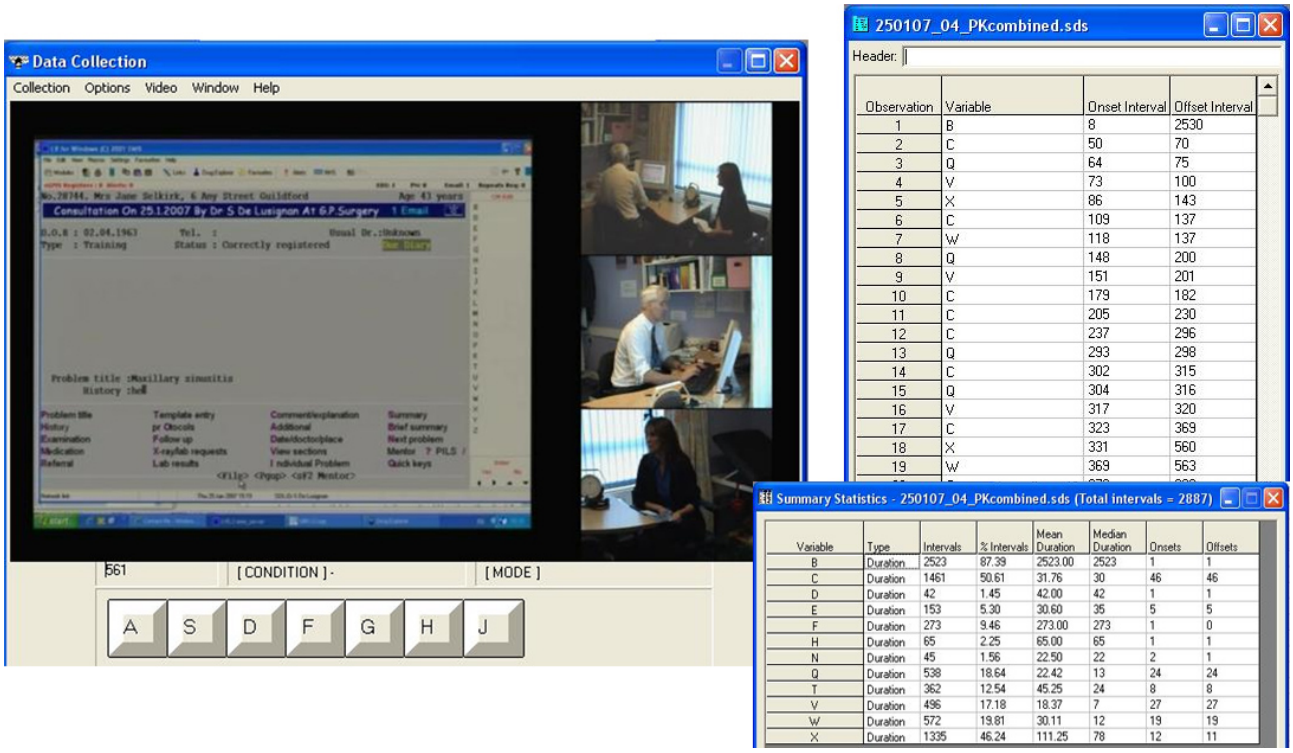
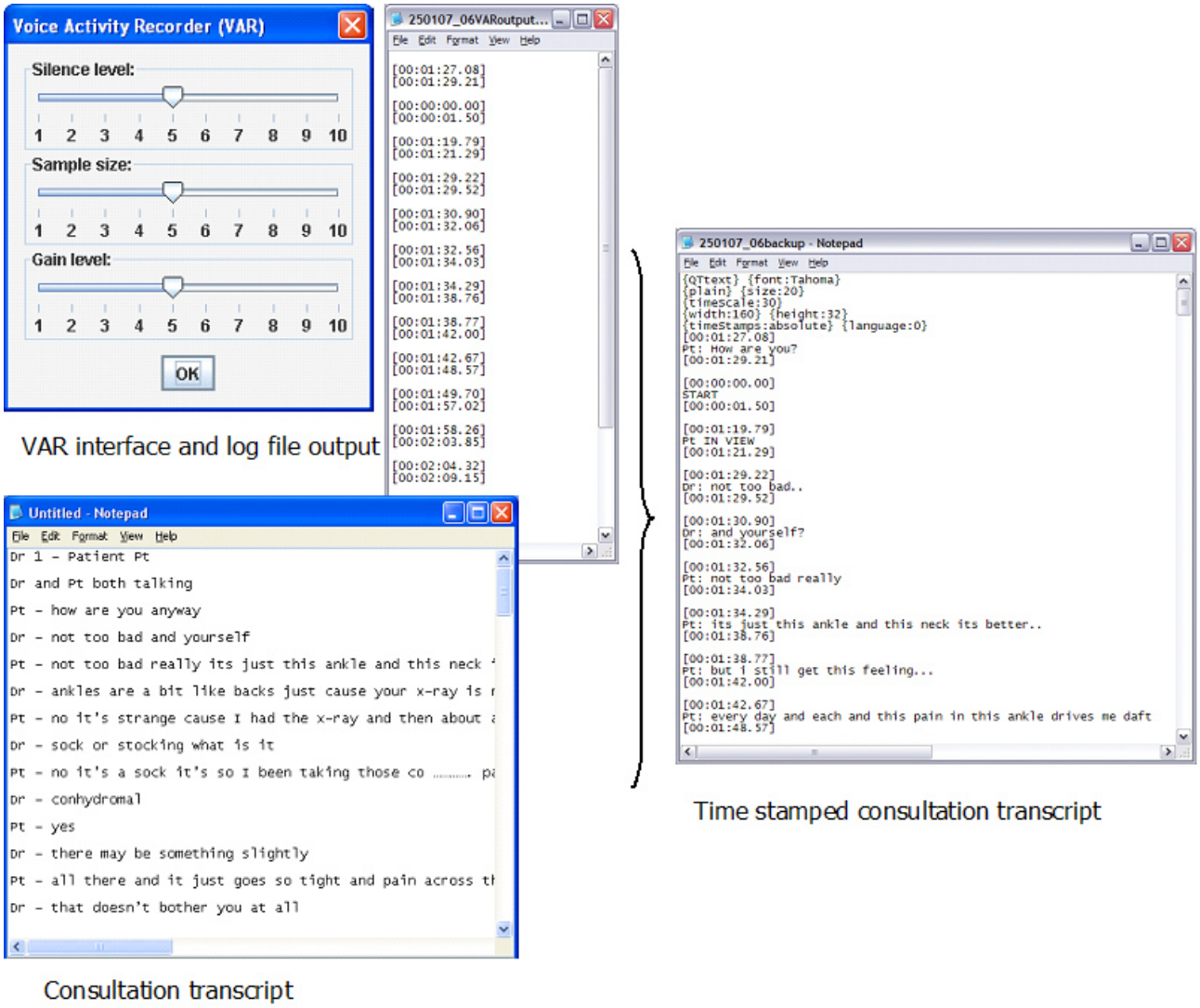


Figure 3. Time-stamped consultation transcript creation using VAR



Automated Capture of Body Language

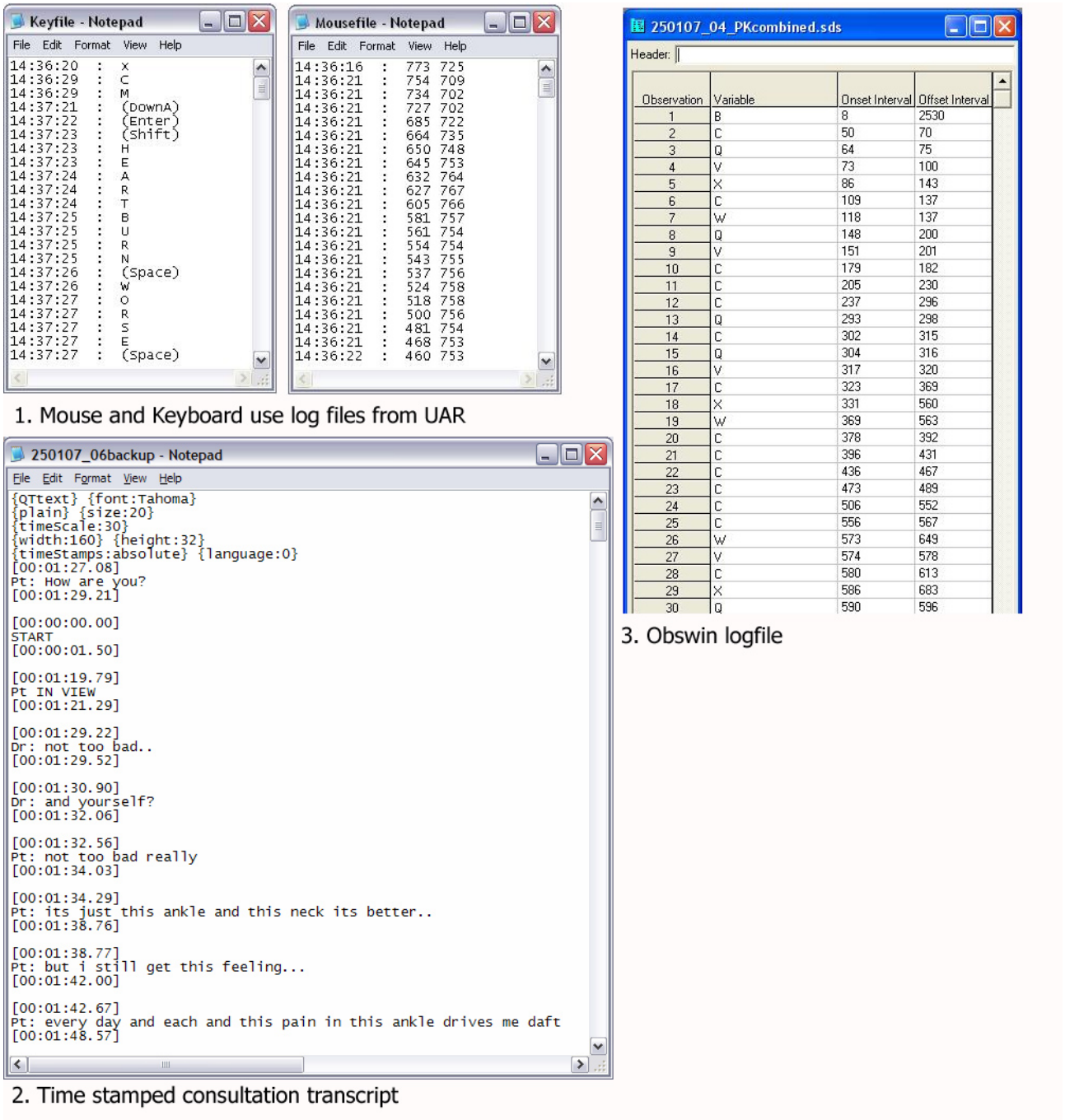
We automated the capture of body language to interpret nonverbal interactions and the direction of gaze to infer eye contact between clinician and patient. We experimented with Algol, an experimental pattern recognition software (PRS) not released as a commercial product (Main Highway Services, Winchester, UK), exploring correlation between movements detected with the software and manually detected activity [15] (Figure 4). We explored the possibility of obtaining software that measured the direction of gaze.

Figure 4. Measurement of nonverbal interactions using PRS, patient's head nodding and doctor's keyboard use

Aggregation and Navigation Application

We needed to aggregate the output from multiple data collection systems (Figure 5) into a single application that would be readily navigable. It needed to be able to flexibly load any number of input files and produce outputs that could be readily utilized in other applications. Unsuccessful effort to identify an appropriate proprietary application resulted in the in-house development of the Log Files Aggregation (LFA) application [16].

Figure 5. Time stamped log files created by three different consultation activity observation methods.



Output That Could Facilitate Better Clinical Computer System Development

We wanted to produce an output that would be readily interpretable by software engineers, so that our findings had a utility beyond the health care community. We specified our aggregation tool to export the combined log files in XML (extensible mark-up language) format, so they can be readily imported and interpreted by other applications. Process models of consultation tasks created using the UML, a standard modeling and specification notation widely used in software engineering, was chosen as our main mechanism for representing the use and impact of clinical system features within the consultation.

Pilot Recording of Consultations

We developed our method using simulated consultations between clinicians and actor patients within a simulated clinical environment. We initially developed the technique using

standard consultations (eg, follow-up blood pressure checks [14]) and then a wider range of clinical problems.

We needed to know whether our technique was practical to set up within a standard consulting room and could cope with background noise, variable lighting including window position, and room size. We next tested our technique using actor patients in GP surgery premises. We found that audio recording from 1 camera was satisfactory; modern cameras coped well with variations in lighting, and 2 people could set up the cameras and install the other data-capture methods in less than 20 minutes. We found that the cameras and other data-capture tools could capture more than an hour's data, but that it was prudent to remove screen capture and video data in a pause between consultations after 45 minutes.

We next developed a protocol that included our technical method, obtaining proper consent from patients and securing the data. We wanted to obtain pilot data from the 4 different most used brands of GP EPR systems, so we could make comparisons. These 4 brands are: (1) EMIS LV, the longest established and, at the time of the study, the most used system; (2) EMIS PCS, a more modern version from the same manufacturer; (3) INPS Vision; and (4) iSoft Synergy. EMIS LV is largely character user interface (CHUI) driven, whereas the other 3 have graphical user interfaces (GUI).

In our pilot analysis, we only included coding carried out using the picking list or other routine coding tools. We did not include data entry forms or templates that could facilitate more rapid data entry. The 4 GPs we filmed had used their current computer system for at least 3 years and had not routinely consulted with paper records for at least this period.

Statistical Methods

We planned to compare the time taken to carry out clinical coding, prescribing, and other routine tasks in the clinical consultation. We expected data from a small pilot to not have a normal distribution. This expectation is for 2 reasons: (1) we have a small sample and (2) we expected a skewed distribution because sometimes these tasks take a long time, but they always take a minimum time. We used box whisker plots to visually compare actions that were frequently recorded. We also used nonparametric tests (Mann-Whitney U test) to differentiate between EMIS LV (the then most used brand of GP EPR system) with the other systems. We next used the Krushkal-Wallis to explore any statistically significant difference in mean ranking. We used SPSS version 15 to carry out these analyses.

Ethical Considerations

We obtained ethical approval for the pilot recording of live consultations via the National Health Services Central Office for Research Ethics Committees (COREC). The protocol included making proper provision for the secure transport and storage of media and limiting access.

We used a 3-step process to obtain consent from patients to be video recorded. First, the video sessions were marked as such in participating practices, so that patients who booked into these sessions knew they were going to have their consultation video taped by 3 cameras as part of a research project. Second, they signed consent at the start of the consultation and were told that, if they did not want the video used after the consultation, they were free to say so. Finally, they and the clinician signed consent after the consultation stating that they remained willing for the consultation data to be used in research.

Results

Technical and Pilot Investigation Results

The results initially report a summary of our final technical method and then the results of our pilot study. The full description of the technical process is contained in Appendix 1.

Number of Video Channels Optimal for Analysis

We found 4 video channels to be optimal for observing the consultation. Our 3-channel video method, which provides an overview of the consultation, the clinician's upper body, and screen capture, overcame most of the problems associated with single-channel observation [17]; however, a qualitative investigation suggested a fourth channel filming the head and upper torso of the patient was essential to capture the patient's body language [11] (see Multimedia Appendix 3). In 2006, we found we could source the necessary hardware for 3-channel video around 1100 Euros [18] (or 1500 Euros for 4 channels).

Coding Consultation Activity

We used our in-house–developed UAR to capture mouse and key movement and VAR to time stamp the start and end of speech. We have piloted the use of UAR to compare the time taken to code a new problem and to issue a single acute prescription on 2 different GP computer systems [19].

The use of VAR overcame the limitations of manual coding of the start and end of speech. Prior to using VAR, we found that training manual raters could reliably code simulated consultations [14], but when presented with a heterogeneous mixture of real consultations, some activities were less reliably coded. The VAR also enables us to identify who initiates and terminates silence. We have observed how the clinician sometimes makes purposeless use of the IT to initiate silence to control the consultation [20].

Automated Capture of Body Language

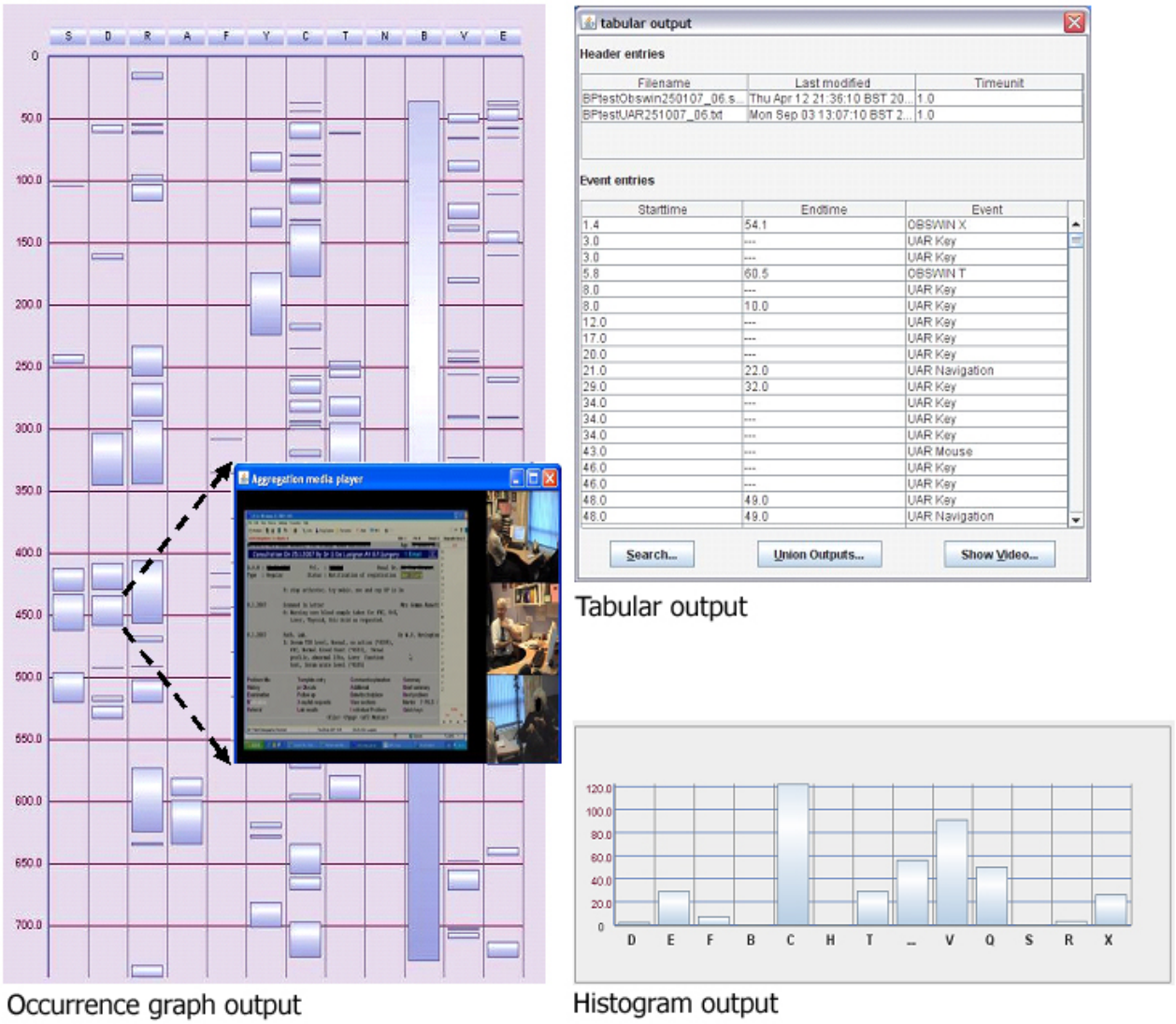
We have extensively tested pattern recognition software to see if we can automate the capture of body language and movements such as affirmative head nodding; however, limitations in this technology, and our ability to process it, have left us unable to correlate this with the output from our manual observations.

The Log File Aggregation (LFA) Tool for Synchronizing and Simultaneous Viewing of Log Files

The LFA tool combines any number of time-stamped log files of different formats. The data imported into LFA can be viewed as histograms or occurrence graphs (Figure 6). The power of this tool in analysis is that clicking on a rectangle representing a specific variable takes the user directly to the appropriate spot in the multichannel video (see Multimedia Appendix 4). This enables users to navigate into any spot in the consultation they

wish to study and simultaneously view all the log files relating to that point in time. Reader programs could successfully interpret XML output from the ALFA tool.

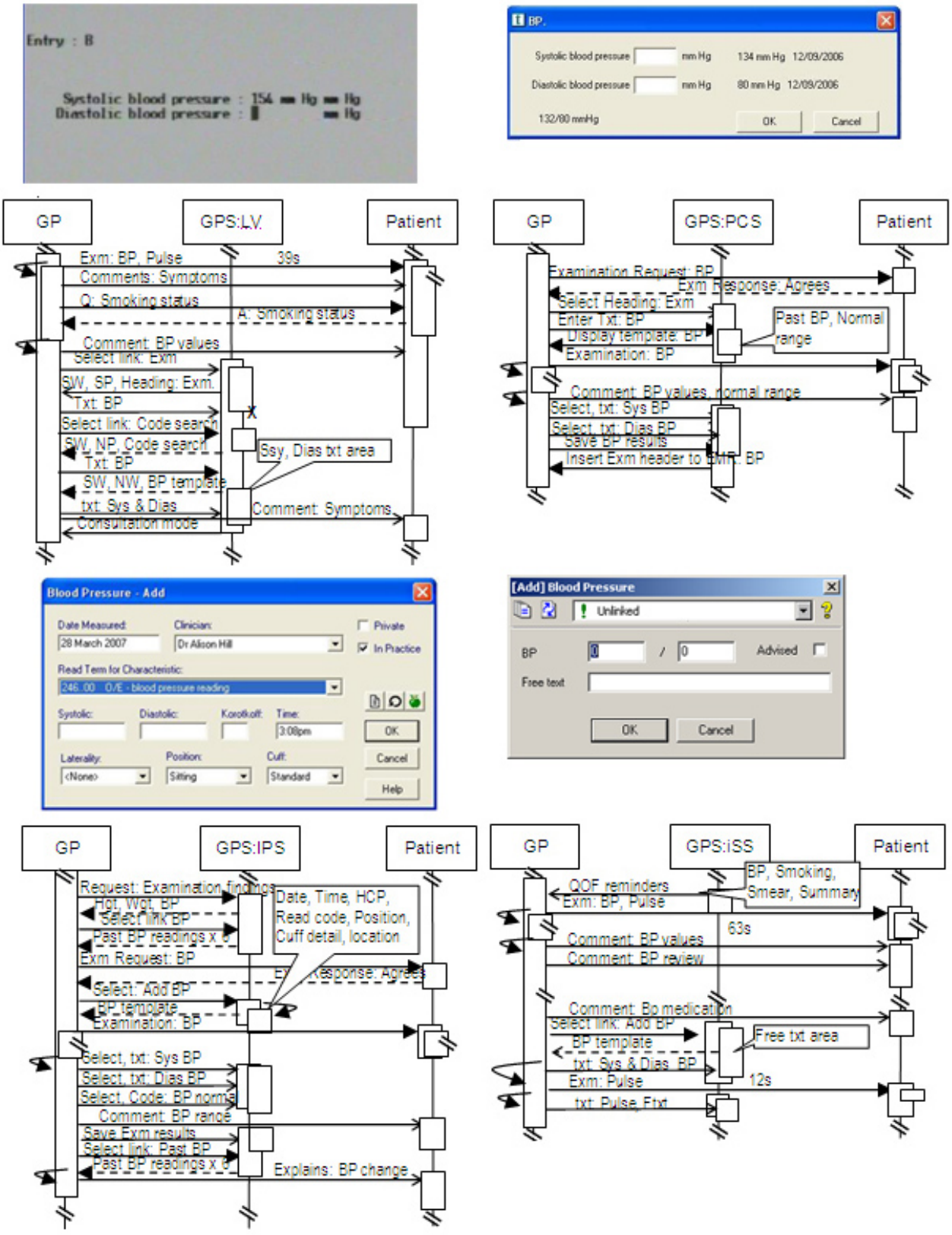
Figure 6. Analyzable outputs of the ALFA tool after aggregation



Output That Can Be Used by Software Developers

UML sequence diagrams demonstrated the clinicians' use of EPR system components within the consultation. They contrasted the variations of computer use and how this might be related to interface features. Software developers could examine these process models to evaluate the use and performance of design characteristics within a consultation. We have used the UML outputs to contrast the definition of the presenting problem, prescribing [21], past encounter reviewing, and BP data entry stages (Figure 7) [22]. Examples for design features that we could identify as having an impact on the consultation are: (1) navigation method (use of icons, function, or arrow keys), (2) structure of the main interface (single, sub, or tab-separated windows, (3) display of alerts or prompts, (4) mechanism for searching coded data, (5) retrieving of historical data, etc. The output from LFA automatically creates the framework of a UML sequence diagram. It takes approximately an hour to manually annotate the remaining sequences in a 10-minute consultation.

Figure 7. Blood pressure data recording interfaces of 4 different EPR systems and sequence diagrams for the interactions observed



Pilot Data

There is considerable heterogeneity of computer use between consultations. We collected initial data from 22 consultations from 4 practices. Each computer system was only used by 1 GP. The GPs generally coded between 1 and 3 items per consultation, though 12 items were coded in one iSoft consultation, and the GP using EMIS LV appeared to code more. The summary of the coding carried out in each consultation is shown in Table 2. Only 2 of the 22 patients seen in this pilot

asked to have the cameras switched off. No patients or clinicians withdrew consent for video material to be used post consultation.

Table 2. Coding carried out in the pilot consultations

EPRsystem	Consultation ID	No. of items coded	Acute prescriptions (Rx) issued	Repeat prescriptions (Rx) issued	BP measured	Other coded/prescription related computer use
EMIS LV	EL1	2	1	0	0	
	EL2	1	0	1	0	
	EL3	3	1	0	1	
	EL4	1	3	0	0	
Total	4	7	5	1	1	
EMIS PCS	EP1	5	1	0	0	Prescription restarted
	EP2	1	1	0	0	
	EP3	2	1	0	0	
	EP4	4	2	0	0	
	EP5	7	2	0	0	
	EP6	1	0	0	0	
	EP7	4	0	0	1	
Total	7	24	7	0	1	
INPS Vision	IV1	3	2	2	1	
	IV2	1	1	1	1	
	IV3	3	1	0	1	Weight
	IV4	1	0	0	0	
	IV5	1	2	0	1	Weight, Rx cancelled
	IV6	3	2	1	0	
	IV7	2	1	0	1	Drug allergy, Rx cancelled
Total	7	14	9	4	5	
iSoft Synergy	IS1	1	0	0	2	BMI, Rx cancelled
	IS2	12	0	0	1	
	IS3	2	0	0	0	
	IS4	3	0	0	0	
Total	4	18	0	0	3	

We observed differences in time taken to code data, prescribe, and repeat prescribe into the computer systems, though we only had sufficient episodes of coding data and acute (new) prescribing to make any sort of statistical comparison. The descriptive findings are shown in Table 3, and the coding and repeat prescribing data are illustrated using box-whisker plots (Figure 8 and Figure 9.) The clinician using EMIS LV (the CHUI interface) appears to take longer to code items than users of other systems. Their mean ranking (Kruskal-Wallis test) was in the following order: EMIS LV, slowest (highest median); then iSoft Synergy was second slowest to code data; the fastest two were INPS Vision and EMIS PCS, having similar medians. The difference in medians was statistically significant (P = .007). Nonparametric (Mann-Whitney U) tests showed that they were all statistically significantly faster than EMIS LV; for EMIS PCS and INPS $P < .01$ and for iSoft Synergy $P < .05$ (Table 3).

Acute prescribing appears to be faster with EMIS LV; however, although the EMIS LV prescriber was consistently at the faster end of prescribing time, there is overlap with the other systems shown in the box-whisker plots. Not surprisingly, the difference in medians was not statistically significantly different from the other two systems for which we have acute prescribing data (P = .71 and P = .64).

Table 3. Comparison between EMIS LV (EL), EMIS PCS (EP), INPS Vision (IV), and iSoft Synergy (iS) of time taken to code data, prescribe, and record BP data

	Coded Data Entry				Acute Prescribing			Repeat Prescribing		BP Recording			
	EL	EP	IV	iS	EL	EP	IV	EL	IV	EL	EP	IV	iS
N	7	24	14	18	5	7	9	1	4	1	1	5	3
Mean (SD)	11.5 (3.0)	8.1 (8.0)	6.8 (2.9)	7.9 (2.5)	23.7 (2.5)	27.1 (10.1)	27.5 (8.5)	21 -	8.4 (3.2)	7.1 -	9 -	9.8 (3.4)	6.7 (1.3)
95% CI	8.7 - 14.2	4.7 - 11.5	5.1 - 8.5	6.6 - 9.2	20-5 - 26.8	17.7 - 36.5	20.9 - 34.0	-	3.3 - 13.5	-	-	5.6 - 13.9	3.5 - 9.8
Median (IQR)	12.1 (2.8)	5.9 (3.2)	5.7 (3.3)	7.2 (2.7)	23.8 (2.1)	22.1 (15.4)	23.6 (9)	21 -	9.4 (3.8)	7.1 -	9 -	8.8 (1)	7.3 (1.1)
MIN	5.7	2.5	3.6	5.1	21	15.7	19.1	21	4	7.1	9	6.7	5.2
MAX	14.4	40.5	12.5	13.6	27.6	41.9	46.2	21	10.7	7.1	9	15.5	7.5
NPAR* P		0.007	0.006	0.012		0.71 (NS)	0.64 (NS)						

*NPAR = nonparametric test compared with EMIS LV; exact statistical significance is shown for the Mann-Whitney U test (2-tailed). NS = not significant.

Figure 8. Box-whisker plot comparing coding times with different brands of GP EPR systems

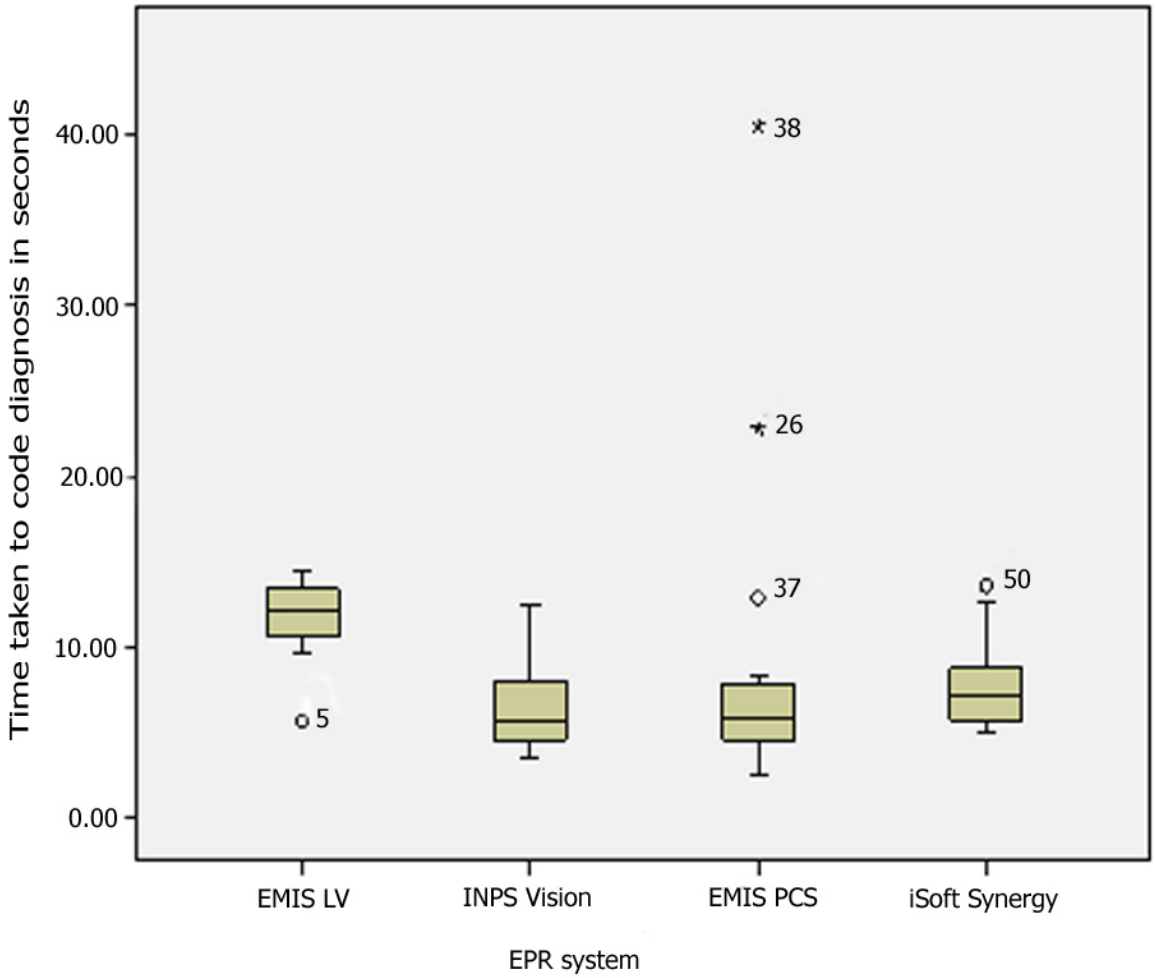
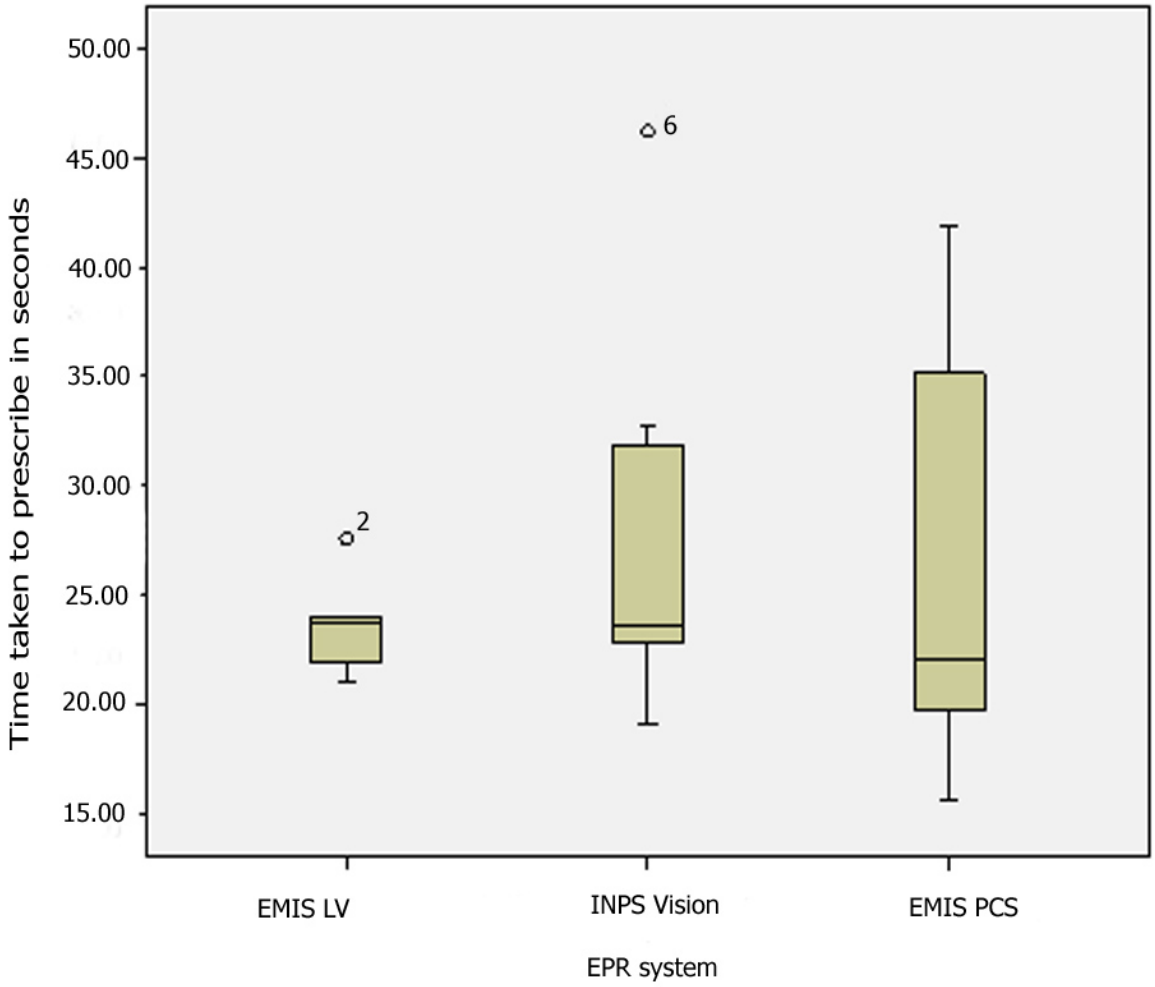


Figure 9. Box-whisker plot comparing prescribing times with different brands of GP EPR systems



Discussion

Principal Findings

The ALFA toolkit allows greater precision of observation of the clinical consultation than other techniques. The current toolkit allows multiple video channels including screen capture, the consultation transcript, computer use, and speech to be precisely synchronized, timed, and navigated through. There is enough scope to add other input as required. Its output can be used to create models that software engineers could use to develop better EPR systems.

The multichannel filming appears to be acceptable to patients; however, the 4 practices involved were teaching and training practices where both medical students and trainee doctors regularly video tape themselves.

Our pilot data shows how the method allows small, but statistically significant, differences between clinical systems and users to be measured. Although these differences in time per coded item and prescription are relatively short, when multiplied up through a clinician's day, better interfaces might result in a considerable time saving.

The UML models of BP recording show how having the previous reading readily available positively influences the clinical process and provide insights into how the new computer interfaces might be developed in the future. This principal could be carried forward into the recording of other common clinical information, for example, recording a smoking habit or adverse reactions to medication.

Implications

We developed this tool to meet our aspirations to evaluate the impact of technology on the consultation. Its precise time stamps could be used to compare clinical computer systems or to contrast the time taken with paper systems versus computerization. Comparative analysis of computer use and clinician-patient interactions could determine the common tasks and be used to develop theoretical models for computer-mediated consultation. We hope that our UML sequence diagrams will enable the clinical system designers to evaluate existing systems and also develop and evaluate new features.

The ALFA toolkit can also be used to measure the performance of the clinician or the reaction of the patient. Colleagues who have seen this technique have suggested that remedial doctors assessed in simulated surgeries could be given multichannel videos of their performance as a tool for reflection; if we could automate measures of body language, then this might be used as a formative assessment of communication skills.

The full set of tools created by the team and their source codes are freely available under a GNU General Public License (GNU GPL). Instructions for download, set up, sample files, and links to other related resources are made available as Web resources [23].

Limitations of the Method

Some of the parts of our development failed. We were unable to use the log file from the motion recognition software effectively. As yet, we have not been able to achieve a transcript from a voice-recognition system; these technologies still require training and are unable to recognize differing patients' voices. We have not been able to access suitable methods to measure direction of gaze; commonly available tool kits are intrusive.

We have run this development as a series of small-scale components, rather than as a comprehensive program. Our pilot data only used one clinician per system. More data are needed to discover if these differences were clinician-related or system-related.

Comparison With the Literature

We are unaware of any similar technique that provides such precision of observation (see Multimedia Appendix 2). Table 4 compares the features of ALFA against popular existing techniques. Although the study of human computer interaction (HCI) is a well developed discipline, it focuses on the interaction between 1 or more individuals and 1 or more computer systems [24]. In HCI, the user-computer interaction has primacy; we wanted instead to develop a toolkit to capture the complex social interaction of the consultation, within which the clinician-patient activity is pre-eminent.

Table 4. Comparison of ALFA toolkit features with existing tools

ALFA element and comparable functionality	Existing tools							ALFA tool kit
	Qualitative research		Transcription and analysis	Usability testing	Screen casting			
	ATLAS.ti	NVivo	Transana	Morae	Camtasia	Adobe Captivate	BB F'Back	
1. Multichannel Video (MCV) recording								
Screen capture	N/A	N/A	N/A	Yes	No	No	Yes	Yes
Video capture	N/A	N/A	N/A	1 camera	No	No	1 camera	3 cameras
Audio capture	N/A	N/A	N/A	Yes	Yes	Yes	Yes	Yes
2. Observational Data Capture (ODC)								
Multimedia import	Yes	Yes	Yes	Yes	No	No	No	Yes
Sufficient video display	Yes	Yes	No	No	N/A	N/A	N/A	Flexible
Video controls	Yes	Yes	Yes	Limited	N/A	N/A	N/A	Yes
Exports durations directly	No	No	No	No	N/A	N/A	No	Yes
Method of coding for interactions	Codes, Memos	Codes, Memos, Nodes	Keywords, Comments	Markers	No	No	No	duration variables
Interaction durations	No	Graphical	No	Yes	No	No	Graphical	Direct export
3. User Activity Recording (UAR)								
Keyboard use	N/A	N/A	N/A	Yes	No	No	Yes	Direct export
Mouse use	N/A	N/A	N/A	Yes	Yes	Yes	Yes	Direct export
Interaction durations	No	No	No	No	No	No	No	No
Lightweight to install	N/A	N/A	N/A	No	No	No	No	Yes
4. Voice Activity Recording (VAR) and transcription								
Indicates voice levels	No	No	Yes	No	No	No	Yes	Yes
Measures verbal interactions	No	Manual	Manual	No	No	No	Manual	Direct export
Import/create transcriptions	Yes	Yes	Yes	No	No	No	No	Yes
Time-stamped transcriptions	No	Yes	Yes	No	No	No	No	Yes.
5. Log File Aggregation								
Combine data from different tools	video and transcript's	video and transcripts	video and transcript's	Screen capture and video	No	No	No	Up to 10. Can extend further
Single exportable file	Yes	No	No	No	Yes	Yes	Yes	Yes, many formats
XML output	Yes	No	No	No	No	No	No	Yes
6. Occurrence graphs								
Time lines for interaction	No, Network diagrams	Yes, small display	No, Clips organised with labels	1 timeline	No	1 timeline	mouse, keyboard and voice	Multiple timelines. Large display
Interactions mapped to video	Yes	Yes	Yes	Yes	No	No, to screen capture	No, to screen capture	Yes
Interaction durations linked to video	No	Yes	No	Yes	No	No, linked to frame	No, linked to frame	No
7. UML process modeling								

ALFA element and comparable functionality	Existing tools							ALFA tool kit
	Qualitative research		Transcription and analysis	Usability testing	Screen casting			
	ATLAS.ti	NVivo	Transana	Morae	Camtasia	Adobe Captivate	BB F'Back	
Use for UML validation	Limited	Limited	No	Limited	No	No	No	No
Indicates interactions and durations in channels	No	Yes, limited by display area	No	Yes, 1 at a time	No	No	Only for mouse, keyboard and voice	Yes, multiple channels of interactions
Shows interaction type directly	No, Using codes	Yes	No, Using labels	No, Using markers	No	No	Only mouse, keyboard and voice	Yes.

Evaluation methods in software engineering combine multiple techniques for observation [25, 26]. The analyzable products of these are often a data file stream combining visual or audio representations of sequence of activities in sensory channels [27]. We are not aware, however, of any application that enables such a range of log files to be aggregated, synchronized, and, where needed, exported into other applications. Some keyboard listening or spyware applications could identify the sequence of keyboard activities. Voice spectrum analyzer applications that can present visual data about sound levels also exist. Unlike UAR and VAR applications, these are not capable of timing the computer use or verbal interactions in an analyzable format.

This method examines the impact of the computer on the consultation from a broad sociotechnical perspective, as advocated by Coiera [28], rather than from a purely technical perspective. Rigorous and broadly acceptable evaluation frameworks of IT in health care should be capable of identifying problems, suitable tools for evaluation, and methods for applying them sensibly [29]. It potentially helps fill some of the gaps in the methods for evaluation of health care systems [30].

Call for Further Research

More research is needed on how to automate data collection regarding the impact of technology on the consultation. Improved voice-recognition techniques would save the time spent in transcribing. As well as filling in the gaps about how to use pattern-recognition software and visual gaze estimation software to capture body language, we need to consider how we might embed logs into active clinical systems so that, for example, the change in length in consultation associated with a new release of software can be automatically measured and potentially investigated.

We also need to explore with a larger sample what are true differences between EPR systems and what is clinician variation. Recording several clinicians using 1 system should enable us to do this.

Conclusions

We set out to develop tools that would provide objective time stamps of activities within the consultation, allowing their simultaneous viewing and analyzing interactions in detail. The ALFA toolkit allows multiple observations of the consultation to be aggregated, simultaneously navigated, and output into other applications. The output from the ALFA tool should provide the evidence, based on which improved technology and models for the consultation can be developed.

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Conflicts of Interest

None declared.

Authors' Contributions

Simon de Lusignan and Pushpa Kumarapeli contributed equally to this work. Simon de Lusignan has set out a strategy for the development of better tools to study the impact of IT on the consultation with Tom Chan. Simon de Lusignan wrote this paper with comments from the other authors. Pushpa Kumarapeli has developed the UAR and VAR applications and specification for UML modeling; he has also been involved in developing the specification and design of the ALFA application. Bernhard Pflug developed the ALFA application. Simon de Lusignan, Beryl Jones, and Tom Chan are Pushpa Kumarapeli's academic supervisory team for his PhD. Jeremy van Vlymen provided technical support and input throughout the project, supporting many critical

technical developments. George K. Freeman is the chair of the SGUL Clinical Consultation Research Group and has contributed to these developments.

Multimedia Appendix 1

Technical design of ALFA toolkit

[PDF file (Adobe Portable Document Format File), 881 KB - jmir_v10i4e27_app1.pdf]

Multimedia Appendix 2

Comparison of ALFA toolkit features with existing tools

[PDF file (Adobe Portable Document Format File), 614 KB - jmir_v10i4e27_app2.pdf]

Multimedia Appendix 3

Sample multichannel video file

[WMV file (Microsoft Windows Media Video File), 3.2 MB - jmir_v10i4e27_app3.wmv]

Multimedia Appendix 4

Demonstration video of navigable occurrence graph created by LFA stage

[WMV file (Microsoft Windows Media Video File), 6.8 MB - jmir_v10i4e27_app4.wmv]

Multimedia Appendix 5

Source code for LFA tool

[PDF file (Adobe Portable Document Format File), 997 KB - jmir_v10i4e27_app5.pdf]

Multimedia Appendix 6

Source code for UAR tool

[PDF file (Adobe Portable Document Format File), 94 KB - jmir_v10i4e27_app6.pdf]

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Abbreviations

ALFA: activity log file aggregation
BP: blood pressure
CHUI: character user interface
COREC: Central Office for Research Ethics Committees
EPR: electronic patient record

GP: general practitioner
GUI: graphical user interface
GPL: general public license
HCI: human computer interaction
LFA: log files aggregation
ODC: observational data capture
PRS: pattern recognition software
UAR: user action recording
UML: unified modeling language
VAR: voice activity recording
XML: extensible markup language

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Original Paper

Rates and Determinants of Uptake and Use of an Internet Physical Activity and Weight Management Program in Office and Manufacturing Work Sites in England: Cohort Study

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Abstract

Background: Internet-based physical activity (PA) and weight management programs have the potential to improve employees' health in large occupational health settings. To be successful, the program must engage a wide range of employees, especially those at risk of weight gain or ill health.

Objective: The aim of the study was to assess the use and nonuse (user attrition) of a Web-based and monitoring device–based PA and weight management program in a range of employees and to determine if engagement with the program was related to the employees' baseline characteristics or measured outcomes.

Methods: Longitudinal observational study of a cohort of employees having access to the MiLife Web-based automated behavior change system. Employees were recruited from manufacturing and office sites in the North West and the South of England. Baseline health data were collected, and participants were given devices to monitor their weight and PA via data upload to the website. Website use, PA, and weight data were collected throughout the 12-week program.

Results: Overall, 12% of employees at the four sites (265/2302) agreed to participate in the program, with 130 men (49%) and 135 women (51%), and of these, 233 went on to start the program. During the program, the dropout rate was 5% (11/233). Of the remaining 222 Web program users, 173 (78%) were using the program at the end of the 12 weeks, with 69% (153/222) continuing after this period. Engagement with the program varied by site but was not significantly different between the office and factory sites. During the first 2 weeks, participants used the website, on average, 6 times per week, suggesting an initial learning period after which the frequency of website log-in was typically 2 visits per week and 7 minutes per visit. Employees who uploaded weight data had a significant reduction in weight (−2.6 kg, SD 3.2, $P< .001$). The reduction in weight was largest for employees using the program's weight loss mode (−3.4 kg, SD 3.5). Mean PA level recorded throughout the program was 173 minutes (SE 12.8) of moderate/high intensity PA per week. Website interaction time was higher and attrition rates were lower (OR 1.38, $P= .03$) in those individuals with the greatest weight loss.

Conclusions: This Web-based PA and weight management program showed high levels of engagement across a wide range of employees, including overweight or obese workers, shift workers, and those who do not work with computers. Weight loss

was observed at both office and manufacturing sites. The use of monitoring devices to capture and send data to the automated Web-based coaching program may have influenced the high levels of engagement observed in this study. When combined with objective monitoring devices for PA and weight, both use of the website and outcomes can be tracked, allowing the online coaching program to become more personalized to the individual.

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KEYWORDS

Employee health; Internet; device; behavior change; body weight; psychology; physical activity; occupational health; diet; technology

Introduction

Overweight and obesity are now major causes of preventable health problems across the world. Obesity has serious implications for the individual's health as well as the population health and economy. A report by the UK National Audit Office (NAO) estimated that, in 1998 alone, the indirect costs of obesity to the UK economy (18 million sick days and 40,000 lost years of working life) were around four times greater (£2.1 billion/year) than the direct costs of treatment (£0.5 billion/year) [1]. A subsequent update by the Health Select Committee in 2004 [2] estimated the cost of obesity to be 27% to 42% higher than the NAO 1998 estimate. These estimates suggest that finding effective interventions that target weight management and physical inactivity within the workplace could potentially be of great value both to employers and to the economy. However, these interventions must be attractive to the employee, scalable, and, most importantly, capable of both initiating and supporting the required behavior change. Interventions must also appeal to employees who are high risk and difficult to reach by other health initiatives, rather than to employees who are already fit and active with a healthy weight.

Health behaviors are personal and complex, and the challenge lies in creating and deploying intervention programs that address this complexity in an engaging, easy to use, and yet effective way. Internet-based interventions serve as a feasible and acceptable delivery method for these programs, thereby providing scale, but evidence suggests that programs must go beyond providing advice and information alone. A review of Internet use for weight loss suggests that successful online programs include a structured approach to modifying energy balance, the use of cognitive-behavioral strategies such as self-monitoring, and individualized feedback and support [3].

Our previous research [4] also shows the importance of interactive design in Internet-based physical activity (PA) motivation programs. Where interactive design is employed, better user engagement and retention are observed. Specifically, in this research [4], the interactive program created higher expectations for PA and increased self-perception of fitness, with increased PA reported in the test group up to 7 months after exposure to the website. In order to test this interactive website with an objective measure of PA, a study was conducted combining the Internet program with a wrist-worn accelerometer [5]. This combination of interactive Web program and monitoring device produced an average increase of 2 hours and 18 minutes of moderate PA per week, with a greater loss of body fat when compared to the control group (wearing the accelerometer but without access to the Web program). To our knowledge, this was the first reported fully automated Internet system with personalized accelerometer feedback to demonstrate increased PA where PA was objectively measured. This study also indicated that engagement with the online program may be important in increasing PA over and above the effects observed from wearing an activity monitor alone.

Following this work with objective PA data collection, we extended the program to include an online weight management module and automated data capture weighing scales. The objective of this study was to assess the level of program engagement of a wide range of employees. A key difference from our previous studies [4,5] was that participants received no payment for taking part in this study. Also, rather than a randomized controlled trial (RCT), the study was conducted in a more naturalistic setting, whereby a branded commercial program (MiLife) was offered to employees as a benefit through collaboration with their company's occupational health professionals.

Methods

Study Design

The study was designed to test the level of engagement with the Web program for employees recruited at 4 work sites in the United Kingdom over a 12-week period and the effects of this on the employees' health. Work sites were chosen that were geographically and demographically different in order to evaluate if engagement with the program varied by location, baseline demographics, or level of interaction with computers during work hours. Two work sites were in the North West of England and 2 work sites were in the South of England in order to determine the influence of region upon uptake and use of the program. This could be important as, on average, 39% of UK households do not have Internet access. This varies by region, with the highest levels of Internet access observed in the South West and around London, compared to lower levels of access in households in the North West of the country [6]. Additionally, the use of 2 manufacturing sites (1 in the north and 1 in the south) and 2 office-based sites (again in the north and south) allowed the comparison of baseline data from these 4 sites, including an assessment of participant characteristics since research suggests that women may be more likely to participate in work-site health promotion programs than men [7] and that shift work may be a barrier to participation in such programs [8]. The study objective was to assess the use of the Web-based and monitoring device–based PA and weight management program in this range of employees and to determine if

engagement with the program was related to the employees' baseline characteristics or the measured outcomes. This was undertaken with a view to share our experiences when implementing an Internet-based health program in a range of occupational settings, and to build the literature on factors to achieve greater accessibility to and engagement with health support tools.

Participants

In order to determine the baseline health profiles and characteristics of all employees who were attracted to the MiLife program, minimal exclusion criteria were applied. The program was offered to adults employed at any of the 4 work sites who had regular Internet and email access or who were willing to access Internet and email via computers installed in communal areas at their workplace. Exclusion criteria were pregnancy, any holiday of more than 2 weeks during the study period without computer access, previous instruction from a health professional not to engage in PA, being severely underweight (body mass index, BMI, < 16 kg/m^2), or already taking part in a clinical trial.

Employees were recruited via leaflet distribution during working hours, including during shift patterns (weekends, nights, etc) at the manufacturing sites. At screening, date of birth, gender, blood pressure (BP), resting heart rate, BMI, and medication were recorded and the Physical Activity Readiness Questionnaire(PAR-Q) [9] and Rose Angina [10] questionnaires were administered. Participants with hypertension (BP ≥ 140/90 mmHg), chronic respiratory conditions, or positive scores on the PAR-Q or Rose Angina questionnaire were not excluded but were required to seek approval from their physician prior to entry into the study.

Intervention

The Web program was combined with a Bluetooth-enabled wrist-worn triaxial accelerometer to measure PA and with Bluetooth-enabled weighing scales to record body weight (see Multimedia Appendix). Both devices sent the captured data back to the user's Web program. The data from these devices were reported back to the individual via their automated coaching Web program, allowing self-monitoring of their PA and body weight and also objective measurement of PA and weight throughout the program. The components of the Web program and the monitoring devices are described in more detail below.

Participants recruited to the program were shown, in a brief training session (approximately 20 minutes, group size of up to 15 participants per trainer), how to register on the website and how to create their own personal password-protected account. The trainer also demonstrated how to upload weight data from the scales to the PA monitor and how then to upload the weight and PA data from the PA monitor to the computer. Basic computer skills training was provided when necessary and included use of a mouse, computer startup, log-in, and website navigation.

MiLife Web-Based Automated Behavior Change System

The Internet, email, and mobile phone behavior change system was similar to that used in previous studies [4,5]. An introductory series of screens helped participants identify their goals and targets and recommended a suitable program mode (ie, weight loss, weight maintenance, or PA only). A weekly series of screens provided constructive feedback on performance relative to their own target. The system included a weekly schedule (or diary) for planning PA sessions over the next 7 days, for which participants could choose to receive email and/or mobile phone reminders, an approach that has been effective in combination with implementation intentions [11].

The system made recommendations to the user of the mode to follow (weight loss, weight maintenance, or PA) based on their baseline weight, height, waist circumference, and stated goals. The major difference between the modes lies in the frequency with which users are encouraged to monitor their energy intake. For weight loss, monitoring energy intake is frequently encouraged; for weight maintenance, monitoring energy intake is encouraged if weight increases; for PA only, monitoring energy intake plays less of a role. The user could follow the recommended mode, choose another mode, or enter a nonactive browse mode with no goal or target setting. Users could also switch between the modes during the 12-week study period. The tools that support each mode are based on best evidence and practice from the literature. For example, in the weight loss mode, the tools were developed based on strategies used within the Diabetes Prevention Program [12] to promote weight loss and PA, such as self-monitoring, planning, goal setting, and structured feedback.

The design of the Web-based system was founded on key behavior change theories. For example, providing users with information on the typical PA levels of people like themselves is based on Festinger's (1954) Social Comparison Theory [13], which asserts that individuals engage in social comparison (comparing themselves with others) to evaluate their opinions and abilities. Social Comparison Theory has previously been applied to prevention and health care [14]. Another part of the system offers users solutions for barriers they perceive to be preventing them from taking up healthier behaviors. This is based on Decisional Balance Theory [15], which suggests that if the perceived number of "pros" for a behavior (eg, regular PA) outweigh the "cons" for an individual, then he or she is more likely to perform the behavior.

Other studies have shown that asking people to form specific plans (implementation intentions) [16] about when and how to eat healthily or to be active can increase their levels of healthy eating and PA [17]. The program encourages users to develop implementation intentions via on-screen, diary-style planning tools in which intentions are specified in terms of their date, time, and place, with environmental cueing via the mobile phone SMS text or email reminder service [11]. Community message boards and discussion forums were designed to provide social support, identified as important for behavior change [18].

Monitoring Devices: Bluetooth-Enabled PA Monitor and Weighing Scales

While pedometers are low cost, they are typically used to record walking and therefore are less appropriate for 24-hour monitoring of PA. Accelerometer-based devices tend to allow a wider range of movement and for total PA to be recorded [19-21] in adults [22] and children [23], and they can be worn in several locations on the body, allowing for continuous use.

We developed a water-resistant, Bluetooth, wrist-worn device that could be worn continuously, including while swimming/bathing. The device contained a miniature triaxial accelerometer unit that produced a signal as the wearer made physical movement, recording all movement up to acceleration levels of 6 g. The acceleration signal was measured and the resultant amplitude integrated. The data were then stored within the PA monitor memory ready for download and analysis. To establish validity of the PA monitor, a lab-based study was conducted in 22 adults (12 males, 10 females). Subjects undertook 10 different semistructured PA conditions: lying down, seated computer work, stacking shelves, washing dishes, sweeping, cleaning windows, and 4 treadmill-based activities (walking at 4 km/h and 6 km/h, running at 8 km/h and 10 km/h). These activities were chosen to represent a range of different physical intensities and metabolic equivalents (METs) and included many tasks that may be undertaken by the participants in their daily living. Oxygen uptake (VO_2)and indirect calorimetry were measured continuously throughout the activities using a K4b2 portable metabolic gas analyzer with data telemetry (Cosmed, Italy) to determine metabolic rate at rest and METs [24] during PA. The activity monitor showed a strong positive correlation with relative VO_2(left wrist: r = 0.934, P< .001; right wrist: r = 0.900, P< .001). Receiver operator curves for discrimination of intensity categories showed the activity monitor was able to predict light (MET 1.5-2.99), moderate (MET 3-5.99), and vigorous (MET ≥6) intensity activity when worn on either the left wrist (area under the curve [AUC], sensitivity, specificity: 0.89 [P< .001], 91%, 75% for light; 0.86 [P< .001], 88%, 81% for moderate; 0.99 [P< .001], 91%, 100% for vigorous) or right wrist (AUC, sensitivity, specificity: 0.90 [P< .001], 91%, 75% for light; 0.76[P= .004], 78%, 71% for moderate; 0.96 [P< .001], 95%, 94% for vigorous). Using this data, cut-points were developed to distinguish moderate intensity and vigorous intensity PA. Further validation of these cut-points in a larger sample is planned with the inclusion of non-lab-based activities such as running and walking outside.

Accelerometer data were analyzed by calculating the number of minutes spent within the range corresponding to moderate intensity (MET level 3) or above [24]. Data points were only counted if they were part of a continuous bout of PA of at least 10 minutes within the MET 3+ range. This was following the American College of Sports Medicine guidelines for moderate-intensity aerobic PA, which state that PA can be accumulated toward the 30-minute minimum on 5 days each week by performing bouts each lasting 10 or more minutes [25,26]. In order to represent the underlying signal, the data were smoothed using a moving average filter of width ± 1 point. Modifying the width of the filter had little effect on the results of the analysis.

Data from the PA monitor were transmitted via a Bluetooth microprocessor to a personal computer (PC). Bluetooth-enabled personal weighing scales also sent data on the user's weight to the PA monitor via Bluetooth. Each weight reading was held within the PA monitor with the PA data until transfer to the PC. The PA monitor memory could store many PA and weight readings before needing to upload the data to the PC. All data were sent via the PC to a central secure database managed by an industry standard commercial infrastructure supplier and held in accordance with the UK Data Protection Act and all relevant regulations. The integration of the PA monitor, weighing scales, and PC permitted direct acquisition of data from the wearer via the Internet throughout the study.

Outcome Measures and Statistical Considerations

The primary outcome of the study was the assessment of use of the Web-based and monitoring device–based PA and weight management program in this range of employees and the relationship between program use and the secondary outcome measures. Use of the program is defined by nonusage attrition data (Is the subject continuing to use the program?), as discussed by Eysenbach [27], and by the level of engagement (How much is the subject using the program?) assessed through website log-in frequency and log-in duration. The duration of time spent on the website at each log-in was recorded from the time of log-in to the last "click" interaction on the website and did not include dormant time between this last click and the automatic log-out function.

Sample size was more than 200 employees in order to improve the accuracy of the confidence intervals around the expected level of engagement (eg, if 80% are engaged in a study size of 200, the confidence interval is 74-85, while reducing the study size to 100 would widen this confidence interval to 71-87). Allocation of each subject to a program mode (weight loss, weight maintenance, PA, or browse) for data analysis was completed by assessing the number of weeks spent in each mode then allocating the participant to the mode in which he or she had spent the greatest number of weeks. Statistical comparison between the program modes was not undertaken as participants were not randomized to modes and could switch between these modes at any time during the study period.

Secondary outcome measures included baseline characteristics (BMI, health profile, age, gender), weight (data captured from Bluetooth weighing scales), PA level (time spent in moderate and vigorous activity measured via the triaxial accelerometer throughout the 12 weeks), BP, resting heart rate, and sleep quality and quantity (Pittsburgh Sleep Quality Index, PSQI [28]). Weight change for each participant was calculated using the first recorded and the last recorded weight during the 12 weeks, with the last observation carried forward (LOCF). BP and resting heart rate were measured using a Bionet BM5 Vital Signs Monitor (BioNet Laboratories Asia Pte Ltd, Singapore).

The health profile data collected at screening (height, weight, BMI, gender, age, BP) were aggregated for each site and compared to health risk appraisal (HRA) data collected around

3 months earlier at the same sites. As the HRA had included a greater number of employees (n = 992), this was undertaken to test if the employees participating in the Web program were similar to the larger group of employees on the same site who attended the HRA.

At the end of the study, process evaluation questionnaires were sent to managers and occupational health (OH) staff at each site to determine the impact of the study at that site, and feedback questionnaires were sent to all participants. All employees were permitted to keep the hardware and software and, if they wished, could continue to use the program.

Analysis of variance (ANOVA) was used for comparison of baseline data (age, gender, systolic BP, diastolic BP, BMI, resting heart rate) between the sites. Fisher exact test was used to compare the nonusage attrition rates between the sites. The probability of attrition in the first 12 weeks was modeled using multivariate logistic regression with the baseline independent variables (age, gender, baseline systolic BP, baseline diastolic BP, baseline BMI, baseline resting heart rate) and the dependent outcome variables (weight change using LOCF, mean daily recorded minutes of MET 3+ PA, BP change at 12 weeks) with site as a covariate. The association between the total interaction time with the website during the 12 weeks and the baseline independent variables and dependent outcome variables as listed above was modeled using multivariate linear regression, again with site as a covariate. The log of the total interaction time was used to preserve normality assumptions of the model. HRA data were compared with the baseline characteristics of MiLife participants using the Kolmogorov-Smirnov test. Weight change (using LOCF) and BP change at the end of the 12-week study were analyzed using analysis of covariance (ANCOVA), with baseline included as a covariate. Multivariate logistic regression with site, age, and gender as covariates was used to examine the relationship between baseline BP and the probability of attendance at the 12-week BP measure. Data were analyzed using SAS version 9.1 (SAS Institute Inc, Cary, NC, USA).

Local Research Ethical Review Requirement

The study was approved by 2 independent research ethics committees, one in the North West and one in the South of England. All research was conducted in accordance with the Helsinki Declaration [29].

Results

Employee Baseline Characteristics

Of the 2302 employees at the work sites, 265 (12%) agreed to take part in the program. The numbers for each site and the characteristics of these participants are shown in Table 1. The mean age across the sites was 40.9 years (SD 8.1), and the mean BMI at the start of the program was 27.1 kg/m^2 (SD 4.8). Ethnicity was also recorded to determine appropriate risk of metabolic disease for a given waist circumference and BMI [30]. Of the 265 employees, 13 (5%) were Asian, 3 (1%) were Black, 244 (92%) were White, and the remaining 5 (2%) classified themselves as other or mixed.

Table 1. Baseline demographic data for participants at each site

	Office North	Factory North	Office South	Factory South	All Sites
Total number of eligible employees at work site, no.	852	252	705	493	2302
Volunteered for trial, no.	71	44	93	57	265
Percentage of employees that volunteered for trial, %	8	17	13	12	12
Referred to physician, %	32	47	40	49	41
Age (years), mean (SD)	39.5 (7.2)	43.4 (8.2)	39.1[a] (7.6)	43.7[b] (8.8)	40.9 (8.1)
Men, %	42	65	31	75	49
BMI (kg/m^2), mean (SD)	25.7[c] (4.0)	29.7 (5.6)	26.4[a] (4.4)	28.4 (4.7)	27.1 (4.8)
Systolic blood pressure (mmHg), mean (SD)	124 (14)	135[d] (13)	130 (16)	135[a] (16)	130 (16)
Diastolic blood pressure (mmHg), mean (SD)	81[e] (10)	87 (8)	87 (11)	91 (12)	86 (11)
Resting heart rate (beats/min), mean (SD)	67.5 (13.6)	73.7 (10.1)	75.2[d] (11.7)	73.1 (9.8)	72.4 (12)

[a]Significantly different to Factory North (at $P < .01$).

[b]Significantly different to both office sites (at $P < .01$).

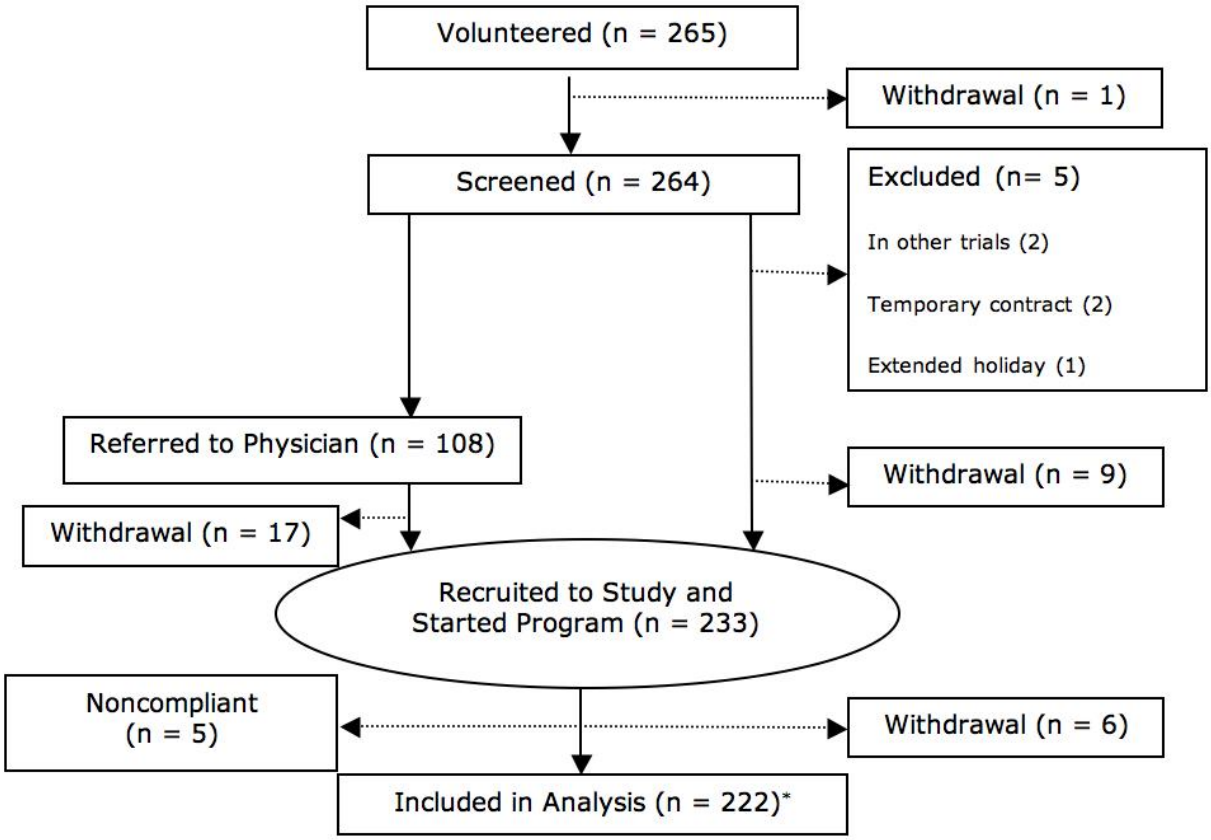
[c]Significantly different to both factory sites (at $P < .01$).

[d]Significantly different to Office North (at $P < .01$).

[e]Significantly different to all other sites (at $P < .01$).

Of the 265 participants who agreed to take part, 233 started the program (Figure 1); 32 participants were excluded or withdrew in the 3-month period between initial recruitment and program start for the following reasons: did not attend screening/training session (n = 5), ineligible employment status (not permanent or leaving employment, n = 8), illness (n = 1), extended holiday (n = 1), or no physician approval received (n = 17).

Figure 1. Flow chart of enrollment, withdrawal, and follow-up (*For LOCF analysis of weight change, the 5 subjects withdrawing after the program start were also included; noncompliant participants were not included in the weight LOCF analysis as no follow-up weight was recorded)



The office sites had a higher total number of employees compared to the factory sites, hence the larger number of participants from these office sites. There were significant differences between the sites at baseline for age, BMI, BP, and heart rate (*P*values for testing equivalence of the sites: age, $P = .009$; BMI, $P < .001$; systolic BP, $P = .004$; diastolic BP, $P = .001$; pulse, $P < .001$), with employees from the factory sites tending to be older and having higher baseline BMI and BP (see Table 1). BP medication was recorded at baseline and at the end of the 12-week study. The use of hypertensive medication was more prevalent in employees at the Factory North site at baseline (6/43, 14%) compared to the other sites combined (5/221, 2%); 3/264 (1%) screened participants started BP medication following the baseline screening.

We compared the baseline health profiles of the 264 employees participating in the MiLife Web program to HRA data collected previously from a larger group of employees at the same sites (n = 992 total). Employees who participated in the Web program were of a similar age as those attending the HRA but had a higher mean baseline BMI (HRA: 25.0 kg/m^2[SD 4.1]; MiLife: 27.1 kg/m^2[SD 4.8]; $P < .001$) and higher mean baseline diastolic BP (HRA: 78.9 mmHg [SD 10.0]; MiLife: 86.0 mmHg [SD 11.0]; $P < .001$). The difference in BMI between the two populations was most noticeable at the factory sites: the mean BMI for Factory North HRA was 26.6 kg/m^2(SD 4.2, n = 174) compared to 29.7 kg/m^{2}for Factory North MiLife (SD 5.6; $P < .001$), and the mean BMI for Factory South HRA was 26.1 kg/m^2(SD 4.2, n = 122), compared to 28.4 kg/m^{2}for Factory South MiLife (SD 4.7; $P < .001$).

Website Use

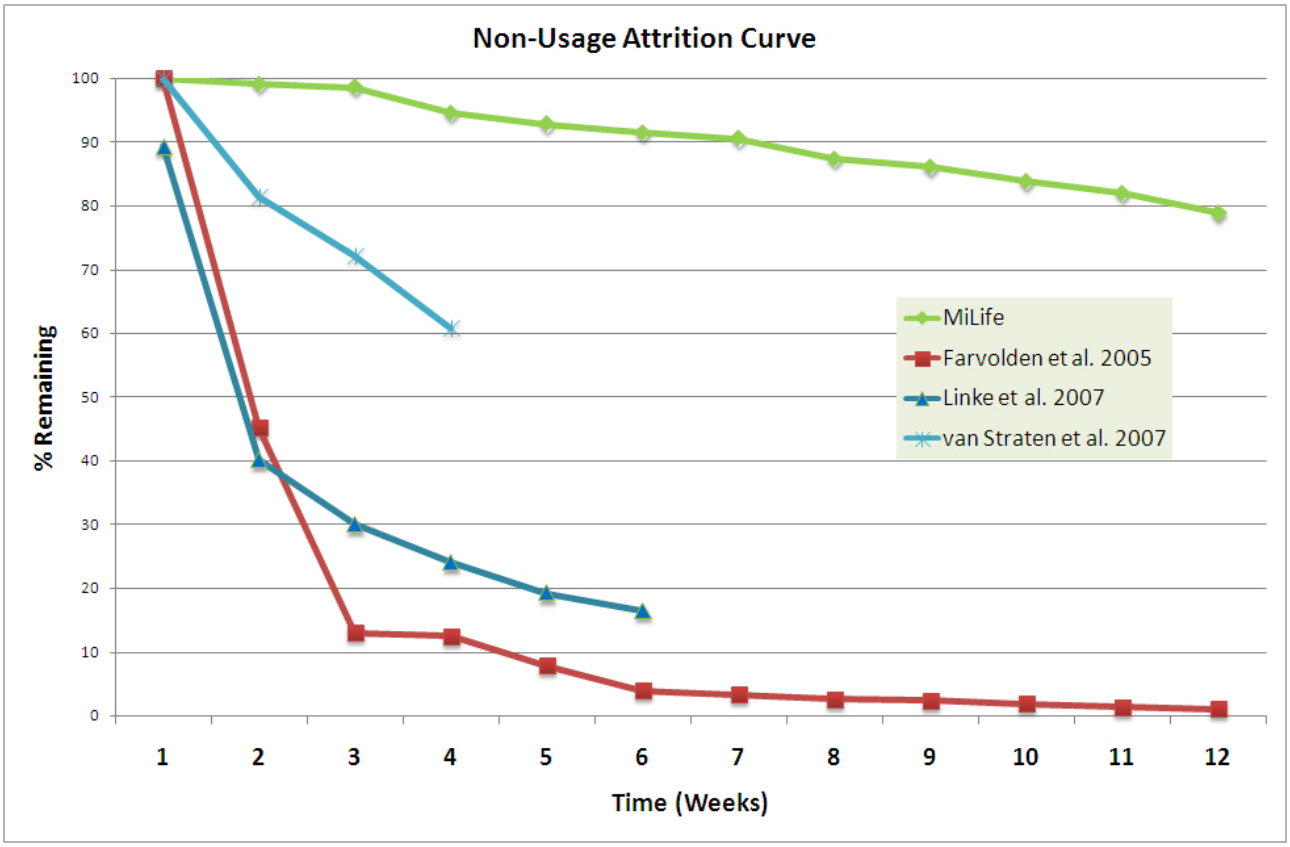
Of the 233 participants starting the program, 6 withdrew and 5 were noncompliant (no data upload or log-in throughout the 12-week period). In the remaining 222 subjects, website use remained high, with 78% (173/222) of the participants still using the website at the end of the 12-week study and 69% (153/222) continuing to use the website after the 12 weeks (Table 2).

Table 2. Employee website use during and following the 12-week study, by work site

	Office North	Factory North	Office South	Factory South	All Sites
Starting program, no.	67	37	79	50	233
Withdrawal during 12 weeks, no.	1	0	3	2	6
Noncompliance, no.	0	1	1	3	5
Website users at week 1, no.	66	36	75	45	222
Website users at week 12, no.	50	19	72	32	173
Website users at week 12, %	76	53	96	71	78
Website use following the 12 weeks, no.	44	14	67	28	153
Website use following the 12 weeks, %	67	39	89	62	69

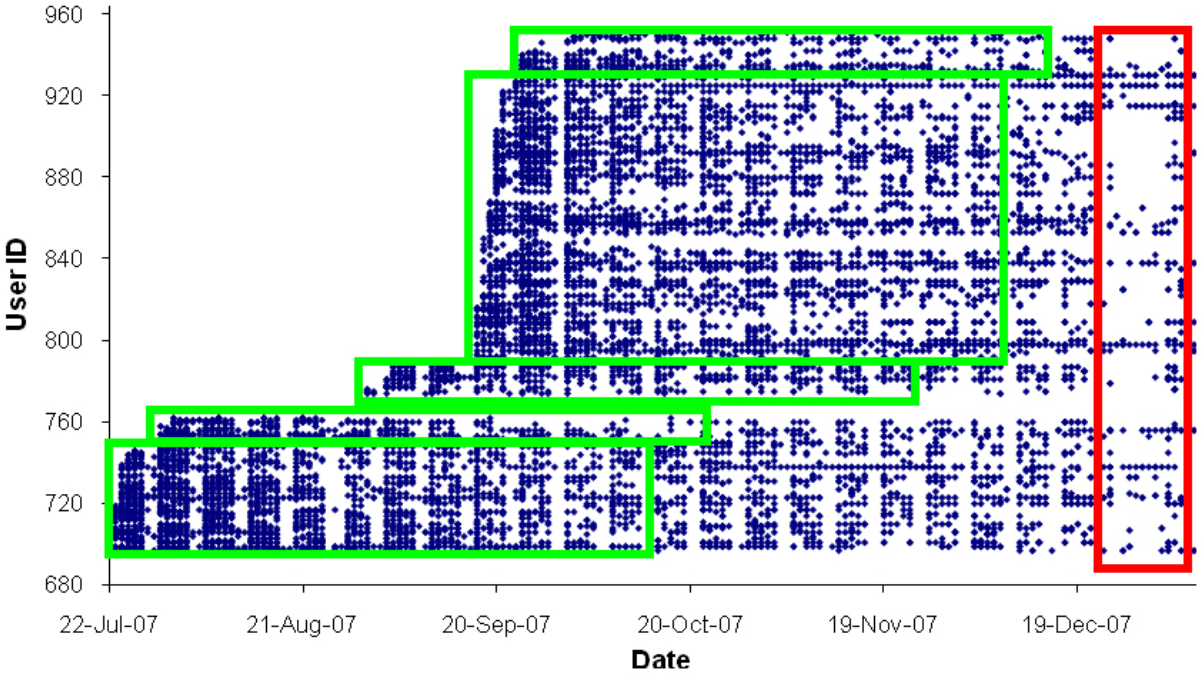
Nonusage attrition data (the proportion of participants who stopped using the program and the proportion who remain) are presented in Figure 2 in comparison to reported nonusage attrition data from other Internet eHealth interventions [31-33]. Nonusage attrition rates were significantly different between the sites, with the highest use at Office South (72/75 using the Web program at 12 weeks) and the lowest use at Factory North (19/36 using the Web program at 12 weeks; $P< .001$). There was no difference in nonusage attrition rates between Factory South and Office North. Logistic regression including the baseline independent variables with site as a covariate showed that nonusage attrition was lower in both Factory North and Factory South as age increased (OR 1.07, $P= .03$). To illustrate this, 30/58 (52%) of participants 48 years old and under were using the program at 12 weeks, compared to 21/23 (91%) of participants over 48 years old. Inclusion of the dependent outcome variables in this model showed that age was no longer significant but that nonusage attrition was lower in those subjects with a greater weight change over the 12-week period, independent of site (OR 1.38, $P= .03$).

Figure 2. Nonusage attrition curves [27] for MiLife and Farvolden et al [31], Linke et al [32], and van Straten et al [33] eHealth interventions



Log-in data are shown in Figure 3). Spaces between weeks can be clearly seen, indicating that most participants were using the website on weekdays and not weekends, with 7381 (92%) of the 8067 log-ins recorded during the 12-week study occurring between Monday and Friday. Data recorded over the Christmas holiday period also suggest that most users did not use the program on non-workdays, although 69 (31%) of the 222 website users did log-in to the program at least once during this 2-week break. Continued use of the program outside of the study period can also be seen on this graph.

Figure 3. Participant's log-in data throughout and following the study period (Each dot represents a user's visit and log-in to the website. Green boxes are the website visits recorded during the 12-week study period. Data within the red box were recorded over the 2-week Christmas holiday period when the work sites were closed.)



During the first 2 weeks of the study, participants were spending more time on the website per log-in compared to the subsequent weeks (mean week 1: 11.6 minutes; mean week 2: 8.6 minutes; Figure 4). After this initial period, the mean time per website log-in (weeks 3-12) was approximately 7 minutes. The total website interaction time per week was also collected for each user. As both the frequency of use and the time per visit dropped with ongoing program use, the total interaction time with the website (Figure 5) was higher in the first 4 weeks, dropping to a mean value between 10 and 20 minutes per week for the remainder of the study. Multivariate linear regression showed that the log total interaction time over the 12 weeks was higher in participants with the greatest weight loss (slope = .082; $P<$ .001). To illustrate the magnitude of this slope (mean log duration 2.472), each additional kilogram of weight loss was approximately equivalent to an extra hour of program use over the 12-week period. Gender was also associated with total interaction time over the 12 weeks, with women spending, on average, 200 more minutes interacting with the Web program over the 12-week period ($P=$ .002).

Figure 4. Mean website log-in duration and frequency throughout the study period (Data points are means with standard error and are presented for all employees as there was no significant difference between the sites based on ANOVA.)

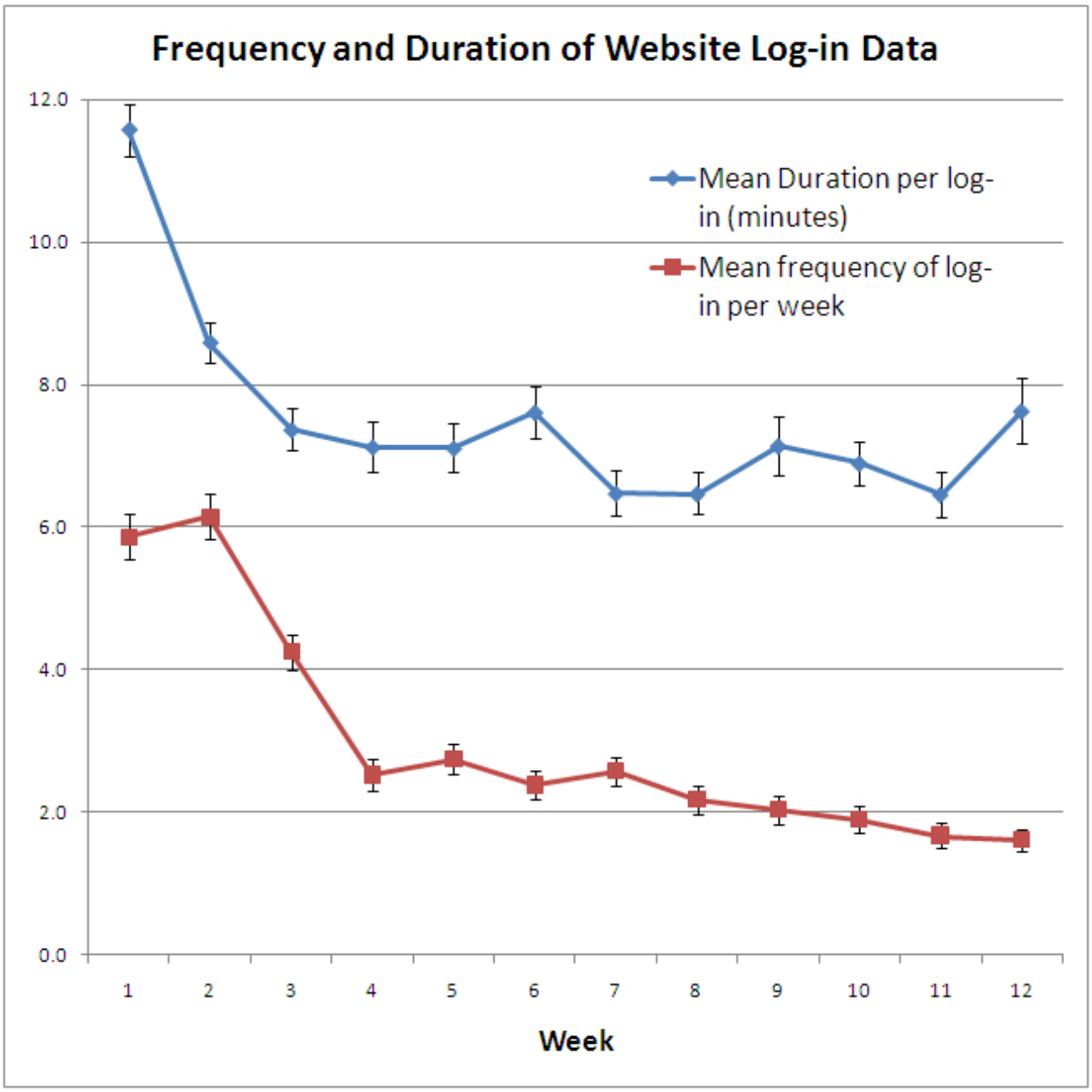
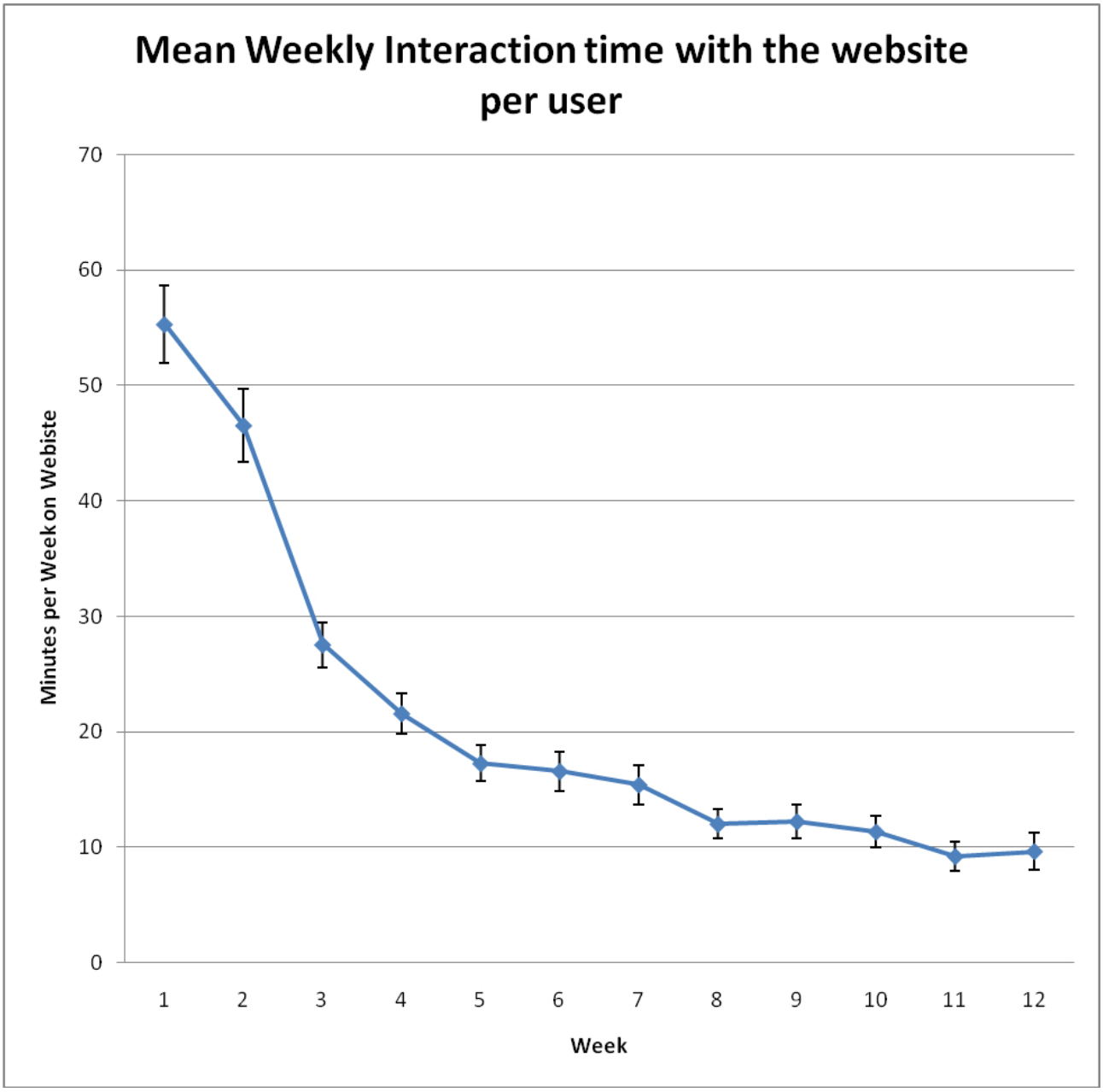


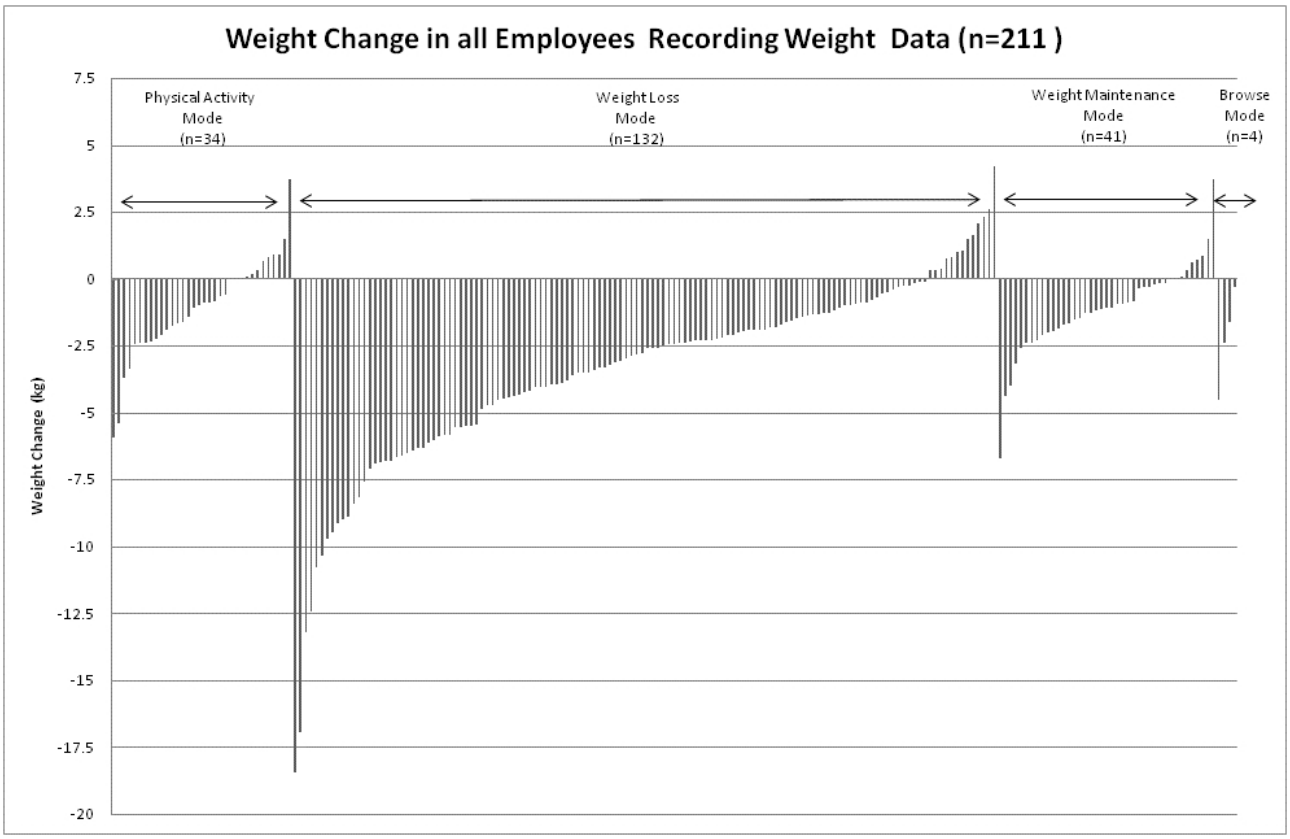
Figure 5. Mean interaction time with the website throughout the study period (Data points are means with standard error and are presented for all employees as there was no significant difference between the sites based on ANOVA.)



Weight Data

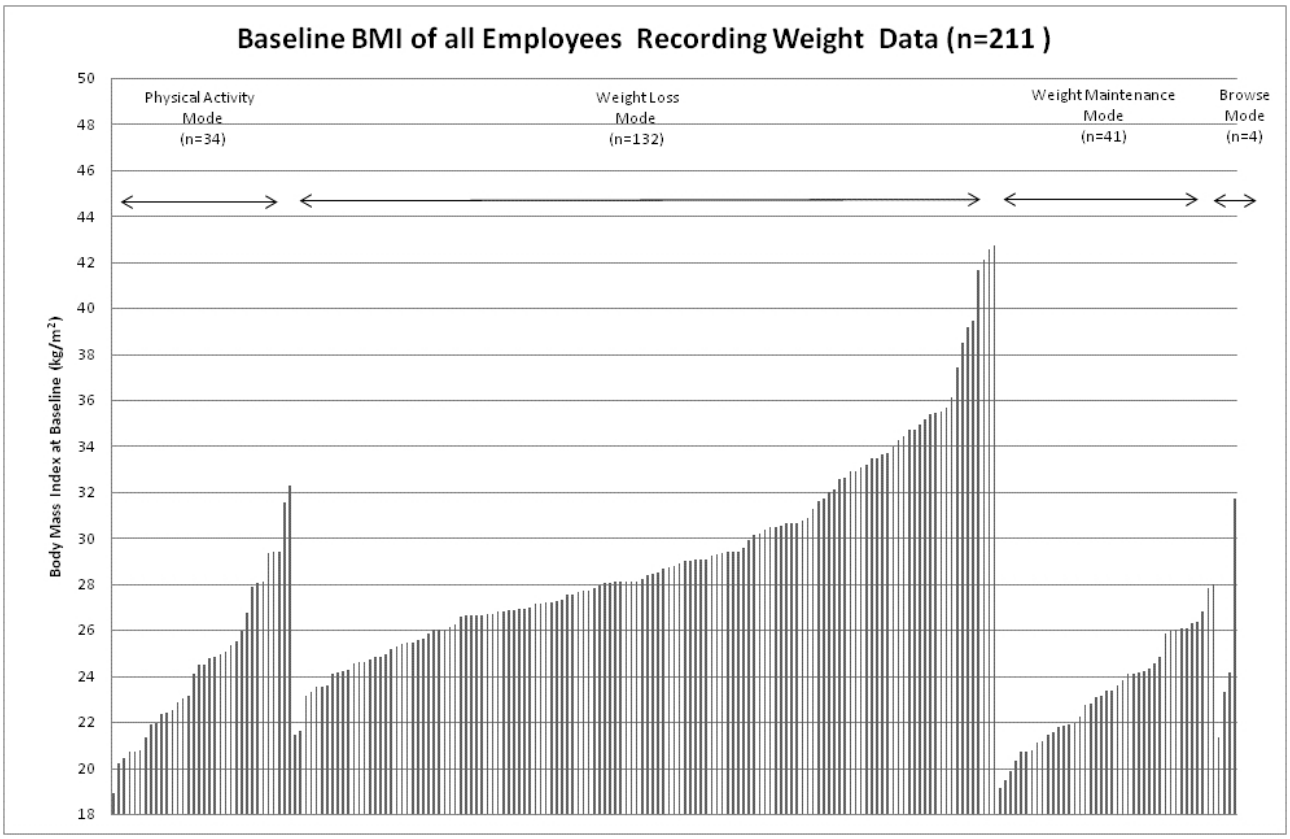
Of the 228 employees using the program (222 starting the program plus 6 withdrawals during the 12-week study), 211 (93%) uploaded weight data that could be used to determine weight change during the study period using the LOCF. The mean weight change in this group was −2.6 kg (SD 3.2; $P<$ .001; Figure 6).

Figure 6. Weight change from baseline using the LOCF and the mode in which the most time was spent for each employee uploading weight data during the 12-week program



Mean weight loss was higher in those employees who spent most of the 12-week period in the weight loss mode (132/212, 63%; mean weight change −3.5 kg, SD 3.6). No statistical comparison was conducted between modes since subjects could switch modes during the study period. There was no significant difference in weight change between the sites, but there was a significant inverse association between baseline BMI and the amount of weight lost over the 12-week period (−0.284, $P <$ .001), indicating that employees with a higher starting BMI, on average, had greater weight loss during the study period. Figure 7 shows the baseline BMI distribution in each of the modes, suggesting that subjects with a higher baseline BMI spent most of their time during the 12-week study in the weight loss mode.

Figure 7. Baseline BMI and mode in which the most time was spent for each employee uploading weight data during the 12-week program



Physical Activity (PA) Data

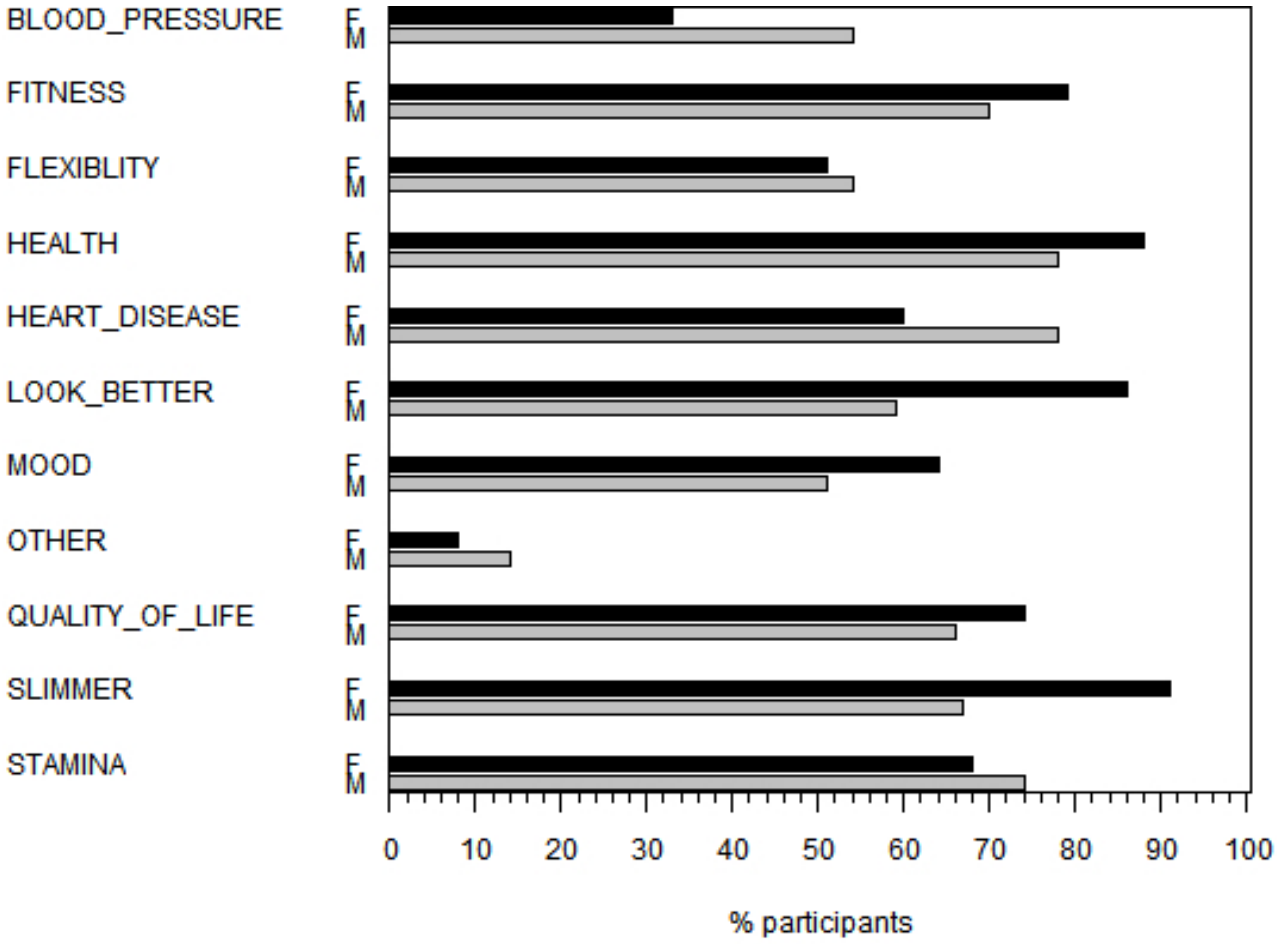
The accelerometer-recorded levels of PA were highly variable between individuals in the group, with values ranging from 12 to 714 minutes of moderate or above PA per person per week. The average recorded level for the group was 173 minutes (SE 12.8) of moderate or above PA per week.

Choice of Goals

At all sites, weight loss was the most popular mode. Of the 228 website users (including those who withdrew during the 12-week study), 138 (61%) spent the most time in weight loss mode, 46 (20%) spent the most time in weight maintenance mode, 39 (17%) spent the most time in the PA only mode, and 4 (2%) spent the most time in the nonactive browse mode of monitoring without goal and target setting.

At the start of the program, each participant was asked to select one or more goals that he or she would most want from a list on the website. Research has shown that people with a strongly desirable goal are more likely to enact their intentions to perform a health behavior [34]. The list consisted of the following goals: improve fitness, increase flexibility, improve health, reduce risk of heart disease, reduce blood pressure, look better, improve mood, improve quality of life, feel slimmer, improve stamina, other. Figure 8 shows the frequency of selection of these items by gender. The most frequently chosen goals for men were “health” and “heart disease,” while the most frequently chosen goal for women was “feel slimmer.” Men were more likely than women to select “heart disease” and “blood pressure” as reasons for participating, while women were more likely to select “look better” and “feel slimmer.”

Figure 8. Frequency of choice of the listed goals prior to beginning the 12-week Web program (F = women, M = men)



Blood Pressure Data

At the 12-week BP assessment, some employees at each site were lost to follow-up (Office South, 28%; Office North, 35%; Factory South, 35%; Factory North, 51%). Logistic regression with site, age, and gender as covariates showed that participants with a higher baseline BP were more likely to attend the follow-up (P= .047).

The high level of participants lost to follow-up was possibly influenced by the proximity of these measures to the Christmas holiday period. As a result, data have been aggregated for all employees who returned for a 12-week BP measure (n = 135, excluding those on hypertensive medication). The mean baseline BP in this group was 129/86 mmHg (SD 15/10, range 94/64 to 181/119), and the mean 12-week BP was 128/80 mmHg (SD 15/10, range 95/59 to 164/100). There was a significant reduction in diastolic BP (−5.9 mmHg, SD 9.9;P< .001).

Sleep Data

Data from the Pittsburgh Sleep Quality Index (PSQI) questionnaire collected at baseline and 12 weeks (n = 93 completed) suggested an increase in sleep quality overall, corresponding to a decrease in the global PSQI score (P = .004). This was particularly evident in the following PSQI components: self-assessed overall sleep quality (P < .001), hours of actual sleep achieved (P = .01), ease of both maintaining attention and/or enthusiasm for everyday tasks (P = .006).

Program Evaluations

Data collected from the exit questionnaires (n = 130) showed that 101 employees (78%) found the website very easy to use, with the most useful tools listed as those providing PA analysis, planning, and information. Many employees liked wearing the PA monitor and found that having it on served as a constant reminder to keep to the program. The site was seen as informative, motivating, and helpful. The PA and weight charts were thought particularly helpful as they enabled participants to monitor their progress and played an important role in providing feedback and motivation. The low response rate (130/222 website users, 59%) to the exit questionnaire may have been influenced by the proximity to the holiday period.

The OH staff at the work sites who responded to the survey (n = 6) agreed that “the study had been a supportive program in the company objective”of vitalizing employee health. Several of the OH staff commented that the study had been a positive initiative that participants had found enjoyable and rewarding and which should be encouraged. Employee participation in the program resulted in some extra work for OH staff in answering participants queries, although OH staff were generally happy with the resources they had received from the study team to support participants.

Feedback from managers at the work sites (n = 6) was overall very positive, and managers received positive feedback from participants. Managers noted that the study appeared to have

been beneficial in the workplace, and participation may even have led to increased job satisfaction in some instances. Managers were also in agreement that they would encourage future staff participation in the Web program and would recommend participation in the program to other sites.

Discussion

Principal Results

The study was designed to test the level of Web program engagement over a 12-week period for a wide range of employees recruited at four work sites in the United Kingdom. Work sites were chosen that were geographically and demographically different in order to evaluate if engagement and outcomes varied by location, baseline demographic and health measures, or level of interaction with computers during work hours.

This study showed that a Web-based PA and weight management program designed to include components known to be effective (a structured approach to modifying energy balance, the use of cognitive-behavioral strategies such as self-monitoring, and individualized feedback and support [3]) was appealing to employees at both office and manufacturing sites. The combination of the automated Web-based coaching program with monitoring devices to record PA level and weight data produced high levels of engagement with the program both during and following the initial 3-month period. Health improvements were also observed, as indicated by changes in body weight, BMI, blood pressure, and sleep. The program appealed equally to both men and women, and shift work was not a barrier to participation.

A key difference in this study compared with our previous studies [4,5] was that participants received no payment for taking part in this study. The 12% employee participation rate is similar to the 10% employee participation rate reported in another Web-based workplace program [35]; however, in that study, employees were offered financial incentives to take part.

Also, rather than an RCT, the current study was conducted in a more naturalistic setting in which a branded commercial program (MiLife) was offered to employees as a benefit in collaboration with their company's OH professionals. One limitation of this approach was the lack of a control group. Subsequent use of the program in an employee wellness setting may provide the opportunity to test engagement with the program against alternative weight management and PA initiatives available to those employees. This would build on the insights generated in this research by using an RCT efficacy design and allowing a full intent-to-treat and per protocol statistical analysis.

Participant Characteristics

Employees who participated in the Web program had a higher average diastolic BP and BMI compared to employees previously taking part in an HRA at the same site. This was most noticeable at the factory sites. This does not mean that the Web program enrolled all high-risk individuals, as not all employees take part in HRAs [36], but it does indicate that the program attracted those employees who would benefit most from PA and weight management. This can also be seen from the number of employees (41%) failing the PAR-Q or the number with hypertension who needed physician approval prior to starting the Web program. The number of withdrawals in this physician-referred group (17/108) was higher than that in the non-referred group (9/151). However, we did not collect data on whether it was the referral process itself that was responsible for this. Future studies that collect more information on physician referrals and uptake of employee programs following the referral would be very useful in determining the effect of referrals on wellness programs.

Further comparison of the baseline demographic data in this adult employee population with the profiles of participants using a Dutch Web-based health promotion program available to the Dutch general public at no cost [37] suggests that the MiLife program recruited a higher proportion of males and participants with a higher average BMI (27.1 kg/m^2). Both programs were Web-based PA and weight management programs, although it is unclear if the difference in the user profiles was due to differences in the programs or to the populations targeted by the interventions. The Dutch Web-based program did conclude that obese people were more likely to participate in Web-based programs, possibly because of the non-stigmatizing way of addressing body weight through the Internet.

Engagement

Nonusage attrition rates were much lower with MiLife than with other Web-based eHealth interventions that have reported this data [31-33]. This may be due to the combination of monitoring devices with the Web program. The inclusion of weight management may also be a driver for continued participation [37]. A weight management Web-based program reporting similar levels of engagement is one described by Stevens et al [38] for weight loss maintenance, which required users to log-in once a month. While the MiLife program has more interaction time with the participant through the data upload and self-monitoring process, both programs share the common feature of automated email reminders to the participants to log-in. Attrition was higher in the Factory North site, and it is possible that the weekly email reminders were less effective here, although attrition in the Factory South site was not different than at the office sites. Use of personalized mail may further enhance engagement with Web-based eHealth interventions [39], especially where PC access may be limited during working hours. The higher levels of nonusage attrition observed in Factory North may also have influenced the higher loss to follow-up for the 12-week BP measure at this site [27]. This reinforces the value of early intervention, if, for example, the number of log-ins or the frequency of data upload declines, to reduce attrition rates.

Recent reviews including more than 50 studies of Internet-based programs for PA and dietary behavior change [40,41] showed that only 6 programs incorporated an objective PA monitoring device. Three of these studies used accelerometers [42-44], and 3 used pedometers [45-47].

Norman et al [41] highlight in their review that an issue for eHealth interventions is getting participants to use the interactive

technology often enough to receive an optimal dose of the intervention and that where utilization and dose are higher, better behavior change is observed. They also discuss how, by assessing smaller milestones more frequently, the technology can automatically create slightly more challenging goals to enhance the likelihood of achieving longer term behavior change goals. We did observe in this study that data capture from the monitoring devices (weight and PA) was significantly greater than data capture from the user, who was required to input data manually into the website and self-report (eg, calorie consumption).

Reinforcement and positive feedback are also an important part of the program, and the PA and weight graphs and charts were the most liked part of the program by users. Where positive feedback is not received for effort, users may be less likely to engage with the program. In a pedometer-based walking program, those users who did not receive positive feedback for all of their effort were 5 times more likely to fail to wear the pedometer compared with a group for whom total effort was recognized [48].

Therefore, in this program, the use of simple monitoring devices to continuously record PA data and weight data combined with automated data upload to the website and positive feedback may have had a number of effects. It is likely that this approach influenced the high levels of data capture, the utilization and engagement rates observed, and also the likelihood of achieving the behavior change. The combination of monitoring devices with a Web-based program is not without challenges, and we did experience some initial hardware reliability issues. This was anticipated to an extent, and part of the study design was to test the robustness of the hardware in such a large group of subjects. While replacement devices were issued to any employee experiencing technical problems, feedback from the exit questionnaires indicated that hardware problems did influence the user experience for some participants. However, Web program use remained high in these employees.

Analysis of the mean interaction time with the website suggests that there was a learning period in the first few weeks, with users spending more time on the website, finding the tools, and navigating the site. Typically by the fourth week of the program, subjects were interacting with the website for 10-20 minutes per week, and the total time spent on the website over the 12 weeks was associated with the amount of weight lost.

The time spent on the website per week is similar to our previously reported work [5], in which subjects were found to interact with the program for an average of 10-12 minutes per week compared to an average of 55 minutes in the first week. The log-in data clearly show that many employees were using the website during the week but less so during weekends, possibly indicating that much of the website interaction time was during their working day. Data from the WebSense 2006 Web@Work Survey [49] suggest that 61% of employees who utilize a work-owned Internet connection spend, on average, 3 hours per week surfing non-work-related websites during the workday. While the effect of this on the company is unclear, there is a clear benefit to the individual and to the company of 10-20 minutes per week of Internet use for improved employee health. Positive effects on weight, PA level, BP, and sleep were observed in this study. Further studies are planned to investigate these outcomes in a randomized controlled study and over a longer period of time.

Conclusions

This study suggests that the MiLife Web-based program designed to support PA and weight management and utilizing simple monitoring devices for weight and PA can be successfully deployed in both office and manufacturing sites. The program received positive feedback from both OH staff and managers at each site. Most importantly, the program appealed to and engaged those employees who would most benefit from changes in PA and weight management, with many employees enjoying the experience, improving their health parameters, and returning to follow a second 3-month program with no financial incentive.

Acknowledgments

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Conflicts of Interest

MiLife Coaching Ltd is a subsidiary company of Unilever.

Multimedia Appendix

Image of the interactive website and of the monitoring devices

[PPT file (Microsoft Powerpoint File), 644 KB - jmir_v10i4e56_app.ppt]

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Abbreviations

BMI: body mass index
BP: blood pressure
HRA: health risk appraisal
LOCF: last observation carried forward
MET: metabolic equivalent
OH: occupational health
PA: physical activity
PAR-Q: Physical Activity Readiness Questionnaire
PC: personal computer
PSQI: Pittsburgh Sleep Quality Index
RCT: randomized controlled trial

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Original Paper

Weight, Blood Pressure, and Dietary Benefits After 12 Months of a Web-based Nutrition Education Program (DASH for Health): Longitudinal Observational Study

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Abstract

Background: The dietary habits of Americans are creating serious health concerns, including obesity, hypertension, diabetes, cardiovascular disease, and even some types of cancer. While considerable attention has been focused on calorie reduction and weight loss, approaches are needed that will not only help the population reduce calorie intake but also consume the type of healthy, well-balanced diet that would prevent this array of medical complications.

Objective: To design an Internet-based nutrition education program and to explore its effect on weight, blood pressure, and eating habits after 12 months of participation.

Methods: We designed the DASH for Health program to provide weekly articles about healthy nutrition via the Internet. Dietary advice was based on the DASH diet (Dietary Approaches to Stop Hypertension). The program was offered as a free benefit to the employees of EMC Corporation, and 2834 employees and spouses enrolled. Enrollees voluntarily entered information about themselves on the website (food intake), and we used these self-entered data to determine if the program had any effect. Analyses were based upon the change in weight, blood pressure, and food intake between the baseline period (before the DASH program began) and the 12th month. To be included in an outcome, a subject had to have provided both a baseline and 12th-month entry.

Results: After 12 months, 735 of 2834 original enrollees (26%) were still actively using the program. For subjects who were overweight/obese (body mass index > 25; n = 151), weight change at 12 months was -4.2 lbs (95% CI: -2.2, -6.2; $P < .001$). For subjects with hypertension or prehypertension at baseline (n = 62), systolic blood pressure fell 6.8 mmHg at 12 months (CI: -2.6, -11.0; $P < .001$; n = 62). Diastolic pressure fell 2.1 mmHg ($P = .16$). Based upon self-entered food surveys, enrollees (n = 181) at 12 months were eating significantly more fruits, more vegetables, and fewer grain products. They also reduced consumption of carbonated beverages. Enrollees who had visited the website more often tended to have greater blood pressure and weight loss effect, suggesting that use of the DASH for Health program was at least partially responsible for the benefits we observed.

Conclusions: We have found that continued use of a nutrition education program delivered totally via the Internet, with no person-to-person contact with health professionals, is associated with significant weight loss, blood pressure lowering, and dietary improvements after 12 months. Effective programs like DASH for Health, delivered via the Internet, can provide benefit to large numbers of subjects at low cost and may help address the nutritional public health crisis.

(J Med Internet Res 2008;10(4):e52) doi:10.2196/jmir.1114

KEYWORDS

Weight loss; blood pressure; hypertension; health education; diet; Internet; behavior change

Introduction

The dietary habits of Americans are creating serious health concerns. The "obesity epidemic" is the most publicized evidence of the problem, but it is only one aspect. Studies have suggested that better dietary habits can, even with only modest weight loss, prevent or help control a number of expensive, chronic conditions like hypertension, cardiovascular disease, diabetes, and even some types of cancer [1-5].

There is a growing need for effective ways to improve Americans' eating habits, but it is difficult to change dietary habits and maintain those changes. Weight loss studies have shown short-term success but gradual regain of weight in the longer term [6]. New approaches are needed that can achieve long-term success at low cost. One promising approach is the use of the Internet. Web-based programs can be developed and delivered to large segments of the population relatively inexpensively. There is some evidence that use of these programs can lead to short-term weight loss [7], but there is little evidence that they are effective "wellness" programs, achieving not just weight loss but other health benefits as well.

We designed a Web-based program, DASH for Health, to improve nutrition and physical activity habits. The nutrition advice was based on the DASH Diet (Dietary Approaches to Stop Hypertension) [1]. Although the DASH Diet was originally developed to prevent or treat high blood pressure, it is essentially a well-balanced diet that is now recommended by the USDA Dietary Guidelines for Americans, 2005 as being an ideal eating pattern for all American adults [8]. The DASH Diet also has the support of the NHLBI. The DASH for Health program was developed to improve eating habits in the general population, not just to treat overweight and obesity. The goal of this study was to explore the effects of the DASH for Health program over the course of one year in 2834 enrollees.

Methods

Research Subjects

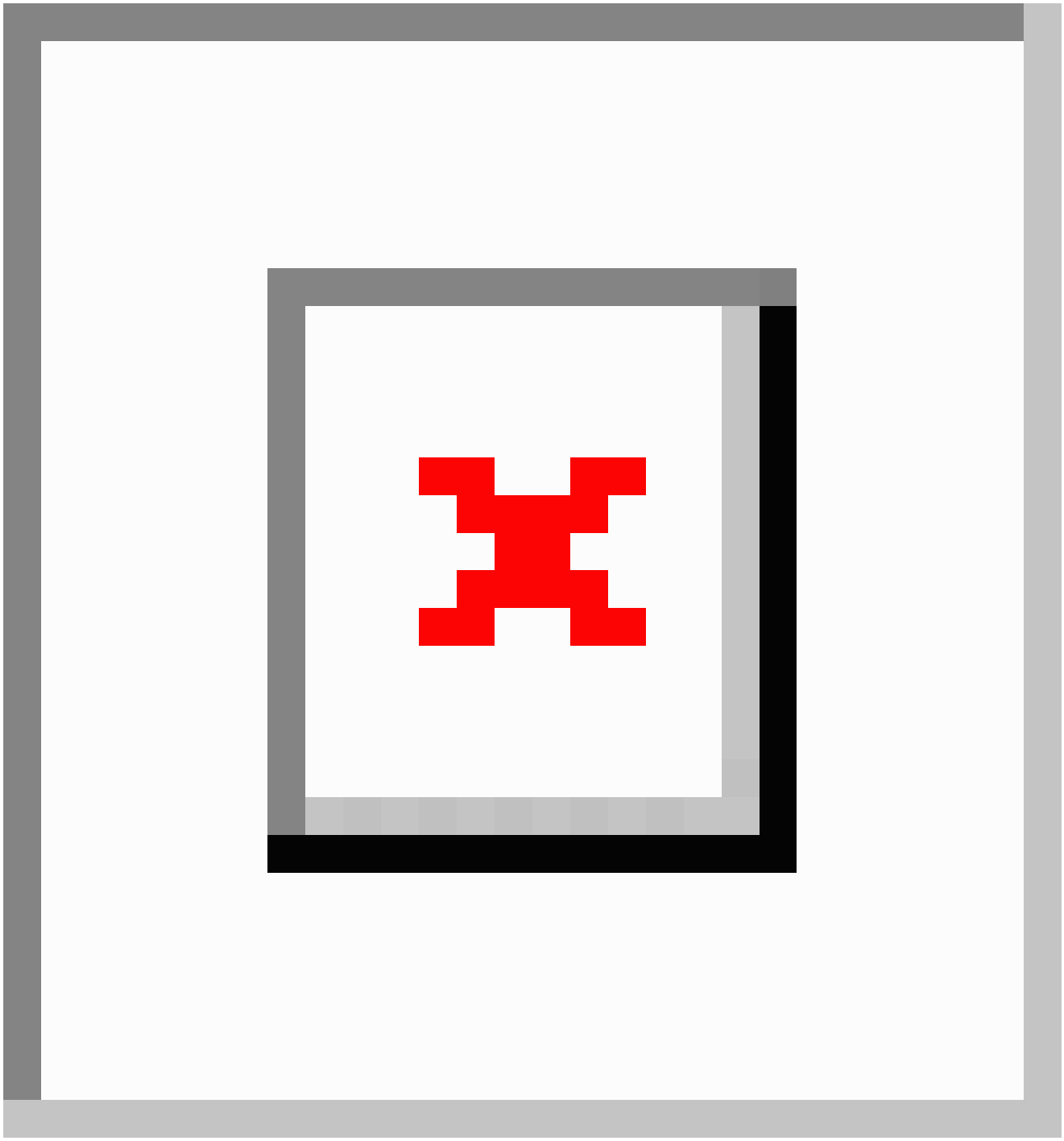
The DASH for Health program was offered as a free employee benefit to all US-based employees (approximately 12,500) of EMC Corporation, a global information infrastructure company based in Hopkinton, Massachusetts. The program was also offered to all adult household members of these employees. Employees and household members were encouraged to join the online program through a series of email communications from EMC leaders. During a three-week open enrollment period, 3479 subjects enrolled in the program and logged on to the website at least once. At the time of enrollment, we asked enrollees if we could use information that they entered about themselves on the website (eg, weight, blood pressure (BP) levels, food intake) to determine whether the program was providing benefit. This report is based upon the 2834 enrollees (81%) who granted consent.

The project was approved by the Institutional Review Board of Boston University Medical Center.

The DASH for Health Program

Enrollees were given access to a personalized, password-protected website. Figure 1 displays a view of the program's homepage as designed for the EMC audience. Through that website, we published new articles once a week. The articles contained information about elements of healthy nutrition. About 15% of the articles also dealt with healthy exercise practices. A sub-article each week addressed specific issues to promote weight loss. Articles were typically published every Friday and a reminder email was sent to each enrollee at the time a new article was posted on the website. The emails contained a brief description of that week's article and a hyperlink to the log-in website. Nutrition advice was based on the DASH Diet, meaning that we instructed people about consuming various servings of the eight DASH food groups (fruits, vegetables, low-fat dairy, meat/fish/poultry, grains, nuts/legumes, sweets, and added fats). The articles were not targeted to specific subsets of the enrollee population. All enrollees received the same articles.

Figure 1. A view of the program's homepage as designed for EMC Corporation employees



Based on an enrollee's gender, age, and activity pattern, algorithms on the website calculated the number of servings of each DASH food group the enrollee should consume each day. Enrollees were encouraged to enter information about themselves on the website such as weight, blood pressure, and 24-hour food recall using a recall instrument which converted common foods into servings of DASH food groups. This DASH recall instrument was designed for this program and was validated against the Block 98.2 Food Frequency Questionnaire (data not shown). The website converted those self-entered data into progress report graphs. Although enrollees had the option of submitting email questions for the investigators to respond to, we designed the program to provide minimal personal contact. The goal was to develop a program which, with only minimal person-to-person interaction, could influence behaviors.

We did not impose any limits or expectations on how enrollees used the website. They were free to select for themselves which articles to read and how frequently to enter information about their weight, blood pressure, or eating habits.

Outcome Measures

We had three primary outcomes, all measured at 12 months: first, change in weight between baseline and 12 months in subjects who indicated a desire to lose weight on their enrollment questionnaire; second, change in systolic blood pressure (SBP) in those who indicated that they either had high blood pressure or were on blood pressure medications or had

been told to watch blood pressure (we defined this as our "High Blood Pressure" group); and third, change in consumption of DASH food groups. Change in diastolic blood pressure (DBP) was a secondary outcome. We also performed exploratory analyses of the relationship between our outcomes and the amount of use of the DASH for Health website.

For weight measurement, we used self-entered weights from the website which may have included weights taken by the subjects themselves or taken in other settings (eg, physician visits). We classified subjects as overweight/obese based on their body mass index (BMI; kg/m^2). Similarly for blood pressure, we used self-entered readings which could have been self-measurements or readings taken by others. We did provide recommendations on the website about how to take one's own blood pressure (seated, left arm, average of two measurements). In addition, the employer, EMC Corp., offered free automated sphygmomanometers (Fore-Care 6400; Forecare Inc., Buffalo Grove, IL) to enrollees with hypertension. Food consumption was estimated from the DASH Online Questionnaire, a 24-hour recall instrument. For weight, blood pressure, and food intake, if there were more than a single entry during the baseline or 12th-month time window, we averaged the entries and used that single value in our analyses. Website use was calculated as the number of log-ons by each enrollee who visited the website (unique users).

Data Analysis

For our analyses, we used the data that enrollees self-entered on the website. There was no randomization and no control group. Our analyses do not allow estimation of what the effects of DASH for Health might have been on enrollees who did not enter any data. The baseline data reflect information that enrollees entered on the DASH for Health website during the three-week enrollment period (before the website was delivering any behavior-changing messages), and the "12th-month" data are those entered during weeks 48-52. The number of subjects analyzed for each outcome was determined by the number of subjects who entered data for that outcome during both the baseline and 12th-month time frame. In analyzing website use, we used the number of log-ins over 12 months. Data are displayed as means unless otherwise noted, and indices of dispersion are standard deviation (SD) or 95% confidence intervals (CI) as noted. All analyses were performed with SigmaStat 3.5. Baseline versus 12th-month comparisons were performed with paired *t*-tests or Wilcoxon signed rank tests. Statistically significant results had *P* values less than .05.

Results

Subjects

Enrollees were widely distributed geographically, residing in 41 states. They were approximately evenly distributed by gender, and their ages ranged from 18-73 years (average 40.7 years). They were highly educated, with 1845 (66%) having completed college or postgraduate work. Of the subjects, 88% were white, and 74% were married (see Table 1 for absolute numbers of subjects). The most commonly stated reasons for enrolling in DASH for Health were desires for general health information and weight loss. Approximately 25% were also concerned about blood pressure or cholesterol levels. Other demographic details are shown in Table 1.

Of the 3479 subjects who enrolled in the program and logged on to the website at least once, 2834 (81%) granted consent to use their data for research purposes. Of these, 735 (26%) were still actively using the website in the 12th month. Their demographics are also shown in Table 1. The groups were comparable except that subjects in the 12-month group were older, included a greater percentage of women, had fewer single and more widowed subjects, and had a greater percentage who were interested in "general health information" at the time of enrollment.

Table 1. Characteristics of all enrollees at baseline and of those still using the program at 12 months, using self-entered data at time of enrollment

	All Enrollees n (%)	Still Active at 12 Months n (%)	*P* Values
All enrollees	2834	735	
Males	1568 (55%)	369 (50%)	.01
Females	1266 (45%)	366 (50%)	.01
Average Age (years)	40.7	42.2	.001
Average Weight (lbs)	182.7	179.8	.11
Education-lowest level achieved			
Grade School	34 (1%)	5 (< 1%)	.23
Some High School	10 (< 1%)	1 (< 1%)	.34
Completed High School	171 (6%)	35 (5%)	.19
Some College	733 (26%)	175 (24%)	.25
Completed College	1140 (41%)	307 (43%)	.45
Postgraduate Work	705 (25%)	199 (28%)	.22
Marital Status			
Single	522 (19%)	110 (15%)	.03
Widowed	19 (1%)	11 (2%)	.03
Married	2063 (74%)	548 (76%)	.34
Divorced/Separated	190 (7%)	52 (7%)	.72
Ethnic Status			
African American	62 (2%)	13 (2%)	.48
Native Hawaiian/Pacific Islander	20 (1%)	4 (1%)	.63
White	2470 (88%)	648 (90%)	.46
American Indian	7 (< 1%)	1 (< 1%)	.57
Native American	13 (< 1%)	4 (1%)	.76
Hispanic	67 (3%)	17 (3%)	.93
Other	221 (8%)	51 (7%)	.43
Reasons for Enrolling and Health Concerns (from enrollment questionnaire)			
Want general health info	2204 (78%)	604 (82%)	.01
Weight concern[a]	2160 (76%)	568 (77%)	.54
High Blood Pressure[b]	664 (24%)	195 (27%)	.08
Have diabetes	98 (3%)	21 (3%)	.42
Have high cholesterol	790 (28%)	206 (28%)	.93

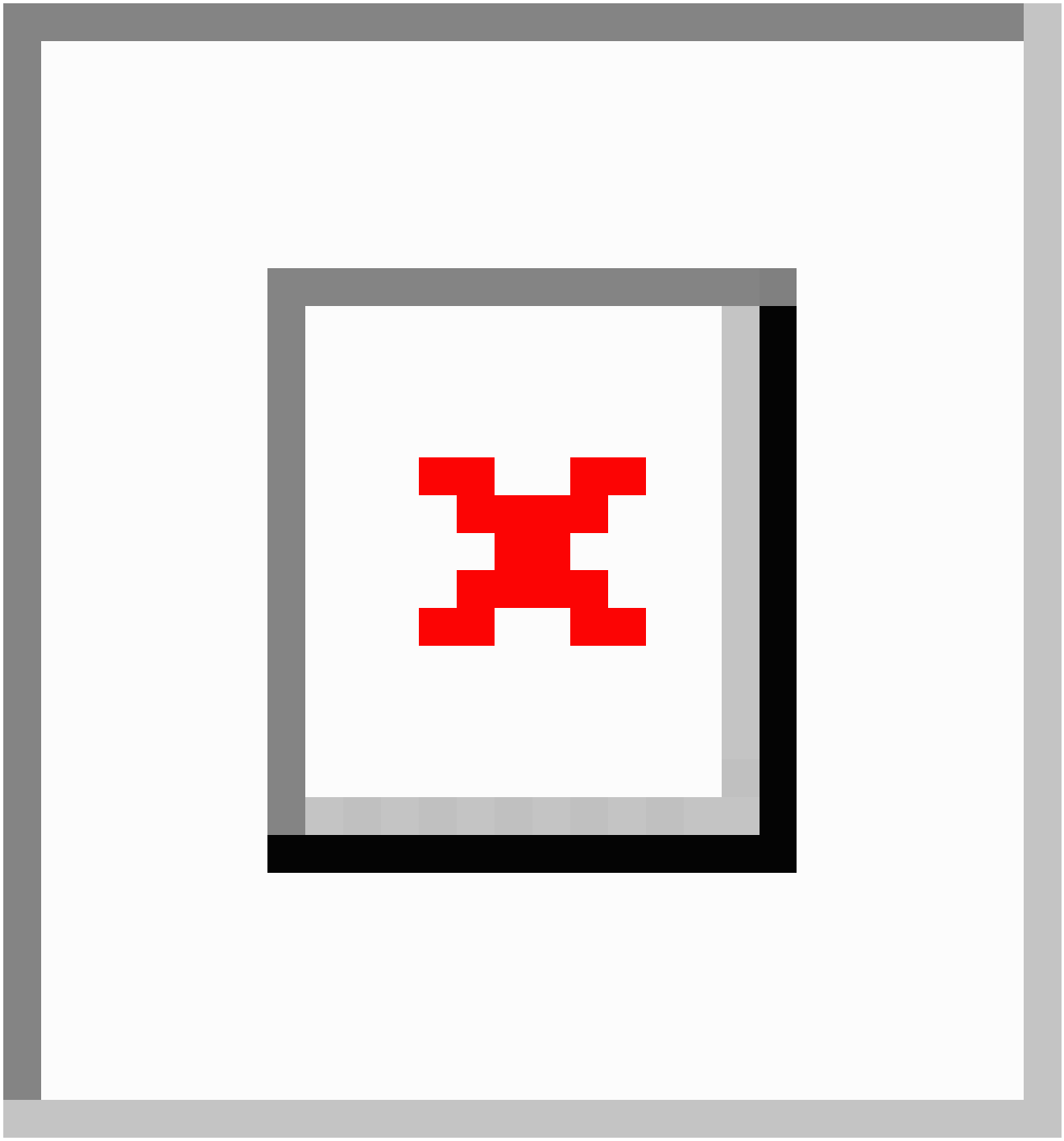
[a]"Weight concern" group includes subjects who indicated they wanted to lose weight.

[b]"High Blood Pressure" group includes subjects who indicated one or more of the following: have high blood pressure; are taking antihypertensive medications; have been told by doctors to "watch" their blood pressure.

Website Use

At the end of 12 months, 735 of the original 2834 enrollees (26%) were still actively visiting the website. Figure 2 displays the pattern of website use during a 3-week baseline period and then in sequential 4-week periods for 12 months. The dropout rate was highest during the first 2 months. The number of users stabilized and remained fairly constant for the final 5 months. On average, users visited the website two to three times during any 4-week period. However, it was not the same group of users who visited the website during each 4-week period: enrollees were dropping out and dropping back in over the entire 12 months.

Figure 2. Pattern of website use during a 3-week baseline period and then in sequential 4-week periods for 12 months



Weight Change

There were 203 subjects who indicated a desire to lose weight when they enrolled in the program and who entered their weight during the baseline period and during the 12th month of the program. Their average weight change was -3.1 lbs (CI -4.7, -1.5; $P < .001$). The overall range of weight change was +30 to -62 lbs. Of these 203 subjects, 151 had BMI in the overweight/obese range, ranging from 25.0 to 50.6 kg/m^2. This was the subgroup for our weight-loss primary outcome. Their average weight change was -4.2 lbs (CI -6.2, -2.2; $P < .001$). Of these, the 74 obese subjects (BMI ≥ 30) lost 5.2 pounds while the 77 overweight subjects (BMI ≥ 25 to 29.9) lost 3.4 pounds (weight change in obese versus overweight, $P = .63$). For the remaining 53 subjects, with BMI 18.5 - 24.9 kg/m^2, the average weight change was +0.2 lbs. Other characteristics of these subjects are shown in Table 2.

Table 2. Weight change from baseline to 12 months

	Baseline weight mean lbs (SD)	Weight change mean lbs (95% CI)	Age yrs (SD)	Males n (%)	Females n (%)
All subjects (n = 203)	187.0 (43.0)	-3.1 (-1.5, -4.7)[a]	42.7 (10.0)	79 (39)	124 (61)
BMI > 25 (n = 151)	202.3 (38.3)	-4.2 (-2.2, -6.2)[a]	43.2 (9.9)	72 (48)	79 (52)
BMI < 25 (n = 52)	142.4 (16.7)	+0.2 (-1.6, +2.0)	41.6 (10.0)	7 (13)	45 (87)

[a]Weight change in *all* subjects and BMI > 25 groups: $P < .001$.

Blood Pressure Change

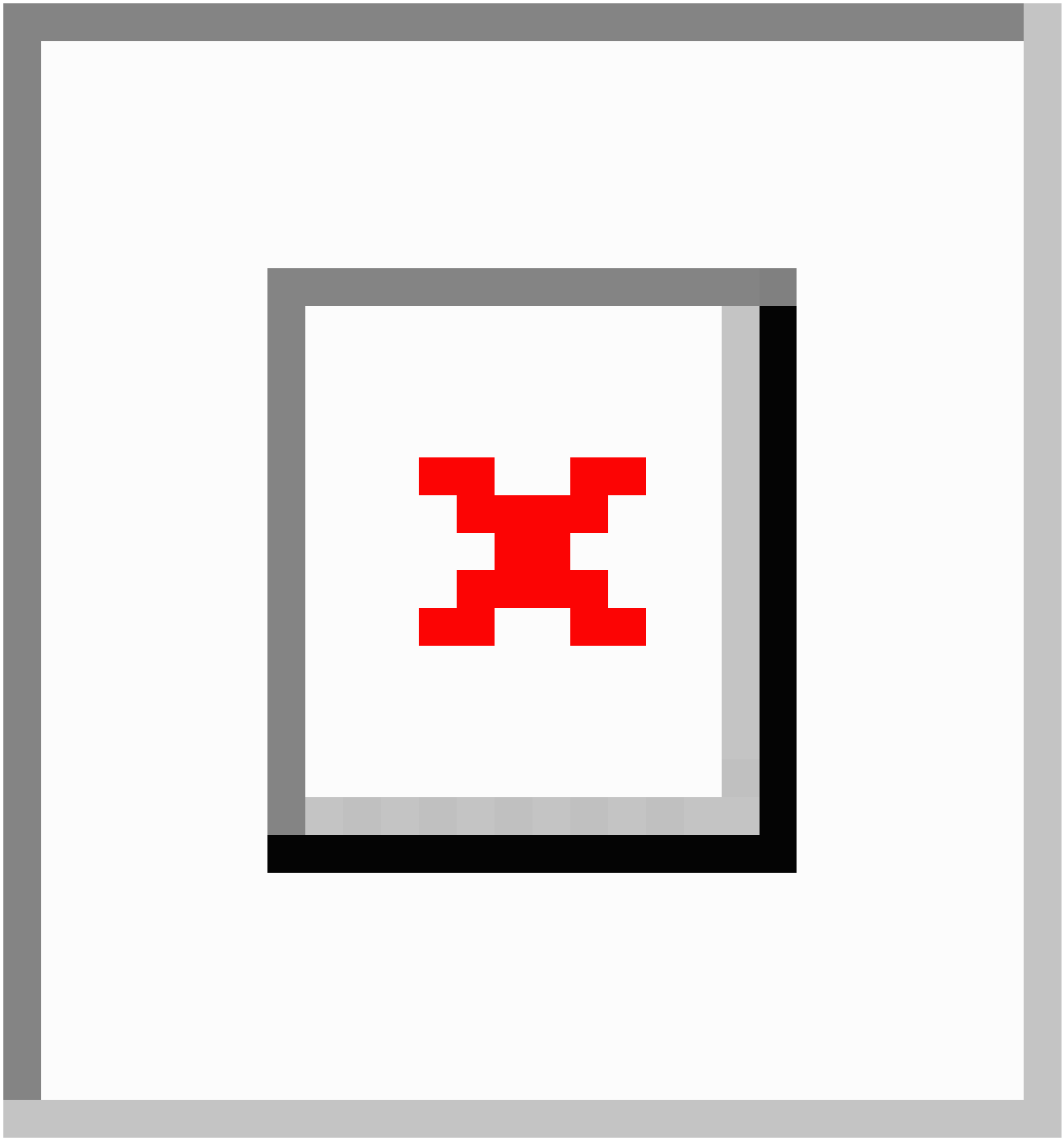
A total of 120 subjects entered blood pressure readings on the website during the baseline period and the 12th month (Table 3 and Figure 3). Of these, 62 met the definition of our high blood pressure group. Their systolic pressure change was -6.8 mmHg ($P < .001$); diastolic change was -2.1 mmHg ($P = .16$). An additional 58 subjects who indicated no blood pressure concern on their baseline questionnaires also entered blood pressure recordings in the baseline and 12th month. Their baseline blood pressure was lower than in the high blood pressure group (Table 3), and their systolic and diastolic pressure change was -2.4/-0.2 mmHg ($P = .09$ and .90, respectively).

Table 3. Blood pressure change

	Baseline BP mmHg	Systolic change mean (95% CI)	Diastolic change mean (95% CI)	Age yrs (SD)	Males n (%)	Females n (%)
High Blood Pressure group (n = 62)	137.3/81.2	-6.8 (-2.6, -11.0)[a]	-2.1 (+0.8, -5.0)	48.6 (7.7)	32 (52)	30 (48)
No High Blood Pressure (n = 58)	118.0/73.5	-2.4 (+1.3, -6.1)	-0.2 (+2.4, -2.8)	41.0 (9.1)	22 (38)	36 (62)

[a]Systolic change in high blood pressure group: $P < .001$

Figure 3. Mean (+ /- 95% CI) systolic and diastolic blood pressure change at 12 months in high and normal blood pressure groups (the systolic change in the high blood pressure group was significant, $P < .001$)



Change in Dietary Habits

A total of 181 enrollees completed at least one DASH online food questionnaire during the baseline period and the 12th month. The median number of completed questionnaires per enrollee was three during baseline and three during the 12th month. The average age was 42.4 years; 107 were women; 74 were men. Table 4 displays the average DASH goal (as servings / day) for each of the eight DASH food groups, as well as the number of servings consumed (as entered in the DASH online questionnaire). Consistent with DASH recommendations, there were significant increases in daily fruit and vegetable intake in the group. There was also a significant decrease in the consumption of grain products, moving counter to the DASH goal. There were no significant changes in any of the other five DASH food groups.

The DASH online questionnaire also provided information on 52 subcategories of these eight main food groups. We performed exploratory analyses to examine changes in these subcategories. There were several significant changes in subgroup consumption. Three categories merit mention. Consumption of carbonated beverages decreased from 9 oz per day to 6.5 oz ($P < .001$). Enrollees reported reducing their consumption of refined-wheat bread products by 0.4 servings per day while increasing consumption of whole grain bread products by 0.3 servings per day ($P < .001$ and $P = .004$, respectively). So, while

grain consumption overall decreased, the shift from refined grains to whole grains is consistent with DASH advice.

Table 4. Changes in consumption of the eight main DASH food groups from baseline to the 12th month of DASH for Health (n = 181)

	DASH Goals (servings/d)	Average Baseline (servings/d)	Average 12th month (servings/d)	Difference (12th month minus baseline)	*P*
Fruit	4	2.0	2.2	+0.2	.03
Vegetables	4	2.6	3.1	+0.5	.002
Grains	7	4.4	4.2	-0.2	.04
Dairy	2.5	2.1	2.0	-0.1	.48
Meat/fish	1.5	1.9	1.9	0	.30
Nuts/beans	0.5	0.4	0.5	+0.1	.76
Added fats	2	1.6	1.5	-0.1	.15
Sweets	0.5	1.3	1.2	-0.1	.13

Relationship Between Website Use and Outcomes

We performed exploratory analyses, relating the amount of website use (measured as number of log-ins over the course of 12 months) versus change in our main outcomes: weight, systolic blood pressure, and consumption of DASH food groups. We divided the sample into two parts based on the median number of log-ins. The median log-in number differed for each outcome, being determined by the number who provided baseline and 12-month data for that outcome. For weight and blood pressure, there were tendencies toward greater effect among those with more log-ins (Table 5). The only significant difference in food group consumption (data not shown) was greater fruit intake among those with a greater number of log-ins ($P = .03$). There were no differences in other food groups. The median log-in number for the group who provided dietary data (food questionnaires) was 44.

Table 5. Comparison of changes in weight and blood pressure in relation to number of DASH website log-ins (median log-ins for blood pressure group was 50; median for weight group was 40)

	≤ Median log-ins	> Median log-ins	*P* (≤ median vs > median)
Systolic BP (mmHg; CI)	-3.9 (-9.9, +2.2)	-9.8 (-15.9, -3.7)	.06
Diastolic BP (mmHg; CI)	+0.7 (-3.8, +5.1)	-4.8 (-8.6, -1.0)	.06
Weight (pounds; CI)	-1.5 (-3.5, +0.5)	-4.6 (-6.9, -2.3)	.09

Discussion

We have found that an online program that provides weekly educational information, motivational messages, and convenient ways for self-monitoring can lead not just to significant weight loss but also to reduction in blood pressure and to healthier dietary habits.

Our results compare favorably to other programs. In terms of retention in the program, 735 of the original 2834 enrollees (26%) were still using the DASH for Health website after 12 months. Very little has been published about long-term subject retention in lifestyle improvement programs in real-world settings, but, as one example, Finley et al reported that, of > 60,000 enrollees in the Jenny Craig program (not Internet-based), only 6.6% were still retained in the program at 52 weeks [9]. One important difference between that program and ours that may have affected retention is that it is expensive (> $1000/year) compared to ours which was free to enrollees. The overweight/obese enrollees in our program lost 4.2 pounds after one year, meeting the definition of an “effective” program as defined in the Center for Disease Control’s review of worksite strategies for weight control [8]. The 6.8 mmHg reduction in systolic pressure represented 60% of the systolic change seen in the hypertensive subjects in the original DASH trial, which was a controlled feeding study [1]. The fact that the weight and blood pressure changes in our study tended to be greater in those enrollees who used the website more often suggests that use of the DASH for Health program was at least partially responsible for these improvements.

There are thousands of websites on the Internet that provide nutrition information, including more than 400,000 websites that mention the DASH diet. Most of these websites provide static content and are not true education programs. Those that are actual education programs, such as eDiets.com or Weight Watchers, focus on weight loss, and there is little evidence that they provide long-term benefit. Womble et al assessed the weight loss effect of eDiets.com for 12 months in 23 women [10]. The women lost on average 0.8 kg. In addition to the standard, online eDiets program, subjects also had five one-on-one sessions with a psychologist which may have enhanced eDiets’ effect, since, in other studies, person-to-person intervention seems to increase the results of an online program (see below).

The Internet has also been used in other ways in research studies. Some investigators have used it as a communication tool

between an individual nutritionist and a client (a strategy to extend a nutritionist's reach to greater numbers of clients). In general, programs with more intense or frequent person-to-person interaction lead to greater retention and health benefits [11-18]. As an example, Tate et al conducted a 6-month randomized controlled trial comparing the weight loss effects of an online program with various levels of additional support: no additional support versus computer-generated feedback versus personalized email from a nutrition counselor [12]. Weight loss at 6 months was related to type of interaction, ranging from -2.6 kg in the no feedback group to -7.3 kg in the personal email group, yet even the no-feedback group in this study had a one-hour counseling session at baseline as well as orientation on how to use the website. Subjects were also given free meal replacements (Slim-Fast) for two meals per day for one week and then coupons for discounted meal replacements for the remainder of the study. In these trials of online approaches to weight loss, the person-to-person intensity of even the least intense treatment arm was greater than what was provided in the DASH for Health program, which we deliberately designed to minimize interactions between the participants and the program team in an attempt to reduce the cost of operating the program. The results of these former studies suggest that adding personal email contact or adding face-to-face sessions may modestly increase the amount of weight loss, although such additions would have also dramatically decreased the scalability of our program and increased its cost.

We believe that scalability and cost are important considerations when addressing a problem as vast as the eating habits of the roughly 140,000,000 Americans who have nutritionally-related health concerns. The physicians and nurses who form the framework of our health care system do not have the time or, in many cases, the background training to counsel patients about nutrition. Additionally, most health insurance products limit the number of allowable visits with a nutritionist. An approach is needed that can be offered without imposing additional burdens on our health care workers or on our health care budget. The Internet, in our view, could potentially provide such a solution.

There were some limitations to this study. First, we relied totally on self-entered data, with no objective measurements to confirm the self-entered results. Second, we could only assess changes in our outcomes after 12 months in people who were, by definition, still using the website. Even though there were no demographic differences between the 12-month users versus all those who enrolled at baseline, it is likely that this group was highly self-selected: people who continued to use the website for the entire year probably did so, in part, because they were deriving some benefit from the website (as observed by Finley et al [9]), although not everyone who reported a weight or blood pressure change after 12 months showed benefit. Relying on self-entered data after 12 months, however, could introduce a bias toward positive benefits for our program. On the other hand, the fact that we minimized contact with the enrollees, specifically avoiding individual contact, and did not take objective measurements of outcomes allowed us to assess how subjects would use a program like ours in a real-world setting. This could be considered an advantage. Another limitation is the absence of a control group: we cannot compare the findings in DASH enrollees against a group of non-enrollees. The one mitigating observation here is that subjects who used the DASH website less often tended to lose less weight and had less blood pressure reduction than those who used the website more often, suggesting that use of the DASH program contributed to the weight and blood pressure changes. Overall, however, our reliance on self-entered data, a self-selected group of 12-month users, and the lack of a control group must be seen as significant limitations to our findings.

In summary, we showed that 26% of original enrollees continued to use the Web-based DASH for Health program at the end of one year and that, at one year, those who continued using the program had not only lost weight but also lowered their blood pressure and made healthy changes in dietary habits. While this study does not prove a causal relationship between using the program and achieving healthy changes, the possibility that well-designed, Internet-based programs can produce or aid in achieving important health benefits is encouraging. Programs like this one could play an important part in our efforts to improve the way Americans eat.

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Conflicts of Interest

Dr. Moore is Chairman of e-Havior Change, LLC which owns the copyright to the DASH for Health™ program. Dr. Apovian, Ms. Murphy, Ms. Cullum-Dugan, and Mr. Coffman have received some salary support from e-Havior Change, LLC.

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Abbreviations

BMI: body mass index
BP: blood pressure
DASH: dietary approaches to stop hypertension
DBP: diastolic blood pressure
NHLBI: National, Heart, Lung, and Blood Institute
SBP: systolic blood pressure
USDA: United States Department of Agriculture

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Original Paper

Use of an Internet "Viral" Marketing Software Platform in Health Promotion

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Abstract

Background: Health-related websites have become a common tool for public health authorities to inform the general public of their health promotion information and programs. However, building traffic in the cluttered health Internet universe is becoming increasingly complex, costly, and challenging for governmental health promotion websites. In 2006, the Canadian Health Network (CHN), a cooperative program made up of the Public Health Agency of Canada (PHAC) and some 20 health non-governmental organizations (NGOs), was looking for an affordable marketing tool for the promotion of its website and contents to specific populations.

Objective: To test new and innovative marketing tools for a health promotion website in Canada.

Methods: Within the context and constraints of a governmental health promotion website, an adaptation of a commercial Internet viral marketing software platform was developed and implemented under the name "The Crazy Race". This process was done interactively between seven NGOs and the CHN staff. The communication objectives were (a) to provide a meaningful visit that could communicate important public health messages, and (b) to increase subscriptions to its e-newsletter. A nine-step standardized Web-user experience (Internet path) was thus defined and experimented with under a pre-determined operating budget of less then Can$50,000, mainly paid for by participating organizations on a pay-per-performance basis.

Results: An initial group of 215 people were sent an invitation to participate in the campaign. Over its 15-day duration, the campaign generated by itself and without any media support a total of 110,200 Web user participants who registered and sent a total of 439,275 invitations (2% of the Canadian Web-user population of 21.8 million in 2006). The epidemic self-dissemination of the campaign occurred in both French and English populations and spread across all age groups. Two-thirds of the participants were women.

Conclusions: The use of an Internet viral marketing platform proved to be effective in bringing thousands of Web users to discover and explore a governmental health promotion website. The exponential growth of the person-to-person dissemination generated by the campaign indicates that public health messages have high viral propagation potential on the Internet ("virulence") when they are presented in the context of an enjoyable online game. This could constitute a promising method to create affordable mass audience public health campaigns, both in Canada and internationally.

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KEYWORDS

Internet; viral marketing; email marketing; email; health promotion; person-to-person communication; viral campaign

Introduction

Offering and maintaining consumer health websites has become a practical and cost-efficient mechanism for public health agencies to communicate health promotion information and programs to the general public. The Internet allows content to be updated instantly and inexpensively in comparison to the available alternatives (eg, paper brochures, CD-ROMs, and software applications, etc) [1]. The Internet has been adopted worldwide over the past decade, including 7.9 million Canadian households in 2005 [2], for a total online population of 21.8 million Web users in 2006, of which 87% had a broadband connection [3]. Furthermore, 58% of Canadian Web users searched for medical or health-related information at home in 2005 [2], indicating a strong demand for online consumer health information and resources.

However, to build traffic in the current Internet universe is a complex and costly challenge for any consumer website, especially in the cluttered health sector. Web users currently have access to more than 25,000 health-related websites in North America alone [4], ranging from general governmental consumer health websites (provincial ministries and state or federal agencies), to websites on diseases, specific topics/groups, and non-profit websites (eg, associations dealing with diabetes, cancer, asthma, mental health, children, women, and seniors, etc) to websites for pharmaceuticals and pharmacists' websites. Health communicators face three challenges when marketing a non-revenue generating consumer health website in order to increase or maintain traffic and to build recognition (branding).

Firstly, the costs of media advertising for radio, TV, newspapers, Internet banners, pay-per-click search engines, and/or email marketing to promote and market a consumer health website are now very high, if not prohibitive, for any governmental public health agency. This is especially true in the context of a geographically widespread country such as Canada, where marketing operations have to be executed in a multilingual and multicultural context and where different segments of the population are targeted (women, men, youth, seniors, Aboriginal peoples, and people living with disabilities, etc). For instance, in 2006 such costs were estimated on average to be $60 per new customer using email in the United States, $8.50 when using search engine strategies such as Google Ads, and approximately $50 for online display ads such as banners [5,6,7].

Secondly, Internet users visit websites they are used to and those offering the contents they seek. When users are searching for new websites they usually do so by typing a keyword or topic in a search engine (proactive action), clicking on a banner (spontaneous action), or requesting a friend's advice via electronic communication, face-to-face communication, or community websites (word of mouth). However, the latter would not likely happen often nor spontaneously for a consumer health website, since health brands are one of the less discussed between consumers, along with other private matters such as finance, home, household products, children, and lifestyle [8].

Thirdly, Web users do not pass along information within their social network if this information does not convey strong viral dissemination potential, for instance messages that are not intriguing, funny, or utilitarian in nature [9,10]. Therefore, public health or health promotion information, which is both serious and private in nature, possibly falls within this low-potential category for being passed along. This becomes a real problem in the current cluttered Internet universe where individuals tend not to pass along messages or even consider email messages that are not received from someone they know and trust.

The field of viral marketing based on person-to-person electronic communications is being increasingly explored and experimented with in the commercial arena to promote and market products or service-related websites. The terminology "person-to-person" or "peer-to-peer" used throughout this paper strictly refers to the phenomenon of people sending email invitations to other people in their close personal social network to play an interactive online game with them on the topic of health, and does not refer to other peer interactions, be they online or offline [11,12]. These viral marketing approaches, tactics, or applications are deployed with the aim of disseminating messages within whole populations or targeted segments of a population with the ultimate goal of gaining new customers. However, success in spreading out across populations varies greatly and is impossible to predict a priori for any given attempt. As mentioned by Phelps et al, "viral marketing remains a relatively neglected academic research topic. In addition, it is recognized as being one of the most inexpensive and efficient methods for organizations to differentiate themselves and to reach their clientele" [9,13].

This paper describes a viral marketing experiment performed in February 2007 to promote a free, Canadian federal government consumer health promotion website offered to English- and French-Canadian populations. This project consisted of transposing and adapting an Internet viral marketing software solution to a public health context, one initially engineered to market merchants, products, or services in the commercial arena. The experiment launched a consumer health promotion website with two of its key topics and functions being to gain new, regular Web users through new subscriptions to the e-newsletter and to communicate important health promotion or public health messages to campaign participants by enticing them to complete short quizzes and win "healthy" prizes.

Methods

Context and Constraints of the Promoter

To help improve the health of individuals, the Canadian Health Network (CHN) website had to become known by the largest number of people possible in order to maximize its impact. The CHN was a consumer health promotion website operated from 2001 to 2008 by the Public Health Agency of Canada (PHAC) which has since merged with other PHAC websites. The CHN's mission was to promote healthy choices by communicating trustworthy information on health promotion, disease, and injury prevention through a network of specialized, expert non-governmental organizations (NGOs). It provided free access to more than 20,000 English and French peer-reviewed, Web-based resources on 25 key thematic health topics and population groups. This formal peer-review process was a key,

distinctive feature of CHN providing quality assurance, credibility, currency, and relevance of the content.

To carry out its mission and increase the number of its users, the CHN faced three key marketing challenges, within the constraint of a modest budget of less than Can$50,000. The first of these challenges was to reach out to as many Web users (consumers) as possible across Canada in both English and French; secondly, to attract consumers to its website for a meaningful visit to exhibit its main features; and thirdly, to convince them to return by demonstrating its relevance and to build loyalty by having them subscribe to its bi-monthly e-newsletter.

An experiment was thus undertaken which consisted of using a spin-off application of a patented Internet viral marketing software platform powered by a Canadian company named YOUge.com Inc. [14,15]. Previous applications of this platform had been successfully applied in the commercial arena to promote product or services websites. Adapted for the CHN, the viral marketing platform adopted the form of an online game using the metaphor of a positive and healthy activity (ie, a real-time virtual human foot race between friends).

The Objectives of the Experiment

Within the framework of a pay-per-performance and pre-determined budget, the objectives of the experiment were set as follows:

- Facilitate the CHN's ability to attract as many Web users as possible to its website for a meaningful first-time visit during which its key features can be exhibited.
- Communicate public health messages to Web users in the following seven areas through the completion of short health quizzes: active living, cardiovascular health, environmental health, respiratory health, healthy eating, injury prevention, and HIV/AIDS.
- Increase significantly and at a sustainable rate the number of subscriptions to the CHN e-newsletter.
- Increase the general level of awareness and recognition of the CHN within English- and French-Canadian populations.

The Internet Viral Marketing Software Platform

The experimentation process consisted in the following nine phases, as follows.

The first phase consisted of adapting and transposing the viral marketing Internet software platform, based on sophisticated and patented mathematical algorithms [15]. The system used patented algorithms allowing participants in the race to overtake the person who invited them and win the race by attributing the value of a participant's individual electronic word of mouth to the one who actually generated it. This unique feature made the game fun and exciting because anyone could win their race, depending on the number of active participants they generated directly (via invitations to their friends) and indirectly (via invitations sent by their friends, by friends of their friends, and so on). More specifically, these algorithms fostered the following behaviors or benefits. Firstly, they enticed game participants to select and invite competitive people. The more motivated competitors that participants had in their race, the faster their runners ran, and the greater were their chances of winning the race. Secondly, the algorithms made it counter-productive for participants to register more than once for the game. Thirdly, for the campaign sponsor (CHN), the algorithms ensured that the number of prizes awarded to winners was exactly correlated to the number of participants. This enabled budget control based on a pay-per-performance formula.

The second phase consisted of designing a Macromedia Flash graphical interface with the following features. The first one was that of a game personifying a real-time foot race between friends encouraging person-to-person pass-along behavior via email invitations (Figure 1). The second feature needed to be as user-friendly as possible to maximize overall participation levels. This was accomplished through the design and programming of a friendly virtual runner named Leonidas who ran on behalf of participants and guided them, via a one-to-one dialogue box, through different stages of the race. Leonidas had three key functions: (a) entice participants to invite good competitors; (b) encourage participants to improve their health by completing up to three health promotion quizzes (embedded incentives) (Figure 3); and (c) guide participants in choosing the best course of action at any given moment during the game (Figure 2).

The third phase included developing text (in both English and French) in order to entice participation and reinforce the importance of taking care of one's health. This included text for game website pages and all email messages, including invitations to join the game, post-registration confirmation, follow-up communications, and reminders.

Figure 1. Online, real-time interface for foot race between friends

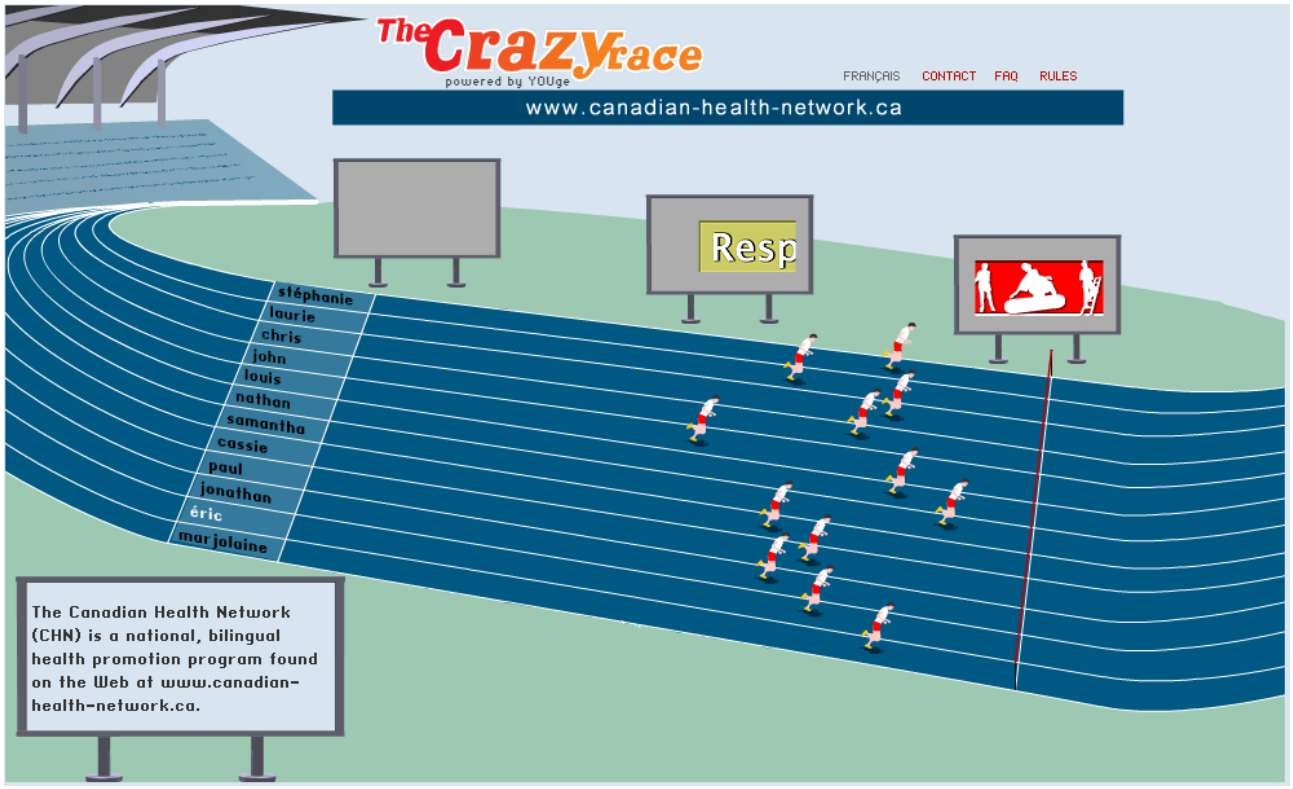


Figure 2. Friendly virtual runner named Leonidas

Figure 3. A health quiz on respiratory health

The fourth phase included designing and programming an intelligent architecture and database system to support the following features: Leonidas' key roles and functions; real-time updating of the races; the invitation panel (engine); real-time online chatting between participants; and the equal distribution of up to three health promotion quizzes per participant among the seven quizzes developed for the campaign.

In phase number five, a prize reinforcing health promotion was prepared and offered to the campaign's first 500 winners. The health prize consisted of a reusable water bottle, a shoe bag, and a book of healthy recipes (approximate value of Can$25).

The sixth phase centered on coordinating the involvement and input of the seven public health-expert NGOs involved in the project from across Canada, along with the Public Health Agency of Canada, namely: the Canadian Public Health Association (HIV/AIDS); CHUQ WHO Collaborating Center (environmental health); Dietitians of Canada (healthy eating); SMARTRISK (injury prevention); the Canadian Lung Association (respiratory health); Alberta Centre for Active Living (active living); and Capital Health Edmonton (cardiovascular health).

Phase seven consisted of defining the topics, format, literacy level, and copywriting of the seven health quizzes to be delivered to participants, promoting timely and easy-to-remember health promotion messages.

Phase eight launched the campaign under the name "The Crazy Race" in English and"La course folle" in French on February 8, 2007, by sending 215 email appeals to people involved in the eight partner organizations and the CHN.

Finally, phase number nine consisted of overseeing the campaign's evolution and analyzing its results and performance. The campaign was ended on February 23, 2007 with the occurrence of the 500th winner.

The Web Users' Experience

The campaign was disseminated by thousands of people who joined a friend's race after receiving and accepting an email invitation, and who did the same by inviting friends by email to join their race. Each participant's experience followed a nine-step standardized path, as described below.

In step one, Web users receive an invitation by email from a person they know with the name of that person appearing in the "From" field, thus confirming that the invitation is not spam. The invitation is personalized with text calling for potential participants to join the race of their friend.

In step two, Web users click on the embedded hyperlink appearing in the invitation message.

In step three, Web users land on the campaign website's homepage where they are invited to register and play.

In step four, while registering, they type in their name, gender, age group, postal code, and email address. After clicking on the registration button, the system sends them a personalized confirmation email with a link to access their race directly at anytime, and the Web users become registered participants in the campaign. Once participants are registered with a given email address, the system blocks any further invitation sent by friends to this email address by indicating to them that the participant is already registered. Also, the system does not allow a second registration with any email address which is already registered.

In step five, new participants are shown a racing track which contains the first name of the friend who invited them in the

bottom lane and their own name in the second lane. The virtual runner Leonidas appears on the screen and introduces himself. He explains that in order to accelerate and win the race, they need to run against competitive runners, and he asks participants to invite the best competitors from amongst their friends. Upon reading the rules, participants will intuitively understand that it is counter-productive to register more than once and that the payoff comes from inviting other runners.

For step six, an invitation panel is presented from which up to ten people (friends, relatives, and colleagues, etc) who may like to be involved can be invited. Participants type in the first name and email address of each guest, choose the appropriate language (French or English), and click on the "Send" button. The invitations are sent by the system and the recipients begin at step 1. Once invitations are sent, participants will observe that Leonidas has progressed forward in his lane. (Each time invitees register with the game, the system automatically sends an email from Leonidas to participants to inform them that a new competitor has joined their race. The more competitors who join the race (up to a maximum of ten) for any participant, the faster Leonidas runs for them. This is the key function of the algorithms described above.

For step seven, after participants have invited at least one potential competitor, Leonidas explains that staying healthy is needed to accelerate in the race. He adds that one of the CHN affiliates (the seven organizations mentioned above) wishes to take care of their health and well-being. He then prompts participants to click on a quiz banner to complete a short health quiz that could improve their health and help them reach their full speed potential.

In step eight, a quiz panel pops up and presents a question with a hint provided as to the location of the answer on a CHN Web page followed by a "Find the answer here" button. By clicking on this button, participants are automatically sent to one of the CHN's topic homepages (one of the seven topics mentioned above) where the answer can easily be found. This provides a unique visitor count on the CHN website for the first quiz. With the answer in mind, participants close the CHN page, return to the race website, and are offered a choice of two answers where they check one, thus providing a correct or incorrect response. If incorrect, the system tells the player and sends the player back to the related CHN webpage so that the right answer will eventually be checked. If answered correctly, participants will observe that Leonidas has moved forward in his lane, realizing the immediate impact of completing the health quiz. This process provides a positive action-reaction pattern and a strong indication that the health message may have been learned, although this cannot be measured in the race. In addition, participants are asked if they would like to subscribe to the free CHN e-newsletter. This appeal is timely, being offered immediately after participants spend a few minutes exploring the health website to locate the quiz answer. If "Yes" is checked, this is counted as an opt-in (a high value, permission-based email address for CHN). If "No" is checked, they are asked again after completing the second and third quizzes, but with a different question (ie, a new trigger) each time.

Finally, in step nine, each time participants verify the status of their race or accomplish an action, Leonidas provides them with timely, tailored messages. The objective is to have participants complete up to three health quizzes and invite up to ten competitors. Ultimately, as more Web users were invited, registered, invited other competitors, and completed quizzes, the campaign process generated thousands of parallel races unfolding simultaneously. Considered all together, these races were evidence of the naturally growing viral dissemination of the campaign throughout the population.

Results

Epidemic Self-dissemination

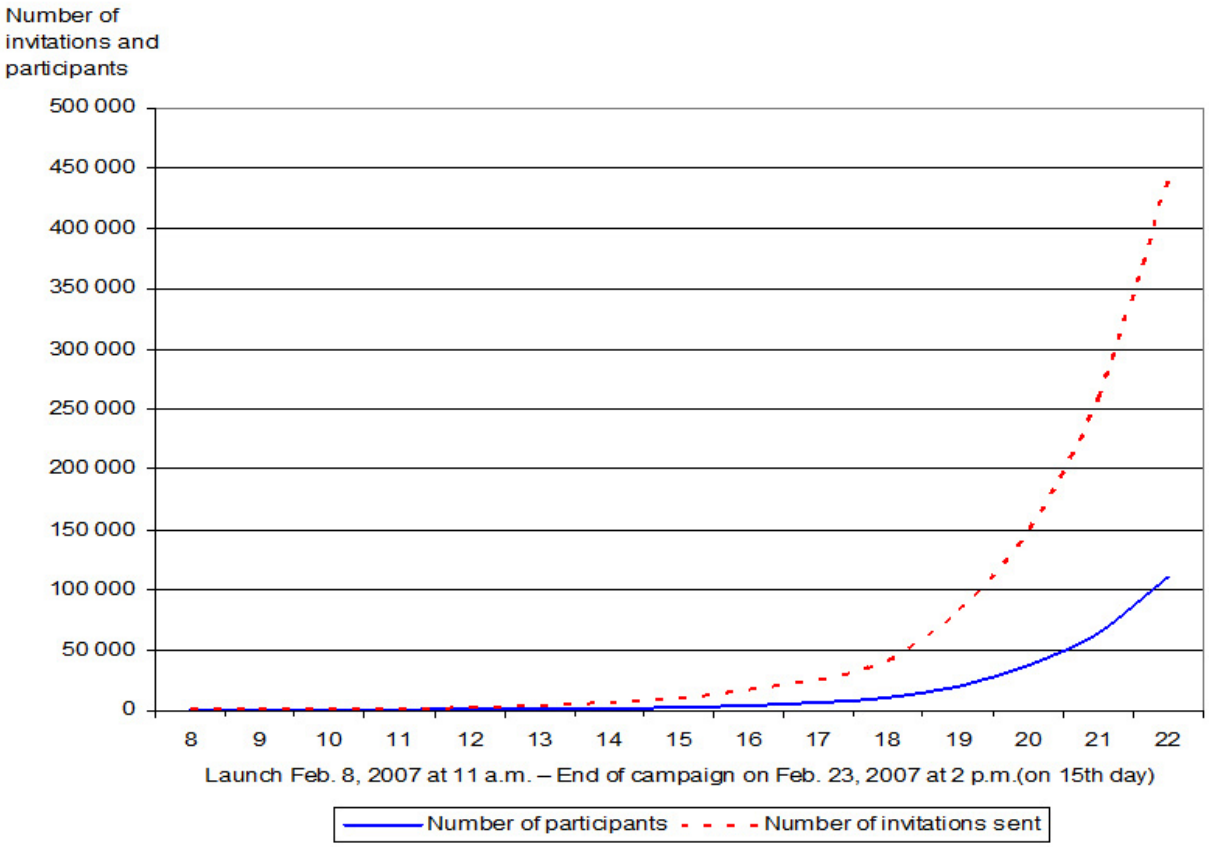
In only 15 days, the campaign generated, without any other offline or online media support than the invitation engine used by game participants, the following results. After the initial 215 invitations were sent to staff of participating CHN affiliates, a total of 68 people were registered and 679 invitations were sent on the very first day of the campaign. After 15 days, a total of 110,200 Web user participants were registered and a total of 439,275 invitations sent through their personal and private networks (Figure 4). Although it was impossible to assess precisely whether each registered participant corresponded to a unique individual, the system characteristics described above certainly acted to keep the number of duplicate registrations very low. The overall daily growth rate of the campaign was an exponential 142%, thus producing an epidemic dissemination within the Canadian population. In other words, the campaign grew naturally by itself and was terminated before reaching saturation in order to respect the fixed budget. The epidemic dissemination occurred in both the French and English populations.

Participants were fairly evenly spread across all age groups (ie, 11% in the 13-17 age group, 30% in the 18-24, 29% in the 25-34, 12% in the 35-44, 11% in the 45-54, and 7% were over 55). Women represented 66% of the campaign participants.

Key Performance Indicators Compared to Initial Objectives

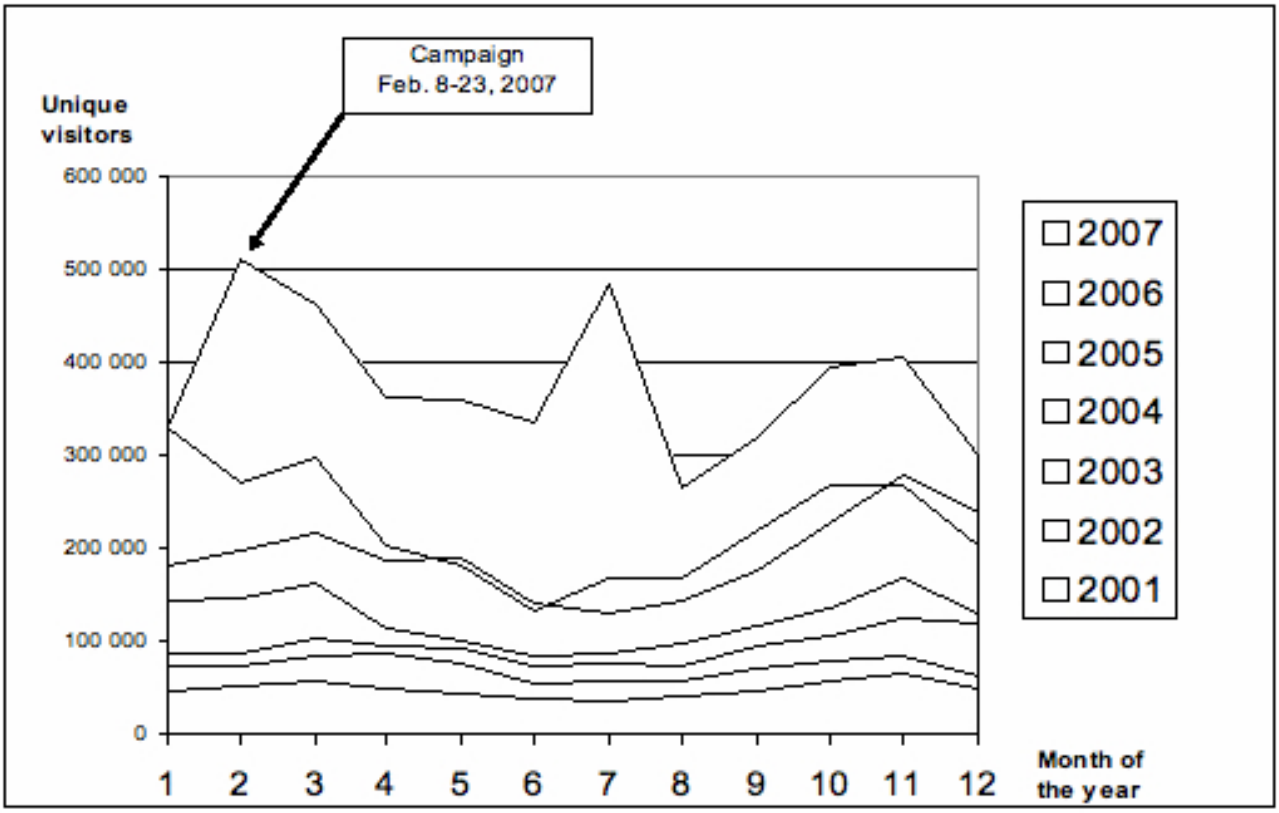
The first objective was to draw as many Web users as possible to the CHN for a meaningful initial visit to show them the website's features and relevance. Approximately 300,000 visits occurred on the CHN website during the campaign, mostly made by new, unique visitors generated by the game who came to the site to find answers to their health quizzes (Figure 5). The CHN defined a visit as a series of actions that begins when a visitor views any first page from the server and ends when the visitor leaves the site or remains idle beyond the default 30 minute idle-time limit. Unique visitors were defined as individuals who visited the site during any (monthly) reporting period and were only counted the first time they visited by noting their IP address.

Figure 4. Exponential growth of registered participants and invitations sent



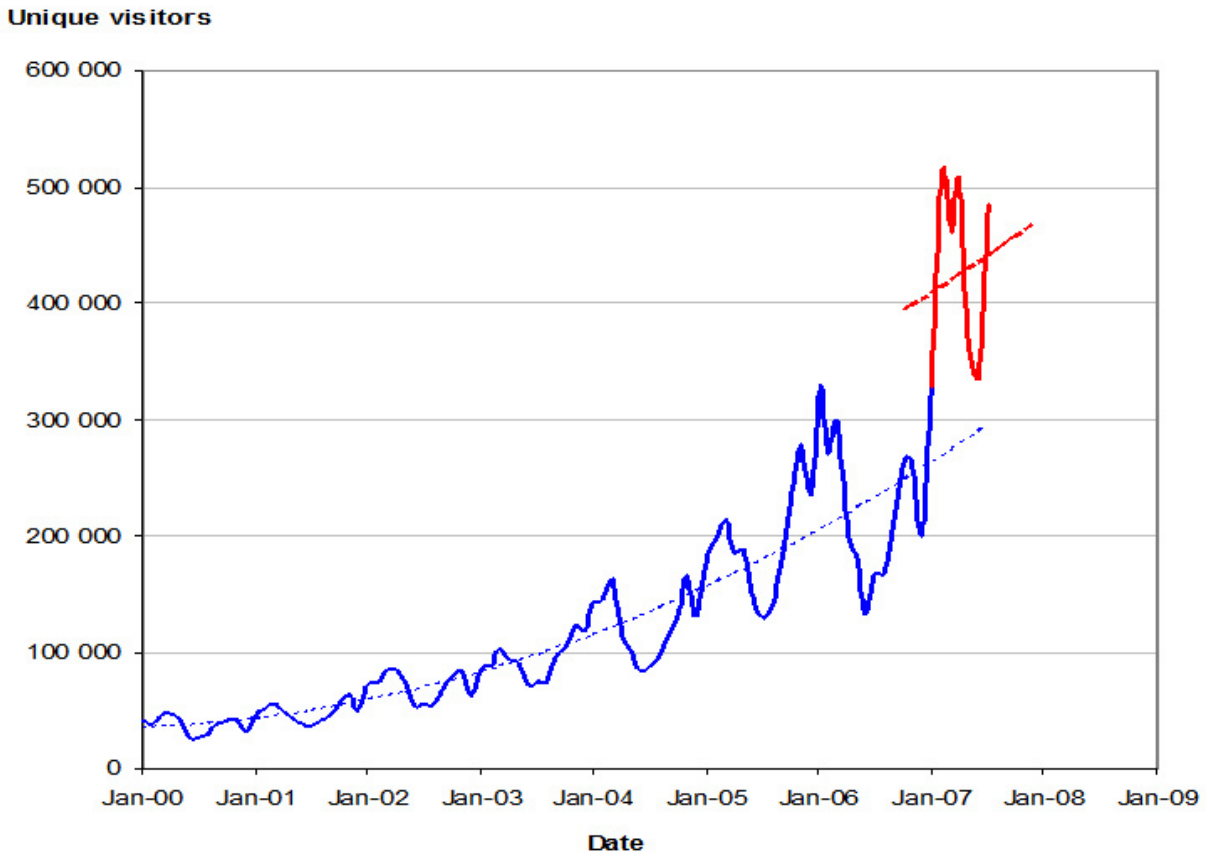
Legend: The noticeable acceleration of the number of participants and invitations sent which occurred around the 12th day (February 19th) is simply the natural (mathematical) outcome of the continuing exponential growth of the campaign. The average daily growth rate of the campaign was 142%. Both lines (participants and invitations) follow an identical path.

Figure 5. Unique visitors' annual growth from 2001 to 2007



In addition, an estimated average accrued increase of 140,000 unique visitors per month was observed after the completion of the campaign during the period from March to July 2007 (Figure 6). This accrued increase means that the growth in traffic exceeded what would have been expected by applying the average traffic growth rate trend of that time. Noticeably, this occurred without any other unusual marketing or promotion initiative from the CHN.

Figure 6. A post campaign accrued increase of unique visitors per month was observed



Legend: The accrued increase was calculated as follows. Step1: A polynomial regression was carried out on the actual monthly unique visitor counts for the historical period preceding the campaign to take into account the growth pattern observed. Step 2: The monthly values generated by the regression equation for the months following the campaign (March to July 2007) were compared to the actual monthly unique visitor count of period. Step 3: The accrued increase of 140,000 (right upper part of the curve) is the average of the monthly variations for the period from March to July 2007).

The second objective was to increase significantly, and in a sustainable way, the number of subscriptions to the bi-monthly CHN e-newsletter. A total of 31,866 participants registered to the e-newsletter, doubling in two weeks the total number of subscribers reached in the previous six years. The conversion rate was 45%, meaning that 45% of the participants who had completed at least one health quiz and were subsequently asked to subscribe chose to do so (gave permission to be sent the e-newsletter). Only 2% of these new subscribers unsubscribed after nine months. Although this does not necessarily mean that the 98% who remained subscribed actively read or paid attention to the bi-monthly e-newsletter, we believe that these new subscribers are probably behind the sharp and sustained increase in the website traffic mentioned above.

The third objective was to communicate health promotion messages through the completion of health quizzes. A total of 70,580 people (64% of the participants) successfully completed between one and three health quizzes. On average, each quizzer completed 1.92 quizzes. In total, 135,395 health quizzes were successfully completed during the 15-day campaign.

The fourth and less tangible objective was to heighten the level of recognition of the CHN website within the Canadian population. The magnitude of the results described above establishes the likelihood that the campaign managed to increase the recognition of the CHN website within the Canadian population. Indeed, more than 400,000 people saw or interacted with the CHN brand, either through the invitation they received from a friend or more actively by participating in the campaign. This corresponds to 2% of the Canadian Web-user population of 21.8 million at the time of the experiment [12]. In addition, two questions posed to those who subscribed to the CHN e-newsletter reinforced this assertion and indicated that the campaign fostered loyalty to the CHN. To question 1, “Had you visited the Canadian Health Network before playing this game?”, 63% of the 18,480 people who were asked this question responded, “No”. To question 2, “Will you visit the Canadian Health Network (CHN) again in the future?”, 92% of the 13,085 respondents said, “Yes”. More importantly, 89% of those who responded “No” to question 1 answered “Yes”, that they would visit the CHN again. This tends to confirm that the campaign provided valuable exposure of CHN benefits for game

participants, thus leading to a positive perception and high appreciation of the CHN.

Discussion

Internet Marketing in Health Promotion

The use of an Internet viral marketing software platform generated outstanding marketing outcomes for the CHN website. These results are interesting both in terms of the epidemic dissemination of health promotion related messages and in terms of the efficacy and efficiency demonstrated in acquiring new and returning Web users. Results may be considered particularly positive for a governmental health promotion website working with a small marketing budget. This experiment represents a first in Web-based, person-to-person viral marketing health promotion campaigns.

In 2006, Suggs presented a 10-year review on the body of research available on the use of new technologies in health communication, including computer-based approaches [1]. The review focused on studies that reported positive outcomes. The review provided insights as to how new technologies were used to communicate health messages and what their outcomes were in terms of supporting or improving health communication efforts. Among the findings, it was noted that the use of new technologies was growing in virtually all areas of health communication, including consumer and health promotion. It also identified computer technology as the most commonly implemented new technology in the past decade and concluded that "most of the innovation in technology-based health communication has been computer driven" [1]. However, the applications included in the review were limited to websites or portals, Web technologies, or Web communications supporting patient-provider interaction or designed to provide education and social support to influence behaviors or increase self-efficacy, with no mention of viral or person-to-person pass-along applications.

Despite the fact that there was no mention of any person-to-person (or peer-to peer) email communication applications, Suggs concluded "that the past decade of research in health communication demonstrates that technology has been used successfully to deliver a variety of messages using multiple mediums" and that further research should strive to answer research questions such as how better to tailor communication content or what technology "channels are most effective in communicating the health message for what populations and for which health topics" [1].

This suggests that the CHN's person-to-person email pass-along experiment used to raise the profile of its consumer health promotion website and communicate public health messages could have been the first project of its kind to have been carried out in the health communication arena which utilized measured self-dissemination results to propagate public health messages. To the best of our knowledge, it is also likely that the experiment identified a new and singular Internet-based channel (ie, a person-to-person pass-along email channel of communication through an Internet viral marketing game platform) to communicate efficiently health messages both in terms of reach and costs, as compared to the available alternatives.

Another interesting angle to examine the singularity of the experiment is to compare its dissemination patterns with what can be found in the existing literature regarding person-to-person electronic communication. According to Léger and Scholz, North American consumers are bombarded with approximately 4000 publicity and promotional stimuli everyday, including electronic ones [16]. Organizations are thus looking for innovative and effective approaches to reach their clientele. Viral marketing through email and other means is one of the approaches that is being explored by marketers from all sectors. Viral marketing is a "phenomenon that facilitates and encourages people to pass along a marketing message voluntarily" [17]. More specifically, the "term refers to marketing techniques that use pre-existing social networks to produce increases in brand awareness, through self-replicating viral processes, analogous to the spread of pathological or computer viruses" [18].

According to Phelps et al [9], marketers use viral marketing to increase product or service knowledge and awareness. Despite the fact that it has attracted a great deal of attention in the marketing industry, viral marketing remains a relatively neglected research topic and almost nothing "is known about the motivations, attitudes, and behaviors of the people (those sending the email to others) that constitute the essential component of any such strategy"[9].

Among the factors explaining a Web user's inclination to circulate information, a range of motivations such as the desire to help, a financial incentive, or having a sense of providing a social benefit to the community have been mentioned [19]. Others have also provided insightful observations on the behavior which motivates people to pass along information by email or other, consumer-mediated, consumer-to-consumer tools, as well as observations on some characteristics of the most passed along types of email messages and other conditions inclining people to forward email messages [9,10]:

- Consumers are much more reluctant to delete a message received from a person they know. Moreover, when a message comes from a friend, there is an implicit level of credibility attached to it, and people assume that the information is of value.
- Email messages received from close, interpersonal sources have a greater chance of being forwarded than messages from unfamiliar impersonal or commercial sources.
- People experience positive emotions when they send pass-along emails. They might feel excited, helpful, happy, or satisfied. The five most reported motives for passing along an email are because it's fun, enjoyable, or entertaining; because it may help others; and because it promotes having a good time.
- Women are more likely than men to pass along email messages.
- People using an Internet broadband connection are more willing to forward messages than those accessing Internet through dial-up modems.

- Messages of a utilitarian or hedonic nature, or that spark strong emotions such as humour, fear, sadness, or inspiration are more likely to be forwarded.
- Consumers are irritated with unsolicited emails received from companies or organizations, and they usually delete these without opening them. Thus, “people are not likely to forward emails from companies because they consider the information company-produced ‘junk’” [9].

Finally, Phelps et al, in their exploratory work, found that jokes were the type of content being forwarded most often, making up close to 50% of this content, and games-related content represented only 1% of emails received by a sample of recipients [9]. They also suggest that offering compensation or incentives to entice consumers to pass along email messages could dilute the power of the recommendation if the recipients were aware of it.

Before comparing the above literature with the pass-along email patterns of the Internet viral platform used by the CHN, it is important to consider how it differs from pass-along email per se. Firstly, the participants had to register with the campaign before being able to invite their friends through the software platform. This represents an extra step as compared to simply forwarding emails from a computer email manager. Secondly, the invitations were designed to encourage participation in a popular online foot race between friends, rather than to promote health or the CHN directly, although the latter’s brand was mentioned in the invitation copy. It is the game and the fun associated with it that caused the viral message to be passed from person to person in a participant’s social network. The introduction to the CHN (ie, the advertisement) was embedded in the game platform and experience. Finally, with each invitation to friends to join their race, campaign participants generated a de facto epidemic dissemination of the game message, which in turn attracted more than 100,000 registered participants to the game. By playing the game, they then discovered the CHN’s main features and eventually became new consumers of the CHN website.

Interestingly, the dissemination patterns generated by the use of an Internet viral game software platform used to promote the CHN appear to coincide with the above literature. First of all, participants of the online virtual foot race came to the game by linking from what would have been perceived to be a utilitarian or hedonic email invitation received from an interpersonal source and not from an organization trying to promote itself. This meets most of the conditions presented above for the most forwarded types of email messages.

Secondly, the point of the invitation was to invite friends to play a healthy online game which would be useful to anyone’s health. This game environment likely provided senders with both the opportunity to have fun with their close social network in an enjoyable setting and an occasion to help others. In other words, the online game setting clearly appealed to participants’ desires for fun, entertainment, and social connections which are the foundation of consumers' motivations regarding pass-along email. Moreover, 66% of the game participants were women, thus corroborating previous observations that women are more likely to pass along messages [9]. Also, the campaign took place in Canada, where 87% of online households use a broadband connection [13] which is a factor known to facilitate pass-along email.

Finally, the observed results of the CHN viral experiment seem to contradict the suggestion that offering compensation or incentives with pass-along emails may negatively impact the pass-along potential of a communication. On the contrary, the self-epidemic dissemination of the experiment, which included both the possibility of winning a healthy gift package by competing with friends and answering health quizzes, and the use of mathematical algorithms which subtly provided incentives to pass along email, clearly demonstrated that these factors were, at the very least, not an impediment to ”virality”.

Limitations and Further Research

The experiment with the Internet viral marketing platform proved to be effective in actually propagating useful public health messages within the Canadian population and in significantly increasing the CHN’s website traffic. However, its impact on behavioral change for CHN’s new Web users, and its a posteriori potential health improvement effect, could not be measured nor assessed either quantitatively or qualitatively. In this regard, this peer-to-peer emailing experiment does not add to the scarcity of knowledge and understanding of the factors and conditions influencing health outcomes from peer education, peer-to-peer interactions, or virtual communities in health as described by Milburn [12] and Eysenbach [11].

The marketing results of the experiment highlighted in this paper should not be used to predict results for any further use of the same platform for other health promotion websites. Indeed, the experiment was completed at a specific time and in a specific media environment with specific topics, and the campaign self-disseminated within specific interpersonal social networks, reaching specific individuals in specific age groups. In fact, the use by the CHN of the same Internet game platform in 2008, with only slight modifications to the scenarios and scripts, delivered a completely different pattern of epidemic self-dissemination, and in different age groups, but with very similar overall marketing outcomes.

Although the use of the Internet viral marketing platform proved to be a promising breakthrough for the efficient marketing and branding of a governmental health promotion website, further experiments and research are necessary. This work will help to assess more thoroughly the extent of the utility, efficacy, and limits of the tool to drive traffic and build loyalty for health promotion websites; to deepen our understanding of the gaps observed in dissemination rates between age groups and languages (French and English populations); and to understand better the Web user’s behavior while using the game platform, as well as the conditions, factors, and drivers behind the epidemic self-dissemination of the game within personal social networks.

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Conflicts of Interest

None declared.

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Abbreviations

CD-ROM: compact disc read-only memory
CHN: Canadian Health Network
CHUQ: Centre hospitalier universitaire de Québec
NGO: non-governmental organization
PHAC: Public Health Agency of Canada

WHO: World Health Organization

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