Journal of Medical Internet Research

Journal Impact Factor (JIF) (2022): 7.4
Volume 13 (2011), Issue 1   ISSN 1438-8871   Editor in Chief: Gunther Eysenbach, MD, MPH

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Which Intervention Characteristics are Related to More Exposure to Internet-Delivered Healthy Lifestyle Promotion Interventions? A Systematic Review

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Abstract

Background: The Internet has become a popular medium for the delivery of tailored healthy lifestyle promoting interventions. The actual reach of Internet-delivered interventions seems, however, lower than expected, and attrition from interventions is generally high. Characteristics of an intervention, such as personally tailored feedback and goal setting, are thought to be among the important factors related to of use of and exposure to interventions. However, there is no systematic overview of which characteristics of Internet-delivered interventions may be related to more exposure.

Objective: The present study aims to identify (1) which potentially exposure-promoting methods and strategies are used in existing Internet interventions, (2) which objective outcome measures are used to measure exposure to Internet interventions, and (3) which potentially exposure-promoting methods and strategies are associated with better exposure.

Methods: A systematic review of the literature was conducted based on the Cochrane guidelines. Papers published between 1995 and 2009 were searched in the PubMed, PsycINFO, and Web of Science databases. In total, 64 studies were included that reported objective exposure measures such as completion of an initial visit, number of log-ins, and time spent on the website. Information about intervention-related characteristics (ie, interactive behavior change strategies, interactive elements for fun, peer or counsel support, email/phone contact, and regular updates of the website) that could potentially contribute to better exposure and objective exposure outcomes were abstracted from the studies and qualitative systematic descriptive analyses were performed.

Results: The results showed that a large variety of behavior change techniques and other exposure-promoting elements were used in the interventions and that these methods and strategies varied for the various lifestyle behaviors. Feedback, interactive elements, and email/phone contact were used most often. In addition, there was much variety and a lack of consistency in the exposure measures that were reported. Of all the categories of intervention characteristics that may be associated with better exposure, there were indications that peer and counselor support result in a longer website visit and that email/phone contact and updates of the website result in more log-ins.

Conclusions: Results of this qualitative systematic review indicate that of all intervention characteristics that could potentially enhance exposure, only peer support, counselor support, email/phone contact with visitors, and updates of the intervention website were related to better exposure. The diversity of intervention methods used and the inconsistency in the report of exposure measures prevented us from drawing firmer conclusions. More research is needed to identify whether other characteristics of Internet interventions are associated with greater exposure.

(J Med Internet Res 2011;13(1):e2) doi:10.2196/jmir.1639

KEYWORDS

Systematic review; Internet; Internet intervention; exposure; behavior change

Introduction

The Internet has become a primary source for obtaining health information by the public [1-3] making it an interesting medium for providing interventions aimed at promoting healthful behaviors. In the last decade, the number of behavior change interventions that have become available through the Internet has greatly expanded. An advantage of using the Internet as a channel for delivery is the opportunity for health professionals to provide interactive, individualized interventions to large numbers of people [4-8] that match each visitor's unique characteristics, circumstances, beliefs, motivation to change, and behavior [5,9]. Furthermore, a large part of the population can potentially be reached since so many people now have Internet access [10]. The Netherlands is one of the countries with the highest Internet penetration rates, together with Australia, the United States, the United Kingdom, and the Scandinavian countries [10]. Further advantages of the Internet are the easy and constant accessibility of interventions; visitors can access the intervention program at any time and location, can work through the program at their own pace, and can be more anonymous than in face-to-face contacts.

The evidence for efficacy of Internet interventions indicates that Internet-delivered interventions can be effective in changing behaviors even though effect sizes are mostly small [11-15]. However, earlier efficacy studies have indicated that the use of and exposure to the content of Internet interventions may often not be optimal [7,16-18]. Furthermore, visitor engagement in Internet interventions has been found to be lower than initially intended [19], that is, visitors tend to leave the intervention website before completing it [19-21]. This hampers them from being optimally exposed to the intervention content. Many Internet interventions consist of multiple visits, and there is growing evidence that repeated website visits are necessary to achieve sustainable changes [22-24]. Vandelanotte et al [13], for example, reported in a review that better outcome measures regarding improvement of physical activity were identified when participants visited the intervention website more than 5 times. However, other studies reported that only a minority of participants visited an intervention more than once [4,23].

These findings indicate that large improvements can be made with regard to exposure to Internet-delivered interventions, which may contribute to improved intervention efficacy and improved overall impact of an intervention. According to the diffusion of innovations theory [25], characteristics of an innovation (eg, an Internet-delivered intervention) are important in the process of implementation and adoption of an intervention, next to characteristics of users, such as personal characteristics and individual cognitions. In previous—mainly qualitative— studies, a number of intervention-related characteristics have been indicated as potential exposure-enhancing factors [26-31]. Interactive behavior change strategies, such as the provision of individualized computer-tailored feedback and goal setting, may enhance engagement in the intervention content and completion of the program [26-28,31]. Furthermore, intervention elements that make the intervention more attractive to use, such as quizzes, small movies, and other multimedia features, may enhance an extended stay on the website [26,28]. In addition, social support by peers and professionals may enhance an extended stay on the website and may encourage a revisit to an intervention website [26-28,31]. Furthermore, the possibility to monitor progress toward behavior change, the provision of regular new content, and periodic prompts and reminders may improve revisits [26-31]. Even though there is some evidence for intervention characteristics that may enhance exposure, there is no systematic overview of which intervention characteristics are associated with more exposure to Internet interventions. With respect to objective exposure measures, various relevant exposure measures have been suggested in previous studies [4,32], such as accessing the intervention content, number of modules or sessions completed during single or multiple visits, webpage viewing, visit duration, frequency of website visits, and use of specific elements in the intervention (eg, use of self-monitoring tool or bulletin board). The aim of the present study was to conduct a systematic review of the literature and to provide an overview of which characteristics of an intervention are related to better use of and exposure to an Internet intervention. Three specific research questions guided our systematic review: (1) Which potentially exposure-promoting methods and strategies are used in existing Internet interventions? (2) Which objective outcome measures are used to measure exposure to Internet interventions? (3) Which potentially exposure-promoting methods and strategies are associated with better exposure?

Methods

The review was conducted using a review protocol that was developed based on the Cochrane guidelines for systematic reviews [33].

Search Strategy

A structured electronic database search of PubMed, PsycINFO, and Web of Science was conducted for Internet intervention studies published from January 1, 1995, through February 8, 2009. The following search terms were used: "Internet" or "Web" or "online" and "health promotion" or "health education" or "health communication" or "health planning" or "prevention" or "intervention" or "behavio* change" or "behavio* modification." The search was limited to the interventions among adults (18 years and older) and English-language peer-reviewed publications. This search strategy was optimized for all consulted databases.

Inclusion and Exclusion Criteria

A study was eligible for inclusion if it described an Internet intervention that aimed at the primary prevention of physical chronic diseases among the general public from the age of 18. Relevant behaviors included physical activity, nutrition, weight management, smoking cessation, alcohol consumption, or a combination of these behaviors. Furthermore, the Internet interventions needed to be developed for use among the general public. Next, objective quantitative exposure measures (eg, number of log-ins, number of pages visited, completion of the entire intervention or parts of the intervention, time spent on the intervention website, number of visits to the intervention) needed to be reported. Finally, studies evaluating an intervention in a randomized controlled trial (RCT), a quasi-experimental design, or describing use of an intervention only in a single group study could be included.

Review Procedure

The selection of studies took place in 3 phases based on title (author WB), abstract (authors WB and WK), and full publication (WB and WK). Title and abstract screening were done blinded for author, journal, and date of publication. If in doubt about suitability of a study in one phase, the study was included in the next phase. Disagreements on inclusion in the third phase were discussed with a third reviewer (author AO) until consensus was reached.

Data Extraction and Analysis

Data from the included studies were extracted by a team of reviewers and then verified and tabulated for this review by WB, WK, and AO. Based on a standardized extraction form, descriptive key elements and objective exposure measures of all included studies were summarized and presented in tables (Multimedia Appendix 1 and Multimedia Appendix 2). For this extraction, we relied on the information about the study and intervention provided in the published literature (ie, the selected publication, publications that evaluated and reported on the same intervention [see Table 1 for applicable studies], and references to additional design papers or appendices).

Potential exposure-increasing methods and strategies that have been found to be effective in previous studies were divided into the following categories: (1) interactive behavior change strategies, which include methods and strategies delivered in an interactive format (eg, tailored feedback, goal setting tools, action planning tools, or self-monitoring tools); (2) interactive elements, which include elements of the program that are more for fun to improve the attractiveness of the intervention or to provide the option for more information (eg, quizzes, searchable databases, or audio/video); (3) peer support (eg, forum, bulletin board, or chat); (4) counselor support (eg, ask-the-expert, email/phone contact, or counselor-led chat sessions); (5) email and/or phone contact, which may include email/phone messages providing intervention content (eg, personal feedback or newsletters) or email/phone prompts to remind users to revisit the intervention; (6) update of the information on the intervention website, which include, for example, new tools, information, or news; (7) intervention incentives, which refer to incentives that are related to using the Internet intervention and not related to taking part in a study.

For consistency and comparability among studies, the taxonomy of Abraham and Michie was used for the description of interactive behavior change strategies [34]. Within computer-tailored feedback, various types of feedback can be distinguished, such as feedback on performance, cognitive constructs, barrier identification and solutions, and cognitive and behavioral processes. In this study, we considered tailored feedback as one interactive behavior change strategy. Feedback on progress was included separately as this kind of feedback can only be given during a revisit.

Due to the significant heterogeneity between the studies and the variation in the reported exposure measures, the data could not be pooled for quantitative analysis. Therefore, qualitative, systematic, descriptive analyses were performed. This method has been proven to be suitable for systematic reviews [35].

To gain insight into which intervention characteristics may result in better exposure, the studies were listed in a matrix, linking the potential exposure-promoting intervention elements with the outcome measures (Tables 3 and 4). The objective exposure measures used in the different studies were very diverse and presented in different statistics (see Multimedia Appendix 1). Therefore, only those objective exposure measures that are used frequently and presented in the same statistic value are presented in Tables 3 and 4. In Tables 3 and 4, a division was made between interventions that offered fewer than 3 versus more than or equal to 3 interactive behavior change strategies, and that offered interactive elements (yes vs no), peer support (yes vs no), counselor support (yes vs no), email/phone contact (yes vs no), update of the intervention website (yes vs no), and intervention incentive (yes vs no). From this matrix, patterns could emerge indicating that the existence of certain intervention characteristics could result in more exposure to the intervention. Criteria for determining that an exposure-promoting element is probably related to an exposure outcome were that at least 50% of the Internet interventions that included the specific exposure-promoting element should be in the highest exposure category and that the number of studies in the highest category differed substantially (at least 35% difference) from the number of interventions without that element in the highest category of exposure. Only when there was a good balance in the number of interventions that did or did not have a specific exposure-promoting element, inferences about a relation between exposure promoting elements and exposure could be made.

Results

Study Selection

The initial cross-database search yielded 7764 unique publications (Figure 1). After reviewing titles, abstracts, and full publications, 70 publications describing 64 studies were eligible for inclusion in the review (see Table 1). In total, 192 publications were excluded based on abstract and full publication. The most common reason for exclusion in this phase was that a publication did not describe an Internet intervention aimed at the primary prevention of physical chronic diseases (n = 112). Other publications were excluded because they focused on persons below the age of 18 (n = 11), were not targeted at the general public as end users (n = 3), or did not describe the evaluation of an Internet intervention (n = 37). Finally, 29 publications were excluded, as they did not include objective exposure outcome measures.

Figure 1. Flow chart review procedure

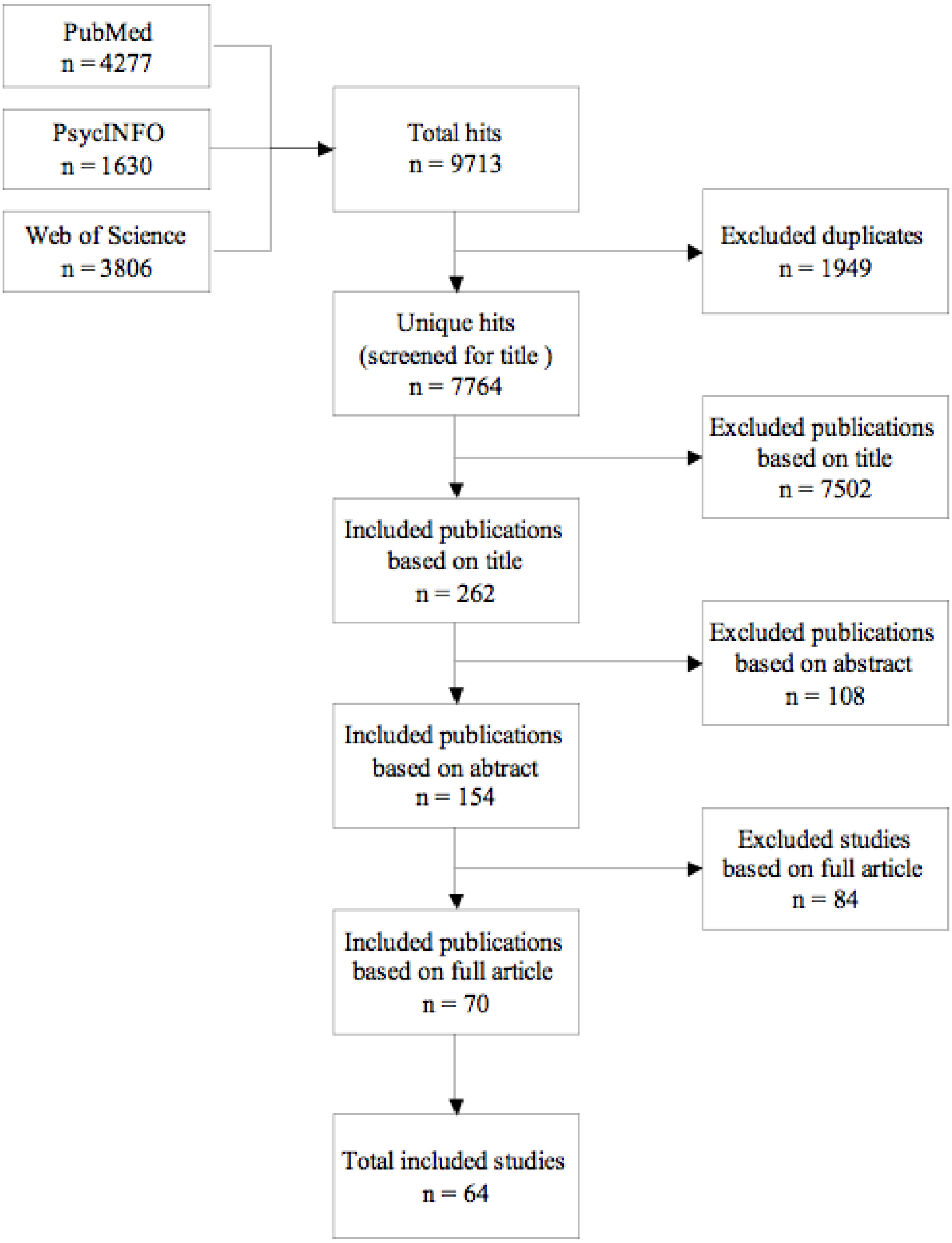

Table 1. List of included publications for review by behavior (see Multimedia Appendix 1 and Multimedia Appendix 2 for details on study characteristics and intervention descriptions)

A. Physical activity
1. Carr et al [36], 2008, United States
2. Dunton and Robertson [37], 2008, United States
3. Ferney et al [28], 2008, Australia
4. Herman et al [38], 2006, United States
5. Hurling et al [39], 2007, United Kingdom
6. Hurling et al [40], 2006, United Kingdom
7. Lewis et al [41], 2008; Marcus et al [42], 2007, United States
8. Leslie et al [16], 2005, Australia
9. Plotnikoff et al [43], 2006, Canada
10. Spittaels and De Bourdeaudhuij [44], 2006, Belgium
11. Spittaels et al [45], 2007, Belgium
12. Steele et al [46,47], 2007, Australia
B. Nutrition
13. Buller et al [48], 2008; Woodall et al [49], 2007, United States
14. Huang et al [50], 2006, Australia
15. McNeill et al [51], 2007, United States
16. Papadaki and Scott [52], 2005; Papadaki and Scott [53], 2006, Scotland
C. Weight management
17. Cussler et al [54], 2008, United States
18. Glasgow et al [21], 2007, United States
19. Gold et al [55], 2007, United States
20. Harvey-Berino et al [56], 2002, United States
21. Hunter et al [57], 2008, United States
22. McConnon et al [58], 2007, United Kingdom
23. McCoy et al [59], 2005, Australia
24. Micco et al [60], 2007, United States[b]
25. Petersen et al [61], 2008, United States
26. Tate et al [62], 2001, United States
27. Tate et al [63], 2006, United States
28. Webber et al [64], 2008, United States
29. Van Wier et al [65], 2009, Netherlands
30. Wing et al [66], 2006, United States
D. Smoking cessation
31. Balmford et al [67], 2008, Australia
32. Brendryen et al [68], 2008, Norway
33. Brendryen and Kraft [69], 2008, Norway
34. Cobb et al [70], 2005, United States
35. Danaher et al [32], 2006, United States
36. Feil et al [71], 2003, United States
37. Graham et al [72], 2007, United States
38. Houston and Ford [73], 2008, United States

39. Lenert et al [22], 2003, United States
40. McKay et al [74], 2008, United States
41. Saul et al [75], 2007, United States
42. Severson et al [31], 2008, United States
43. Stoddard et al [76], 2005, United States
44. Stoddard et al [77], 2008, United States
45. Strecher et al [78], 2005, England and Ireland
46. Strecher et al [79,80], 2008, United States
47. Swartz et al [81], 2006, United States
48. Wang and Etter [82], 2004, Switzerland

E. Alcohol reduction

49. Cloud and Peacock [83], 2001, United States
50. Cunningham et al [84], 2000, Canada
51. Lieberman [85], 2006, United States
52. Linke et al [86], 2004; Linke et al [87], 2005, United Kingdom
53. Linke et al [88], 2007, United Kingdom
54. Matano et al [89], 2007, United States
55. Riper et al [90], 2008, Netherlands
56. Saitz et al [91], 2004, United States
57. Westrup et al [92], 2003, United States

F. Combination of behaviors

58. Cook et al [93], 2007, United States
59. Cowdery et al [94], 2007, United States
60. Oenema et al [95], 2008, Netherlands
61. Verheijden et al [23], 2007, Netherlands
62. Ware et al [96], 2008, United Kingdom
63. Winett et al [97], 2007, United States
64. Woolf et al [98], 2006, United States

Characteristics of Selected Studies

Of the 64 included studies, 39 were performed in the United States, 6 in Australia, 6 in the United Kingdom and Ireland, 4 in the Netherlands, 2 in Belgium, 2 in Canada, 2 in Norway, and 1 in Switzerland. In all, 12 studies described in 14 publications (hereafter, the number of publications referenced may exceed the number of studies to which they refer) targeted physical activity [16,28,36-47], 4 targeted nutrition (eg fruit, vegetable, or saturated fat consumption) [48-53], 14 targeted weight management (eg, weight loss/reduction or weight maintenance/control) [21,54-66], 18 targeted smoking cessation [22,31,32,67-82], 9 targeted alcohol reduction [83-92], and 7 targeted multiple behaviors [23,93-98]. Most studies had an RCT design and 14 studies were observational one-group studies evaluating use of the Internet intervention. The length of the interventions varied from a one-time visit to 18 months with multiple visits. The majority of the Internet interventions were explicitly informed by one or more behavioral theories. The social cognitive theory [99], the transtheoretical model in total [100], or the stages of change concept from this model only [100] were used most often. A more detailed description of the study characteristics can be found Multimedia Appendix 2.

Characteristics of Study Populations

Multimedia Appendix 2 shows that the number of study participants ranged from 32 to 67,324 with an overall mean of 3367 participants and a median of 408. The mean age varied from 32 to 52 years and the percentage of female participants ranging from 2% to 100%. The percentage of participants with education at a level higher than high school (if reported) varied from 41% to 100%.

Exposure-Improving Methods and Strategies

Table 2 lists the potential exposure-improving methods and strategies used in the interventions. If two or more Internet interventions were described in one publication, the most extended intervention or the intervention that delivered the content mostly through the Internet is taken into account.

Table 2. Potential exposure-improving methods and strategies applied in the Internet interventions for the various health-related behaviors (see Multimedia Appendix 1 for details)

	Physical Activity (n 12)		Nutrition (n = 4)		Weight Management (n = 14)		Smoking Cessation (n = 18)		Alcohol Consumption (n = 9)		Multiple Behaviors (n = 7)		Total (N = 64)	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Interactive Behavior Change Strategy														
Feedback[a]	8	67	1	25	7	50	15	83	9	100	7	100	47	73
Goal setting	7	58	0	0	5	36	0	0	1	11	3	43	16	25
Action/activity planning	8	67	0	0	2	14	12	67	0	0	3	43	25	39
Self-monitoring	8	67	0	0	11	79	6	33	5	56	3	43	33	52
Feedback on progress	7	58	0	0	6	43	2	11	3	33	5	72	23	36
Interactive elements[b]	9	75	4	100	8	57	10	56	8	89	5	72	44	69
Peer support	5	42	1	25	9	64	10	56	5	56	1	14	31	48
Counselor support	4	33	1	25	10	71	9	50	0	0	0	0	24	38
Email/phone contact	9	75	3	75	12	86	14	78	2	22	3	43	43	67
Update	5	42	2	50	8	57	6	33	3	33	2	29	26	41
Intervention incentive	2	17	2	50	6	43	1	6	0	0	0	0	11	17

[a] Feedback includes feedback on performance, cognitive constructs, barrier identification and solutions, and cognitive and behavioral processes.

[b] Interactive elements are, for example, quizzes, searchable databases or libraries, heart rate/BMI calculator, and website links.

Multimedia Appendix 1 provides a more detailed description of the methods and strategies applied in each Internet intervention.

The provision of tailored feedback (eg, on performance, cognitive constructs, barrier identification and solutions, and cognitive and behavioral processes) was the most often used behavior change strategy across the behaviors except for nutrition and weight management interventions. Goal setting was offered more often in physical activity interventions; action/activity planning was most often used in the physical activity and smoking cessation interventions and self-monitoring in the physical activity and weight management interventions. Feedback on progress was most often used in the multiple behavior interventions, followed by physical activity. The majority of the interventions in all behavioral domains included interactive elements such as quizzes, searchable databases or libraries, heart rate/BMI calculator, and website links, with less use of these elements in weight management and smoking cessation interventions. Peer support was most often used in the weight management, smoking cessation, and alcohol consumption interventions, while counselor support was most common in the weight management interventions, followed by the smoking cessation interventions. Email/phone contact was frequently used in most interventions except for the alcohol consumption and multiple behavior interventions. Regular updates of the intervention website or provision of an incentive for using the intervention were not often used, but when they were, they were used most in the weight management, nutrition and PA interventions.

Objective Exposure Outcome Measures

A large variety of exposure measures were used in the included studies (see Multimedia Appendix 1). The frequency of visits by means of log-in rates was the most commonly used exposure outcome measure (n = 33) although the way in which the data were presented was not consistent across studies as different statistics were used (eg, mean or median). There were also several studies that did not present log-in rates but did present the percentage of users that revisited the intervention (n = 9). Other often used outcome measures were how many people landed on the website, which was mostly registered by “hits” on the website (n = 10), the number of visitors that accessed the program content (n = 24), the number of pages visited (n = 6), completion of the first visit or module (n = 13), and completion of the whole intervention (n = 8). Furthermore, use of intervention methods and/or strategies were also presented as exposure measures, such as use of specific intervention components (interactive behavior change strategies and interactive elements [n = 26], use of peer support [n = 12], and use of counselor support [n = 10]).

Combining Outcome Measures With Potential Exposure-Promoting Methods and Strategies

In Tables 3 and 4, the studies are listed in matrices combining the objective outcome measures that were mostly presented and the potential exposure-promoting elements. Of all the potential exposure-promoting elements listed in Tables 3 and 4, indications were found for peer support, counselor support, email and/or phone contact with visitors, and updates of the intervention website to be related with more exposure. The provision of peer and counselor support appears to have had a positive influence on the time visitors spent on the website. This can be deduced from the finding that at least 50% of the studies evaluating interventions that included peer or counselor support were listed in the higher category of average time spent on the website compared with the lower percentage of studies evaluating interventions that did not include peer or counselor support, and that the difference in number of interventions listed in the higher category was at least 35%. Both email/phone contact with visitors and updates of the intervention website were related to more average log-ins on the intervention websites, indicated by the higher number of studies on interventions that included these elements listed in the higher average log-in categories, as compared with interventions without these elements.

Table 3. Listing of studies by potential exposure-promoting elements (interactive behavior change strategies, interactive elements, peer support, and counselor support) and the result of exposure measures (also see Table 4 below)

Exposure Measures	Interactive Behavior Change Strategies				Interactive Elements				Peer Support				Counselor Support			
	0-3 Strategies		≥ 3 Strategies		Yes		No		Yes		No		Yes		No	
	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]
Percent of participants completing modules/intervention during first visit (n = 16)																
Total n for element and exposure	15		1		10		6		4		12		3		13	
< 70%	5	35a, 35b, 39, 52, 59			4	35a, 35b 52, 59	1	39	2	35a, 52	3	35b, 39, 59	2	35a, 39	3	35b, 52, 59
70%-90%	6	14a, 29, 50, 51a, 51b, 53			3	14a, 51a, 53	3	29, 50, 51b	1	53	5	14a, 29, 50, 51a, 51b	1	29	5	14a, 50, 51a, 51b, 53
> 90%	4	10, 14b, 43, 64a	1	60	3	10, 43, 64a	2	14b, 60	1	10	4	14b, 43, 60, 64a			5	10, 14b, 43, 60, 64a
Average duration of visits in minutes (n = 16)																
Total n for element and exposure	8		8		11		5		9		7		6		10	
< 10 minutes	5	7b, 13, 40a, 42b, 56	5	5, 7a, 8, 40b, 62	7	5, 7a, 7b, 8, 13, 42b, 56	3	40a, 40b, 62	4	5, 40a, 40b, 62	6	7a, 7b, 8, 13, 42b, 56	2	13, 40a	8	5, 7a, 7b, 8, 40b, 42b, 56, 62
10-20 minutes	3	42a, 44a 44b	3	37, 54a, 54b	4	37, 42a, 54a, 54b	2	44a, 44b	5	37, 42a 44a, 54a 54b	1	44b	4	37, 42a, 44a, 44b	2	54a, 54b
Average number of pages visited (n = 4)																
Total n for element and exposure	2		2		4		0		1		3				3	
< 10 pages	1	49			1	49					1	49			1	49
10-50 pages	1	15	1	8	2	8,15					2	8,15	1	37	2	8,15
> 50 pages			1	37	1	37			1	37						
Average number of log-ins on website (n = 27)																
Total n for element and exposure	16		11		19		8		15		12		11		16	
1-5 times	6	3b, 13, 15, 40a, 42a, 42b	3	40b, 54a, 54b	6	13, 15, 42a, 42b, 54a, 54b	3	3b, 40a, 40b	5	40a, 40b, 42a, 54a, 54b	4	3b, 13, 15, 42b	3	13, 40a, 42a	6	3b, 15, 40b, 42b, 54a, 54b
5-10 times	3	3a, 26b, 36	1	6b	3	3a, 26b, 36	1	6b	2	3a, 36	2	6b, 26b	2	3a, 36	2	6b, 26b
> 10 times	7	16, 21, 26a, 28a, 28b, 32, 33	7	5, 6a, 12a, 12b, 22, 37, 62	10	5, 6a, 12a, 12b, 16, 21, 26a, 28a, 28b, 37	4	22, 32, 33, 62	8	5, 6a, 16, 26a, 28a, 28b, 37, 62	6	12a, 12b, 21, 22, 32, 33	6	12a, 12b, 21, 26a, 28a, 37	8	5, 6a, 16, 22, 28b, 32, 33, 62
Percent of participants who revisited website (n = 8)																

Exposure Measures	Interactive Behavior Change Strategies				Interactive Elements				Peer Support				Counselor Support			
	0-3 Strategies		≥ 3 Strategies		Yes		No		Yes		No		Yes		No	
	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]
Total n for element and exposure	3		5		5		3		5		3		3		5	
< 20%	2	48, 61	1	9	1	61	2	9, 48	1	48	2	9,61			3	9,48,61
20%-50%	1	31	2	11a, 41	2	11a, 41	1	31	2	11a, 41	1	31	1	41	2	11a,31
> 50%			2	34, 37	2	34, 37			2	34, 37			2	34,37		
Percent of participants who completed all modules in multiple visits (n = 10)																
Total n for element and exposure	4		6		6		4		5		5		1	9	9	
< 20%	2	52, 53			2	52, 53			2	52, 53					2	52, 53
20%-50%			4	6b, 62, 63a, 63b	2	63a, 63b	2	6b, 62	1	62	3	6b, 63a, 63b			4	6b, 62, 63a, 63b
> 50%	2	32, 33	2	6a, 37	2	6a, 37	2	32, 33	2	6a, 37	2	32, 33	1	37	3	6a, 32, 33

[a] The numbering of studies corresponds with the numbering of studies in Table 2 and the Multimedia Appendices: physical activity study numbers are 1-12; nutrition, 13-16; weight management, 17-30; smoking cessation, 31-48; alcohol consumption, 49-57; and multi-behaviors, 58-64. The letters a and b are used when in a study different Internet interventions are described (see Multimedia Appendix 1 and Multimedia Appendix 2.)

Table 4. Listing of studies by potential exposure-promoting elements (email/phone contact, updates, and intervention incentives) and the result of exposure measures[a]

Exposure Measures	Email/Phone Contact				Update				Intervention Incentive			
	Yes		No		Yes		No		Yes		No	
	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]
Percent of participants completing modules/intervention during first visit (n = 16)												
Total n for element and exposure	6		10		4		12		0		16	
< 70%	3	35a, 39, 52	2	35b, 59	2	35a, 52	3	35b, 39, 59			5	35a, 35b, 39, 52, 59
70%-90%	2	29, 53	4	14a, 50, 51a, 51b	2	29, 53	4	14a, 50, 51a, 51b			5	14a, 50, 51a, 51b, 53
> 90%	1	64a	4	10, 14b, 43, 60			5	10, 14b, 43, 60, 64a			6	10, 14b, 29, 43, 60, 64a
Average duration of visits in minutes (n = 16)												
Total n for element and exposure	10		6		4		12		2		14	
< 10 minutes	6	5, 7a, 7b, 8, 13, 62	4	40a, 40b, 42b, 56	3	7a, 8, 13	7	5, 7b, 40a, 40b, 42b, 56, 62	1	13	9	5, 7a, 7b, 8, 40a, 40b, 42b, 56, 62
10-20 minutes	4	37, 42a, 44a, 44b	2	54a, 54b	1	42a	5	37, 44a, 44b, 54a, 54b	1	37	5	42a, 44a, 44b, 54a, 54b
Average number of pages visited (n = 4)												
Total n for element and exposure	3		1		1		3		2		2	
< 10 pages			1	49	1	8	1	49			1	49
10-50 pages	2	8, 15					1	15	1	15	1	8
> 50 pages	1	37					1	37	1	37		
Average number of log-ins on website (n = 27)												
Total n for element and exposure	18		9		11		16		5		22	
1-5 times	4	3b, 13, 15, 42a	5	40a, 40b, 42b, 54a, 54b	2	13, 42a	7	3b, 15, 40a, 40b, 42b, 54a, 54b	2	13, 15	7	3b, 40a, 40b, 42a, 42b, 54a, 54b
5-10 times	2	3a, 36	2	6b, 26b	1	3a	3	6b, 26b, 36			4	3a, 6b, 26b, 36
> 10 times	12	5, 6a, 12a, 12b, 16, 21, 22, 26a, 32, 33, 37, 62	2	28a, 28b	8	12a, 12b, 16, 21, 28a, 28b, 32, 33	6	5, 6a, 22, 26a, 37, 62	3	12a, 16, 37	11	5, 6a, 12b, 21, 22, 26a, 28a, 28b, 32, 33, 62
Percent of participants who revisited website (n = 8)												

Exposure Measures	Email/Phone Contact				Update				Intervention Incentive			
	Yes		No		Yes		No		Yes		No	
	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]	n	Study Number[a]
Total n for element and exposure	7		1		1		7		1		7	
< 20%	2	48, 61	1	9	1	61	2	9, 48			3	9, 48, 61
20%-50%	3	11a, 31, 41					3	11a, 31, 41			3	11a, 31, 41
> 50%	2	34, 37					2	34, 37	1	37	1	34
Percent of participants who completed all modules in multiple visits (n = 10)												
Total n for element and exposure	7		3		6		4		1		9	
< 20%	2	52, 53			2	52, 53					2	52, 53
20%-50%	1	62	3	6b, 63a, 63b	2	63a, 63b	2	6b, 62			4	6b, 62, 63a, 63b
> 50%	4	6a, 32, 33, 37			2	32, 33	2	6a, 37	1	37	3	6a, 32, 33

[a] The numbering of studies is explained in the footnote to Table 3.

Discussion

Nonoptimal exposure to Internet interventions has been pointed out as a major concern in the field of development, evaluation, and implementation of Internet interventions [19]. According to the diffusion of innovations theory [25], characteristics of (potential) users and characteristics of an intervention (ie, the innovation) are associated with adoption and implementation of interventions. The present review is one of the first to systematically investigate which specific characteristics of an Internet intervention can be associated with better exposure to the intervention and its contents. The study was qualitative in nature and allowed us to point out indications of possible patterns in associations between intervention characteristics and exposure. Of the categories of potential exposure-improving intervention elements that we distinguished in the review (the number of interactive behavior change strategies used, and whether the intervention included interactive elements, peer support, counselor support, email and/or phone contact, update of the intervention website, and intervention incentives), peer and counselor support were related to a longer visit duration, and email/phone contact and update of the intervention website were related to a higher frequency of website log-ins. There were a large variety of potentially exposure-increasing elements applied in the various interventions, and there was a large variety and little consistency in the exposure measures that were reported.

In previous studies, interactively delivered educational content, such as the provision of computer-tailored feedback and goal setting, has been indicated as a potentially exposure-improving element [26-28,31]. The active involvement required for using interactive elements, the personal relevance of feedback, and goals generated may result in more involvement in and better exposure to an intervention program. In this study, however, we did not find an association between the number of interactive behavior change strategies and exposure. This may be due to the fact that there was little variability in the use of these elements. For example, in about three quarters of the interventions, some type of tailored feedback was provided. What this review showed is that there was a marked difference in the use of other interactive educational content between the interventions for the various target behaviors. This may reflect differences in the importance of the underlying determinants and change methods needed to facilitate effective and maintained change in the various behaviors. It may also reflect that Internet applications are more advanced for the promotion of some of the health related behaviors (eg, promotion of physical activity, weight management, and smoking cessation) than for others.

Peer support was offered more often in weight management, alcohol, and smoking cessation interventions as compared with the other behaviors. Based on our criteria, peer support was related to more time spent on the intervention website. This does not necessarily mean, however, that visitors are exposed to and actively engaged in the intervention content, but they may at least be chatting about their target behavior, for example, in a forum or a chat room. Furthermore, it should be noted that previous studies reported that peer support is used to a limited extent and that not all visitors may use peer support [26,27,31]. Peer support was, for example, more often sought by smoking quitters than by visitors that continued smoking [70,72], and women have been found to be more likely to post more messages than men on a message board about smoking cessation [71].

Counselor support was more often a distinct part of the weight management and smoking cessation interventions. The results indicate that counselor support was related to a longer website visit. Although there were an insufficient number of interventions in our study to draw any conclusions about the potential relation between counselor support and revisiting intervention websites, there may be a positive relation. These findings may add positively to the results of previous single studies where inconsistent findings were reported for the relation of counselor support and submission of dietary reports. Tate et al [63], for example, showed that additional human email counseling resulted in higher online diary submissions, whereas Webber et al [64] found the opposite.

Nearly half of the interventions sent email/phone prompts to encourage revisits. Next to that, weight management interventions made more use of emails sent by counselors, whereas physical activity and smoking cessation interventions used automatically generated emails to send intervention content. This review shows that email/phone contact might indeed be useful in promoting repeated visits as has already been indicated in single studies addressing this topic. Furthermore, the postulation that regular updates of the intervention website would be related to repeated visits seems to be supported by the findings of this review. There is growing evidence that repeated website visits are necessary to achieve sustainable changes [22-24]. However, disappointing results regarding revisiting have been published, as website visits tend to decrease sharply after the initial weeks of participation [4,23,39]. It is, therefore, promising that email prompts and regular updates of intervention content may contribute to more visits, since these are relatively easy to implement exposure-promoting strategies.

Another important finding in this review is that there was a large variety in the report of objective exposure measures but also that many studies that did not report exposure data at all. We had to exclude 29 publications solely because they did not present any objective exposure measures. The number of log-ins on the intervention website was the most frequently reported exposure measure, but this measure was presented in different ways, which limited the options of pooling the data. Other often-presented exposure measures were completion of the initial visit, visit duration, and completion of the intervention program in case revisits were required. It is not only important that objective exposure measures (eg, starting intervention, completing modules/intervention, frequency of visiting, and duration of visit) are presented in studies evaluating Internet interventions [32,101], but it is also important that these measures are presented in a standardized way. Furthermore, for the purpose of systematic reviews, it is very important that accurate and complete descriptions of intervention content and interactive applications are provided in the future. This would make it possible to compare and pool different studies and enlarge the strength of the conclusions that can be drawn. In addition, objective exposure measures should be linked to visitor characteristics to get a more thorough impression about who is reached with what kind of intervention and to what extent. Furthermore, this registration on the individual level would also make it possible to study possible mediating effects of exposure to these objective exposure outcome measures.

To be able to relate the potentially exposure-improving intervention characteristics with exposure measures, we developed a matrix containing both elements. We listed all studies in this matrix by categorizing them according to, for example, the number of interactive behavior change strategies used and the presence of peer or counselor support and the result of the exposure outcome. From this qualitative integrative approach, we derived that peer support was associated with a longer stay on the website, whereas email/phone contact and update of the intervention website were related to more log-ins on the intervention website. We did not find an indication of better exposure to the intervention for the other categories of potential exposure-enhancing intervention characteristics, even if these have been indicated as such in previous studies [26-31]. This is also in contrast with the findings of individual studies in which a more extensive version of an intervention with more interactive characteristics was compared with a more basic version. A more interactive intervention resulted, for example, in a longer visit to the intervention [31,77] and in more log-ins on the intervention website [28,31,62]. One possible reason for not finding differences in exposure according to the use of more as compared with fewer interactive behavior change strategies is the way in which we divided the interventions (< 3 or ≥ 3 interactive behavior change strategies) and that we pooled all the interventions targeting different health-related behaviors together.

The findings of our study are partly in line with the only other study that investigated the same topic among adolescents and young adults [102]. Similar to our study, they also found a heterogeneity of exposure measures and identified different exposure-increasing methods and strategies, such as tailored feedback, use of interactive elements, email support, and reminders. Furthermore, single studies showed that more interactive interventions resulted in a higher exposure to the intervention content than a basic version. Nevertheless, we have to keep in mind that younger people use the Internet differently than adults [3,103].

Limitations

There are some limitations to this review study that need to be mentioned. The search strategies were limited to include only peer-reviewed English language publications. Therefore, we could have missed important “gray literature” and publication in languages other than English. Next, for this review we relied on the information that was provided in the published literature regarding the description of the intervention and identification of potentially exposure-promoting methods and strategies. Some of the intervention descriptions were very brief, and even the more extensive descriptions available in the literature may not always have been complete. Therefore, we may have missed some of the potential exposure-promoting elements that an intervention contained. In addition, this review can be qualified as a qualitative review as the extracted data from the included studies were summarized and not statistically pooled, which limits the strength of the conclusions that can be drawn. Finally, the used cutoff points for making a ranking within the categories of potential exposure-promoting interventions elements (ie, < 3 or ≥ 3 interactive behavior change strategies, and yes vs no interactive elements) may not have been sensitive enough to detect differences in exposure.

Conclusion

The studies included in this review showed that in the Internet interventions currently available, a wide variety of potentially exposure-improving methods and strategies were used. These methods and strategies were markedly different for the healthy lifestyle behaviors that were studied. Also, a large variety of objective exposure outcome measures were used and there was a lack of consistency in exposure measures reported. Peer support, counselor support, email/phone contact with visitors through sending intervention content and prompts and updates of the intervention website were indicated to result in a longer visit and more log-ins on the website, respectively. More research is needed to gain insight into how intervention characteristics can be used to improve exposure to Internet interventions. More accurate and consistent description of intervention content and more consistency in the report of objective exposure outcomes are recommended. This will enable researchers to better assess associations between intervention characteristics and exposure to health behavior change Internet interventions in the future.

Acknowledgments

We would like to thank Mara van Dooremaal and Linda Springvloet for their assistance during the title screening. We would also like to thank Mirjam van Beelen, Marielle Beenackers, Tinneke Beirens, Pepijn van Empelen, Vicki Erasmus, Nicole Ezendam, Lenneke van Genugten, Amy van Grieken, Meeke Hoedjes, Rick Prins, Suzan Robroek, Mirjam Struijk, and Lidy Veldhuis for their assistance during the data extraction.

Conflicts of Interest

None declared

Multimedia Appendix 1

Overview of study and intervention characteristics and objective outcome measures of exposure to Internet interventions by behavior

[PDF file (Adobe PDF), 376 KB - jmir_v13i1e2_app1.pdf]

Multimedia Appendix 2

Summary of studies included in this review: target behavior, study characteristics, brief description of Internet intervention content and duration, theory, number of study participants and characteristics of study population

[PDF file (Adobe PDF File), 408 KB - jmir_v13i1e2_app2.pdf]

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Abbreviations

RCT: randomized controlled trial

Edited by G Eysenbach; submitted 31.08.10; peer-reviewed by M Wanner, B Cugelman; comments to author 16.10.10; revised version received 17.11.10; accepted 03.12.10; published 06.01.11.

Please cite as:
Brouwer W, Kroeze W, Crutzen R, de Nooijer J, de Vries NK, Brug J, Oenema A
Which Intervention Characteristics are Related to More Exposure to Internet-Delivered Healthy Lifestyle Promotion Interventions? A Systematic Review
J Med Internet Res 2011;13(1):e2
URL: http://www.jmir.org/2011/1/e2/
doi:10.2196/jmir.1639
PMID:21212045

Original Paper

Patient Ability and Willingness to Participate in a Web-Based Intervention to Improve Hypertension Control

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Abstract

Background: Patient-shared electronic health records provide opportunities for care outside of office visits. However, those who might benefit may be unable to or choose not to use these resources, while others might not need them.

Objective: Electronic Communications and Home Blood Pressure Monitoring (e-BP) was a randomized trial that demonstrated that Web-based pharmacist care led to improved blood pressure (BP) control. During recruitment we attempted to contact all patients with hypertension from 10 clinics to determine whether they were eligible and willing to participate. We wanted to know whether particular subgroups, particularly those from vulnerable populations, were less willing to participate or unable to because they lacked computer access.

Methods: From 2005 to 2006, we sent invitation letters to and attempted to recruit 9298 patients with hypertension. Eligibility to participate in the trial included access to a computer and the Internet, an email address, and uncontrolled BP (BP ≥ 140/90 mmHg). Generalized linear models within a modified Poisson regression framework were used to estimate the relative risk (RR) of ineligibility due to lack of computer access and of having uncontrolled BP.

Results: We were able to contact 95.1% (8840/9298) of patients. Those refusing participation (3032/8840, 34.3%) were significantly more likely ($P < .05$) to be female, be nonwhite, have lower levels of education, and have Medicaid insurance. Among patients who answered survey questions, 22.8% (1673/7354) did not have computer access. Older age, minority race, and lower levels of education were risk factors for lack of computer access, with education as the strongest predictor (RR 2.63, 95% CI 2.30-3.01 for those with a high school degree compared to a college education). Among hypertensive patients with computer access who were willing to participate, African American race (RR 1.22, 95% CI 1.06-1.40), male sex (RR 1.28, 95% CI 1.18-1.38), and obesity (RR 1.53, 95% CI 1.31-1.79) were risk factors for uncontrolled BP.

Conclusion: Older age, lower socioeconomic status, and lower levels of education were associated with decreased access to and willingness to participate in a Web-based intervention to improve hypertension control. Failure to ameliorate this may worsen health care disparities.

Trial Registration: Clinicaltrials.gov NCT00158639; http://www.clinicaltrials.gov/ct2/show/NCT00158639 (Archived by WebCite at http://www.webcitation.org/5v1jnHaeo)

(J Med Internet Res 2011;13(1):e1) doi:10.2196/jmir.1625

KEYWORDS

electronic medical record

Introduction

There is increasing evidence that patient access to practice-based electronic health records (defined here as patient-shared electronic health records) [1], combined with secure Web-based communications between patients and health care providers, improves the treatment of chronic diseases [2,3], and may result in improved health outcomes and decreased costs [4,5]. Their use is consistent with the Institute of Medicine's *Crossing the Quality Chasm* report, which states that care should not just occur with face-to-face visits, but that continuous "access to care should be provided over the Internet" [6] and that meaningful use of health information technology should be implemented [7]. However, some patients may choose not to engage in Web-based health care and others may be unable. Older patients, ethnic and racial minorities, and those with lower education levels or who are unemployed have less access to the Web, typically described as the "digital divide" [8-11]. Other patients with Web access might be healthier than those without access, potentially increasing health outcome disparities.

The Electronic Communications and Home Blood Pressure Monitoring (e-BP) study was a randomized controlled trial designed to test whether use of home blood pressure (BP) monitoring, use of an existing patient Web portal with a patient-shared electronic health record and secure email, and Web-based pharmacist-assisted care led to hypertension control. During recruitment we attempted to contact all patients with hypertension from 10 clinics to determine whether they were eligible and willing to participate. Patients randomized to home BP monitoring and Web-based collaborative care with a pharmacist were almost twice as likely as those in usual care to have controlled BP at the 12-month follow-up visit (adjusted relative risk [RR] 1.84, 95% CI 1.48-2.29) [2]. We describe here characteristics of patients with hypertension who were not eligible to participate because of lack of computer access. Of those with computer access, we also compared characteristics of patients with controlled and uncontrolled hypertension. Identifying characteristics of these populations will provide a context for engaging participation in and designing future Web-based interventions that lead to improved health outcomes for all populations.

Methods

We attempted to contact all patients with a diagnosis of hypertension and taking medications for this from 10 primary care clinics to invite them to participate in the e-BP trial. During recruitment patients could refuse to participate (either actively or passively, by not responding) or be ineligible to participate because of lack of computer access, having controlled BP, or having other ineligibility medical conditions. We attempted to survey all patients contacted regardless of their willingness and eligibility to participate in the e-BP trial. Eligible patients who provided consent were randomly assigned to (1) usual care, (2) receive a home BP monitor and training to use it, and training to use an existing patient Web portal with secure messaging and other Web services, or (3) group 2 interventions plus collaborative pharmacist care management delivered via Web communications. The study design was based on the chronic care model [12]. A complete description of the methods and recruitment processes of the e-BP study were reported elsewhere, but an overview follows [13].

Study Setting

We recruited participants between June 2005 and December 2006 at 10 primary care medical centers within Group Health, a nonprofit, integrated group practice that provides both medical coverage and care to more than 600,000 residents of Washington State and Idaho. Group Health Research Institute's Institutional Review Board reviewed and approved this study.

Group Health has a comprehensive electronic health record system, EpicCare (Epic Systems Corporation, Verona, Wisconsin, USA), which integrates clinical communication and information processes into a single interface that includes physician order entry (eg, laboratory tests, prescriptions, and referrals), documentation of all patient encounters, clinical decision support, clinical messaging between physicians, secure online messaging with patients, and automated reminders at the point of care. Group Health provides patients with access to the electronic health record via a patient Web site (myGroupHealth), which they can use to refill medications, make appointments, view portions of their medical record (current health conditions, laboratory test results, after-visit summaries, allergies, and medications), and send secure messages to their health care team. Detailed description of the patient Website and its integration into overall access to care at Group Health is described elsewhere [14,15].

Recruitment

We used clinical and administrative data routinely collected and maintained by Group Health to identify all patients age 25-75 years with a diagnosis of hypertension and taking antihypertensive medications, with no diagnoses of diabetes, cardiovascular or renal disease, or other serious conditions (such as dementia or active treatment of cancer). Research assistants telephoned potential participants to confirm eligibility, including computer access (defined as access to a computer, the Internet, and an email address), and willingness to attend screening visits. All patients surveyed by telephone, including those ineligible or refusing to participate in the study, were asked to answer several demographic questions (race and ethnicity, education level, occupation), computer access questions, and whether they owned a home BP monitor.

Patients with a hypertension diagnosis, computer access, and no other exclusions were invited to an in-person screening visit at their primary care medical center to obtain BP measurements. Patients who had not previously signed up to use the myGroupHealth patient Website secure services were assisted in doing so and given Group Health pamphlets on the various functionalities of the Web portal. Patients were eligible to participate in the trial if their BP was elevated at both of two in-person screening visits. BP was measured three times at each visit using a validated Omron Hem-705CP automated monitor (OMRON Corporation, Schaumburg, IL, USA) with a cuff fitted for the patient's upper arm circumference [16]. The first measurement was dropped and the last two were averaged. If the mean diastolic BP was 90-109 mmHg or systolic BP was 140-199 mmHg at both visits, the patient was invited to participate, and written informed consent was obtained. Patients were randomly assigned to one of three study conditions. Group 1 (usual care) received Group Health's pamphlet on elevated BP and were advised to work with their doctor to improve their BP control. Group 2 (Web only) received a home BP monitor and training to use it proficiently on their own and a tour of the functionalities of the myGroupHealth Website. Group 3 (Web plus pharmacist) was the same as group 2 plus Web-based pharmacist collaborative care. Intervention components are described in more detail elsewhere [2,13].

Measures

We used automated databases to obtain sex, age, insurance plan type (commercial, Medicare, Medicaid, or state-subsidized basic health), prior use of secure messaging, and body mass index (BMI) using the most recently recorded weight and height. The Johns Hopkins Adjusted Clinical Group's case-mix system was used to measure each individual's overall level of morbidity burden. Their software assigns each individual a level of overall morbidity depending on age, sex, and number and types *International Classification of Diseases*, ninth revision, codes over a 12-month period [17,18]. Patients were classified as having high, medium, or low expected clinical need. Demographic variables not available in the Group Health databases, including education level, employment status, marital status, and race, were collected during the telephone survey. When participants chose more than one category for race, coding precedence was given to Hispanic, non-Hispanic black, Asian, other, and non-Hispanic white categories, in that order. Survey participants were also asked if they used a home BP monitor.

Statistical Analysis

We present frequencies of patient characteristics by four recruitment outcomes (unable to contact, refused, ineligible, and randomized) and applied Pearson chi-square tests to assess any differences between groups. To evaluate factors related to computer access we used generalized linear models with a log link and robust sandwich variance estimator using a modified Poisson regression framework to estimate RR of not having computer access [19]. Logistic regression models were not used because computer access was not rare. We present two sets of adjusted RRs: (1) adjusted for age and sex only, and (2) adjusted for all variables shown in Table 2 including age, sex, socioeconomic measures, BMI, expected clinical need, and having a home BP monitor.

Modified Poisson regression models were also used to estimate the RR of uncontrolled BP among participants attending the screening visits. We present two sets of adjusted RRs for uncontrolled BP: (1) adjusted for age and sex only, and (2) adjusted for age, sex, education, race, and BMI. In our full model, we adjusted only for covariates that were associated with the uncontrolled BP in the first model. The primary analysis defined BP control based on the BP measurement from the first screening visit. A sensitivity analysis was also performed using a more conservative definition of uncontrolled BP based on study recruitment guidelines requiring uncontrolled BP at both screening visits.

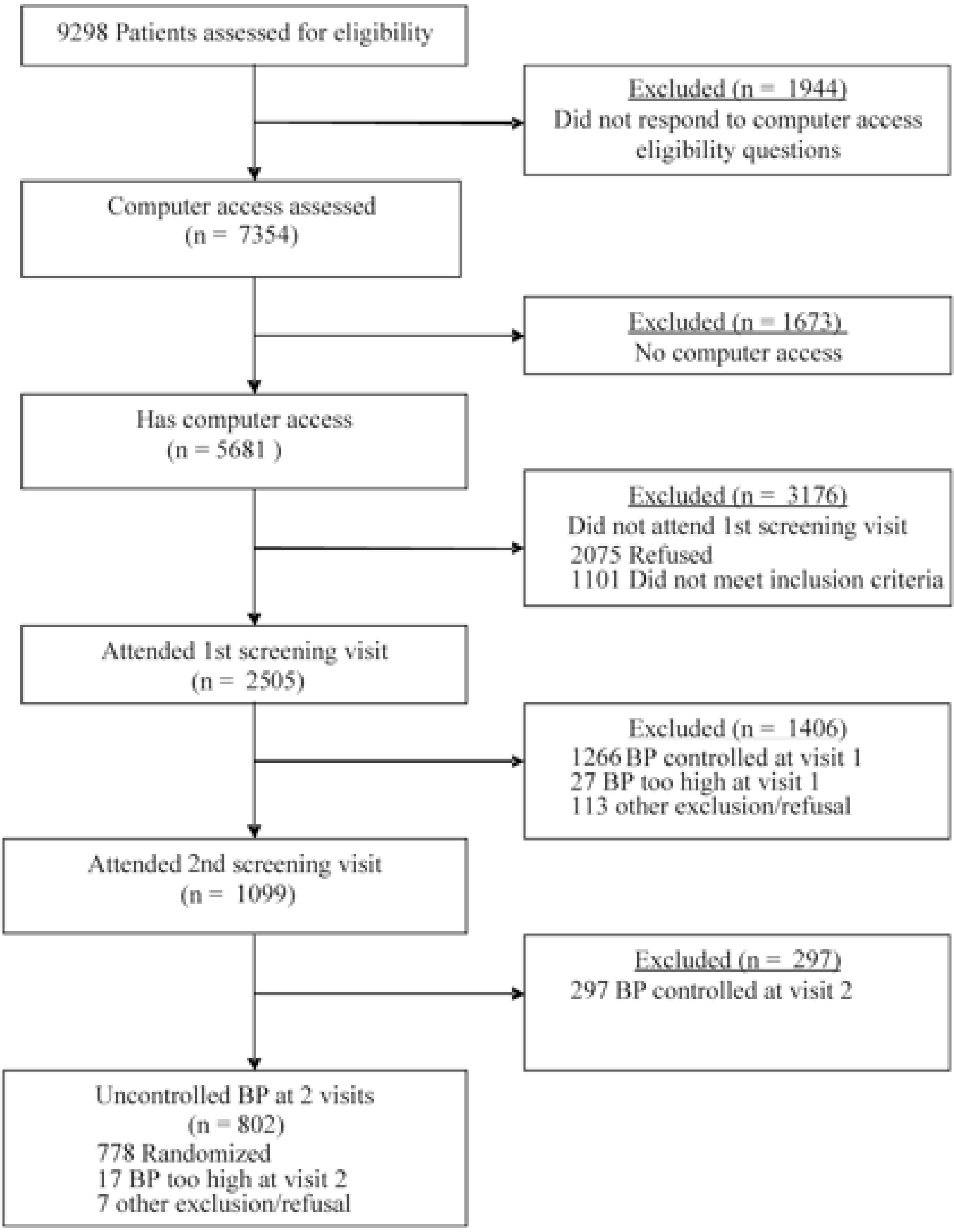
Medicare insurance was omitted from multivariable models including both insurance type and age because of the significant overlap with the age category 65-75 years. In models estimating the RR of uncontrolled BP, the employment categories disabled, unemployed, and other were combined due to small sample sizes.

All analyses were performed using Stata version 11.0 statistical software (StataCorp LP, College Station, TX, USA). All reported *P*-values and 95% CIs are two sided with significance defined at the 0.05 alpha level and are based on the Wald statistic unless otherwise specified.

Results

Our recruitment sample (N = 9298) included all patients age 25-74 years from 10 primary care medical centers with administrative data indicating they had a diagnosis of hypertension, were taking antihypertensive medications, and had no exclusionary conditions (Figure 1). Automated data were available on all 9298 hypertension patients who were sent invitation letters. Of the 8840 (95.1%) patients we were able to contact, 83.2% (7354/8840) responded to the survey questions assessing computer access eligibility, including 71.0% (2153/3032) of those who refused participation in the trial.

Figure 1. Recruitment Flow



Refusal and Ineligibility to Participate

Of those we attempted to contact, 32.6% (3032/9298) refused participation, 2598 at the time of the telephone survey and 434 after agreeing to attend a screening visit (either by not attending or by refusing at the time of the screening visit) (Table 1). Compared to trial participants, patients refusing participation were significantly more likely to be female ($P = .002$), to be younger ($P = .002$), to be from a racial or ethnic minority group ($P < .001$), and to have lower levels of education ($P = .002$). The most common reasons for refusal were either being too busy or not being interested in participating. Only 15% (447/3032) listed unwillingness to use the patient Web portal as a reason for refusal.

Over half of the sampled patients (5030/9298, 54%) were ineligible for the study. The most common reasons for ineligibility were lack of computer access (n = 1673), and controlled BP at either the first or second screening visit (n = 1563). If patients lacked computer access they were not invited to have screening BP visits. Thus, patients might have had more than one reason for exclusion that was not ascertained. The demographic characteristics of ineligible patients differed by reason for ineligibility; therefore, we separately examined characteristics associated with the two most common reasons for eligibility, lack of computer access and controlled BP.

Table 1. Demographic characteristics by recruitment outcome (N = 9298)

	Unable to contact		Refused		Ineligible		Randomized	
	n = 458		n = 3032		n = 5030		n = 778	
	n	%	n	%	n	%	n	%
Sex (% female)	246	53.7	1638	54.0[a]	3040	60.4[a]	372	47.8
Age (years)								
25-39	22	4.8[a]	109	3.6[a]	137	2.7[a]	13	1.7
40-54	191	41.7	906	29.9	1322	26.3	214	27.5
55-64	169	36.9	1319	43.5	1951	38.8	334	42.9
65-75	76	16.6	698	23.0	1620	32.2	217	27.9
BMI[b] (kg/m^2)								
Normal/low (<25)	58	17.0[a]	430	16.7[a]	728	17.6[a]	67	9.5
Overweight (25-30)	122	35.8	885	34.3	1375	33.3	227	32.1
Obese (≥30)	161	47.2	1268	49.1	2026	49.1	414	58.5
Missing[c]	117	(25.6)	449	(14.8)	901	(17.9)	70	(9.0)
Insurance product								
Commercial	379	82.8[a]	2328	76.8[a]	3362	66.8[a]	574	73.8
Medicare	66	14.4	661	21.8	1529	30.4	200	25.7
Basic health/Medicaid	13	2.8	43	1.4	139	2.8	4	0.5
Expected clinical need								
Low	156	35.1[a]	632	21.1	809	17.4[a]	145	18.7
Medium	232	52.3	1819	60.7	2803	60.4	507	65.3
High	56	12.6	544	18.2	1032	22.2	124	16.0
Missing[c]	14	(3.1)	37	(1.2)	386	(7.7)	2	(0.3)
Prior use of secure messaging								
(% yes)	101	22.1[a]	1063	35.1[a]	1430	28.4[a]	338	43.4
Race	NA[d]							
White, non-Hispanic			1592	74.6[a]	3335	77.3[a]	637	82.0
Black, non-Hispanic			178	8.3	297	6.9	60	7.7
Hispanic			59	2.8	122	2.8	16	2.1
Asian			159	7.5	294	6.8	28	3.6
Other			147	6.9	264	6.1	36	4.6
Missing[c]			897	(29.6)	718	(14.3)	1	(0.1)
Education	NA[d]							
<HS[e] graduate			24	1.1[a]	129	3.0[a]	5	0.6
HS graduate/GED[f]			257	12.1	672	15.6	57	7.3
Some post-HS			855	40.1	1723	39.9	324	41.7
College graduate			511	24.0	961	22.3	195	25.1
Postgraduate			485	22.8	834	19.3	197	25.3
Missing[c]			900	(29.7)	711	(14.1)	0	(0.0)

	Unable to contact n = 458		Refused n = 3032		Ineligible n = 5030		Randomized n = 778	
	n	%	n	%	n	%	n	%
Employment	NA[d]							
Full-time			1268	59.4	2050	47.4 [a]	435	56.0
Retired			624	29.2	1686	39.0	270	34.8
Part-time			153	7.2	324	7.5	51	6.6
Disabled			23	1.1	68	1.6	4	0.5
Unemployed			22	1.0	63	1.5	7	0.9
Other			44	2.1	133	3.1	10	1.3
Missing[c]			898	(29.6)	706	(14.0)	1	(0.1)
Home blood pressure monitor	N/A[d]							
Yes			1452	67.6[a]	2533	58.4	437	56.2
No			697	32.4	1808	41.7	341	43.8
Missing[c]			883	(29.1)	689	(13.7)	0	(0.0)

[a] *P* < .05, compared to randomized group.

[b] BMI: body mass index.

[c] Percentages with missing data (in parentheses) are not included in column percentages.

[d] NA: not available – survey data not collected from patients we were unable to contact.

[e] HS: high school.

[f] GED: general equivalency diploma.

Computer Access

The majority (7354/8840, 83.2%) of patients we contacted were willing to answer questions on computer access, even those who refused to participate in the study (2153/3032, 71%). Of those answering the computer questions, 22.8% (1673/7354) lacked computer access (no access to a computer, the Web, or email) (Table 2). The RR for lack of computer access was 2.63 (CI 2.30-3.01) for those with a high school diploma and 3.62 (CI 3.05-4.29) for those with less than a high school diploma compared to college graduates. There was a similar relationship between age and lack of computer access. Those ages 65-75 years were two times more likely to not have computer access compared to those ages 40-54 (RR 2.37, CI 2.11-2.67). Being any race or ethnicity other than white was also associated with increased risk for not having computer access, as was being disabled or unemployed, and having Medicaid or state-supported insurance. Age, race-ethnicity, employment, and insurance associations were not attenuated by controlling for education or other covariates. Patients without home BP monitors (at baseline) were also more likely to not have computer access (RR 1.32, CI 1.21-1.44). Anticipated clinical need was not associated with computer access.

Having computer access did not guarantee participation. Almost 40% (2152/5681, 37.9%) of patients with computer access refused participation. Similar to those who refused overall, computer-able refusers were significantly more likely to be female (*P* < .001), younger (*P* = .008), nonwhite (*P* < .001), and less educated (*P* = .002) than those randomized to participate in the study. They also were less likely to have used secure messaging (*P* = .01) and own a home BP monitor (*P* < .001). Even though the majority of people with computer access agreed to go on with the recruitment process, 78.0% (2751/3529) were not eligible, mainly because of controlled BP, discussed in more detail below.

Table 2. Adjusted relative risk (RR) of not having computer access by demographic characteristics among patients for whom computer access was ascertained during the telephone screening survey (n = 7354)

	Access		No Access		Adjusted for age and sex		Adjusted for all variables[a]	
	n	Row %	n	Row %	RR	95% CI	RR	95% CI
Total	5681	77.3	1673	22.8				
Sex								
Female	3207	75.5	1042	24.5	1.00	Referent	1.00	Referent
Male	2474	79.7	631	20.3	0.85	0.78-0.92	1.01	0.91-1.11
Age (years)								
25-39	168	87.1	25	13.0	0.87	0.59-1.26	0.89	0.58-1.36
40-54	1675	84.8	300	15.2	1.00	Referent	1.00	Referent
55-64	2437	81.4	557	18.6	1.23	1.08-1.40	1.33	1.15-1.54
65-75	1401	63.9	791	36.1	2.37	2.11-2.67	2.27	1.92-2.67
BMI[b] (kg/m^2)								
Normal/low (<25)	750	73.8	266	26.2	1.00	Referent	1.00	Referent
Overweight (25-30)	1646	77.5	478	22.5	0.93	0.81-1.05	0.92	0.81-1.04
Obese (≥30)	2543	78.7	687	21.3	0.96	0.85-1.08	0.91	0.80-1.03
Insurance product								
Commercial	4292	83.1	872	16.9	1.00	Referent	1.00	Referent
Basic health/Medicaid	58	52.7	52	47.3	2.74	2.24-3.35	1.98	1.52-2.59
Expected clinical need								
Low	1006	77.1	299	22.9	1.00	Referent	1.00	Referent
Medium	3456	78.9	924	21.1	0.83	0.74-0.93	0.83	0.73-0.95
High	1073	73.2	394	26.8	0.96	0.85-1.09	0.94	0.82-1.09
Race								
White, non-Hispanic	4483	80.5	1085	19.5	1.00	Referent	1.00	Referent
Black, non-Hispanic	398	74.4	137	25.6	1.56	1.34-1.81	1.38	1.17-1.62
Hispanic	138	70.1	59	30.0	1.81	1.47-2.23	1.58	1.26-1.99
Asian	320	66.5	161	33.5	1.86	1.63-2.12	1.96	1.70-2.27
Other	315	70.2	134	29.8	1.60	1.38-1.85	1.42	1.22-1.66
Education								
<HS[c] graduate	57	35.9	102	64.2	3.62	3.05-4.29	3.22	2.67-3.87
HS graduate/GED[d]	560	56.7	427	43.3	2.63	2.30-3.01	2.53	2.18-2.93
Some post-HS	2222	76.5	681	23.5	1.55	1.36-1.77	1.56	1.36-1.80
College graduate	1421	85.2	247	14.8	1.00	Referent	1.00	Referent
Postgraduate	1401	92.9	117	7.7	0.51	0.41-0.62	0.53	0.42-0.66
Employment								
Full-time	3184	84.8	571	15.2	1.00	Referent	1.00	Referent
Retired	1806	70.0	776	30.1	1.26	1.11-1.42	1.18	1.04-1.34
Part-time	423	80.0	106	20.0	1.14	0.95-1.37	1.12	0.92-1.37
Disabled	56	59.0	39	41.1	2.60	2.03-3.33	1.84	1.41-2.40
Unemployed	65	69.9	28	30.1	1.95	1.44-2.66	1.41	1.00-1.99
Other	129	69.0	58	31.0	1.72	1.38-2.16	1.22	0.95-1.56

	Access		No Access		Adjusted for age and sex		Adjusted for all variables[a]	
	n	Row %	n	Row %	RR	95% CI	RR	95% CI
Home blood pressure monitor								
Yes	3527	79.7	897	20.3	1.00	Referent	1.00	Referent
No	2150	75.4	700	24.6	1.32	1.21-1.44	1.26	1.15-1.38

[a] All variables shown in this table are included in the model.

[b] BMI: body mass index.

[c] HS: high school.

[d] GED: general equivalency diploma.

Blood Pressure Control

After the telephone survey, 2937 hypertensive patients with computer access agreed to attend a screening visit to have their BP measured to verify eligibility (uncontrolled BP). Of these, 2505 patients attended the first screening visit (Table 3), where 49.5% (1239/2505) had uncontrolled BP and were invited to a second screening visit. Using our stricter definition of uncontrolled BP at two screening visits, only 33.9% (802/2365) of the patients who completed screening had uncontrolled BP (Table 4). We were unable to determine BP control status for 134 patients who had uncontrolled BP at the first screening visit but did not attend the second visit. This group was excluded from the sensitivity analysis, which used the more strict definition requiring two measures to verify uncontrolled BP.

Male sex, non-Hispanic black race, and being overweight or obese were risk factors for uncontrolled BP regardless of whether uncontrolled BP was defined based on a single screening visit (Table 3) or on two screening visits (Table 4). These risks were somewhat more pronounced when we used the stricter study definition for uncontrolled BP. In the primary analysis, adjusted RR for uncontrolled BP for obese patients was 1.60 (CI 1.28-2.00) when compared to normal-weight individuals in the model that included age, sex, education, race, and BMI. Patients who reported not having a home BP monitor had a marginally higher risk of uncontrolled BP, with the RR attenuating in the fully adjusted models. Expected clinical need was not related to BP control.

Among patients attending at least one screening visit, 44 had severe hypertension with BP too high to be eligible to participate in the trial (defined as an average systolic BP ≥ 200 mmHg or diastolic BP ≥ 110 mmHg; data not shown). Compared to those enrolled with uncontrolled BP, ineligible patients with very high BPs were significantly more likely to be less than age 55 years (61.4% [27/44] vs 34.6% [269/778], $P < .001$) and non-Hispanic black (15.9% [7/44] vs 7.7% [60/778], $P = .05$). However, they did not differ in level of obesity ($P = .56$).

Table 3. Adjusted relative risk (RR) of uncontrolled blood pressure (BP) among patients completing the first screening visit (n = 2505)

	Controlled BP[a]		Uncontrolled BP[a]		Adjusted for age and sex		Adjusted for age, sex, education, race, and BMI[b]	
	n	Row %	N	Row %	RR	95% CI	RR	95% CI
Total	1266	50.4	1239	49.5				
Systolic BP[a] (mmHg), mean (SD)	126.3 (8.4)		151.1 (12.4)					
Diastolic BP[a] (mmHg), mean (SD)	77.7 (7.2)		89.3 (9.2)					
Sex								
Female	795	55.8	630	44.2	1.00	Referent	1.00	Referent
Male	471	43.6	609	56.4	1.28	1.18-1.38	1.29	1.19-1.40
Age (years)								
25-39	24	51.1	23	48.9	1.00	0.73-1.36	0.90	0.65-1.26
40-54	374	52.3	341	47.7	1.00	Referent	1.00	Referent
55-64	544	50.3	537	49.7	1.04	0.94-1.14	1.04	0.94-1.15
65-75	324	48.9	338	51.1	1.08	0.97-1.20	1.14	1.02-1.27
BMI (kg/m^2)								
Normal (<25)	215	65.0	116	35.1	1.00	Referent	1.00	Referent
Overweight (25-30)	391	50.9	377	49.1	1.36	1.16-1.61	1.34	1.14-1.58
Obese (≥30)	537	46.1	628	53.9	1.53	1.31-1.79	1.47	1.25-1.72
Insurance product								
Commercial	950	50.8	919	49.2	1.00	Referent	1.00	Referent
Basic health/Medicaid	7	43.8	9	56.3	1.10	0.71-1.69	1.02	0.60-1.75
Expected clinical need								
Low	229	49.5	234	50.5	1.00	Referent	1.00	Referent
Medium	814	50.5	797	49.5	0.99	0.90-1.10	0.99	0.89-1.11
High	218	51.5	205	48.5	0.98	0.86-1.12	0.96	0.84-1.11
Prior use of secure messaging								
No	664	48.4	708	51.6	1.00	Referent	1.00	Referent
Yes	602	53.1	531	46.9	0.92	0.85, 0.99	0.99	0.91, 1.07
Race								
White, non-Hispanic	1067	51.4	1011	48.7	1.00	Referent	1.00	Referent
Black, non-Hispanic	65	42.2	89	57.8	1.22	1.06-1.40	1.26	1.10-1.45
Hispanic	25	47.2	28	52.8	1.09	0.84-1.41	1.12	0.86-1.47
Asian	63	59.4	43	40.6	0.85	0.67-1.08	0.95	0.74-1.22
Other	43	39.8	65	60.2	1.22	1.04-1.43	1.18	1.00-1.29
Education								
<HS[c] graduate	10	52.6	9	47.4	0.98	0.59-1.64	0.94	0.53-1.64
HS graduate/GED[d]	97	47.8	106	52.2	1.13	0.97-1.32	1.10	0.94-1.29
Some post-HS	436	46.8	496	53.2	1.15	1.04-1.27	1.10	0.99-1.22
College graduate	339	52.4	308	47.6	1.00	Referent	1.00	Referent
Postgraduate	384	54.6	320	45.5	0.94	0.84-1.06	0.95	0.84-1.07

	Controlled BP[a]		Uncontrolled BP[a]		Adjusted for age and sex		Adjusted for age, sex, education, race, and BMI[b]	
	n	Row %	N	Row %	RR	95% CI	RR	95% CI
Employment								
Full-time	690	49.9	692	50.1	1.00	Referent	1.00	Referent
Retired	429	49.9	430	50.1	0.98	0.88-1.09	0.98	0.88-1.10
Part-time	101	56.4	78	43.5	0.91	0.77-1.09	0.94	0.78-1.14
Other	46	54.8	38	45.2	0.97	0.76-1.23	0.89	0.68-1.17
Home BP monitor								
Yes	747	51.6	702	48.5	1.00	Referent	1.00	Referent
No	518	49.2	536	50.9	1.07	0.99-1.16	1.03	0.94-1.12

[a] BP and BP control measured at the first screening visit.

[b] BMI: body mass index.

[c] HS: high school.

[d] GED: general equivalency diploma.

Table 4. Adjusted relative risk (RR) of uncontrolled blood pressure (BP) based on study recruitment guidelines requiring two measures to define uncontrolled BP (n = 2365)

	Controlled BP[a]		Uncontrolled BP[a]		Adjusted for age and sex		Adjusted for age, sex, education, race, and BMI[b]	
	n	Row %	n	Row %	RR	95% CI	RR	95% CI
Total	1563	66.1	802	33.9				
Systolic BP[c] (mmHg), mean (SD)	129.9 (11.2)		152.8 (11.7)					
Diastolic BP[c] (mmHg), mean (SD)	79.4 (8.0)		89.7 (8.7)					
Sex								
Female	966	71.5	386	28.6	1.00	Referent	1.00	Referent
Male	597	58.9	416	41.1	1.44	1.29-1.62	1.50	1.33-1.69
Age (years)								
25-39	27	67.5	13	32.5	0.93	0.59-1.48	0.78	0.48-1.29
40-54	450	66.9	223	33.2	1.00	Referent	1.00	Referent
55-64	678	66.3	345	33.7	1.01	0.88-1.16	1.04	0.90-1.20
65-75	408	64.9	221	35.1	1.08	0.93-1.25	1.15	0.99-1.35
BMI (kg/m^2)								
Underweight/normal (<25)	244	77.5	71	22.5	1.00	Referent	1.00	Referent
Overweight (25-30)	499	68.2	233	31.8	1.34	1.07-1.69	1.31	1.04-1.64
Obese (≥30)	670	61.1	427	38.9	1.67	1.35-2.08	1.60	1.28-2.00
Insurance product								
Commercial	1169	66.3	594	33.7	1.00	Referent	1.00	Referent
Basic health/Medicaid	394	65.5	208	34.6	0.86	0.38-1.92	0.62	0.18-2.20
Expected clinical need								
Low	290	66.2	148	33.8	1.00	Referent	1.00	Referent
Medium	1003	65.8	522	34.2	1.04	0.89-1.20	0.96	0.82-1.12
High	265	67.1	130	32.9	1.01	0.84-1.23	0.95	0.78-1.16
Prior use of secure messaging								
No	831	64.5	458	35.5	1.00	Referent	1.00	Referent
Yes	732	68.0	344	32.0	0.91	0.81-1.02	1.00	0.88-1.12
Race								
White, non-Hispanic	1321	66.9	654	33.1	1.00	Referent	1.00	Referent
Black, non-Hispanic	76	54.3	64	45.7	1.43	1.18-1.74	1.52	1.26-1.83
Hispanic	33	66.0	17	34.0	1.03	0.69-1.52	1.01	0.66-1.55
Asian	72	71.3	29	28.7	0.89	0.65-1.22	1.05	0.76-1.45
Other	57	60.6	37	39.4	1.17	0.90-1.52	1.15	0.88-1.49
Education								
<HS[d] graduate	13	72.2	5	27.8	0.83	0.38-1.84	0.87	0.40-1.88
HS graduate/GED[e]	125	67.2	61	32.8	1.08	0.85-1.36	1.06	0.83-1.35
Some post-HS	544	61.8	336	38.2	1.23	1.07-1.42	1.17	1.01-1.35
College graduate	416	67.8	198	32.3	1.00	Referent	1.00	Referent
Postgraduate	465	69.7	202	30.3	0.92	0.79-1.09	0.95	0.80-1.12

	Controlled BP[a]		Uncontrolled BP[a]		Adjusted for age and sex		Adjusted for age, sex, education, race, and BMI[b]	
	n	Row %	n	Row %	RR	95% CI	RR	95% CI
Employment								
Full-time	850	65.3	452	34.7	1.00	Referent	1.00	Referent
Retired	539	66.3	274	33.7	0.95	0.81-1.11	0.99	0.84-1.16
Part-time	117	68.4	54	31.6	0.98	0.78-1.24	1.06	0.83-1.35
Other	57	73.1	21	26.9	0.86	0.59-1.24	0.80	0.53-1.21
Home BP Monitor								
Yes	928	67.4	449	32.6	1.00	Referent	1.00	Referent
No	633	64.2	353	35.8	1.12	1.00-1.26	1.06	0.94-1.19

[a] BP control based on study recruitment guidelines requiring two measures (visits) to define controlled and uncontrolled BP.

[b] BMI: body mass index.

[c] BP measured at the first screening visit.

[d] HS: high school.

[e] GED: general equivalency diploma.

Discussion

Patient-shared electronic health records and secure Web communications allow new opportunities for patients to be uniquely involved in their own care, including viewing their medical records, communicating asynchronously by secure email, and receiving other Web-based services. The e-BP trial demonstrated that the use of these tools and Web-based collaborative pharmacist care led to significant decreases in both systolic and diastolic BP and improved BP control.

Our recruitment efforts included contacting almost all patients with a hypertension diagnosis from 10 primary care clinics. The majority of people we contacted were interested in continuing with the recruitment process; however, one third declined. Those refusing were more likely to be from racial minority and lower socioeconomic groups. Difficulty recruiting from underserved and minority groups has been documented [20,21]. Enrolling people in Web-related research poses additional challenges, as the same groups that have been less likely to participate in clinical trials are also less likely to have computer access.

In 2005 and 2006, over 20% of the patients we attempted to recruit could not participate in a Web-based intervention because of lack of computer access. Lack of computer access was strongly related to lower levels of education, older age, and minority race and ethnicity. Adjustments for potential confounders made little difference. These groups are those typically described as being part of the "digital divide." Multiple observational studies have documented age, race, socioeconomic, and educational disparities in the use of patient electronic health records and eHealth services [22-24]. These same groups are more likely to experience disparities in health access and outcomes. Blacks, on average, die 6 years earlier than whites from heart disease [25]. Paradoxically, those who might benefit the most from eHealth innovations may be less able or unwilling to use these resources. Eysenbach has called this association between vulnerable populations and lack of computer and information access *"the inverse information law"*: Access to health information is often most difficult for those who need it most [10].

Interestingly in our analysis, expected clinical need was not related to refusal, lack of computer access, or BP control. Others have found no or increased associations between comorbidity and health status, and Internet and use of patient electronic health records. Ralston et al [26] and Weppner et al [27] found increased use of secure messaging in those with the highest levels of comorbidity. Gracia and Herrero [28] found that, once socioeconomic factors were controlled for, older adults (age 55-74 years) with poor self-reported health were more likely to use the Internet.

Over half of the patients we attempted to recruit had controlled BP and did not need a pharmacist's intervention. Using the stricter criteria of uncontrolled BP at two separate visits, 66.1% (1563/2365) of the patients had controlled BP, compared to 52.1% (1304/2505) at a single visit. After the diagnosis of hypertension is established, medication decisions are often based on measurements at a single office visit, which according to our findings might lead to misclassifying many people as having uncontrolled BP. While there is a direct relationship between increasing systolic BP and cardiovascular disease events [29], there is no evidence for those with essential hypertension that lowering BP ≤ 140/90 mmHg leads to improved outcomes. Misclassifying people as having uncontrolled BP could result in harm and unnecessary costs [30]. At the time the study was conducted, the patient-shared electronic health record had just been implemented, and there were not enough BP data to prescreen participants. Over 98% of Group Health patients with a primary care visit have at least one BP measure in their electronic health record in any given year. Automated data now could be used to more efficiently identify patients with uncontrolled BP.

Concordant with the literature, non-Hispanic blacks were more likely than other racial and ethnic groups to have uncontrolled BP [31]. Obese patients were also more likely to have uncontrolled BP. Only 7.2% of the trial participants with uncontrolled BP had a normal BMI (using baseline clinical measurements). Obesity is a known risk factor for hypertension incidence and uncontrolled BP [32]. Obesity is also more common in those from minority racial and ethnic groups, and with lower income and lower levels of education [33]. Despite these relationships, in our analysis obesity was not related to either refusing to participate or lack of computer access. Patients were not assessed for metabolic syndrome and sleep apnea, likely contributory factors to uncontrolled BP. Our finding that men were more likely to have uncontrolled BP has also been cited in the literature [34]. The mechanisms for these differences are not well understood. Others have reported higher incidence of uncontrolled BP in women, but generally in older populations [35,36]. Level of education and expected clinical need were not related, and age was only weakly related, to BP control. The association between these covariates and BP control might have changed had we invited those without computer access to attend screening visits.

Our analysis has several important limitations. Almost 21% of the patients we attempted to contact did not answer the survey questions, and we have no information on race, education level, self-monitoring, computer access, or BP control for this group. Additionally, almost all patients at Group Health have health insurance, few have Medicaid, and our results may not be representative of populations without health insurance. Additionally, the Pacific Northwest is known for being “wired” and potential eHealth-associated disparities may be greater in other communities [37].

A particular strength of our analysis is that we were able to collect administrative and electronic medical record data on the entire recruitment sample. Of those successfully contacted (8840/9298, 95.1%), over 80% (7354/8840, 83.2%) consented to answering a brief nonparticipant questionnaire. Few trials, including hypertension and eHealth studies, have access to nonparticipant data. In the Antihypertensive and Lipid-lowering Treatment to Prevent Heart Attack Trial (ALLHAT) over one third of the 33,357 participants in the hypertension trial component were black; however, because recruitment occurred by a variety of methods (radio and newspaper ads, letters, flyers, referral), the researchers were unable to characterize eligible nonparticipants. Glasgow et al [38], in a Web-based weight-loss intervention, found that people age 60 years and older were less likely to enroll, but did not have data for race or education. Stopponi et al [39], in a Web-based nutrition trial, imputed education and income level by census tract. Similar to our results, their results showed that nonparticipants were more likely to be less educated and older. Our analysis adds to these studies, by systematically attempting to invite all patients with hypertension to participate and by capturing a richer set of data. Additional information on type of Internet connection, proficiency with, time spent on, and different usages of the Internet, and their perceptions of Web-based care would have provided further insight, but we were limited in the number of questions we were allowed to ask patients who refused further participation in the recruitment process.

Over 65% of adults who receive care at Group Health clinics are registered and have access to their patient-shared electronic health record and comprehensive Web services, and 30.7% of outpatient primary care encounters occur virtually, over the Web (with phone visits at 15.3% and in-person visits, 54.0%, accounting for the rest) [40]. Patients are very satisfied with these services, particularly secure email, medical test results, and medication refill services [14]. In contrast, only a small proportion of the US population has access to an electronic health record; however, in surveys, most would like access [41,42].

Patient Web portals will likely be increasingly available in other media forms, such as cell phones. In 2008, 84% of American adults owned a cell phone, compared to 74% having access to the Internet [43]. Web communications also have the potential to be translated into different languages, adapted to different literacy levels, and used by people with physical disabilities, which over time might help to mitigate disparity gaps. Patient Web portals also may lead to decreased health care utilization and costs. After the introduction of a patient Web portal in Kaiser Permanente, there was a 20% decrease in primary care and specialty care visits [5,44]. For these reasons and the success of the e-BP trial, we believe that increasing the availability of Web portals is warranted. However, our data show that it is necessary to ensure equity for those without access.

Systematic reviews and meta-analyses have found strong evidence that “team-based” care for hypertension (care provided by a health professional such as a pharmacist or nurse separate from office visits) improves BP control [45,46]. Successful studies have been conducted in a variety of settings (clinic, worksite, and community facilities) and have used different communication techniques (face-to-face visits, telephone, or facilitated transfer of data), and use of e-communication is only one of many different effective options. Which type of program offered could be based on the targeted population, local resources, satisfaction, and costs.

In conclusion, patients unwilling or unable to participate because of lack of computer access in a Web-based intervention to improve hypertension control were more likely to be from populations that already experience disparities in health care. The majority of those willing and able to receive Web-based care had controlled BP and did not need additional Web-based pharmacist medication management. As we strive to learn how best to use patient-shared electronic health records with Web communications to improve the care of chronic conditions, specific attention will be required to insure that health disparities are minimized.

Acknowledgments

We would like to thank Annie Shaffer on her assistance in manuscript preparation and editing. This research was funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health; grant R01-HL075263.

Conflicts of Interest

James D Ralston received grant funding from Sanofi-Aventis between 7/1/2004 and 6/30/2006. No other conflicts of interest.

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Abbreviations

ALLHAT: Antihypertensive and Lipid-lowering Treatment to Prevent Heart Attack Trial
BMI: body mass index
BP: blood pressure
e-BP: Electronic Communications and Home Blood Pressure Monitoring
RR: relative risk

Edited by G Eysenbach; submitted 02.08.10; peer-reviewed by J Finkelstein, R Burkhard; comments to author 21.08.10; revised version received 07.12.10; accepted 08.12.10; published 20.01.11.

Please cite as:
Green BB, Anderson ML, Ralston JD, Catz S, Fishman PA, Cook AJ
Patient Ability and Willingness to Participate in a Web-Based Intervention to Improve Hypertension Control
J Med Internet Res 2011;13(1):e1
URL: http://www.jmir.org/2011/1/e1/
doi:10.2196/jmir.1625
PMID:21371993

Original Paper

A Theory-Based Video Messaging Mobile Phone Intervention for Smoking Cessation: Randomized Controlled Trial

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Abstract

Background: Advances in technology allowed the development of a novel smoking cessation program delivered by video messages sent to mobile phones. This social cognitive theory-based intervention (called “STUB IT”) used observational learning via short video diary messages from role models going through the quitting process to teach behavioral change techniques.

Objective: The objective of our study was to assess the effectiveness of a multimedia mobile phone intervention for smoking cessation.

Methods: A randomized controlled trial was conducted with 6-month follow-up. Participants had to be 16 years of age or over, be current daily smokers, be ready to quit, and have a video message-capable phone. Recruitment targeted younger adults predominantly through radio and online advertising. Registration and data collection were completed online, prompted by text messages. The intervention group received an automated package of video and text messages over 6 months that was tailored to self-selected quit date, role model, and timing of messages. Extra messages were available on demand to beat cravings and address lapses. The control group also set a quit date and received a general health video message sent to their phone every 2 weeks.

Results: The target sample size was not achieved due to difficulty recruiting young adult quitters. Of the 226 randomized participants, 47% (107/226) were female and 24% (54/226) were Maori (indigenous population of New Zealand). Their mean age was 27 years (SD 8.7), and there was a high level of nicotine addiction. Continuous abstinence at 6 months was 26.4% (29/110) in the intervention group and 27.6% (32/116) in the control group ($P = .8$). Feedback from participants indicated that the support provided by the video role models was important and appreciated.

Conclusions: This study was not able to demonstrate a statistically significant effect of the complex video messaging mobile phone intervention compared with simple general health video messages via mobile phone. However, there was sufficient positive feedback about the ease of use of this novel intervention, and the support obtained by observing the role model video messages, to warrant further investigation.

Trial registration: Australian New Zealand Clinical Trials Registry Number: ACTRN12606000476538; http://www.anzctr.org.au/trial_view.aspx?ID=81688 (Archived by WebCite at http://www.webcitation.org/5umMU4sZi)

(J Med Internet Res 2011;13(1):e10) doi:10.2196/jmir.1553

KEYWORDS

smoking cessation; cellular phone

Introduction

While smoking prevalence has been declining in many countries [1,2] high prevalence rates are a cause for concern in developing countries [3-5], in disadvantaged or vulnerable populations [6-8], and in young people [8-10]. New Zealand Maori (the indigenous population of New Zealand) have particularly high smoking prevalence rates (40.4% of males and 49.7% of females aged 15-64 years [10]) and new interventions must be appropriate for this population group in New Zealand.

Smoking quit rates are low even where intensive behavioral and pharmacological support is available [11], although most smokers who try to quit do so without extra assistance [12]. Providing more options for smoking cessation support is one strategy to try to encourage more quit attempts. Mobile phones have good potential as one option because they tend to be always with people, and messages can be sent directly to quitters wherever they are and at the most appropriate times (eg, for cravings or for usual cues to smoke). There is some evidence of more equitable access to mobile phones than to other communications services in developed countries [13,14] and rapid uptake in developing countries [15,16]. There is also emerging evidence that those with high health needs may use mobile phones more than those without [13,17,18].

Our successful text messaging smoking cessation program [19] was recently implemented as a national government-funded program in New Zealand [20]. In order to use new advances in mobile phone technology to continue to improve uptake and effectiveness, we proposed and developed an updated intervention (“STUB IT”).

A randomized controlled trial was undertaken between November 2007 and August 2009 to determine whether a video-based smoking cessation intervention delivered via mobile phone was effective at increasing smoking cessation rates compared with a control group over a 6-month period. In this paper we describe this trial, and reflect on challenges faced in recruitment that undermined its capacity to adequately test the effectiveness of the intervention.

Methods

Recruitment was targeted at young adults (16-25 years) and particularly toward young Maori. The study was advertised extensively via radio, internet, mobile phone (to those who had signed up for such a service), paper-based and online magazines, Maori-specific media of all types, local and national newspapers, and media releases to national media outlets. Advertisements were placed in tertiary education institutions (via campus posters, student magazines, student websites, student health services, and student radio), primary health care services, smoking cessation services, large employer health promotion programs, and posters or leaflets at cafes, bars, and sports grounds.

Participants were eligible if they were at least 16 years of age, smoked daily, and wanted to quit. Participants were required to have a mobile phone that was capable of receiving video messages. The video messages were sent as a text message with a universal resource locator (URL) address in the text. Participants highlighted the URL to trigger automatic downloading and playing of the video on the phone (Figure 1; see also Multimedia Appendix 1 and 2 for sample videos). Participants could return to the text message to replay the video if desired. This process does not require extremely high-end technology phones, but was available on most recent mobile phones. The video messages were made as small as possible (<300 kB) to allow the lowest-specification common phone to be able to access them. Due to a partnership with Vodafone New Zealand Ltd (one of only two mobile phone networks in New Zealand at the time), this whole process was free to participants.

Figure 1. Screenshot of the intervention

Potential participants completed an online eligibility check and, if eligible, were advised to read the study information online (or it could be emailed or posted) and reply to a consent text message with the words "I consent." Consenting participants were directed to complete baseline data collection on an online form. On submission of this information, computer randomization allocated participants to an intervention or control group, using stratified minimization for age (25 years and under, over 25 years), ethnicity (Maori, non-Maori), and level of nicotine dependence (time to first cigarette 30 minutes or less, more than 30 minutes).

Both groups nominated a quit day (QD) on which they aimed to stop smoking that was between 1 and 3 weeks from randomization. Participants also nominated two time periods (in a 24-hour clock) during which they wished to receive the mobile phone messages.

Those in the intervention group were also directed to an online brief description and photograph of the six role models (three of whom were Maori) and asked to select one person from whom they would receive messages (although they were able to change this later if desired). The steps in the development of the intervention have been described in detail elsewhere [21]. In brief, we drew on social cognitive theory [22] to inform the use of role models via short video messages providing observational learning. We hypothesized that this role modeling by "ordinary" young people would enhance self-efficacy to quit smoking and thereby increase the chances of a quit attempt being successful [23-25]. The video messages were filmed as video diaries during a quit attempt, with the role models discussing issues they had found difficult and the techniques and coping strategies they used to remain smoke-free. These vignettes were based on the role model's own story (all six role models were ex-smokers), plus theory and evidence-based behavior change techniques usually taught in cessation counseling (such as setting goals, being reminded of reasons for quitting, identifying triggers and cues to smoking, planning to manage or avoid triggers and cues, receiving positive reinforcement, and using social support).

The intervention was arranged into a chronological schedule of mobile phone messages that included the role model videos, text messages (short message service; SMS), and other video messages (animations about reasons to stop smoking; and "truth" campaign mass media advertisements supplied by the American Centers for Disease Control and Prevention). Table 1 shows the number and type of messages in each phase, along with the duration of each phase.

Table 1. Chronological sequence of mobile phone messages

Phase	Number of messages	Timing and duration of phase	Format of messages in each phase
Countdown to QD[a]	1/day	For 1 week prior to QD	Role model videos and texts
QD	3/day	1 day (QD)	Role model videos and texts
Intensive phase	3/day	For 4 weeks post-QD	Role model videos and texts
Maintenance phase	1 every 2 days	For 2 weeks after intensive phase	SMS[b] messages, other mixed videos
Maintenance continued	1 every 4 days	For about 20 weeks until 6 months after randomization	SMS messages, other mixed videos

[a] Quit day.

[b] Short message service, or text messages.

Additional features included a website for intervention group participants that allowed them to review video messages they had been sent (and rate them if desired), change their selected time periods, and change (or add to) their selected role model. Intervention group participants could also ask for extra support messages on demand by texting keywords to the study shortcode (four-digit number). Texting “crave” and the context (either “stress,” “bored,” or “drinking” – three common triggers for smoking in young adults) would result in the immediate automated sending of an appropriate video or text message on how to beat cravings within that context. Texting “relapse” would result in three messages over the next 90 minutes to motivate to keep going with the quit attempt and suggest ways of getting extra support. The control group participants received one video message every 2 weeks with general health messages and reminders about the study for 6 months.

The primary outcome for the study was continuous abstinence as defined by the Russell standard [26], which allows up to five cigarettes over 6 months after QD. Other outcomes were 7-day point prevalence abstinence; confidence in ability to quit/stay quit (as a percentage on a scale from 0%, not confident, to 100%, fully confident); number of quit attempts and use of nicotine replacement therapies during the study period; participant satisfaction with aspects of the program (intervention group only); and any motor vehicle accidents that occurred while driving and using a mobile phone during the study period (as possible adverse events).

Smoking status was verified on a random sample of 10% of eligible participants prior to randomization. Verification of quitting status was attempted in all participants reporting continuous abstinence at 6 months using salivary cotinine reading on a mailed-out and returned NicAlert (Nymox Pharmaceutical Corporation, Hasbrouck Heights, NJ, USA) test-strip pack. Salivary cotinine has a half-life of 15-40 hours and is able to distinguish smokers from nonsmokers using a cutoff of 10 ng/mL of cotinine (sensitivity 93%, specificity 95%, and a positive predictive value of 95%) [27]. Two staff members independently read the NicAlert test strips.

The nature of the intervention ensured the study could only be single blinded – that is, participants were aware of which group they were allocated to. However, most data were collected via web-based forms completed by participants, and researchers involved in data collection, particularly outcome assessment, were blind to allocation.

Initial calculations indicated that a target sample size of 1300 participants would detect a relative risk of 1.75 for a control group 6-month quit rate of 8.5% (intervention group quit rate of 15%), with 90% power at $P = .05$. This included a loss to follow-up of 20%. All statistical analyses were performed using SAS version 9.1.3 (SAS Institute Inc, Cary, NC, USA), all statistical tests were two-tailed, and a 5% significance level was maintained throughout the analyses. The main analyses were based on the intention-to-treat principle as recommended for cessation studies [26], where participants lost to follow-up were considered not to have quit at follow-up. Simple chi-square analyses compared the proportion quit at different stages of follow-up between the intervention groups.

Results

Participants were recruited into the study between November 2007 and February 2009, and this proved much more difficult than expected. We attempted multiple sequential “waves” of recruitment efforts via new and multiple sources. However, each wave did little to change the overall recruitment rate. The study catchment area was also increased sequentially from the Auckland region (population approximately 1.4 million), to the Northern Region of the North Island (population approximately 2.3 million), to the whole of New Zealand (population 4.1 million). Initial incentives of monthly prize draws of new third-generation (3G) phones were deemed insufficient to attract new participants, and reimbursements to all participants for their time and participation were later added. Due to these problems, and the costs involved in recruitment, we decided to close the study to recruitment with 226 randomized participants. Figure 2 shows the numbers of registrants, randomized participants, and those completing follow-up. Due to the nature of online data collection at follow-up points, it was possible for participants to enter some follow-up data but not complete the entire form. The follow-up numbers presented in the figure are based on those providing the primary outcome data (at 6 months) and the main smoking outcomes data (at 4 and 12 weeks).

Figure 2. Consort flowchart for the randomized controlled study of STUB IT

Table 2 shows the baseline characteristics of randomized participants. Due to the targeted recruitment strategies, the mean age of participants was 27 years; although there was no upper age limit and the oldest person in the study was 63 years old. The majority of participants were of New Zealand European ethnicity, with nearly 24% (54/226) of participants self-selecting Maori ethnicity. Baseline smoking characteristics were similar in the two groups, with some indication that this was a highly addicted cohort due to Hooked on Nicotine Checklist mean scores of 8 (SD 1.9) out of 10 [28].

Table 2. Baseline characteristics of randomized participants, n (%)[a]

	Intervention (n = 110)	Control (n = 116)
Mean (SD) age, years	27.5 (9.5)	26.6 (7.8)
Female	58 (52.7)	49 (42.2)
Ethnicity		
New Zealand European	55 (50.0)	63 (54.3)
Maori	24 (21.8)	30 (25.9)
Pacific	12 (10.9)	5 (4.3)
Asian	10 (9.1)	13 (11.2)
Other	6 (5.5)	5 (4.3)
Missing	3 (2.7)	0 (0)
Total income in previous 12 months		
Less than NZ$30,000	53 (48.2)	51 (44.0)
NZ$30,001-60,000	35 (31.8)	40 (34.5)
Over NZ$60,000	7 (6.4)	12 (10.3)
Don’t wish to answer	15 (13.6)	13 (11.2)
How soon after waking do you smoke?		
Within 5 minutes	26 (23.6)	27 (23.3)
6-30 minutes	45 (40.9)	52 (44.8)
31-60 minutes	21 (19.1)	24 (20.7)
After 60 minutes	18 (16.4)	13 (11.2)
Have you ever tried to quit smoking but couldn’t? Yes	102 (92.7)	104 (89.7)
Do you smoke now because it is really hard to quit? Yes	75 (68.2)	82 (70.7)
Have you ever felt addicted to tobacco? Yes	98 (89.1)	107 (92.2)
Mean (SD) Hooked on Nicotine Checklist (HONC) score	7.99 (2.11)	8.03 (1.68)
Mean (SD) confidence in being able to quit this time %	62.4 (22.0)	66.5 (21.8)

[a] Unless otherwise stated.

Table 3 reports continuous abstinence rates (the primary outcome). Intention-to-treat continuous abstinence at 6 months was 26.4% (29/110) in the intervention group and 27.6% (32/116 in the control group (*P* = .8). Of the 61 participants reporting continuous abstinence at 6 months, 10 were either noncontactable or stated they had relapsed since the end of the study period (when they had claimed to have quit) and therefore could not undergo verification of quitting status. The remaining 51 were sent NicAlert test-strip packs and were contacted repeatedly to return the strips. Fourteen quitters in the intervention group (48% of 29) returned the strip and seven (24%) were confirmed as nonsmokers. Fifteen quitters in the control group (47% of 32) returned the strip and 11 (31%) were confirmed as nonsmokers.

Table 3. Continuous abstinence from quit day to 6 months, n (%)

Have you smoked tobacco at all since quit day?	Intervention	Control	*P*-value[a]
Responders-only analysis			.7
Not a single puff or between 1 and 5 cigarettes	29 (38.7)	32 (35.6)	
More than 5 cigarettes	46 (61.3)	58 (64.4)	
Missing data	35	26	
Intention - to - treat analysis			. 8
Not a single puff or between 1 and 5 cigarettes	29 (26.4)	32 (27.6)	
More than 5 cigarettes or missing data	81 (73.6)	84 (72.4)	

[a] *P*-value for chi-square test comparing groups.

No significant difference was found between the groups in the intention-to-treat point prevalence abstinence (no smoking at all in the past 7 days), which was recorded at three time points and is shown in Table 4.

Table 4. Point prevalence abstinence at 4 weeks, 12 weeks, and 6 months, n (%)

Have you smoked at all in the past 7 days?	Intervention	Control	*P*-value[a]
4 weeks			.8
Not a single puff	12 (10.9)	14 (12.1)	
Yes or missing data	98 (89.1)	102 (87.9)	
12 weeks			.3
Not a single puff	30 (27.3)	25 (21.6)	
Yes or missing data	80 (72.7)	91 (78.4)	
6 months			.99
Not a single puff	25 (22.7)	26 (22.4)	
Yes or missing data	85 (77.3)	88 (77.6)	

[a] *P*-value for chi-square test comparing groups.

At 6 months those who reported quitting were asked to rate their confidence in being able to stay quit, and those who had relapsed were asked to rate their confidence in being able to quit again. There were no significant differences between the intervention and control group mean scores at any of these points (data not shown).

At 6 months all participants were asked how many quit attempts they had made during the study period. In the intervention group 7/73 respondents (9.6%) and in the control group 4/81 (4.9%) (*P* = .3) stated they did not attempt to quit at all, but the majority of respondents in both groups made multiple quit attempts. In the intervention group 17 of 69 respondents (25%) and in the control group 26 of 68 respondents (38%) (*P* = .2) had used pharmacological quitting support (nicotine patches, nicotine gum, or nortryptiline) at any stage in the 6-month study period.

Participants in the intervention group were asked for their feedback on the program. In general the majority of responders stated they liked the video messages from quitters, and appeared to appreciate the frequency and timing of messages (Table 5, 6).

Table 5. Intervention group satisfaction with the program, n=67 (%)[a]

Which aspects did you…	like?	dislike?	no comment	did not use
That I would relate to quitters	46 (69)	3 (4)	13 (19)	5 (7)
What quitter has to say	44 (66)	6 (9)	10 (15)	7 (10)
Video messages from quitters	43 (64)	6 (9)	9 (13)	9 (13)
The timing of messages	41 (61)	15 (22)	10 (15)	1 (1)
Receiving lots of messages	39 (58)	20 (30)	6 (9)	2 (3)
The website	34 (51)	3 (4)	16 (24)	14 (21)
Crave messages	32 (48)	8 (12)	8 (12)	19 (28)
Antitobacco industry messages	25 (37)	13 (19)	10 (15)	19 (28)
Animations	23 (34)	3 (4)	8 (12)	33 (49)

[a] Missing data have been excluded.

Table 6. Aspects of the program that aided cessation in the intervention group

Which aspects helped you to stop smoking even if you relapsed later?	Yes
Watching someone like me go through the quitting process	59 (88)
Being supported to feel like I could do it	55 (86)
Feeling like I belonged/like others were going through same thing	52 (81)
Things the people in the video clips said	50 (76)
Getting messages at the right times	47 (75)
The free stuff	44 (69)
It was fun	39 (61)
Made me get support from my friends or family	39 (60)
The website/other people videos	35 (57)
Realizing I had been manipulated by tobacco industry	31 (48)
Messages/games/whatever distracting me from cravings	30 (47)
Crave messages	29 (45)

Free text answers to what they liked most about the program could be divided into three groups: those who reported something about feeling supported (29/54, eg, from the role model, because they felt part of a group, because others were going through it too); those whose comments related to the program (11/54, eg, timing of messages, constant messages, nonintrusiveness, use of technology); and those who said all of it (5/59).

When asked what they disliked most about the program, 20/49 said they disliked nothing, six complained of some sort of technical issue, and seven did not feel the content was right or did not relate to the models. Five said there were too many messages, one said the messages reminded them to smoke, and one had the (false) perception they were being charged for messages. The most common suggestions to improve the program were around having more personal (human) contact, individually or via support groups or internet social networking.

A report from the intervention program confirmed that 29/110 participants (26.4%) had used the text “crave” function and 18/110 (16.4%) the text “relapse” function.

Equal numbers of participants in each group (n = 4) reported having a motor vehicle accident during the study period where the participant was the driver. In the control group one such accident occurred while the participant was using their mobile phone, one within 5 minutes of receiving a message, and two while the participant was smoking, whereas none of the accidents in the intervention group were reported as being temporally related to mobile phone use or smoking.

Discussion

This study is the first to have developed and trialed a smoking cessation intervention delivered via video messaging on mobile phones. We found no significant differences in quit rates between the intervention and control groups (with trends in different directions depending on time point and type of analysis). However, the trial was substantially underpowered due to our failure to recruit sufficient participants to reach the desired sample size and the higher than expected self-reported control group quit rate. In fact, quit rates in both groups were high compared to New Zealand’s quitline quit rates of 17% (6-month continuous abstinence) and 10% in the 18- to 24-year age group, but similar to those reported in our previous study of a text messaging cessation intervention [19]. Therefore, it is possible that with adequate power, an effect may have been found.

The strengths of the study include a study design in accordance with CONSORT guidelines and the strict definitions and analysis of smoking abstinence outcomes. We also used theory on which to base the intervention: this has been shown to be important in technology-based health behavior change [29] and ensures the intentions and drivers in the development of the intervention are clear and replicable. Indeed, participants commented positively on the use of role models as a means of support in their quitting attempts.

The obvious limitation of the study is the suboptimal recruitment. There are several potential reasons for this, which present challenges to be addressed in future trials. First, our recruitment efforts were targeted at adolescents (16 years and over) and young adults. We found that, despite indicating their interest in quitting, most young people were not actually ready to commit to a cessation intervention. This has been demonstrated elsewhere in focus groups and surveys of young people [30-32]. The recent updated Cochrane review of smoking cessation interventions for young people [33] commented that many of the included studies were underpowered, with only 5032 participants from 24 studies. Only two of these studies recruited directly from the community as we did. Lipkus and colleagues randomized 402 participants despite approaching nearly 40,000 young people in shopping malls [34], while Patten et al required 42 months to randomize 139 participants [35]. Recruitment to youth smoking cessation services has also been shown to be problematic [36], as has recruitment of youth to other types of research [37].

Second, the costs of messaging and advanced technology may have proved a barrier for some. At the time of recruitment, New Zealand mobile phone data charges (or anything other than SMS and voice calling) were expensive. We spoke to two participants who were wary of being charged (despite being advised the program was free) and there may have been more who did not register for this reason. Also many people were unaware whether their mobile phone could receive video messages. These factors may have dissuaded people even registering their interest and therefore we have no information on their relative importance in our recruitment. However, if poor recruitment was related to a wariness of new multimedia messaging, we feel that this will have been short-lived: in our current trial of a multimedia mobile phone program to prevent adolescent depression we have recruited 1200 participants over 30 school weeks.

Thirdly, plans to incentivize participation were hampered by several factors. Monetary incentives are considered to be effective in encouraging participation of adolescents in research [38], so we planned to offer free data or top-ups to participants' mobile phone accounts. After commencing the study this was deemed not technically possible, so instead we instituted monthly prize draws of new 3G mobile phones. However, the ethics committee did not approve promotional material that advertised the prize draws. Nevertheless, when recruitment was found to be falling behind target, we obtained ethics approval to provide participants with vouchers (for a mobile phone, the supermarket, or gasoline) as reimbursements for their time, and recruitment rose in response but was not sufficient to make a large difference.

Finally, and somewhat ironically, the text messaging cessation program trialed in our own earlier study [19] may have provided competition with our trial: the *tx2quit* program went live in New Zealand in June 2008 with national promotion by Quitline, and recruited approximately 4000 participants in the following 12 months [20].

Mobile phones are increasingly being used globally in health services as a means of more frequent and convenient contacts with health providers [39,40], remote monitoring of progress [41,42], and to reduce wastage of scarce health resources [40,43]. There are several aspects of mobile phones that also make them a valuable component of healthy behavior change support, such as being with people in times of need, providing two-way communications for help on demand, allowing proactive reminders of motivations to change behavior, providing social support from people's own networks, and providing a long-term means of support [44]. A Cochrane systematic review of the use of mobile phones in smoking cessation support programs [45] demonstrated short-term effectiveness of mobile phone-only programs and long-term effectiveness of a mobile phone and internet program.

This study adds to this body of knowledge by demonstrating the feasibility and participant appreciation of video messages via mobile phones to provide observational learning and support for healthy behavior change. It is also of note that participants were happy to complete research procedures such as consent and data collection by mobile phone. Indeed we achieved higher response rates to text message questions (217/226 or 96% response rate to a question about confidence at QD and 170/226 or 75% response rate to a smoking status question at 12 weeks post-QD) than to our online data collection forms (despite text message reminders to complete them).

In conclusion, this trial struggled to recruit participants, in particular young adults who wanted to quit smoking. This may explain the failure to show an effect of the intervention, or it may be that the complex theory-based intervention is no more effective than simple less-frequent video messages from researchers. However, there was sufficient positive feedback about the support obtained by observing the role models in the program to warrant further investigation in this area. Further research should explore the effect of this role model-based mobile phone smoking cessation intervention for older adults – a group that are perhaps more serious about stopping smoking and are becoming higher users of newer mobile phone technology.

Acknowledgments

This study was funded by the Health Research Council of New Zealand. It was supported by Vodafone New Zealand Ltd, who provided free access to their mobile phone network but was otherwise uninvolved in the study. Students at the Freelance Animation School provided animated clips for the intervention. The intervention was based on work previously funded by the Digital Strategy Community Partnership Fund, Department of Internal Affairs, New Zealand.

Conflicts of Interest

None declared

Multimedia Appendix 1

Example of one of the role model video messages from the STUB IT intervention

[WMV file (Microsoft WMV video), 971 KB - jmir_v13i1e10_app1.wmv]

Multimedia Appendix 2

Second example from another role model of their last video message in the intervention program

[WMV file (Microsoft WMV video), 1081 KB - jmir_v13i1e10_app2.wmv]

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Abbreviations

3G: third-generation mobile phone network
QD: quit day
SMS: short message service/text messages
URL: universal resource locator

Edited by G Eysenbach; submitted 20.04.10; peer-reviewed by C Norman; comments to author 07.08.10; revised version received 29.08.10; accepted 21.10.10; published 21.01.11.

Please cite as:
Whittaker R, Dorey E, Bramley D, Bullen C, Denny S, Elley CR, Maddison R, McRobbie H, Parag V, Rodgers A, Salmon P
A Theory-Based Video Messaging Mobile Phone Intervention for Smoking Cessation: Randomized Controlled Trial
J Med Internet Res 2011;13(1):e10
URL: http://www.jmir.org/2011/1/e10/
doi:10.2196/jmir.1553
PMID:21371991

Original Paper

Engagement in a Diabetes Self-management Website: Usage Patterns and Generalizability of Program Use

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Abstract

Background: Increased access to the Internet and the availability of efficacious eHealth interventions offer great promise for assisting adults with diabetes to change and maintain health behaviors. A key concern is whether levels of engagement in Internet programs are sufficient to promote and sustain behavior change.

Objective: This paper used automated data from an ongoing Internet-based diabetes self-management intervention study to calculate various indices of website engagement. The multimedia website involved goal setting, action planning, and self-monitoring as well as offering features such as “Ask an Expert” to enhance healthy eating, physical activity, and medication adherence. We also investigated participant characteristics associated with website engagement and the relationship between website use and 4-month behavioral and health outcomes.

Methods: We report on participants in a randomized controlled trial (RCT) who were randomized to receive (1) the website alone (n = 137) or (2) the website plus human support (n = 133) that included additional phone calls and group meetings. The website was available in English and Spanish and included features to enhance engagement and user experience. A number of engagement variables were calculated for each participant including number of log-ins, number of website components visited at least twice, number of days entering self-monitoring data, number of visits to the “Action Plan” section, and time on the website. Key outcomes included exercise, healthy eating, and medication adherence as well as body mass index (BMI) and biological variables related to cardiovascular disease risk.

Results: Of the 270 intervention participants, the average age was 60, the average BMI was 34.9 kg/m^2, 130 (48%) were female, and 62 (23%) self-reported Latino ethnicity. The number of participant visits to the website over 4 months ranged from 1 to 119 (mean 28 visits, median 18). Usage decreased from 70% of participants visiting at least weekly during the first 6 weeks to 47% during weeks 7 to 16. There were no significant differences between website only and website plus support conditions on most of the engagement variables. In total, 75% of participants entered self-monitoring data at least once per week. Exercise action plan pages were visited more often than medication taking and healthy eating pages (mean of 4.3 visits vs 2.8 and 2.0 respectively, $P < .001$). Spearman nonparametric correlations indicated few significant associations between patient characteristics and summary website engagement variables, and key factors such as ethnicity, baseline computer use, age, health literacy, and education were not related to use. Partial correlations indicated that engagement, especially in self-monitoring, was most consistently related to improvement in healthy eating ($r = .20$, $P = .04$) and reduction of dietary fat ($r = -.31$, $P = .001$). There was also a significant correlation between self-monitoring and improvement in exercise ($r = .20$, $P = .033$) but not with medication taking.

Conclusions: Participants visited the website fairly often and used all of the theoretically important sections, but engagement decreased over 4 months. Usage rates and patterns were similar for a wide range of participants, which has encouraging implications for the potential reach of online interventions.

Trial Registration: NCT00987285; http://clinicaltrials.gov/show/NCT00987285 (Archived by WebCite at http://www.webcitation.org/5vpe4RHTV)

(J Med Internet Res 2011;13(1):e9) doi:10.2196/jmir.1391

KEYWORDS

Engagement; Internet; diabetes self-management; research methods; health disparities

Introduction

There is now strong evidence that Internet-based behavior change programs can be efficacious. Promising results have been reported for several lifestyle change programs relevant to diabetes management, including healthy eating and weight management [1,2], physical activity [3], and smoking cessation [4,5]. Reviewers of interactive behavior change programs for diabetes self-management have identified more than 20 randomized trials [6,7]. Many of these studies have been conducted in primary care or health system settings and have targeted high-risk individuals, including those who had low health literacy or low income or who were medically underserved [6]. The results of these trials have generally been positive.

When combined with information that the "digital divide" is shrinking in at least some respects [8], this is good news for patients with diabetes. Given the recent dramatic increases in diabetes prevalence [9] and the general reluctance of patients with diabetes to attend diabetes classes and group sessions [10,11], Internet-based and other eHealth approaches to diabetes self-management education (DSME) have great potential.

Increased access to the Internet, especially among older adults [8], and the availability of efficacious, interactive DSME programs are encouraging developments. Remaining challenges, however, are the generally low level of engagement and high attrition [12] in Internet programs [13]. Although the relationship between level of engagement and outcomes of Internet programs is unclear [5], most program developers believe that a threshold level of involvement is necessary to obtain benefit. There are also relatively few investigations of patient psychosocial characteristics associated with engagement in Internet programs. There is a substantial literature on the relationship of factors such as depression, self-efficacy, and readiness to change with engagement in DSME in general, but more data are needed on generalization of these findings to Web-based interventions.

The best methods for defining and measuring website engagement are a subject for ongoing debate [14]. Some studies have reported number of website visits; others, time spent on a site; and still others, number of components used [5,14]. In their recent review, Danaher and Seeley [14] concluded that no single, universally accepted measure of engagement exists, and they encouraged more research in this area. Given the continuing health disparities among patients with diabetes [15], investigations of patient characteristics associated with engagement are also needed. This is a complex area as different patient characteristics may be associated with participation/nonparticipation than for engagement once a person has joined a program. Different patient characteristics may also be associated with retention, level of improvement in results [13], and with level of use of different components of Web-based programs.

In this paper, we present data about program engagement from an ongoing Internet-based multimedia DSME intervention study. The intervention program was designed to address 3 self-management behaviors for adults with diabetes: medication adherence, exercise, and food choices. The website offered a number of interactive and multimedia features to enhance engagement. These included user choice of language (Spanish or English), optional audio voice-overs, choice in setting behavioral goals, and choice among various features. The site also included a changing variety of practical and fun features to keep the user experience fresh, such as rotating quiz questions and motivational tips. Significant new content at 6 weeks provided interventions more specifically tailored for each individual on the 3 primary self-management behaviors. The program integrated a variety of media, including video, still pictures, animation, and audio-narrated action plan development/refinement. Action plans listed the specific goal the patient had along with individually tailored reasons for working on this goal, barriers to be on the lookout for, and strategies to overcome these barriers. Also integrated were user forums, graphical displays of self-monitoring and laboratory test results, and prompts to return to the site via both email and interactive voice response phone calls.

The primary purpose of this paper was to report on (1) the overall rate of use of the My Path/Mi Camino diabetes self-management website among a heterogeneous sample of adults with type 2 diabetes; (2) the components of the website that were used most and least often; (3) which of a number of participant characteristics, including health literacy, ethnicity, baseline level of computer use, and medical risk factors, were associated with greater engagement with the website; and (4) the relations between different measures of engagement and 4-month outcomes.

Methods

Design Overview

A 3-arm, patient-level randomized practical effectiveness trial [16, 17] was employed to evaluate the impact of 2 interactive, multimedia, diabetes self-management programs, relative to “enhanced” usual care. The 2 Internet-based interventions were (1) a self-administered, computer-assisted self-management condition based on social-ecological theory and the “5 A’s” (assess, advise, agree, assist, and arrange) self-management model [18] and (2) the computer-assisted self-management program with the addition of social support from the health care team and peer group meetings. These study conditions were compared with an enhanced usual care intervention that provided health risk appraisal feedback and recommended preventive care behaviors but did not include the hypothesized key intervention processes of goal setting, barriers identification, problem solving, or social-environmental support. The remainder of this paper deals only with the 270 intervention participants.

Recruitment

The study was conducted in primary care clinics within Kaiser Permanente Colorado (KPCO). Utilizing KPCO’s electronic prevention and disease population management system, HealthTrac, and the associated electronic medical record (EMR) system, HealthConnect, adults with type 2 diabetes were identified from 5 of the 14 KPCO primary care medical offices. Clinics were selected based on variability in size, location, and socioeconomic status of surrounding neighborhoods, and to maximize percentage of Latino patients to enhance generalizability and evaluate impacts across subgroups. Recruitment procedures are described in detail in Glasgow et al [19]. In brief, 37.9% of patients with type 2 diabetes that we contacted and who were assumed to be eligible, completed baseline assessments. Compared with those who declined, the 270 participants were likely to be younger, less likely to be Latino, had higher incomes, were much more likely to have completed postsecondary education (79% vs 53.5%), much less like to smoke (11.8% vs 19.2%, and had lower systolic blood pressure. Participants were reimbursed $25 for follow-up assessment.

Eligibility criteria included a diagnosis of type 2 diabetes made at least 1 year prior to contact, body mass index (BMI) of 25 kg/m^2 or greater, and at least 1 other risk factor for heart disease (ie, hypertension, low-density lipoprotein [LDL] > 100 or on a lipid-lowering agent, hemoglobin A_{1c} > 7%, or being a current smoker). In addition, participants were considered eligible if they were between 25 and 75 years of age, lived independently with access to a telephone and at least biweekly access to the Internet, were able to read and write in English or Spanish, and were able to perform mild to moderate physical activity.

Demographic data were collected during the recruitment phone call. Participants were read categories from which to choose, and race and ethnicity were self-reported. Survey data, as well as height and weight, were completed via a written questionnaire collected during the baseline study visit, after informed consent and data use authorization agreements were signed. Immediately following completion of baseline surveys, participants were randomized via computer program to 1 of the 3 conditions. Information from patients’ medical records and website use data were captured electronically. The rest of this paper concerns data from the intervention conditions only.

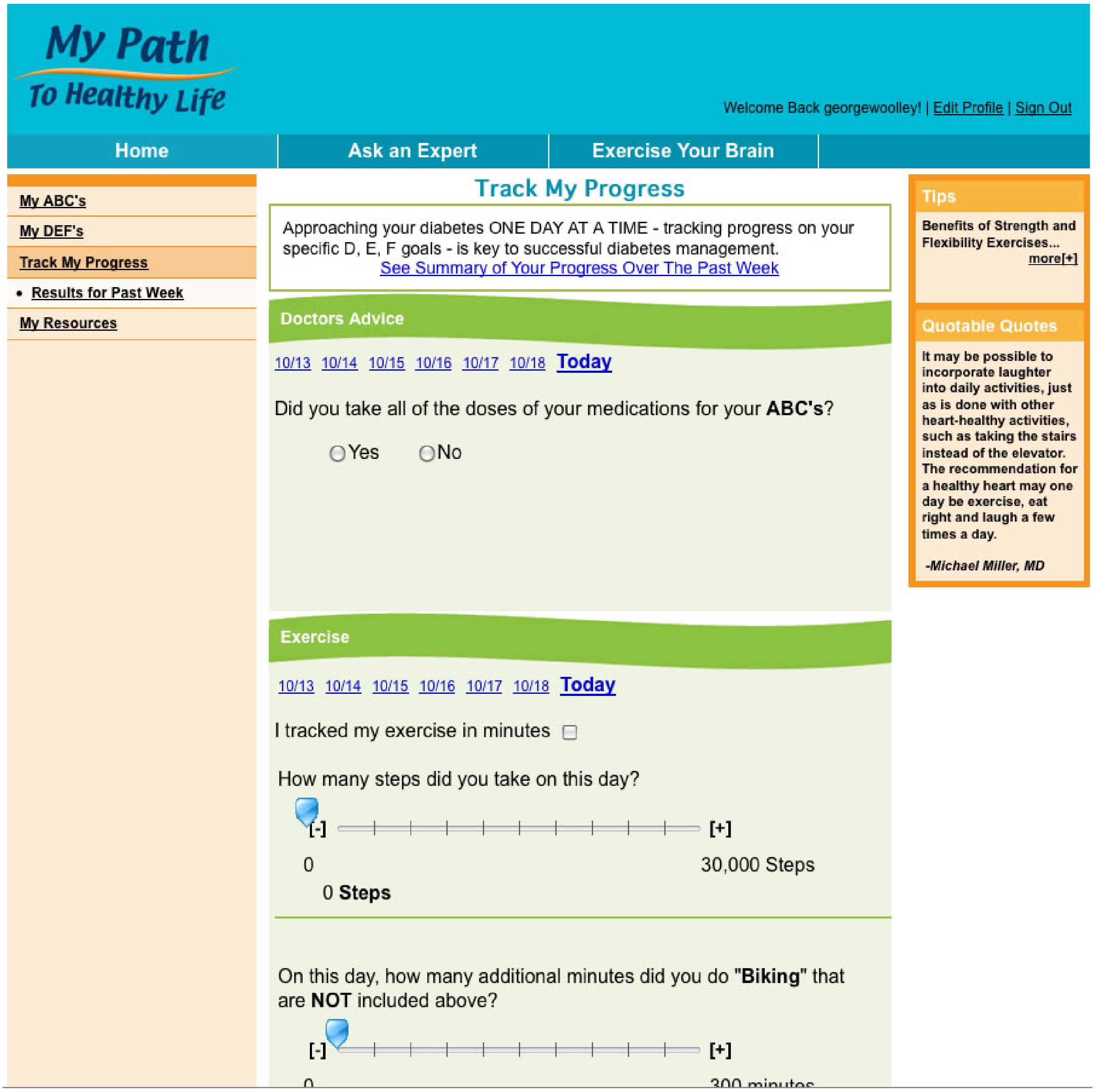
Interventions

The interventions were guided by a behavioral systems approach to diabetes self- management [20-23] that applies validated behavior change principles at patient, health care provider, and social-environmental levels. This strategy draws on the pioneering work of Bandura on social-cognitive theory and self-efficacy and application of social-ecologic approaches to health issues. The interventions were available in the participant’s choice of English or Spanish and were based on refinements for the Internet of interactive diabetes self-management programs found effective in our prior research [24,25].

Computer-Assisted Self-management

Participants randomized into the computer-assisted self-management condition were given access to an Internet-based website called “My Path to Healthy Life” (“My Path,” for short) in English and “Mi Camino a la Vida Sana” (or “Mi Camino”) in Spanish, which was developed in collaboration with and managed by InterVision Media, a technology company based in Eugene, Oregon. At the first visit, participants watched a short video introduction to the program narrated by coinvestigator Diego Osuna, MD, that emphasized that diabetes self-care encompassed more than sugar and blood glucose control. Dr Osuna reviewed the importance of controlling the ABCs (hemoglobin *A*$_{1c}$, *b*lood pressure, and *c*holesterol) of diabetes by self-managing one’s “DEFs” (*d*octor’s advice regarding medication adherence, *e*xercise, and *f*ood choices). Participants were tutored in website log-in, navigation, and usage by the attending research staff member. Participants were then asked to select initial, easily achievable goals to enhance self-efficacy [7] in each of 3 areas: medication adherence, exercise, and food choices. The initial medication adherence goal involved taking doctor-prescribed diabetes, blood pressure, and cholesterol medications “the right way every day.” For exercise, participants were asked to set an initial goal of keeping track of how many steps or minutes they walked every day (pedometers were provided). Finally, for the initial dietary goal, participants were asked to eliminate their choice of fast foods, fried foods, or sugar-sweetened beverages. Participants recorded their progress on these 3 daily goals using the tracking section of the website (Figure 1) at least weekly, or alternatively, users could enter data via the interactive voice response (IVR) phone system. Participants received immediate feedback on success or struggles in tracking and meeting their goals over the past 7 days through motivational messages via both Web and IVR modalities.

Figure 1. Track my progress



Track My Progress

Approaching your diabetes ONE DAY AT A TIME - tracking progress on your specific D, E, F goals - is key to successful diabetes management.
See Summary of Your Progress Over The Past Week

Did you take all of the doses of your medications for your **ABC's**?

○ Yes ○ No

I tracked my exercise in minutes ☐

How many steps did you take on this day?

0 **Steps**

On this day, how many additional minutes did you do "**Biking**" that are **NOT** included above?

Benefits of Strength and Flexibility Exercises... more[+]

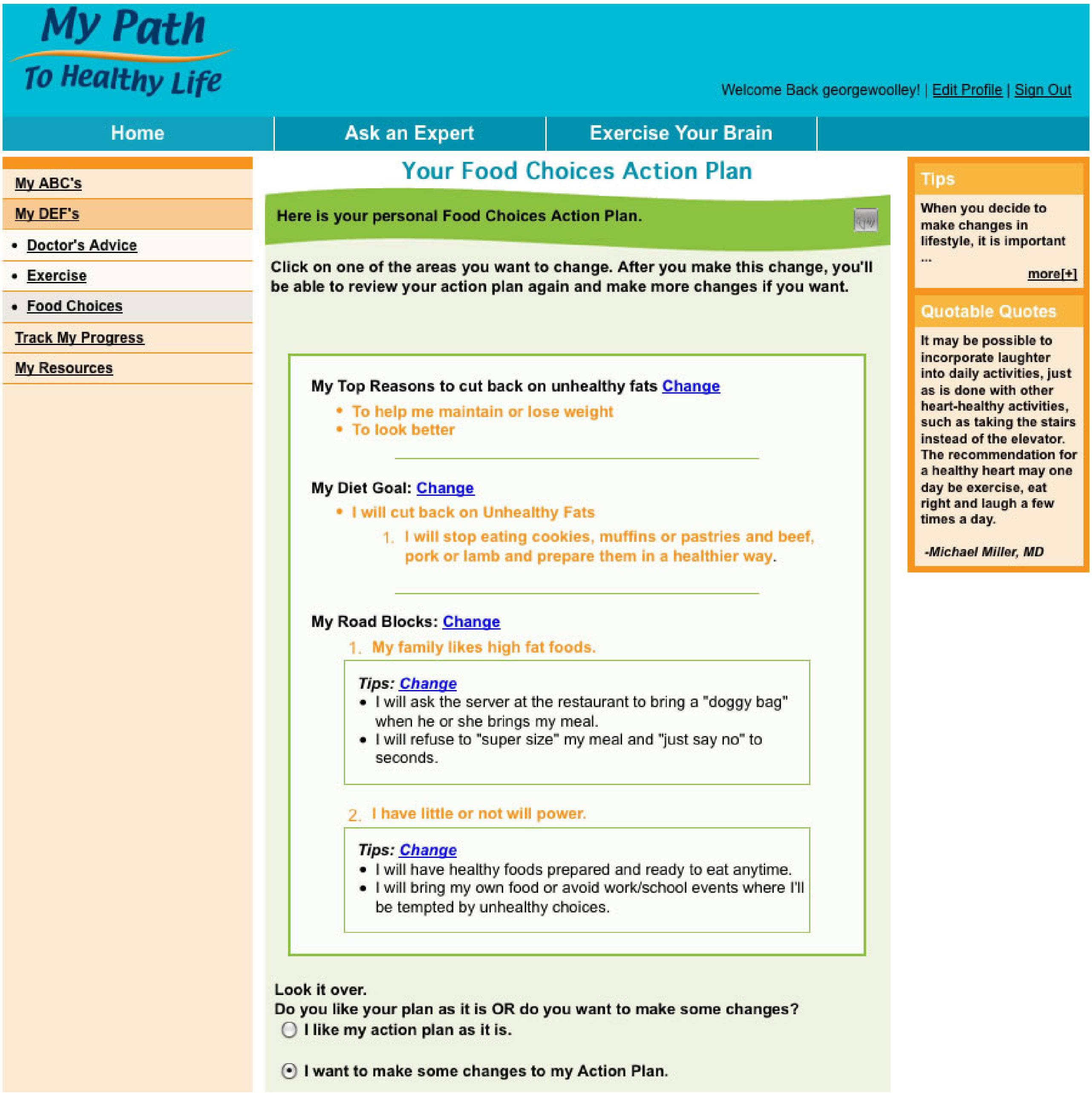
It may be possible to incorporate laughter into daily activities, just as is done with other heart-healthy activities, such as taking the stairs instead of the elevator. The recommendation for a healthy heart may one day be exercise, eat right and laugh a few times a day.

-Michael Miller, MD

During the first study visit, the research assistant briefly showed the participant each of the sections of the My Path/Mi Camino website, which included a graphical display of the patient's hemoglobin A_{1c}, blood pressure, and cholesterol results in the "My ABCs" section; a moderated forum called "Ask an Expert" where users could post or view questions to staff experts; and "My Resources," which consisted of resources (eg, Web links, healthful recipes, and printable handouts) for diabetes self-management and healthy lifestyles. The website also contained several features designed to enhance user engagement, such as rotating quiz questions and motivational tips.

After 6 weeks, participants were instructed to return to My Path/Mi Camino and further tailor their 3 self-management goals by creating action plans. To create action plans, participants were asked to identify motivating factors for goal attainment from a list on the screen; the option to "write your own" was also available. The medication adherence goal remained unchanged from the baseline goal to continue taking doctor-prescribed medications. For the exercise action plan, participants were shown graphs comparing their average physical activity level to national recommendations. Then, to increase their number of daily steps (or minutes of moderate exercise per day), users were asked to select 2 specific activities from a list of common activities (eg, gardening, jogging, bicycling, and walking); the "write your own" option also was available. For the food choices action plan, participants answered questions about fruit, vegetable, and fat intake, and used immediate, on-screen feedback to choose either to increase their daily number of servings of fruits and vegetables or to decrease their consumption of unhealthy fats and adhere to recommended portion sizes. To complete the problem-solving-based action-planning sequence [26] for each of the 3 areas, participants identified 2 likely barriers to achieving each of the goals they had selected and then chose from a list of strategies to overcome those barriers. Each user's action plan (Figure 2) was stored on the website for easy reference and/or revision, and his or her EMR was updated to indicate participation in the study and include his/her action plan.

Figure 2. Your food choices action plan



Your Food Choices Action Plan

Here is your personal Food Choices Action Plan.

Click on one of the areas you want to change. After you make this change, you'll be able to review your action plan again and make more changes if you want.

My Top Reasons to cut back on unhealthy fats Change
- To help me maintain or lose weight
- To look better

My Diet Goal: Change
- I will cut back on Unhealthy Fats
  1. I will stop eating cookies, muffins or pastries and beef, pork or lamb and prepare them in a healthier way.

My Road Blocks: Change
1. My family likes high fat foods.

Tips: Change
- I will ask the server at the restaurant to bring a "doggy bag" when he or she brings my meal.
- I will refuse to "super size" my meal and "just say no" to seconds.

2. I have little or not will power.

Tips: Change
- I will have healthy foods prepared and ready to eat anytime.
- I will bring my own food or avoid work/school events where I'll be tempted by unhealthy choices.

Look it over.
Do you like your plan as it is OR do you want to make some changes?
○ I like my action plan as it is.
● I want to make some changes to my Action Plan.

Tips

When you decide to make changes in lifestyle, it is important ...
more[+]

Quotable Quotes

It may be possible to incorporate laughter into daily activities, just as is done with other heart-healthy activities, such as taking the stairs instead of the elevator. The recommendation for a healthy heart may one day be exercise, eat right and laugh a few times a day.

-Michael Miller, MD

In addition to the website, computer-assisted self-management participants received periodic prompting using IVR, a computer-based telephone system that initiates outbound calls, receives inbound calls, provides information to users, and collects data from users. Study participants received a welcome call 3 days after enrolling in the study. At 6 weeks after enrollment, the action plan feature was added to the website and participants were prompted by IVR and email to revise their D, E, and F goals through completing the action plans in each of the 3 areas. They were reminded again after 5, 15, and 25 days if action plans had not been completed. The IVR also prompted participants to return to the website to track their progress after 6 days of missed tracking. Participants were first reminded via email, and then 3 IVR contact attempts were made per day for 3 consecutive days at 5, 15, and 25 days after the initial email.

Computer-Assisted Self-management Plus Social Support

Participants randomized to the computer-assisted self-management plus social support group received all aspects of the website intervention with the addition of follow-up calls and were invited to attend group visits with other participants in the same study condition. The 2 extra follow-up calls occurred 2 and 8 weeks after the initial visit. The first follow-up call was completed by the same study staff member who conducted the initial visit; its purpose was to answer any study-related questions and troubleshoot problems with the website or initial self-management goals. The second call was completed by a KPCO diabetes care manager to discuss the participant’s action plans. These semistructured calls lasted approximately 10 minutes. In addition, 1 group session was held prior to the 4-month assessment. The session focused on healthy eating. Led by a bilingual KPCO nutritionist, the meeting included information on healthy restaurant eating behaviors and grocery shopping tips.

Measures

Patient Characteristics

Demographic variables included self-reported age, gender, race, Latino ethnicity (yes vs no), household income, and education. Self-efficacy was assessed with Lorig’s 8-item Diabetes Self-Efficacy Scale [27]. In addition, 6 similarly constructed self-efficacy items recommended by Bandura [28] were added to measure confidence regarding taking diabetes medications, exercising, and limiting high-fat foods. Self-efficacy subscales were calculated for healthy eating, physical activity, and medication taking. Problem-solving skill was assessed with the Positive Transfer of Past Experience from the Diabetes Problem Solving Scale of Hill-Briggs [29].

Health Literacy and Baseline Computer Use

During the recruitment call, all participants were assessed for health literacy using the 3 items identified as most sensitive from the widely used instrument to assess health literacy, the Short Test of Functional Health Literacy (STOFHL) [13]. Extent of computer use was assessed by a single question asking how many hours per week on average the respondent spends on a computer.

Eating Patterns

Fat intake was measured by the National Cancer Institute Percent Energy from Fat Screener (PFAT) [30], which assesses intake of 15 foods selected to optimally predict percent energy from fat. Eating behaviors were assessed using the 7-item dietary assessment, Starting the Conversation instrument [31].

Physical Activity

The 28 physical activity items from the Community Healthy Activities Model Program for Seniors (CHAMPS) questionnaire [32] were used to measure self-reported physical activity, calculated as total weekly caloric expenditure in all physical activity. In studies of older adults that compared interviewer data and activity logs with the CHAMPS, the latter demonstrated good construct validity, stability, and sensitivity to change [32, 33] and has also been previously validated with estimated maximal oxygen consumption [34].

Medication Adherence

Adherence to diabetes, blood pressure, and cholesterol medications was assessed through the medication-taking items of the Hill-Bone Compliance Scale [35] that determines how often and why respondents missed taking medications.

Biological Outcomes

Biologic variables included: BMI, hemoglobin A_{1c}, total cholesterol, LDL cholesterol, high-density lipoprotein (HDL) cholesterol, systolic blood pressure, smoking status (yes/no and number of cigarettes per day for smokers), and diabetes medication regimen. Hemoglobin A_{1c} was measured on a Bio-Rad Variant II Turbo liquid by high-pressure liquid chromatography. BMI (kg/m^2) was obtained from electronic medical records as well as height and weight measurements obtained during in-person assessments. Lipids were assayed on a modular chemistry analyzer from Roche Diagnostics. The total cholesterol test was a serum test that first removed the cholesterol from its esters and then measured the free concentration biochemically through a modified version of the Abell Kendal method. LDL cholesterol was calculated unless the triglyceride was greater than 399 mg/dL, in which case it was measured directly with Roche assay on the modular chemistry analyzer. The UKPDS (United Kingdom Prospective Diabetes Study) 10-year heart disease risk score [36] was calculated for all study participants. The formula predicts occurrence of new heart disease in people with type 2 diabetes and incorporates hemoglobin A_{1c}, systolic blood pressure, and lipid levels along with age, sex, race, smoking status, and time since diabetes diagnosis [37].

Website Usage

Website use was calculated from automated data in multiple ways due to the nonnormal distributions of several of the use statistics. Use of various sections was indexed by presentation of mean number of visits, median number of visits, and the percentage of patients who visited each section of the website at least twice (eg, “Tracking My Progress,” “Action Planning,” “My ABCs,” “Ask an Expert,” and “Resources”). The number of action plans created (out of a possible 3) also was computed. For the self-monitoring activities, we calculated the percent of days for which tracking data were entered on the website for each of the 3 target behaviors. Time spent on the site for each visit was calculated as follows (excluding page view times exceeding 30 minutes): total time on site per visit = (last page visit time – log-in time) +(last page visit time – log-in time)/(n – 1 total pages visited). Visit times were summed to reflect total time engaged in the site across the intervention period. Key summary engagement variables were: total number of log-ins per participant and the number of website components visited at least twice (range 0 to 5).

Analyses

All survey data were entered and verified, and scores were calculated for multiple-item instruments according to previously established procedures (eg, dietary fat intake, UKPDS risk of coronary heart disease). EMR data were merged with website use and survey data for analysis. Descriptive statistics were computed for all variables to determine the nature of the data and to test for normality assumptions.

Chi-square and *t* tests were used to compare baseline participant characteristics between the website and website plus human support conditions and to test for treatment group differences in website usage.

To investigate potential patient characteristics associated with website use, Spearman nonparametric correlations were calculated between participant characteristics and 5 summary variables characterizing website usage.

To identify potential website engagement factors associated with outcomes, partial correlations were computed between the website use variables and the key behavioral outcomes of healthy eating, physical activity, and medication taking, and the key biological outcomes of BMI, hemoglobin A_{1c}, and the UKPDS heart-disease risk measure. These partial correlations controlled for treatment condition, baseline scores on the relevant outcome measure, and participant characteristics that were significantly related to outcomes (gender, age, and ethnicity).

Results

Participant Characteristics

As can be seen in Table 1, participants were fairly typical of patients with type 2 diabetes in general. The average age of the 270 participants was 60 years, 48% (130/270) were female, their mean BMI was 34.9 kg/m^2 (classified as obese), and they had an average baseline hemoglobin A_{1c} of 8.2%. As with type 2 diabetes nationally, this sample contained a higher proportion of Latino, African American, and Native American individuals than were in the general KPCO membership. The majority of participants reported using a computer 9 or more hours per week, although 18% (49/270) reported using computers 2½ or fewer hours per week. Income was highly variable with 45% (122/270) of participants reporting annual family incomes less than US $50,000 and 18% (49/270) reporting annual family incomes over $90,000. There were no significant between-condition differences of participant characteristics at baseline.

Table 1. Baseline characteristics of participants (n = 270)

	All	Website n = 137	Website Plus Human Support n = 133	*P* Value
Age (years), mean (SD)	57.8 (9.3)	58.0 (0.4)	57.6 (9.3)	.697
% Female	48.1%	45.3%	51.1%	.334
Race				.891
American Indian/Alaska Native, %	4.2%	5.1%	3.0%	
Asian, %	1.5%	1.5%	1.5%	
Black or African-American, %	18.1%	16.8%	19.5%	
White, %	67.4%	69.3%	65.4%	
No information/other, %	8.9%	7.3%	10.5%	
Latino ethnicity (yes vs no)	22.3%	24.8%	19.8%	.333
Income				.965
Less than US $49,999, %	44.8%	45.6%	44.4%	
US $50,000 to US $89,999, %	30.7%	30.0%	31.6%	
US $90,000 or more, %	18.5%	18.2%	18.8%	
No information, %	5.9%	6.6%	5.3%	
High School or less education, %	20.4%	18.4%	22.6%	.396
Health literacy score, mean (SD)	4.8 (0.4)	4.8 (0.5)	4.8 (0.4)	.314
Computer use, %				.813
Never to 2.5 hrs per week, %	17.8%	16.8%	18.8%	
3 to 6.5 hrs per week, %	15.6%	19.0%	12.0%	
7 to 8.5 hrs per week, %	7.0%	5.8%	8.3%	
9 or more hrs per week, %	59.6%	54.4%	60.9%	
Smokes cigarettes, % (yes/no)	11.1%	9.5%	12.8%	.389
Body mass index (kg/m^2), mean (SD)	34.9 (6.6)	34.6 (6.3)	35.2 (6.9)	.479
Systolic blood pressure (mm Hg), mean (SD)	130.3 (15.7)	130.7 (16.6)	129.9 (14.7)	.680
Diastolic blood pressure (mm Hg), mean (SD)	77.7 (10.4)	77.9 (9.8)	77.5 (11.0)	.762
Hemoglobin A_{1c}, mean (SD)	8.2 (1.8)	8.1 (1.9)	8.3 (1.7)	.395

Website Use

As can be seen in Table 2, participants demonstrated large variability in website usage over the 4 months of data collection, ranging from 1 to 119 website visits (mean 28 visits, median 18). Usage decreased over time, with 70% of those randomized visiting at least weekly during the first 6 weeks and 47% during weeks 7 to 16. More detailed analyses by week revealed a gradual decrease in the frequency of use over the 16 weeks, with a modest spike around the time of the 6-week prompts and addition of the action planning component. Total time spent on the website during the 4 months averaged a little over 3 hours, or about 7 minutes per visit, with a median of 152 minutes total time on the site. There were no significant differences between website alone and website plus human support conditions on any of the overall use variables.

The “Track My Progress” self-monitoring section, as anticipated, was the most frequently visited part of the website. More than 75% (208/270) of all participants used the tracking feature an average of at least once per week. Across the 4-month period, percent of days tracked ranged from 50% to 58% (mean and median) for each of the 3 targeted behaviors. Participants with access to the website plus human support entered tracking data for medication adherence more frequently than did participants with access to the website alone ($P = .02$), but this was not true for the other 2 behaviors. In general, participants who entered data for 1 behavior also entered data for the other behaviors at that time.

The “Action Plan” section of the website was considered by the program designers to be the other most important component. Participants completed an average of 1.7 of the 3 action plans, with about two-thirds completing exercise and healthy eating plans, and slightly less than half completing medication-taking plans. As can be seen in Table 2, users visited the exercise section of the “Action Plan” area significantly more often than for the other 2 behaviors (mean of 4.3 visits vs. 2.8 and 2.0 for medication and healthy eating, respectively, $P < .001$).

All pages of the website were used relatively often. The “My ABCs” page that graphically displayed the user’s lab results was the third most frequently visited page after the “Track My Progress” and “Action Plan” pages, followed by the “Resources” and “Ask an Expert” pages. The various pages were each visited at least twice by 43% or more of the users, and 19% of users visited all pages at least twice. Participants allocated to website plus human support visited most of the pages slightly more often than participants with access to the website alone, which cumulatively resulted in a composite website section use summary score that indicated significantly greater overall usage among participants in the website plus human support condition ($P = .04$).

Table 2. Website usage (0 to 4 months) overall and by treatment condition

Variable and Measure	All n = 270	Website n = 137	Website Plus Human Support n = 133	*P* Value
Total number of visits to website				
Mean (SD)	27.8 (26.6)	27.9 (31.2)	27.7 (25.9)	.936
Median	18	15	20	
Range	1-119	1-119	1-112	
Participants that visited at least weekly				
From 0 to 6 weeks, %	70%	66%	74%	.149
From 6 weeks to 4 months, %	47%	44%	51%	.228
Total time spent on website (minutes)				
Mean (SD)	190 (174)	183 (177)	196 (171)	.537
Median	152	143	165	
Range	9-1008	11-882	9-1008	
Self-monitoring (% days tracked)				
Medications				
Mean	50%	43%	57%	.017
Median	53%	39%	69%	
Range	1% - 100%	1% -100%	1% - 100%	
Physical activity				
Mean	53%	50	55	.260
Median	58%	51	61	
Range	0% - 100%	0% - 100%	0% - 100%	
Healthy eating				
Mean	53	51	55	.402
Median	58	52	62	
Range	0% - 100%	0% - 100%	1% - 100%	
Self-monitoring (% of participants that tracked an average of at least once per week)				
Medications, %	78%	76%	80%	.459
Physical activity, %	77%	74%	79%	.381
Healthy eating, %	78%	76%	80%	.459
Total number of action plans completed excluding those ineligible for medication adherence action planning				
Mean (SD)	1.7 (1.4)	1.5 (1.4)	1.9 (1.4)	.083
Median	3	2	3	
Range	0-3	0-3	0-3	
Action plan visits				
Medications (among eligible participants)				
Mean (SD)	2.8 (5.1)	2.4 (4.3)	3.3 (5.8)	.140
Median	3	0	3	
Range	0-41	0-21	0-41	
Physical activity				
Mean (SD)	4.3 (5.7)	4.0 (4.6)	4.7 (6.7)	.321
Median	3	3	3	

Variable and Measure	All n = 270	Website n = 137	Website Plus Human Support n = 133	*P* Value
Range	0-46	0-25	0-46	
Healthy eating				
Mean (SD)	2.0 (2.0)	1.9 (1.9)	2.2 (2.1)	.276
Median	2	2	2	
Range	0-12	0-25	0-12	
Ask an expert visits				
Mean (SD)	2.7 (4.7)	2.5 (4.6)	2.9 (4.8)	.438
Median	1	1	1	
Range	0-45	0-45	0-43	
ABC visits				
Mean (SD)	5.3 (6.0)	5.1 (5.3)	5.5 (6.6)	.574
Median	4	3	4	
Range	1-54	1-36	1-54	
Resources visits				
Mean (SD)	4.9 (5.6)	4.6 (4.3)	5.2 (6.6)	.410
Median	3	3	3	
Range	0-54	0-11	1-54	
Progress summary page visits				
Mean (SD)	19.4 (24.2)	19.5 (25.5)	19.3 (22.8)	.957
Median	10	10	10	
Range	0-145	0-145	0-124	
Composite score				
Mean (SD)	3.3 (1.6)	3.1 (1.7)	3.6 (1.5)	.041
Median	4	4	4	
Range	0-5	0-5	0-5	

Correlates of Website Use

Of the large number of nonparametric correlation coefficients computed between patient characteristics and website use, none was larger than .19 and there was no consistent pattern of relationships. None of the clinical variables in Table 1 was significantly related to any of the summary website use variables nor were ethnicity, education, health literacy, or baseline level of self-efficacy, problem-solving skill, or computer use. These results suggest that a wide range of participants, including those at highest risk, were equally able and likely to use the site.

Relationship Between Use and Outcomes

The final issue analyzed was the relationship between website use, using the same 5 summary usage variables as above and improvement in key outcome variables from baseline to the 4-month assessment. Table 3 presents partial correlations between the website use variables and the key 4-month behavioral and biological outcomes controlling for treatment condition, baseline scores on the relevant outcome measure, and participant characteristics that were significantly related to outcomes (gender, age, and ethnicity). Website use was most consistently related to the dietary measures. These moderate-sized correlations indicate that greater use of the website, and especially engagement in self-monitoring, was related to greater improvement in eating patterns. There was also a significant relation between self-monitoring and improvement in physical activity but not with medication adherence. None of the biological outcomes was significantly associated with the engagement measures.

Table 3. Behavioral and clinical correlates of website usage (n = 167 for the 4 behavioral measures; n = approximately 157 for the 3 biological measures; slight variation by measure in that n = 110 for medication because not all on diabetes medications)

	Healthy Eating *r*	Fat Intake *r*	Physical Activity *r*	Medication Adherence *r*	BMI *r*	Hemoglobin A_{1c} *r*	10-year UKPDS *r*
Self-monitoring							
Medication taking (n = 110)	.31[b]	-.28 [b]	.17	.16	-.03	.04	-.15
Physical activity	.29 [b]	-.20 [a]	.20 [a]	.16	-.05	-.03	-.17
Healthy eating	.29 [b]	-.20 [a]	.22 [a]	.15	-.05	-.04	-.16
Number of action plans	.21 [a]	-.20 [a]	.05	.15	.01	.05	-.15
Total number of visits	.20 [a]	-.11	.14	.17	-.09	-.07	-.07
Total time (minutes)	.37 [c]	-.20 [a]	.17	.15	-.09	-.03	-.15
Comprehensive Web use score (n = 123)	.20[a]	-.31 [b]	.00	.11	.00	.06	-.14

[a] $P < .05$

[b] $P < .01$

[c] $P < .001$

Discussion

Our primary goal was to report on the level of use of our Internet DSME and the site components used most and least often. Overall, and compared with a number of prior Internet lifestyle change programs [5,17], the My Path/Mi Camino website was well used. During the initial weeks of the program, the vast majority of users logged into the site at least once per week, the minimum expectation of users, and some users visited the site daily. As has been reported previously in a study of another Web-based diabetes self-management program [38], use of the My Path/Mi Camino site decreased over time but was still moderately high by 4 months. Website utilization varied widely. By 4 months, some users had stopped or visited only sporadically; many users visited the site approximately weekly (usually to enter self-monitoring data), and some continued to use the site almost daily. Continued usage by the latter groups may have been due to a combination of the design features of the website to promote “stickiness,” including a high degree of interactivity and choice, voice-overs, a variety of visual and auditory displays, frequent updates and changes, the ability for users to further tailor the recommendations and strategies by writing their own alternatives, and feedback on both behavior-change targets and laboratory results, along with prompts and reminders to keep users involved.

Usage rates were similar on most engagement measures in the website and the website plus human support conditions, with the website plus human support condition producing slightly higher rates that occasionally reached statistical significance (eg, on the composite section use score and the number of days self-monitoring data were entered on medication use, but not on the other 2 target behaviors). Given moderately high use in the website alone condition, it may be that more frequent or intensive added support or contacts are needed to substantially increase usage above this level. Increased linkage to the primary care team, such as individualized emails to participants from health counselors as used successfully in weight loss website interventions by Tate and colleagues [2], might enhance usage but would also add costs and staff time.

All of the key features of the My Path/Mi Camino site were utilized. As expected, a high percentage of participants fairly regularly reported self-monitoring data (78% at least weekly), but use of the action plan pages was more infrequent than expected. In particular, the healthy eating action planning section use was low. This may have been because of navigational difficulties in updating or modifying dietary goals and strategies compared with the ease of revising the more frequently visited physical activity action plans. Our data suggest that older patients with diabetes can simultaneously monitor multiple health behaviors [39].

After the “Track My Progress” section, the next most frequently visited section of the My Path/Mi Camino website was the “ABCs” section that presented graphical displays of laboratory results. Given these results and the availability of the “Ask an Expert” section, which was used moderately often, especially initially, users may have found the website a useful extension of their diabetes care.

A secondary goal was to evaluate the association between a variety of patient characteristics and website use. Even given heterogeneity in both participant characteristics and website engagement measures, the associations between these variables were low. Though a large number of correlations were computed, none reached the Spearman r = .20 level and thus are not considered to be clinically important; the few patient characteristics that were significantly associated with 1 or 2 engagement measures did not replicate across other engagement measures. On one hand, the general lack of patient characteristics predictive of engagement fails to suggest how to improve the website. On the other hand, our results indicate that a wide range of persons with a variety of education, age, income levels, ethnic backgrounds, sociodemographic, psychosocial, and clinical characteristics were able to use the website. It was especially encouraging that participants who were older or of Latino ethnicity as well as those with a higher risk of diabetes complications, or who had moderate to lower health literacy, or who had little baseline computer use were as engaged with the website as other participants. It may have been that efforts made during website development to address issues of literacy, cultural appropriateness, patient-centeredness, and personal choice and to maximize initial success served to make the program engaging to a broad variety of patients. Given the emphasis on self-monitoring and graphical feedback, it would have been helpful to have collected measures of health numeracy as well as general health literacy.

Several of the engagement measures (self-monitoring measures, action plan engagement, total number of visits, total time on the site, and the composite section use index) were moderately related to improvement in healthful eating behaviors over 4 months. Website engagement was not, however, related to improvement in the other target behaviors or in biological outcomes.

We created a number of engagement measures that were relevant to our particular study. The pattern of results does not suggest the superiority of any particular engagement measure over the others. As measures that could be used across a variety of Internet intervention areas, we recommend (1) total visits and (2) a composite score to reflect overall use of different sections similar to that used by Strecher et al [5]. Because of the often skewed and nonnormal distribution of engagement scores, we also recommend inspection of scatter plot displays of the relationship between engagement and outcomes and investigation of dichotomous “threshold use” indices (eg, percent of participants that used the site or a section a minimum number of times believed to be required). To understand the engagement construct, additional qualitative data such as patient interviews would have been helpful.

Limitations of this report included the use of a single managed care setting and the relatively short 4-month time frame. Strengths included a large and diverse sample, inclusion of a number of patient health-disparity characteristics, digital divide issues (eg, baseline level of computer use, gender, race, and age), and the variety of engagement measures available from automated data. Future research recommendations include investigation of levels of engagement across different clinical settings and qualitatively different components of interactive programs (eg, information vs problem-solving or peer support components) with different levels of linkage to the primary care team, use of a sophisticated measure of health numeracy, as well as a more sophisticated measure of health literacy.

Acknowledgments

This research was funded by Grant 2 R01 DK035524-21 from the National Institute of Diabetes and Digestive and Kidney Diseases.

Conflicts of Interest

None declared

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Abbreviations

BMI: body mass index
CHAMPS: Community Healthy Activities Model Program for Seniors
DSME: diabetes self-management education
EMR: electronic medical record
HDL: high-density lipoprotein
IVR: interactive voice response
KPCO: Kaiser Permanente Colorado
LDL: low-density lipoprotein
PFAT: percent energy from fat
RCT: randomized controlled trial
STOFHL: Short Test of Functional Health Literacy
UKPDS: United Kingdom Prospective Diabetes Study

Edited by G Eysenbach; submitted 28.10.09; peer-reviewed by ML Lustria, S Fonda; comments to author 02.03.10; revised version received 08.07.10; accepted 14.07.10; published 25.01.11.

Please cite as:
Glasgow RE, Christiansen SM, Kurz D, King DK, Woolley T, Faber AJ, Estabrooks PA, Strycker L, Toobert D, Dickman J
Engagement in a Diabetes Self-management Website: Usage Patterns and Generalizability of Program Use
J Med Internet Res 2011;13(1):e9
URL: http://www.jmir.org/2011/1/e9/
doi:10.2196/jmir.1391
PMID:21371992

Original Paper

Online Interventions for Social Marketing Health Behavior Change Campaigns: A Meta-Analysis of Psychological Architectures and Adherence Factors

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Abstract

Background: Researchers and practitioners have developed numerous online interventions that encourage people to reduce their drinking, increase their exercise, and better manage their weight. Motivations to develop eHealth interventions may be driven by the Internet's reach, interactivity, cost-effectiveness, and studies that show online interventions work. However, when designing online interventions suitable for public campaigns, there are few evidence-based guidelines, taxonomies are difficult to apply, many studies lack impact data, and prior meta-analyses are not applicable to large-scale public campaigns targeting voluntary behavioral change.

Objectives: This meta-analysis assessed online intervention design features in order to inform the development of online campaigns, such as those employed by social marketers, that seek to encourage voluntary health behavior change. A further objective was to increase understanding of the relationships between intervention adherence, study adherence, and behavioral outcomes.

Methods: Drawing on systematic review methods, a combination of 84 query terms were used in 5 bibliographic databases with additional gray literature searches. This resulted in 1271 abstracts and papers; 31 met the inclusion criteria. In total, 29 papers describing 30 interventions were included in the primary meta-analysis, with the 2 additional studies qualifying for the adherence analysis. Using a random effects model, the first analysis estimated the overall effect size, including groupings by control conditions and time factors. The second analysis assessed the impacts of psychological design features that were coded with taxonomies from evidence-based behavioral medicine, persuasive technology, and other behavioral influence fields. These separate systems were integrated into a coding framework model called the communication-based influence components model. Finally, the third analysis assessed the relationships between intervention adherence and behavioral outcomes.

Results: The overall impact of online interventions across all studies was small but statistically significant (standardized mean difference effect size d = 0.19, 95% confidence interval [CI] = 0.11 - 0.28, $P < .001$, number of interventions k = 30). The largest impact with a moderate level of efficacy was exerted from online interventions when compared with waitlists and placebos (d = 0.28, 95% CI = 0.17 - 0.39, $P < .001$, k = 18), followed by comparison with lower-tech online interventions (d = 0.16, 95% CI = 0.00 - 0.32, $P = .04$, k = 8); no significant difference was found when compared with sophisticated print interventions (d = –0.11, 95% CI = –0.34 to 0.12, $P = .35$, k = 4), though online interventions offer a small effect with the advantage of lower costs and larger reach. Time proved to be a critical factor, with shorter interventions generally achieving larger impacts and greater adherence. For psychological design, most interventions drew from the transtheoretical approach and were goal orientated, deploying numerous influence components aimed at showing users the consequences of their behavior, assisting them in reaching goals, and providing normative pressure. Inconclusive results suggest a relationship between the number of influence components and intervention efficacy. Despite one contradictory correlation, the evidence suggests that study adherence, intervention adherence, and behavioral outcomes are correlated.

Conclusions: These findings demonstrate that online interventions have the capacity to influence voluntary behaviors, such as those routinely targeted by social marketing campaigns. Given the high reach and low cost of online technologies, the stage may be set for increased public health campaigns that blend interpersonal online systems with mass-media outreach. Such a combination of approaches could help individuals achieve personal goals that, at an individual level, help citizens improve the quality of their lives and at a state level, contribute to healthier societies.

(J Med Internet Res 2011;13(1):e17) doi:10.2196/jmir.1367

KEYWORDS

Meta-analysis; intervention studies; behavioral medicine; social marketing; behavior; psychology; motivation; online systems; Internet; Web-based services

Introduction

Research suggests that online intervention can motivate people to adopt healthy behaviors, such as reducing binge drinking [1], stopping smoking [2], and managing healthy weight [3]. Frequently, these online interventions are individually tailored programs, resembling two-way interpersonal therapy. It is now conceivable that health campaigners can deploy mass-interpersonal campaigns, where online media are used to engage large populations in automated relationships that resemble the support offered by dieticians, fitness trainers, or smoking cessation counselors.

At present, numerous factors are driving health promotion campaigns online. First, the Internet offers health campaigners a convenient channel to increase the reach of large-scale campaigns. The Internet is now a major source of information for health advice [4], and presently there are over 1.5 billion Internet users [5]. Second, interactivity offers many benefits and may render online communication more effective than traditional approaches [6-8]. In this regard, online communications can utilize multimedia and interactive capabilities, which offer new ways to engage public audiences. Third, meta-analyses demonstrate that online interventions can match and occasionally outperform traditional interventions [8-10]. Systematic reviews tend to be less conclusive but still show a marginal advantage over traditional interventions [11,12].

Fourth, the cost-effectiveness of preventative medicine and online outreach are both driving the innovation of online health solutions. Governments are recognizing that it is more cost-effective to market healthy lifestyles rather than pay to treat the outcomes of unhealthy lifestyles [13]. This is set against a backdrop where rising health care costs are driving the search for affordable eHealth solutions [14]. Some preventative lifestyle programs have offered significant costs savings to insurance companies in the range of 50% within one year and 20% to 30% in subsequent years [15]. Given the reach and interactivity of the Internet, transcribing these programs to online contexts can bring these types of lifestyle programs to millions but at a fraction of the cost of traditional interventions. For instance, smoking cessation telecounseling interventions were estimated to cost US $150 to US $250 per smoker, tailored print interventions ranged from US $5 to US $40 per smoker, while tailored online smoking cessation interventions could cost less than US $1 per smoker, depending on the population size [2].

When designing campaigns to enhance citizen well-being, health officials draw from numerous fields, theories, frameworks, and techniques. With almost 40 years of academic and practical development, social marketing is an established approach to behavioral change [16]. Social marketing is the use of marketing principles and techniques to influence a target audience to voluntarily accept, reject, modify, or abandon a behavior for the benefit of individuals, groups, or society as a whole [17]. It is based on influencing voluntary behavior, often through incentives in the form of marketing offers targeted to key population segments [18]. It is commonly used by governmental health departments—such as Health Canada [19], the United Kingdom’s Department of Health [20], and the United States’ Centers for Disease Control and Prevention [21]—to design large-scale campaigns promoting healthy lifestyles to millions.

Designing Online Behavioral Change Interventions

Social marketers frequently use the Internet to promote healthy lifestyles as part of multichannel campaigns, increasingly with social media tools. However, several authors have argued that new media have introduced changes that are shifting how social marketing campaigns should be carried out and that the old one-way communication model does not make sense in online environments [22] or that social marketers have not yet taken full advantage of the Internet’s potential [23]. These criticisms may be due to the lack of empirical research that can inform the design of online interventions suitable to social marketing contexts.

To understand how online intervention design can influence users' behaviors, some researchers have examined health behavioral change interventions that can be found through Internet search engines. Their studies tend to offer uncertain and sometimes pessimistic conclusions. One evaluation of existing health behavioral change websites concluded that many of these sites did not include the basic requirements to achieve health behavior change [24]. Another study of physical activity websites assessed the extent to which interventions appeared to reflect various behavioral change theories and techniques. The authors concluded that interventions provided little assessment, feedback, or tailored support. Given the lack of intervention features believed to influence behavior, the authors called for more randomized controlled trials to assess long-term impacts [25]. Another research team concluded that government anti-tobacco websites lacked the capacity to disseminate persuasive communications, while grassroots organizations offered the only viable online outreach due to their advocacy capacity [26]. A similar class of research are case studies of online campaigns [27-30]. They often provide in-depth descriptions of particular campaigns and their associated online interventions. These studies provide useful details on how applied online interventions are designed, and they also make the case for how interventions should be designed, but they do not offer empirical evidence that online intervention design is associated with behavioral impacts.

Other types of research that can inform intervention design include meta-analyses [8-10] and systematic reviews [12,31] of online interventions. These studies suggest that online interventions offer small advantages over traditional intervention media, such as websites versus print publications. In some cases, these studies provide insights into intervention design features associated with behavioral impacts. However, these prior studies are limited in their ability to generalize to numerous campaign contexts, where large-scale social marketing campaigns routinely focus on voluntary behavioral change. This is because these prior review studies have not distinguished between interventions targeting behaviors that are voluntary and those that are mandatory. Rather, these studies have pooled interventions targeting voluntary behaviors more suitable to social marketing applications, along with mandatory behaviors that are more suitable to medical applications, such as managing chronic diseases or coping with psychological disorders. Perhaps one exception was a systematic review that offered good evidence that online interventions can influence voluntary behaviors but lacked the statistical insight offered by meta-analysis [11].

Thus far, no meta-analyses have quantified how the psychological design of online interventions can influence behaviors that are typically targeted in social marketing campaigns. To overcome this gap, there is a need to identify a sample of online behavioral change interventions that resembles those used in large-scale public health campaigns and which also offers insight into the psychological architectures associated with voluntary behavioral change.

Dose

In clinical studies, the more people adhere to lifestyle change programs, the more their health improves. Similarly, those with life threatening diseases who stick to diet and lifestyle programs can potentially prevent their condition from worsening [15]. However, in longitudinal studies of interventions that are neither mandatory nor critical to participants' well-being, one can expect significant attrition [32]. This trend has prompted researchers to focus on strategies to increase adherence to online interventions [33].

Research suggests that exposure to programs (their dose), is a key predictor of behavior change. In one systematic review, the majority of participants failed to engage in more than half of the expected eHealth activities. However, those interventions with high utilization showed better behavioral outcomes [11]. Similarly, high attrition in person-to-person health behavioral change programs has prompted researchers to argue that online interventions need to put in more effort to prevent dropouts in person-to-computer interventions [24, 32].

In this paper, the term *attrition* describes the proportion of people who stop using an intervention over time [32]. The opposite of this term is *adherence*, which describes the proportion of participants who continue using an intervention over time. Regardless of which term is used, the amount of exposure that people receive when using an intervention is also called *dose*. For interventions that are not mandatory, and participation is voluntary, users will receive a dose that is proportional to their chosen level of adherence or attrition.

There are two types of adherence. First, *intervention adherence* describes the proportion of participants who use an intervention over time. This is negatively called *nonusage attrition* [32]. Second, *study adherence* describes the proportion of participants who stay in a study over time. It is negatively called *dropout attrition* [32], which describes participants who leave a study. Under the law of attrition, it has been proposed that study adherence and intervention adherence are correlated and explained in part by a third variable: *participant interest*, which is in turn influences by other factors, such as usability, push factors, personal contact, positive feedback, peer-to-peer communication, etc. [32]. As intervention adherence is considered critical to intervention efficacy, and study adherence and intervention adherence are believed to be related, there is a need to empirically investigate these relationships.

Describing the Design of Online Interventions

Although online interventions are frequently described as a homogenous group, they may be radically different in terms of their purpose, design, and psychological architectures. In order to describe the diversity of existing online interventions, any coding system would need to accommodate a large variety of complex factors that may explain intervention efficacy. However, there is no consensus on what constitutes the best theoretical framework or list of factors that may be used to describe interventions and which may also explain their efficacy. The literature offers numerous competing behavioral change theories and taxonomies that are founded on different assumptions, application contexts, and academic disciplines. This has resulted in numerous overlapping and ill-fitting taxonomies, none of which is comprehensive enough to describe online interventions on their own [34, 35]. Moreover, the majority of online health intervention design guidelines do not focus on behavioral outcomes, which renders them inappropriate for assessing design factors that may be associated with behavioral outcomes. For instance, one review of 20 health intervention guidelines found that just 2 addressed outcomes [36].

To overcome the lack of intervention design guidelines addressing behavioral outcomes, this study first reviewed numerous influence systems and then developed a communication-based framework to consolidate taxonomies across various fields into a simple coding system. When describing these various systems, the following terms are used: *influence system* describes any research that classifies approaches to psychological and/or behavior change, and *influence component* describes a particular technique or package of techniques designed to influence a person's psychology and/or behavior. The review looked at influence systems from evidence-based behavioral medicine [37-40], persuasive technology and the media equation [7,41,42], persuasive communication research [43-45], stages of change [46,47], and community-based social marketing [48,49]. Of these various systems, two influence system taxonomies offered highly robust coding guidelines that reflected commonly reported behavioral change techniques and psychological constructs [38,50]. However, across all studies, no single system was suitable to coding online intervention psychology on their own.

In order to develop a comprehensive coding system to describe the psychological architectures of online interventions, a model was developed to consolidate influence systems across a range of fields. It is called the communication-based influence components model (CBICM). The model views interaction between audiences and online interventions as roughly equal to the relationship between a therapist and client, where the therapist's treatment is just one of many factors that may explain efficacy. For instance, many therapists may offer the same treatment to their patients; however, for some therapists, their reputation, communication style, flexibility, and willingness to adapt to the client's needs can influence the efficacy of their treatment. The CBICM is based on the principle that the strength of an intervention is the result of its influence components [38,40]. Moreover, each of these influence components exists within different parts of the communication process such as those attributed to the source, message, how the message is expressed, and whether the message can be tailored with audience feedback. Given that numerous influence techniques require audience feedback and that social media campaigns are primarily based on two-way communication, the CBICM offers a circular communication model that also describes either one-way or two-way interventions or campaigns. The CBICM was developed for this meta-analysis and is described within prior publications [34,35]. See the Multimedia Appendix for a brief overview of the CBICM.

Study Objectives

This meta-analysis assessed online intervention features that can be used to guide the development of population-wide campaigns targeting voluntary lifestyle behaviors. Furthermore, it assessed relationships proposed under the law of attrition, which offers insights into the role of intervention exposure (dose) and intervention efficacy. Toward these objectives, the study assesses psychological design factors, time trends, and the role of dose in online interventions.

Methods

Searching

To identify qualifying studies for this meta-analysis, a 3-step systematic review approach was used [51]. First, a pilot search was conducted to assess and finalize keywords and bibliographic databases. Next, query terms were constructed from keyword combinations across three categories, including spelling variations. The three keyword categories include (1) *online media terms*: internet, online, on-line, web, website, webpage, web-based, www, cyber, cyberspace, hypertext, email, e mail, and e-mail; (2) *intervention terms*: intervention and interventions; and (3) *behavioral outcome terms*: behavior, behaviour, behavioral, and behavioural. To combine these keyword categories, the first query combined online media and intervention terms; the second, online media and behavioral outcome terms. The syntax was as follows: (word category 1 AND word category 2) OR (word category 1 AND word category 2) OR (etc). These combinations produced 84 separate queries.

Second, these terms were used to identify and retrieve abstracts from relevant databases. In all, 5 bibliographic databases were selected. To cover the timeframe from 1999 through 2008, these databases were searched on September 20, 2008, and then on January 16, 2009, to cover 2008. The outcomes from both search sessions resulted in the following number of potential studies: 652 from Web of Knowledge, 292 from PsycINFO, 244 from MEDLINE, 327 from PubMed, and 7 from the Cochrane Library.

Third, additional strategies were employed to identify potential studies from the gray literature. A total of 59 additional studies were retrieved from the bibliographies of similar meta-analyses [9,10,52]. Further, requests for suitable publications were sent to relevant online discussion forums. These included listservs for the Georgetown University social marketing group, Community Based Social Marketing, Association of Internet Researchers, and the Medicine 2.0 Conference discussion group. For gray literature, searches were undertaken in Google and Yahoo. These strategies produced 6 additional papers.

Selection

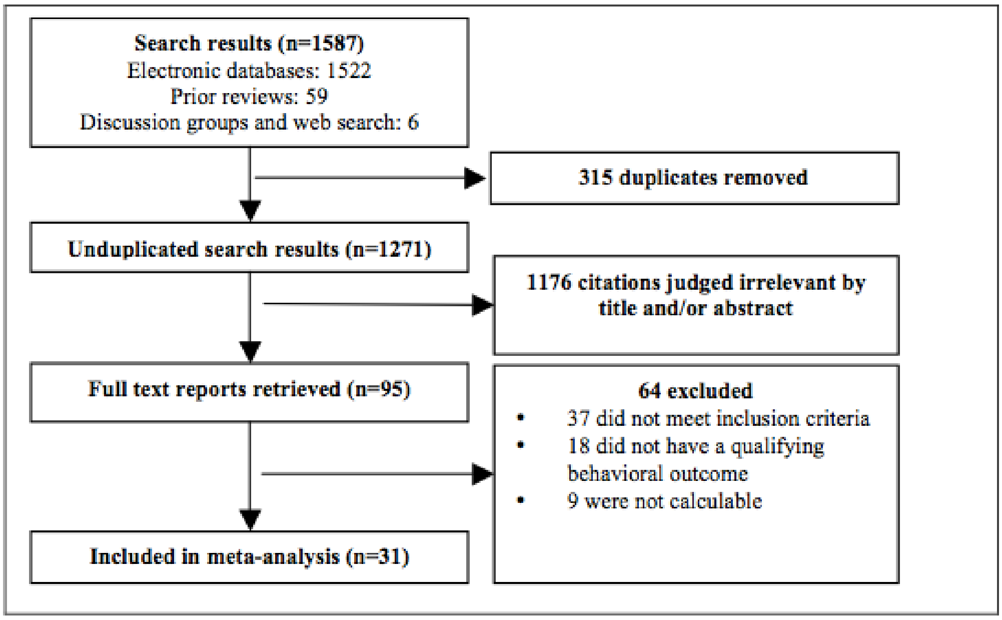
Eligible studies for this meta-analysis included published or unpublished research and reports in English. Qualifying papers included experimental, quasi-experimental, and correlational studies, including those with randomized and nonrandomized allocations. The substantive criteria in Table 1 were used to screen studies that reflected audiences and behaviors similar to those targeted by social marketing campaigns and studies where effect sizes statistics could be extracted.

Table 1. Inclusion and exclusion criteria

Area	Criteria
Timeframe	Inclusion: Years 1999 through 2008
Age	Inclusion: Preteens to older persons Exclusion: Studies containing persons 9 years and younger
Behavioral domains	Inclusion: Health, safety, environmental, and community development behaviors Borderline inclusion: Subjects with ailments for which the behavior was beneficial but not critical and occupational groups for which the target behavior was voluntary Exclusion: Compulsory behaviors, critical behaviors linked to chronic illness, and psychological disorders
Behavioral outcome (dependent variable)	Inclusion: A clear behavioral change outcome Borderline inclusion: Interventions that blended change with maintenance objectives such as interventions encouraging both weight loss and maintenance Exclusion: Psychological outcomes and behavioral maintenance defined as *not changing*, that is, conceptually distinct from behavioral change
Intervention types	Inclusion: Web-based or Web and email-based Borderline inclusion: Interventions stored on a CD-ROM, USB stick, or intranet provided they contained an intervention designed for Internet deployment and technology, such as pedometers, provided both intervention and control groups received them so that any statistical difference was explained by the Web-based intervention, not the additional treatment
Intervention mechanism	Inclusion: Primarily automated interventions (human-computer) Borderline inclusion: Interventions that were primarily human-computer, but included minor computer-mediated communication; cases where both the experimental and control groups received similar human contact, so the difference lay with the online intervention; cases where human interaction was secondary, such as technical support, voluntary help lines, or minor councilor engagement Exclusion: Primarily computer-mediated communication (human-human)
Control treatments	Inclusion: Control group intervention comprising print, Web-based interventions, waitlists, placebos, and therapists Exclusion: Studies that contrasted different behavioral outcomes; studies where the difference between interventions was a non-Web based factor, such as contrasting populations or administering a mobile phone to one group; studies where the difference between the 2 interventions was unclear

Figure 1 shows the intervention selection process. From all sources, 1587 abstracts, references, and papers were reviewed; 315 were duplicates resulting in a pool of 1271 potentially qualifying papers. After manually reviewing titles, abstracts, and full texts, 1176 were assessed as irrelevant. For the remaining 95, the full texts were obtained and evaluated. A further 64 were excluded for not meeting the inclusion criteria, not containing a qualifying behavioral outcome, or not being suitable for calculation.

Figure 1. Selection process flow chart



In total, 31 studies were included in this meta-analysis and coded. There were 2 studies that met the inclusion criteria that were removed from the overall analysis but were included in the dose analysis. The first study [53] was the only correlational investigation that required separate analysis [54]. The second study [55] was the only investigation that reported only a therapist control group, which could not be included in the moderator analysis as a single case.

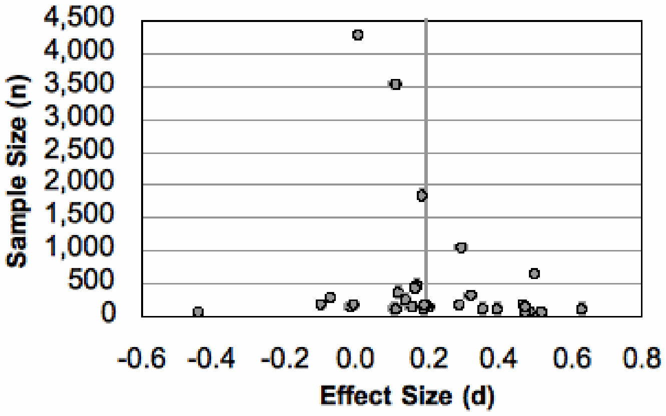
Validity Assessment

To evaluate the studies and test for potential publication bias, three validity assessment methods were employed: research quality assessment, cumulative meta-analysis, and a funnel plot assessment [56]. First, as the inclusion criteria covered both experimental and correlational studies, research quality was assessed with the Downs and Black instrument for randomized and nonrandomized studies [57], a checklist of 27 items pertaining to reporting, external validity, internal validity, and selection bias. However, the one item on statistical power was removed, as this factor is addressed by the meta-analysis weighting. This assessment instrument was highly rated in a review of research evaluation tools [58]. No minimum research quality score was used to screen studies, but rather, the quality score was used to assess whether research quality may have biased the pool of studies. A meta-regression analysis showed a small statistically insignificant positive correlation between research quality and effect size where k refers to the number of interventions used in the analysis (r = .116, P = .55, k = 30). This indicates that research quality is probably not correlated with effect size. However, one quasi-experimental study [59] required special treatment as it scored lowest on the research quality assessment but had the largest population.

Second, a cumulative meta-analysis did not show that small studies were contributing a large impact on the final effect size. Thus, the small studies are unlikely to be biasing the sample of studies [56].

Third, the funnel plot in Figure 2 displays interventions arranged with sample size on the y-axis and effect size on the x-axis. In the absence of publication bias, studies should spread out evenly around the combined effect [60]. To assess publication bias, a manual check was made; two issues were found. There is a significant discrepancy between large and small studies: 4 studies had sample sizes over 1000, while the remainder were significantly smaller. Further, the study with the largest sample size (and lowest research quality score) did not line up as would be expected in an ideal funnel plot distribution. The funnel plot suggests the sample of studies is not fully ideal, indicating some bias, but appears acceptable.

Figure 2. Funnel plot of interventions



Publication bias is conventionally assessed according to three categories: *trivial*, which does not change the results; *modest*, where the results change, but the conclusions stay the same; or *substantial*, where the conclusions may be called into question [56]. This analysis revealed 2 possible sources of bias: a less than ideal distribution of interventions (indicated by the funnel plot) and the impact of one study (with the largest population size and lowest research quality score). Given the random effects model used for this meta-analysis, these possible sources of bias do not change the final statistical outcomes by more than a small margin. The small potential bias seems modest and unlikely to alter the conclusions, though in one case, the suspect study has been given special consideration.

Data Abstraction

Data was extracted from studies using calculations by Borenstein et al and Lipsey and Wilson [56,61]. When the reported data was insufficient for coding, procedural work-arounds were used [61]. When it was impossible to code qualifying papers, a request for data was sent to the authors. For each effect size, only one outcome measure was selected per independent intervention sample [61]. When more than one follow-up measure was reported, these were also coded for the longitudinal analysis, which was analyzed within separate time groupings to avoid dependence [56]. Additionally, when more than one behavioral outcome was reported, if they were dissimilar or measured on different scales, the most relevant outcome was selected, and if several similar outcomes were reported and measured on the same scale, they were pooled. When interventions targeted multiple behaviors, a single outcome that best reflected both behaviors was selected. Coding was carried out by a single researcher who conducted the initial coding and then 1 month after completing all papers, conducted a second confirmatory coding.

For the analysis of psychological design, the CBICM was used as a framework to group influence components from various influence systems. When coding influence components, 2 approaches were used. First, *absolute coding* describes when an intervention uses an influence component whether or not the control group received the same treatment. Absolute coding is used for descriptive statistics and shows how often a particular influence component was used. Second, *relative coding* records when a particular influence component was only administered to the experimental group. If an influence component was applied to both the experimental and control groups, then the component was not coded, as it could not statistically explain the psychological difference between treatments. Relative coding is used to calculate associations between influence components and behavioral outcomes.

For the dose analysis, when coding the adherence variables, study adherence was measured as the percentage of participants in a study at a given time compared with the baseline. Coding intervention adherence was more challenging, as it was conceived and reported in many ways. Across studies, intervention adherence was reported as log-ins, visits, page views, core pages viewed, percent of required reading completed, and complex multi-item measures. Researchers reported intervention adherence by the total number of users, averages per user, or percentages over various time units. In some cases, the variables were measured on continuous scales, in others, they were dichotomous, but more often, continuous variables were cut into arbitrary categories, such as high/low log-in groups. To deal with this diversity, 2 coding and meta-analytical approaches were employed to assess the relationship between intervention adherence and behavioral outcomes. The first approach coded any reported intervention adherence construct, while the second approach only coded adherence constructs that could be converted into a percentage.

Full intention to treat groups may distort the results by including many unmotivated participants, while the fully exposed group are likely to represent the most motivated participants [32]. In aiming to keep subject groupings comparable across studies when papers reported both intention to treat and full exposure groups, the 2 were pooled to render effect size calculations more comparable with the majority of studies that did not employ these distinctions.

Quantitative Data Synthesis

This study presents three analyses. The first analysis provides the overall effect size estimates, including groupings by control conditions and time moderators. The second analysis assesses psychological design features, presenting overall correlations, descriptive statistics, and behavioral outcomes associated with influence components. The third analysis examines correlations between adherence variables and behavioral outcomes.

Following recommendations to select statistical models a priori on the basis of substantive justifications [51,56], a random effects model was selected. Intervention effect size, standard error, and inverse variance statistics were calculated with equations and the spreadsheet tool by Lipsey and Wilson [61]. Overall effect sizes and analogue to analysis of variance (ANOVA) analyses were carried out in comprehensive meta-analysis. Meta-regression was conducted in SPSS, version 14 (SPSS Inc, Chicago, IL) with macros using maximum likelihood [61].

The majority of studies were randomized controlled trials, measured with continuous or dichotomous data with pre and post measures, while in some cases only post measures were reported. For group contrasts, that is, between-subject studies, the standardized mean difference, d, was used as the primary effect size measure. To assess categories used to explain heterogeneity in the analogue to ANOVA, the between-group heterogeneity statistic and its significance value Q_b (P) are used to assess the strength of the categories. Likewise, the within-group heterogeneity statistics Q_w (P) and I^2 are used to assess the strength of categories [51,56]. As standard notation, *r* designates meta-regression correlations, and k, the number of interventions.

Results

Study Characteristics

Table 2 lists the 30 interventions from 29 studies that qualified for the primary analysis. One study contained 2 interventions, which are designated as *a* and *b* [62]. Across these studies, 17,524 participants were allocated to 30 interventions, with 14,895 participants completing postintervention surveys. Of the interventions, 24 used random assignment, 1 was nonrandom, and it was not possible to determine the type of assignment for 5 interventions.

Table 2 presents the pre and post number of subjects across the experimental and control groups. For the experimental group, Table 2 presents the mean age, the percentage of male participants, study adherence, and intervention adherence (recorded at first postintervention measure). Finally, the research score is presented as a percentage.

Table 2. Interventions

Author (Year) and Reference Number	Experimental and Control Groups		Experimental Group					Research Score (%)
	Pre (n)	Post (n)	Participant Characteristics	Mean Age	Male (%)	Study Adherence (%)	Intervention Adherence (%)	
Bersamin et al (2007) [63]	139	139	Students (who drink alcohol)	18	48.0%	57.4%		73.1%
Bewick et al (2008) [64]	506	317	Students	21.3	31.0%	59%		73.1%
Bruning Brown et al (2004) a [62]	153	153	Students (female)	15.1	0.0%	66.7%		69.2%
Bruning Brown et al (2004) b [62]	69	69	Parents		3.4%	100.0%	50.0%	69.2%
Celio et al (2000) [65]	52	47	Students (female)	19.6	0.0%	96.3%	71.0%	92.3%
Chiauzzi et al (2005) [1]	265	215	Students (who are heavy drinkers)	20	44.8%	80.2%	86.0%	80.8%
Dunton and Robertson (2008) [66]	155	128	Women	42.8	0.0%	78.6%		92.3%
Gueguen and Jacob (2001) [67]	1008	1008	French citizens					61.5%
Hunter et al (2008) [68]	451	446	Military personnel	33.5	50.0%	85.0%		80.8%
Jacobi et al (2007) [69]	97	97	Students (female)	22.5	0.0%	100.0%	83.0%	80.8%
Kim and Kang (2006) [70]	50	50	Diabetics	55.1	53.4%			73.1%
Kosma et al (2005) [71]	151	75	Disabled persons			45.5%		84.6%
Kypri et al (2004) [72]	104	83	Students	19.9		82.4%	100.0%	76.9%
Kypri and McAnally (2005) [73]	146	122	Students	20.3	46.0%	82.0%	100.0%	76.9%
Lenert et al (2004) [74]	485	144	Smokers	39	42.0%	26.0%		57.7%
Marshall et al (2003) [75]	655	258	University faculty and staff	43	50.0%	76.5%	26.0%	73.1%
McConnon et al (2007) [3]	221	131	Obese persons	45.8	23.0%	48.7%	53.0%	76.9%
McKay et al (2001) [76]	78	68	Diabetics	52.3	18.0%	92.1%		84.6%
Moore et al (2005) [77]	100	100	Students	21.7	42.2%	86.2%		65.4%
Napolitano et al (2003) [78]	65	52	Hospital staff	42.8	16.1%	70.0%		80.8%
Oenema et al (2005) [79]	521	384	Employees	42	57.0%	72.0%		69.2%
Petersen et al (2008) [59]	4254	4254	Employees			21.2%		38.5%
Roberto (2007) [80]	378	103	Students (high school)	15.5	41.7%	84.8%	88.5%	53.8%
Severson et al (2008) [81]	2523	1801	Smokeless tobacco users	36.7	97.9%	44.1%	50.0%	57.7%
Strecher et al (2005) [2]	3501	3501	Smokers trying to quit with the nicotine patch	36.9	43.5%	46.6%		80.8%
Strom et al (2000) [82]	102	45	Headache sufferers	41.5	25.0%	39.2%		80.8%
Swartz et al (2006) [83]	351	274	Employees	40.9	46.8%	50.9%	70.2%	80.8%
Tate et al (2001) [84]	91	81	Overweight persons	40.6	11.0%	78.3%		96.2%
Verheijden et al (2004) [85]	146	130	Persons at risk of cardiovascular disease	62	72.0%	84.9%	32.9%	84.6%
Winett et al (2007) [86]	707	620	Church congregation	53.13	33.0%	88.5%	57.0%	57.7%

Table 3 shows experimental group demographics that have been weighted by pretest experimental group totals. With demographic records for 8813 pretest participants, the average age was 34.7 and weighted average age was 36.5 (k = 26, n = 6057). The age standard deviation was 6.6; the weighted average standard deviation was 9.0 (k = 21, n = 5691). In general, the balance between genders was similar, with just slightly more men. The majority were white and possessed a university degree.

Table 3. Demographic descriptives

Demographic Descriptives	k	n	Percent
Gender	26	6028	100%
Men		3152	52.3%
Women		2876	47.7%
Education	15	2341	100%
Bachelor’s level		1347	57.6%
Master’s level		552	23.6%
Secondary		404	17.2%
Primary		38	1.6%
Descent	19	2957	100%
White		2475	83.7%
African		144	4.9%
Mixed		116	3.9%
Asian		82	2.8%
Latin American		74	2.5%
Aboriginal		33	1.1%
Unclassified		33	1.1%

Overall Effect Size Estimates

Table 4 reports the primary effect sizes estimates, while the forest plot with all interventions is available in Figure 3. Query 1 used the first posttest effect size from all 30 interventions. Query 2 included all posttest effect sizes, resulting in 38 effect sizes across 3 timeframes.

Table 4. Effect size estimates

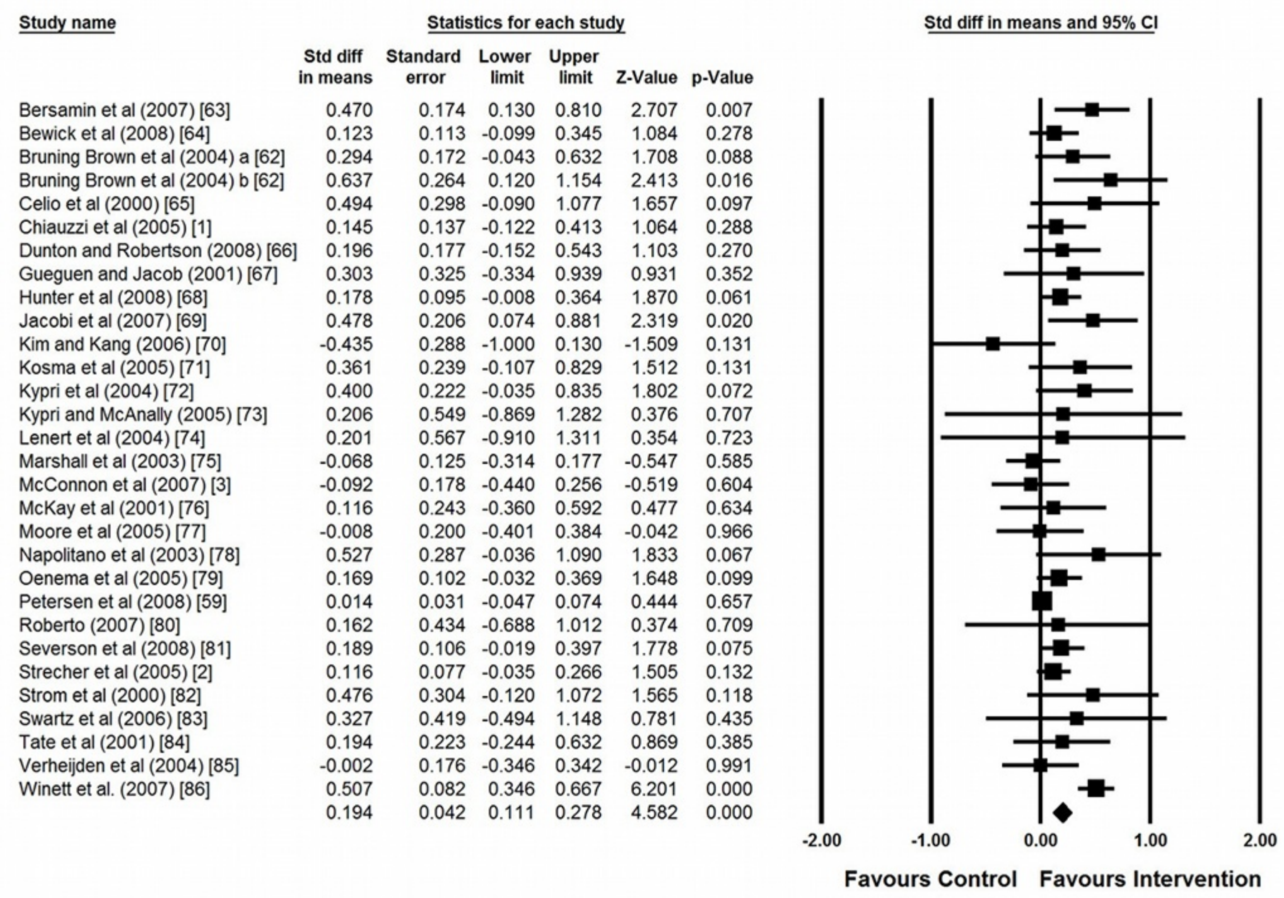
Groupings	k	d (95% confidence interval [CI])	*P*	Q_b (*P*)	Q_w (*P*)	I^2
Overall effect size [a]	30			N/A		
All interventions	30	0.194 (0.111 - 0.278)	< .001		64.125 (< .001)	54.776
Control group [a]	30			9.109 (.01)		
Waitlist or placebo	18	0.282 (0.170 - 0.393)	< .001		55.163 (< .001)	69.183
Website	8	0.162 (0.006 - 0.318)	.04		0.650 (.10)	< 0.001
Print	4	-0.110 (-0.343 to 0.123)	.35		1.623 (.65)	< 0.001
Intervention duration [a]	30			6.611 (.16)		
Single-session	4	0.404 (0.130 - 0.677)	.004		0.367 (.95)	< 0.001
From 2 days to 1 month	5	0.205 (0.026 - 0.383)	.024		4.511 (.34)	11.336
Over 1 month to 4 months	16	0.220 (0.116 - 0.324)	< .001		30.131 (.01)	50.218
Over 4 months to 7 months	3	0.090 (-0.077 to 0.258)	.29		3.235 (.20)	38.186
Over 7 months to 13 months	2	-0.047 (-0.337 to 0.243)	.75		0.130 (.72)	< 0.001
Long-term impacts [b]	38			N/A		
From 1 day to 1 month	24	0.194 (0.107 - 0.282)	< .001		39.329 (.02)	41.519
Over 1 month to 4 months	10	0.226 (0.089 - 0.363)	.001		7.139 (.62)	< 0.001
Over 4 months to 7 months	4	0.157 (0.002 - 0.312)	.048		15.261 (.002)	80.342

[a] Query 1

[b] Query 2

Table 4 shows the overall effect size, which is small and statistically significant. However, the various interventions are not likely to represent a single homogenous group, as indicated by the 2 within-group heterogeneity statistics Q_w (*P*) and I^2 that show a level of heterogeneity that cannot be explained by sampling error alone. Control group comparisons provide the best way to model the heterogeneity across interventions, as indicated by the significant between-group heterogeneity statistic Q_b (*P*) that was less than .05, revealing a large difference between control group categories. In general, online interventions showed the largest effect size when compared with waitlists and placebos, a smaller effect when compared with lower-tech online interventions, and a negative statistically insignificant effect size when compared with print interventions.

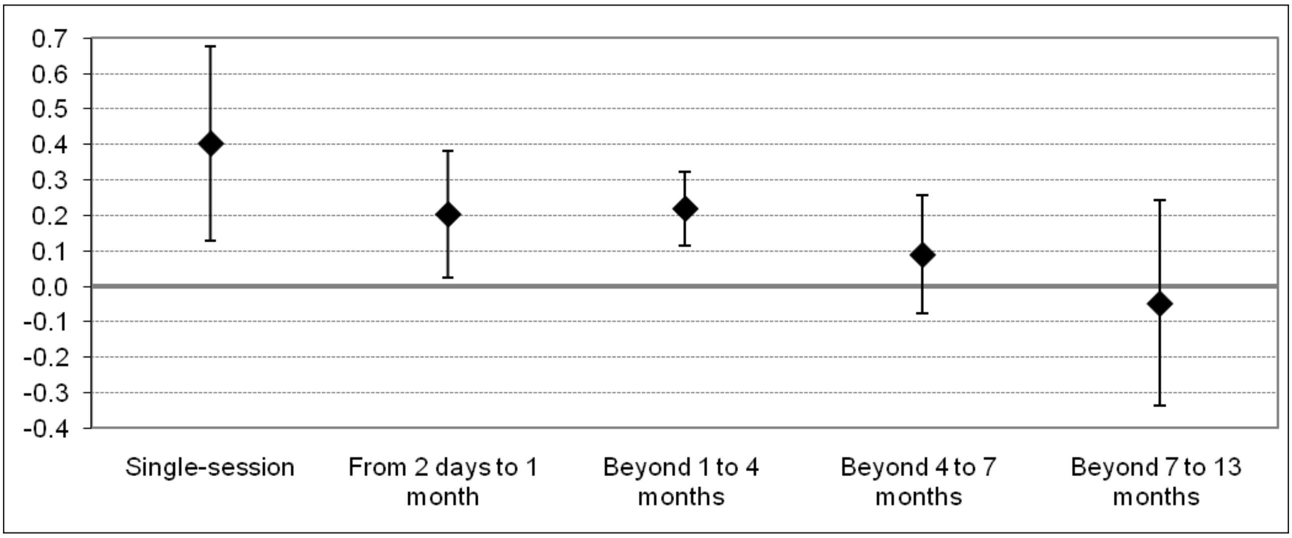
Figure 3. Forrest plot



Study name	Std diff in means	Standard error	Lower limit	Upper limit	Z-Value	p-Value
Bersamin et al (2007) [63]	0.470	0.174	0.130	0.810	2.707	0.007
Bewick et al (2008) [64]	0.123	0.113	-0.099	0.345	1.084	0.278
Bruning Brown et al (2004) a [62]	0.294	0.172	-0.043	0.632	1.708	0.088
Bruning Brown et al (2004) b [62]	0.637	0.264	0.120	1.154	2.413	0.016
Celio et al (2000) [65]	0.494	0.298	-0.090	1.077	1.657	0.097
Chiauzzi et al (2005) [1]	0.145	0.137	-0.122	0.413	1.064	0.288
Dunton and Robertson (2008) [66]	0.196	0.177	-0.152	0.543	1.103	0.270
Gueguen and Jacob (2001) [67]	0.303	0.325	-0.334	0.939	0.931	0.352
Hunter et al (2008) [68]	0.178	0.095	-0.008	0.364	1.870	0.061
Jacobi et al (2007) [69]	0.478	0.206	0.074	0.881	2.319	0.020
Kim and Kang (2006) [70]	-0.435	0.288	-1.000	0.130	-1.509	0.131
Kosma et al (2005) [71]	0.361	0.239	-0.107	0.829	1.512	0.131
Kypri et al (2004) [72]	0.400	0.222	-0.035	0.835	1.802	0.072
Kypri and McAnally (2005) [73]	0.206	0.549	-0.869	1.282	0.376	0.707
Lenert et al (2004) [74]	0.201	0.567	-0.910	1.311	0.354	0.723
Marshall et al (2003) [75]	-0.068	0.125	-0.314	0.177	-0.547	0.585
McConnon et al (2007) [3]	-0.092	0.178	-0.440	0.256	-0.519	0.604
McKay et al (2001) [76]	0.116	0.243	-0.360	0.592	0.477	0.634
Moore et al (2005) [77]	-0.008	0.200	-0.401	0.384	-0.042	0.966
Napolitano et al (2003) [78]	0.527	0.287	-0.036	1.090	1.833	0.067
Oenema et al (2005) [79]	0.169	0.102	-0.032	0.369	1.648	0.099
Petersen et al (2008) [59]	0.014	0.031	-0.047	0.074	0.444	0.657
Roberto (2007) [80]	0.162	0.434	-0.688	1.012	0.374	0.709
Severson et al (2008) [81]	0.189	0.106	-0.019	0.397	1.778	0.075
Strecher et al (2005) [2]	0.116	0.077	-0.035	0.266	1.505	0.132
Strom et al (2000) [82]	0.476	0.304	-0.120	1.072	1.565	0.118
Swartz et al (2006) [83]	0.327	0.419	-0.494	1.148	0.781	0.435
Tate et al (2001) [84]	0.194	0.223	-0.244	0.632	0.869	0.385
Verheijden et al (2004) [85]	-0.002	0.176	-0.346	0.342	-0.012	0.991
Winett et al. (2007) [86]	0.507	0.082	0.346	0.667	6.201	0.000
	0.194	0.042	0.111	0.278	4.582	0.000

The figures for intervention duration are presented in Table 4 and Figure 4. The results suggest that shorter interventions offer larger impacts, while longer interventions offer lower impacts. The strongest effect sizes resulted from the single-session interventions. Interventions lasting up to 4 months provided an effect size close to the overall effect size. However, interventions that operated longer than 4 months were statistically insignificant, demonstrating no substantial behavioral impact.

Figure 4. Effect Size by intervention duration



To examine the long-term impact after an intervention had ended, all postintervention measures were grouped into 3 time categories. This resulted in the 38 distinct postintervention measures; these are referred to as Query 2 in Table 4. As it is only possible to analyse 1 measure from each intervention sample, no between-group heterogeneity analysis was undertaken. In general, the long-term impact appears to last several months. The pooled effect size of the 24 interventions in the first time frame is similar to the overall effect size. The effect size rises slightly from 1 to 4 months and then drops slightly for the final postintervention measure, from 4 to 7 months.

Psychological Design

This section presents two analyses of psychological design. The first assesses the relationship between the overall psychological design and behavioral outcomes. The second analysis presents the psychological architecture of online interventions, reporting how frequently influence components are used and their associated effect sizes.

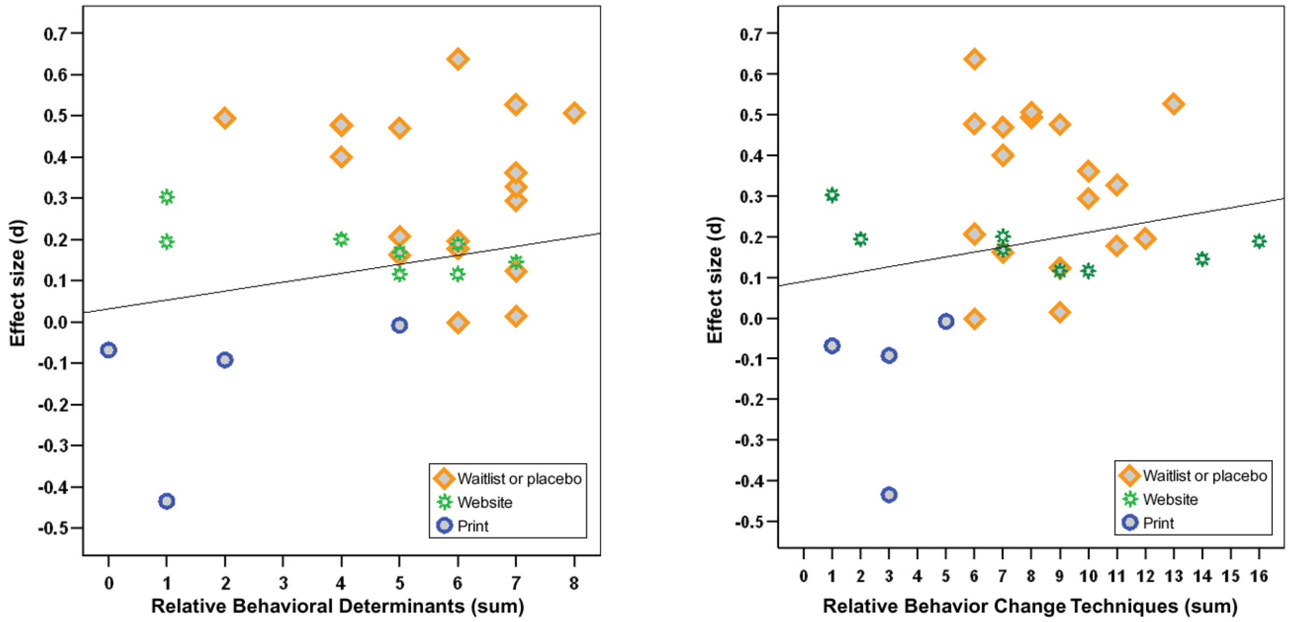
Of the theories used to design interventions, the transtheoretical approach was the most popular, being used across 47% (14/30) of the interventions. Other theories used to design interventions included social cognitive (4/30, 13%), cognitive behavioral therapy (4/30, 13%), behavioral therapy (3/30, 10%), extended parallel process model (2/30, 7%), health belief model (2/30, 7%), and the theory of reasoned action (2/30, 7%).

Psychological Design: Overall Correlations

This section assesses relationships between an intervention's overall psychological architecture and its effect size. The analysis is based on the coding systems of behavioral change techniques [38] and of behavioral determinants [50], which were relative coded in order to assess influence components administered to the experimental group only.

Groups of online interventions with the largest number of influence components demonstrated the largest effect sizes. Nonetheless, statistical correlations between influence components and effect size were inconclusive. Figure 5 compares effect sizes with the sum of relative influence components for two clusters: the first, behavioral determinants, and the second, behavior change techniques. The trend line is derived from the meta-regression analysis. Each intervention is clustered according to its control condition. Interventions matched against waitlist or placebo control groups achieved the highest effect sizes and contained the largest number of relative influence components (average of 5.7 behavioral determinants and 8.6 behavior change techniques). Interventions compared with website control groups attained a smaller but significant effect size and possessed fewer influence components (average of 4.4 behavioral determinants and 8.3 behavior change techniques). Finally, interventions compared with the sophisticated print intervention control groups were statistically no different from print publications and possessed the fewest influence components (average of 2 behavioral determinants and 3 behavior change techniques).

Figure 5. Sum of influence components by effect size



Meta-regression demonstrated a moderate but statistically insignificant correlation between an intervention's total influence components and their effect size. However, there are reasons to suspect an association exists nonetheless. The meta-regression correlation between the sum of behavior change techniques and effect size is (r = .219, P = .26, k = 30), and the correlation between the sum of behavioral determinants and effect size is (r = .327, P = .09, k = 30). Although these meta-regression analyses demonstrated no statistically significant correlation, the following evidence suggests a relationship. The groups of interventions with the largest number of influence components achieved the largest outcomes, while the groups of interventions with fewer influence components achieved lower behavioral impacts. Moreover, the same calculations were conducted without the study [59] that was shown to be suspect in the validity assessment. After removal, the correlation between behavior change techniques and effect size remained statistically insignificant. However, the relationship between behavioral determinants and effect size was large and statistically significant (r = .470, P = .007, k = 29).

Psychological Design: Influence Component Frequency and Effect Sizes

This section uses the CBICM as a framework to describe the psychological architectures employed by online interventions. Influence components are clustered within the social context, media channel, feedback message, source interpreter, source encoding, intervention message (behavior change techniques), and audience interpreter (behavioral determinants and demographics). To encourage personal change, many of the interventions helped participants adopt healthy habits by motivating them to set goals, record their behavior, learn new skills, and then use feedback to track their progress.

Absolute coding describes how frequently a particular influence component is used across the 30 interventions. *Relative coding* is used to assess the pooled effect size associated with each influence component. In general, the absolute coding number of interventions k is larger than the relative coding number of interventions k. This is because an intervention may have used a particular influence component, such as tailoring. However, if the control condition also used tailoring, then tailoring could not explain the statistical difference between the 2 conditions. Consequently, absolute coding provides insight into how often an influence component is used, while relative coding draws on a smaller number of studies to assess the effect size of each influence component. Effect sizes were only calculated where there were at least 2 qualifying studies.

The *social context* describes the social and environmental contexts that can influence an intervention's effectiveness. The majority of interventions (15) operated through direct interaction between participants and the intervention system. A slightly smaller number (13) of interventions occurred in contexts where there was at least 1 point of contact within an institutional setting. Just 2 interventions drew on family and friends.

Table 5 presents the CBICM media channel, audience feedback message, source interpreter, and source encoding. The *media channel* describes the communication channels used to distribute an intervention. Interventions primarily combined websites with email, while a third were just Web-based. Although the results show that Web-based interventions are more effective than combined websites with email, this is likely due to the strong effect of the single-session interventions that did not use email.

The *feedback message* describes information that users send to the intervention system, which is used to design personally relevant intervention messages. Systems that do not factor user feedback into their interventions are not able to deploy these influence components. Tailoring is the most common feedback component and offered a reasonable effect size. Tailoring was frequently combined with personalization: the 12 interventions that used personalization also used tailoring. The most effective influence component was *providing feedback on performance*, which fits with the goal directed nature of these interventions, as discussed subsequently.

The *source interpreter* describes influence components that are based on audiences' perceptions of the source, either the organizations operating the intervention or the website itself. Few studies explicitly mentioned source factors, making it difficult to reliably code the components and calculate their associated effect sizes. Nonetheless, the few interventions that demonstrated similarity to the audience members showed a strong effect size. Visually attractive design did not show any advantage, and just one study mentioned credibility factors.

Source encoding describes how an intervention is expressed. The vast majority of interventions were source encoded as processes that engaged users through multiple interactions over time. Those interventions that occurred in a single interaction were highly effective, which is consistent with the prior trend showing that single-session interventions were most effective. Only one intervention used a sequential request technique, the *foot in the door* technique.

Table 5. Media channel, feedback message, source interpreter, and source encoding

	Absolute Coding		Relative Coding				
CBICM clusters	k	%	k	d (95% CI)	*P*	Q_w (*P*)	I^2
Media channel							
Website and email	20	66.7%	14	0.165 (0.054 - 0.276)	.004	24.914 (.02)	47.820
Website	10	33.3%	8	0.309 (0.150 - 0.467)	<.001	16.636 (.02)	57.922
Audience feedback message							
Tailoring	25	83.3%	22	0.201 (0.107 - 0.296)	<.001	53.428 (<.001)	60.695
Provide feedback on performance	20	67.0%	18	0.215 (0.109 - 0.321)	<.001	52.985 (<.001)	67.915
Personalization	12	40.0%	11	0.193 (0.048 - 0.337)	.009	7.651 (.66)	< .001
Adaptation/content matching	2	6.7%	2	0.191 (-0.138 - 0.521)	.26	0.135 (.71)	< .001
Source interpreter							
Attractiveness	5	16.7%	3	0.080 (-0.215 - 0.375)	.60	2.631 (.27)	23.975
Similarity	3	10.0%	3	0.324 (0.015 - 0.632)	.04	1.078 (.58)	< .001
Credibility	1	3.3%	1				
Source encoding							
Multiple interactions	23	77.0%	16	0.208 (0.098 - 0.319)	<.001	43.657 (<.001)	65.641
Single interaction	3	10.0%	2	0.473 (0.154 - 0.792)	.004	0.001 (.98)	< .001
Sequential requests (foot in the door)	1	3.0%	1				

Table 6 presents influence components within the *source intervention message*, which represents the overt treatment designed to impact audience psychology and/or behavior. The taxonomy of behavior change techniques [38] is used for this cluster with *providing feedback on performance* moved to the feedback message cluster (as it can only exist when feedback mechanisms are employed). Most of the intervention messages informed users about the consequences of their behavior, focused on goal setting, and provided instructions on performing the behavior. The majority of self-monitoring was directed toward the behavior, with a few interventions focused on monitoring behavioral outcomes. However, both approaches produced similar effect sizes. Although *action planning* is a popular and effective approach, *setting graded tasks* showed no significant contribution. Both *agreeing to a behavioral contract* and *time management* stood out as influence components that were infrequently used but were associated with an above average effect size.

Table 6. Source intervention message (behavioral change techniques)

	Absolute Coding		Relative Coding				
Behavioral Change Techniques	k	%	k	d (95% CI)	*P*	Q_w (*P*)	I^2
Provide information on consequences of behavior in general	23	76.7%	16	0.306 (0.173 - 0.438)	< .001	11.365 (.72)	< 0.001
Goal setting (behavior)	21	70.0%	16	0.245 (0.131 - 0.359)	< .001	49.984 (< .001)	69.991
Prompt self-monitoring of behavior	19	63.3%	16	0.223 (0.108 - 0.339)	< .001	52.600 (< .001)	71.483
Provide instruction on how to perform the behavior	18	60.0%	15	0.212 (0.102 - 0.323)	< .001	27.927 (.02)	49.870
Action planning	17	56.7%	13	0.240 (0.119 - 0.360)	< .001	46.702 (< .001)	74.305
Provide normative information about others' behavior	12	40.0%	12	0.246 (0.120 - 0.373)	< .001	6.893 (.81)	< 0.001
Fear arousal	12	40.0%	10	0.193 (0.042 - 0.344)	.01	6.491 (.69)	< 0.001
Barrier identification/problem solving	10	33.3%	10	0.224 (0.076 - 0.372)	.003	4.372 (.89)	< 0.001
Provide information on where and when to perform the behavior	10	33.3%	10	0.218 (0.095 - 0.340)	< .001	20.104 (.02)	55.232
Set graded tasks	10	33.3%	9	0.095 (–0.017 to 0.207)	.10	11.464 (.18)	30.216
Plan social support/social change	9	30.0%	5	0.250 (0.035 - 0.465)	.02	1.940 (.75)	< 0.001
Facilitate social comparison	9	30.0%	9	0.226 (0.070 - 0.382)	.004	4.439 (.82)	< 0.001
Model/demonstrate the behavior	8	26.7%	8	0.210 (0.056 - 0.365)	.008	3.886 (.79)	< 0.001
Provide information on consequences of behavior relevant to the individual	8	26.7%	8	0.208 (0.040 - 0.375)	.02	3.447 (.84)	< 0.001
Environmental restructuring	7	23.3%	4	0.189 (–0.028 to 0.406)	.09	1.229 (.75)	< 0.001
Prompt review of behavioral goals	7	23.3%	7	0.138 (–0.018 to 0.294)	.08	6.888 (.33)	12.887
Agree behavioral contract	5	16.7%	4	0.275 (0.105 - 0.446)	.002	13.001 (.005)	76.925
Prompt self-monitoring of behavioral outcome	5	16.7%	5	0.263 (0.080 - 0.446)	.005	36.961 (< .001)	89.178
Prompt identification as role model/position advocate	5	16.7%	4	0.078 (–0.107 to 0.263)	.41	1.738 (.63)	< 0.001
Time management	4	13.3%	4	0.343 (0.018 - 0.669)	.04	1.476 (.69)	< 0.001
Stress management	4	13.3%	4	0.185 (–0.009 to 0.380)	.06	1.517 (.68)	< 0.001
Prompt self talk	3	10.0%	3	0.319 (0.058 - 0.581)	.02	2.168 (.34)	7.747
Provide rewards contingent on successful behavior	3	10.0%	3	0.291 (0.023 - 0.560)	.03	1.478 (.48)	< 0.001
Provide information about others' approval	3	10.0%	3	0.206 (–0.040 to 0.453)	.10	0.461 (.79)	< 0.001
Use of follow-up prompts	3	10.0%	3	0.183 (–0.098 to 0.463)	.20	0.968 (.62)	< 0.001
Goal setting (outcome)	3	10.0%	1				
Relapse prevention/coping planning	3	10.0%	2	0.149 (–0.100 to 0.398)	.24	0.310 (.58)	< 0.001
Shaping	3	10.0%	3	0.091 (–0.236 to 0.418)	.59	0.524 (.77)	< 0.001
General communication skills training	2	6.7%	2	0.295 (–0.031 to 0.622)	.08	2.737 (.10)	63.458
Emotional control training	2	6.7%	2	0.253 (–0.061 to 0.568)	.11	.796 (.37)	< 0.001
Prompting focus on past success	1	3.3%	1				
Prompt use of imagery	1	3.3%	1				
Motivational interviewing	1	3.3%	1				
Prompting generalization of a target behavior	1	3.3%	1				

	Absolute Coding		Relative Coding				
Behavioral Change Techniques	k	%	k	d (95% CI)	*P*	Q_w (*P*)	I^2
Provide rewards contingent on effort or progress toward behavior	1	3.3%					
Teach to use prompts/cues	1	3.3%					
Prompt anticipated regret	0	0%					
Prompt practice	0	0%					
Prompt review of outcome goals	0	0%					

The *audience interpreter* describes the demographic disposition and psychology of the individual or population targeted to adopt a behavior. In the CBICM, this is where audience demographics are clustered. This is also where behavioral determinants are grouped—these are the psychological constructs believed to directly influence behavior.

Table 7 presents the demographic moderators for participants' age and gender. Both groups were divided into 3 equal categories, and then effect sizes were calculated for each group. Across both age and gender groupings, the overall between-group heterogeneity statistics Q_b (*P*) was greater than .05, indicating that the categories were quite similar and did not explain the heterogeneity. Among the 3 age groups, interventions with younger audiences (average age 15 to 21.4 years) tended to achieve the largest outcomes, followed by middle-aged (average age 21.5 to 41.8 years), and finally older participants whose average age was greater than 41.9 achieved the lowest outcomes with statistically insignificant results. For the gender groupings, the intervention group with more females showed greater impact than the mixed gender group, and a far larger impact than the statistically insignificant male-dominated group.

Table 7. Demographic moderators

Groupings	k	d (95% CI)	*P*	Q_b (*P*)	Q_w (*P*)	I^2
Age Groups (years)	30			1.248 (.74)		
Younger (15.0 - 21.4)	8	0.271 (0.095 - 0.446)	.002		4.676 (.70)	< 0.001
Middle (21.5 - 41.8)	9	0.198 (0.045 - 0.352)	.01		4.725 (.79)	< 0.001
Older (41.9 and over)	9	0.141 (–0.003 to 0.286)	.06		29.017 (< .001)	72.430
Unknown	4	0.190 (–0.033 to 0.414)	.10		8.196 (.04)	63.397
Gender groups	30			5.889 (.12)		
More female (66.6% - 100%)	12	0.307 (0.187 - 0.427)	< .001		18.290 (.08)	39.857
Mixed	12	0.122 (0.010 - 0.235)	.03		11.354 (.41)	3.116
More male (66.6% - 100%)	2	0.123 (–0.111 to 0.357)	.30		0.864 (.35)	< 0.001
Unknown	4	0.124 (–0.049 to 0.297)	.16		5.685 (.13)	47.233

Table 8 shows the audience's behavioral determinants targeted by interventions. These are the psychological constructs employed by various behavioral change theories. The coding is based on the list of behavioral determinants [50]. The psychological architecture of the websites resembled behaviorist-type therapies where the focus was on knowledge, awareness of risks, goal setting, and skill building. Across interventions, knowledge was the most common and effective behavioral determinant, while emotional appeals alone were used by a third of interventions and were associated with a lower effect size. Similarly, skill building offered an effective influence component, while self-efficacy was surprisingly low. One noteworthy exception is the strong contribution of social norms, which was both common and effective. The least frequent behavioral determinant was an appeal to the participant's social-professional role or identity, which on its own, was an exclusion criteria in this study.

Table 8. Audience interpreter (behavioral determinants)

	Absolute Coding		Relative Coding				
Behavioral Determinants	k	%	k	d (95% CI)	*P*	Q_w (*P*)	I^2
Knowledge	30	100.0%	16	0.291 (0.166 - 0.416)	< .001	53.257 (< .001)	71.835
Motivation and goals (intention)	26	86.7%	20	0.229 (0.129 - 0.329)	< .001	54.332 (< .001)	65.030
Social influences (norms)	22	73.3%	18	0.250 (0.147 - 0.354)	< .001	52.042 (< .001)	67.334
Beliefs about consequences	21	70.0%	19	0.268 (0.182 - 0.353)	< .001	23.034 (.19)	21.855
Skills	19	63.3%	15	0.185 (0.069 - 0.300)	.002	46.753 (< .001)	70.055
Memory, attention, and decision processes	18	60.0%	17	0.188 (0.080 - 0.297)	.001	42.480 (< .001)	62.335
Behavioral regulation	17	56.7%	14	0.218 (0.103 - 0.332)	< .001	40.971 (< .001)	68.270
Emotion	10	33.3%	9	0.183 (0.026 - 0.341)	.02	6.966 (.54)	< 0.001
Nature of the behaviors	9	30.0%	6	0.274 (0.137 - 0.411)	< .001	16.142 (.006)	69.024
Beliefs about capabilities (self-efficacy)	8	26.7%	7	0.083 (–0.051 to 0.218)	.23	4.545 (.60)	< 0.001
Environmental context and resources	6	20.0%	3	0.180 (–0.044 to 0.404)	.12	1.060 (.59)	< 0.001
Social-professional role and identity	3	10.0%	2	0.275 (–0.321 to .871)	.37	0.024 (.88)	< 0.001

Dose (Adherence and Attrition)

To assess correlations among the 3 dose variables (intervention adherence, study adherence, and behavioral outcomes), 2 meta-analytical methods were employed and combined in Figure 6. The analyses show a significant correlation between study adherence and intervention adherence and a significant correlation between study adherence and behavioral outcomes. However, the two methods produced one contradictory result, with one method showing the association between intervention adherence and outcome to be statistically significant, and the other, insignificant. Though, for methodological reasons, the association is likely to be significant.

The first analysis pooled correlation effect sizes; is designated *c* in Figure 6. This analysis included 2 papers that qualified for the dose analyses [53,55] but which were excluded from the primary investigation. Only 5 studies were used to assess the relationship between study adherence and intervention adherence. However, the association was strong and significant (r = .374, 95% CI = .246 to .489, P < .001, k = 5). Similarly, the relationship between intervention adherence and behavioral outcomes was modest, yet significant (r = .240, 95% CI = .133 - .341, P < .001, k = 9).

In Figure 6, the second meta-regression method uses *m* to designate the two meta-regression effect size calculations. The heavily dichotomized data used for this analysis is based on the adherence percentages presented in Table 2. This analysis shows a moderate and significant relationship between study adherence and behavioral outcomes (r = .481, P = .006, k = 28). It also showed a moderate but statistically insignificant association between intervention adherence and behavioral outcomes (r = .455, P = .109, k = 13).

Despite the two contradictory conclusions, there are compelling reasons why the relationship between intervention adherence and effect size is probably significant. Although the insignificant meta-regression analysis drew from more studies, the analysis was based on data that was heavily dichotomized, which is known to underestimate effect sizes [61]. Conversely, the significant correlation effect size drew from fewer studies with the advantage of including statistics that are closer to the original raw figures. Given the strong but insignificant correlation from the meta-regression (known to underestimate effect sizes) and the moderate and statistically significant correlation effect size analysis, it is likely that both intervention adherence and behavioral outcomes are related.

Table 9 presents the adherence averages presented in Table 2, which were used in the meta-regression dose analysis. These figures offer an explanation for the relationships between dose variables. The adherence percentage is given with a simple average and weighted average based on the posttest experimental group sample size. As the duration of an intervention increases, behavioral outcomes decrease, intervention adherence decreases, and study adherence roughly follows a downward trend with some variations.

Figure 6. Correlations between adherence variables and effect size (c = correlation effect size, m=meta-regression effect size)

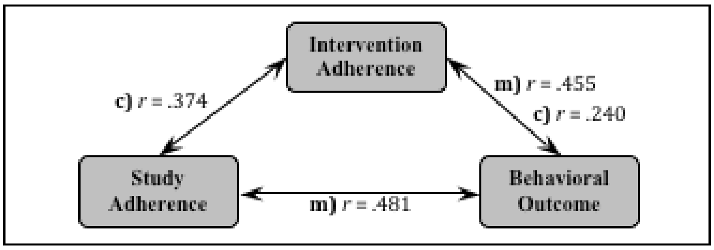


Table 9. Intervention duration, adherence, and behavioral outcomes

	Study Adherence			Intervention Adherence			Behavioral Outcomes	
Intervention Duration	k	Average %	Weighted Average %	k	Average %	Weighted Average %	k	d (95% CI)
Single-session	3	73.9%	72.9%	2	100.0%	100.0%	4	0.404 (0.130 - 0.677)
From 2 days to 1 month	5	76.8%	74.4%	2	68.0%	79.8%	5	0.205 (0.026 - 0.383)
Over 1 month to 4 months	15	67.9%	53.6%	7	63.7%	53.4%	16	0.220 (0.116 - 0.324)
Over 4 months to 7 months	3	61.5%	28.1%				3	0.090 (–0.077 to 0.258)
Over 7 months to 13 months	2	66.8%	68.0%	2	43.0%	42.3%	2	–0.047 (–0.337 to 0.243)

Discussion

The overall impact of online interventions is small, with the control conditions explaining much of the variance across studies. This suggests that online intervention efficacy should be regarded as a relative advantage in comparison to different intervention media. The largest impact was exerted from online interventions when compared with waitlists and placebos, followed by comparison with lower-tech online interventions; no significant difference was found when compared with sophisticated print interventions. In other words, online interventions offer a small effect and are probably as good as print interventions but with the advantage of lower costs and larger reach.

As a general guideline, an effect size d can be considered small (d $\leq$ 0.2), medium (d = 0.5), or large (d $\geq$ 0.8). Likewise, correlation effect sizes r can be considered small ($r \leq 0.1$), medium ($r = 0.25$), and large ($r \geq 0.4$) according to Cohen as cited by Lipsey and Wilson [61]. By Cohen's criteria, the overall results of this meta-analysis are small (d = 0.194, 95% CI = .111 - .278, $P < .001$, k = 30). However, this figure is consistent with other meta-analyses of online interventions. One comparison of 5 Web- and non-Web-based interventions produced effect sizes on knowledge and behavior (d = –0.24 to 0.44, k = 5) [10]. Another study showed effect sizes, from the first measurement, on physical activity (d = 0.05, 95% CI = –0.05 to 0.15, k = 11); weight loss (d = 0.10, 95% CI = –0.11 to 0.29, k = 8); and tobacco use (d = 0.33, 95% CI = 0.08 - 0.59, k=11) [9]. Still another showed an overall Hedges' g effect size (d = 0.16, 95% CI = 0.09 - 0.23, $P < .001$) [8].

Time proved to be a critical factor with shorter interventions achieving the largest impacts. In general, as the length of an intervention increased, behavioral impacts and intervention adherence decreased. When examining the long-term impacts after interventions had ended, the impact appeared to increase from 1 to 4 months and then decline afterwards. These trends may be partially explained by the relationship between adherence and behavioral outcomes, where the shortest interventions achieved both the highest behavioral impacts and also the highest levels of adherence. Discussed below, this trend is proposed to be a function of decreasing motivation.

Psychological Design

Many of the interventions appeared to be simple but, in fact, were highly complex programs that used tailoring algorithms and which in some cases, contained libraries with potentially hundreds of messages that could offer thousands of message combinations. When designing interventions, the transtheoretical approach was the most popular theory used. Interventions were primarily goal orientated. In general, the interventions in this study informed users about the consequences of their behavior, encouraged them to set goals, then encouraged them to track their progress toward those goals while providing feedback on their performance. Popular behavioral determinants targeted by these interventions included knowledge, motivation, and social norms. Regarding demographics, younger audiences achieved the largest behavioral impacts, with impact strength decreasing as participants increased in age. Female dominated groups achieved larger behavioral outcomes in comparison with mixed gender and male dominated groups. Most interventions used feedback mechanisms, with 83% using tailoring, while the 40% that used personalization also combined it with tailoring. The most effective feedback mechanism was providing feedback on performance. Source factors were rarely reported; however, interventions that reflected similarity with users demonstrated efficacy. Just one intervention reported source credibility even though credibility has been recommended by numerous design guidelines [36,87,88].

Influence components approaches [38,40,89] posit that the strength of an intervention is a function of its psychological components. This meta-analysis did not find conclusive support for this assertion, but the evidence suggests a likely trend. The inconclusive findings may be due to three factors: coding limitations, the moderate number of qualifying studies, and a potentially nonlinear relationship.

First, accurate relative coding of influence components could only take place when authors described the experimental and control groups in equal detail. Many authors did not fully describe control conditions, resulting in an overestimate of relative influence components, which may have caused measurement distortions. Additionally, interventions using stages of change frameworks tended to report a large number of influence components. However, depending on participants' stage, they would likely be exposed to a smaller number of influence components, resulting in an overestimate in the number of relative influence components.

Second, the strong and statistically insignificant correlations found in this study suggest that this relationship may require a larger pool of studies to overcome measurement distortions. For instance, Webb et al [8] drew on a larger pool of studies and found a statistically significant correlation.

Third, the relationship may not be linear but rather resemble an inverted u-shaped parabola curve. For example, one research team argued that websites that provide fewer individually tailored features may be more effective in promoting and maintaining behavior than ones that offer numerous poorly presented strategies [25]. If the relationship is nonlinear, few influence components may be too few to significantly influence behavior. Too many may potentially overwhelm users with complex and demanding interventions, while there is probably a middle ground where a small number of relevant (and mutually reinforcing) influence components are most effective.

Through absolute and relative coding, it was possible to examine an influence component's frequency of use and associated effect sizes. In general, the frequency of use demonstrated a loose association with effect size. For instance, the most commonly used influence components were often the most effective ones, though there were exceptions to this rule. This suggest that, in general, intervention researchers are probably drawing from common approaches that have been proven to work, with a smaller amount of experimental work assessing less conventional approaches.

Dose

The law of attrition posits that study adherence and intervention adherence are likely to be correlated because they are impacted by a third variable, participant interest [32]. This assertion is somewhat supported by the results of the meta-analysis. Despite one contradictory relationship, the results suggest the relationship is likely to include 3 variables: study adherence, intervention adherence, and behavioral outcomes.

Instead of hypothesizing that attrition is a function of loss of participant interest, a slightly different proposal is that adherence is a function of participant's motivation. By explaining the correlations as the result of motivation, this explains participant's interest (in the terms of goal commitment) but also a second construct that encompasses ability and/or efficacy. Across different research, motivation generally encompasses these two dimensions: goal commitment and either self-efficacy or ability [90-93].

The law of attrition further proposes that study and intervention adherence follow a systematic pattern declining over time, similar to an inverse s-shaped diffusion curve [32], which can be found in the logarithmic shaped relapse curves of smokers [94]. In this meta-analysis, effect sizes, study adherence, and intervention adherence generally depreciated over time, indicating a downward trend consistent with the law of attrition.

Practitioner and Research Implications

Intervention length proved to be a critical factor, with shorter interventions generally achieving the largest impact and intervention impact fading as an intervention's length increased. This has implications for intervention designers who need to make interventions as short as possible to cope with rapid attrition and the probable loss of motivation over time. Moreover, for some behaviors, highly tailored single-session interventions produced the strongest effect sizes. This suggests that short and tailored interventions can be as effective, if not more effective, than some longer and demanding ones. However, this trend is likely to be limited to particular behaviors, such as responsible drinking [63,72] and diet choices [63], but is less applicable to demanding change processes, such as tobacco cessation or weight loss.

Adherence variables demonstrated correlations with behavioral outcomes. This has implications for practitioners who generally seek to maximize behavioral impacts and researchers who must subject study participants to adequate dosage levels in order to conduct sound studies. To increase an intervention's efficacy, it may be possible design adherence systems that encourage higher levels of intervention adherence. In some cases, interventions did not explicitly implement measures to maximize participant adherence, with 1 intervention attaining a median of 1 visit in 8 months [85]. At the other extreme, 1 intervention (that did not meet the inclusion criteria) encouraged users to log in at least once per week. When users did not log into the system during a given week, the systems would email them a reminder message, and if they still did not log in, the reminder was repeated the following week. After not logging in for 2 weeks, the system made 2 subsequent telephone calls to the users. If they still did not log in, staff would follow up with the user to encourage their participation [95].

By better understanding the components of motivation, promoters of healthy lifestyles can potentially design better interventions. Motivation is a likely explanation for the relationship between study adherence, intervention adherence, and behavioral outcomes. Intervention designers could potentially increase adherence by addressing the 2 common dimensions of motivation: participants' goal-commitment and their ability/self-efficacy. For example, campaigns could benefit by intentionally designing online interventions around goals that appeal to the target audiences (following the social marketing approach), while also offering tailored support to aid participants who may lack ability or self-efficacy. Such an approach is similar to the Fogg behavioral model [93], which offers guidelines on when to address users' motivation, ability, or both.

The capacity to develop mass-interpersonal online interventions may be limited by existing influence taxonomies that are not suitable to describing the psychological profile of interventions from an interpersonal or campaign perspective. During this study's initial review of influence systems [35], no systems were identified that offered a full range of influence components within a theoretically based framework suitable to campaign applications. The CBICM developed for this meta-analysis [34,35] integrates influence research from various disciplines into a simple model that can aid intervention analysis or design whether interventions are modeled on interpersonal, mass-media, or mass-interpersonal interaction or whether they are modeled on one-way or two-way communication. However, the CBICM is only as good as the taxonomies it integrates. Within this study, the taxonomies of behavioral change techniques [38] and of behavioral determinants [50] proved to be highly robust coding instruments though they did not capture the full range of factors that may explain intervention efficacy. To compensate, it was necessary to add factors from persuasive technology and other behavioral science fields. During this meta-analysis, the CBICM proved to be an effective framework that can aid the science of online intervention research and design. Additionally, as a broad framework, there is scope to further expand and refine the CBICM.

Limitations

The scope of online interventions in this study is limited to those targeting voluntary behavioral change, similar to the types of interventions conventionally used in social marketing campaigns for public health. While coding influence components, some papers only provided vague descriptions, while others did not describe influence components other than those that comprise conventional therapy. It would have been ideal to code influence components directly from the interventions rather than research papers. Control conditions were rarely described in enough detail to code relative influence components with full confidence. As some influence components were used more often than others, this study may offer more reliable figures for popular influence components, which draw from a larger pool of studies. As there are few studies of online interventions targeting voluntary behaviors, it was necessary to combine effect sizes across behavioral domains. It would have been ideal to have at least 2 coders from which intercoder reliability calculations could have been estimated.

Although authors of similar meta-analyses have conducted numerous univariate analyses to assess effect sizes associated with moderator variables [8,9], by calculating many influence component effect sizes, this approach may have led to type I errors: false positives. While there is consensus that numerous independent calculations will increase the odds of producing false positives, there is no consensus on how to handle this problem [56]. In light of this common methodological limitation, readers may reconsider the findings with a Bonferroni correction. The psychological analysis contained 52 independent univariate effect size calculations (excluding the demographic factors). Consequently, the CBICM presentation of influence component effect sizes may be judged in light of a Bonferroni correction where the traditional statistical significance test of less than .05 is divided by the number of independent effect size calculations (.05/52), which rounds up to a stringent significance test of less than .001. A sizable proportion of the psychological mediator analyses effect sizes met this conservative statistical significance test.

Conclusions

The studies in this meta-analysis demonstrate that online interventions targeting voluntary behavior change can work. Compared with waitlists, they demonstrate moderate efficacy, while compared with print materials, they offer similar impacts but with the advantages of lower costs and broader reach.

In general, the interventions informed users about the consequences of their behavior, helped them set and achieve goals, taught them skills, and provided normative pressure. Feedback mechanisms were common, with many interventions using tailoring along with personalization and offering services to track and report users' progress toward their goals.

Motivation may be the critical factor that drives study adherence, intervention adherence, and impact. Time proved to be a critical factor, with impacts and adherence appearing to fade over time, perhaps as motivation depreciated.

Psychological design appears relevant to intervention efficacy. Although the relationships between the number of influence components and behavioral outcomes were inconclusive, there may be a relationship: Too few influence components may not be enough to influence behavior, while too many may be counterproductive. However, there may be a middle ground comprising a modest number of relevant influence components.

These findings suggest it is feasible to deploy online interventions that target individual-level behavior change, which can be scaled to achieve population-level health benefits. Given the high-reach and low-cost of online technologies, the stage may be set for increased social marketing campaigns that blend mass-media outreach with interpersonal digital support. For example, this means fewer public health campaigns that just disseminate warnings or advice and more campaigns that offer online tailored support in the form of digital therapists that help citizens help themselves.

Conflicts of Interest

None declared

Multimedia Appendix 1

Communication-based influence components model

[PDF file (Adobe PDF File), 131 KB - jmir_v13i1e17_app1.pdf]

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Abbreviations

ANOVA: analysis of variance
CBICM: communication-based influence components model
CI: confidence interval

Edited by G Eysenbach; submitted 16.10.09; peer-reviewed by T Webb, R Botelho; comments to author 17.03.10; revised version received 21.06.10; accepted 20.08.10; published 14.02.11.

Please cite as:
Cugelman B, Thelwall M, Dawes P
Online Interventions for Social Marketing Health Behavior Change Campaigns: A Meta-Analysis of Psychological Architectures and Adherence Factors
J Med Internet Res 2011;13(1):e17
URL: http://www.jmir.org/2011/1/e17/
doi:10.2196/jmir.1367
PMID:21320854

Original Paper

Impact and Costs of Incentives to Reduce Attrition in Online Trials: Two Randomized Controlled Trials

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Abstract

Background: Attrition from follow-up is a major methodological challenge in randomized trials. Incentives are known to improve response rates in cross-sectional postal and online surveys, yet few studies have investigated whether they can reduce attrition from follow-up in online trials, which are particularly vulnerable to low follow-up rates.

Objectives: Our objective was to determine the impact of incentives on follow-up rates in an online trial.

Methods: Two randomized controlled trials were embedded in a large online trial of a Web-based intervention to reduce alcohol consumption (the Down Your Drink randomized controlled trial, DYD-RCT). Participants were those in the DYD pilot trial eligible for 3-month follow-up (study 1) and those eligible for 12-month follow-up in the DYD main trial (study 2). Participants in both studies were randomly allocated to receive an offer of an incentive or to receive no offer of an incentive. In study 1, participants in the incentive arm were randomly offered a £5 Amazon.co.uk gift voucher, a £5 charity donation to Cancer Research UK, or entry in a prize draw for £250. In study 2, participants in the incentive arm were offered a £10 Amazon.co.uk gift voucher. The primary outcome was the proportion of participants who completed follow-up questionnaires in the incentive arm(s) compared with the no incentive arm.

Results: In study 1 (n = 1226), there was no significant difference in response rates between those participants offered an incentive (175/615, 29%) and those with no offer (162/611, 27%) (difference = 2%, 95% confidence interval [CI] –3% to 7%). There was no significant difference in response rates among the three different incentives offered. In study 2 (n = 2591), response rates were 9% higher in the group offered an incentive (476/1296, 37%) than in the group not offered an incentive (364/1295, 28%) (difference = 9%, 95% CI 5% to 12%, $P < .001$). The incremental cost per extra successful follow-up in the incentive arm was £110 in study 1 and £52 in study 2.

Conclusion: Whereas an offer of a £10 Amazon.co.uk gift voucher can increase follow-up rates in online trials, an offer of a lower incentive may not. The marginal costs involved require careful consideration.

Trial registration: ISRCTN31070347; http://www.controlled-trials.com/ISRCTN31070347 (Archived by WebCite at http://www.webcitation.org/5wgr5pl3s)

(J Med Internet Res 2011;13(1):e26) doi:10.2196/jmir.1523

KEYWORDS

Nonresponse; attrition; Internet; alcohol drinking; randomized controlled trial

Introduction

Attrition from follow-up is a major methodological challenge in randomized trials, and the proportion of participants who provide follow-up data is a recognized quality marker [1,2]. Poor follow-up rates reduce the power of analyses and may introduce nonresponse bias, where the likelihood of providing follow-up data is related to the outcome under study [3]. The Internet is increasingly important in the delivery of health care and its evaluation, yet online trials appear to be particularly vulnerable to high rates of attrition from follow-up [4]. Response rates as low as 11% and 15% have been reported at the 3-month follow-up in studies of Web-based health promotion interventions [5,6]. Reasons for the high attrition rates in online trials are unknown. There could be a variety of explanations, such as the ease of entering and leaving an online trial in comparison with a conventional “offline” trial, having little or no direct contact with the research team, or through limited usage or nonusage of the intervention [4].

One approach to increasing response is the use of incentives, which has been effective at increasing response rates in surveys [7-9]. Incentives (such as gift vouchers or lottery participation) have been found to almost double the odds of response to electronic surveys [7]. Varying the levels of incentives was not found to influence response to electronic surveys, although low level comparisons were generally made (eg, US $1 vs US $2) [7]. It is not clear whether these data on improving response in cross-sectional surveys generalize to boosting follow-up in online trials as there are relatively few studies examining this question. One trial of a Web-based program designed to promote healthy eating evaluated 24 different combinations of levels and conditionality of monetary incentives to promote recruitment and retention [10]. The optimal incentive combination was a US $2 unconditional incentive for enrollment and promise of US $20 (conditional incentive) on completion of follow-up measures. The highest rate of retention was achieved with the highest value of incentive. This study thus incentivized recruitment in addition to retention.

With the paucity of empirical research in this area, there is a clear need to evaluate the impact of different incentive levels and types before using them to boost retention in online trials. Even relatively small incentives such as £5 can have an important impact on research budgets, particularly in online trials where large numbers of participants can be recruited reasonably easily [11]. To determine the impact of incentives on follow-up rates in an online randomized trial, we undertook 2 sequential substudies. Both were embedded in a large trial of an online intervention to help hazardous drinkers reduce their alcohol consumption [12,13]. This large study included a pilot phase, followed by the main Down Your Drink trial (the DYD-RCT). Follow-up rates had been identified as an important methodological challenge early in the piloting phase, and a number of initiatives to improve response were tried, including reducing measurement burden by randomizing participants to 1 of 4 secondary outcome measures and adding postal or telephone follow-up to email reminders [14,15]. Despite these attempts, 5 months into the pilot our response rates were low. At this point we decided to explore the use of incentives.

The primary hypothesis in both incentive studies was that offer of an incentive would increase the response rate compared with no offer of incentive. Secondary objectives were to determine the relative effectiveness of 3 different types of incentive (study 1 only), identify predictors of response to incentives, and calculate the cost of achieving an additional response.

Methods

Design

We conducted two randomized controlled trials. Ethical approval was obtained for both trials from University College London ethics committee.

Setting

Both incentive studies were embedded in the Down Your Drink online trial of a Web-based intervention to reduce alcohol consumption [12,13]. The DYD trial and both incentive studies were conducted entirely online (see Textbox 1 for further information on the DYD trial).

Participants

In both incentive studies, participants were already enrolled in the larger DYD study and, thus, were drinking above recommended levels of alcohol and were interested in reducing their drinking (see Textbox 1). The first incentive study was undertaken with participants in the DYD pilot who did not respond to an email invitation to provide follow-up data within 1 week at its final (3-month) follow-up point. The second study was undertaken with all participants in the main DYD trial at its final (12-month) follow-up point during a defined time period of approximately 9 months.

Textbox 1. Down Your Drink Randomized Controlled Trial

Aim

To determine the effectiveness and cost-effectiveness of the Down Your Drink (DYD) website in reducing alcohol consumption.

Design

A 2-arm randomized controlled trial. Participants were randomized to receive access to either an online behavior change program to help people reduce their alcohol consumption or an information-only website on the potential harms of alcohol.

Methods

The trial was conducted entirely online through the DYD website [12]. Participants were adults who self-recruited to the trial while looking on the Web for help to reduce their drinking. Visitors to the site were asked to complete a screening test, the 3-item Alcohol Use Disorders Identification Test (AUDIT-C) [16]. Those scoring 5 or more on the AUDIT-C test were invited to participate in the trial. Participants completed baseline measures online before being randomized to 1 of 2 different areas of the website. The intervention area consisted of an extensive behavior change program based on the principles of motivational interviewing, cognitive behavior therapy, behavioral self-control, and relapse prevention [13]. The comparator area of the website consisted of text-based information on the harms of excessive alcohol consumption.

The primary outcome was total past week alcohol consumption, measured by the TOT-AL [17]. Secondary outcomes were: EQ-5D [18], Alcohol Use Disorders Identification Test (AUDIT) [19], Alcohol Problems Questionnaire (APQ) [20], Leeds Dependence Questionnaire (LDQ) [21] and the Clinical Outcomes for Routine Evaluation (CORE-10) measure of mental health [22]. All participants were followed up by email prompt at 1 and 3 months (pilot phase) and 3 and 12 months (main phase).

Participant profile

The trial randomized 7935 people who had self-recruited to the trial. The trial recruited slightly more women than men (57%). The majority of participants were white British (84%), with a mean age of 38 years. Around half of the participants were educated to degree level and above (52%). Average alcohol consumption (geometric mean) was 46 (SD 31.2) units per week, where 1 UK unit = 8 g ethanol. Follow-up rates were 55% at one month and 42% at 3 months (pilot trial) and 46% at 3 months and 34% at 12 months (main trial).

Intervention

Study 1

In view of the paucity of literature on incentives for this population, we undertook some preliminary research to identify a range of potentially effective incentives. This included identification of commonly used incentives in the survey literature, discussion with the DYD user representatives, and interviews with a convenience sample of hazardous drinkers demographically similar to the target audience. This preliminary work resulted in the choice of 3 incentives for initial study. Amazon is one of the most popular websites in the United Kingdom, with online shopping being a common use of the Internet [23]. Charitable donations have been widely used in the survey literature [7], with Cancer Research UK being Britain's largest fundraising charity [24]. We also included an online prize draw (another widely used incentive), which was likely to cost less overall if found to be effective. In light of the current literature, we decided to fix the value of the incentives at £5 (€6 or US $8) for the Amazon voucher and charitable donation and at £250 (€289 or US $387) for the prize draw.

Study 2

The results of study 1 informed the decision on level and type of incentive in study 2, for which a £10 Amazon.co.uk voucher was chosen.

In both studies, offer of an incentive was compared with no offer of incentive.

Study Procedures

Study 1

In study 1, DYD pilot trial participants were emailed a request to provide follow-up data at 3 months (between September 9, 2007, and January 15, 2008). The email contained a hyperlink to the study questionnaires, stressed the importance of providing follow-up data, and conveyed our gratitude to participants for providing this information. Those participants who had not completed the outcome measures 1 week after the first email request were randomized to receiving an offer of an incentive or no offer of an incentive. Study 1 is thus restricted to those who did not respond to the initial request to provide follow-up data. Within the incentive arm, participants were also randomly allocated to receive either the £5 Amazon.co.uk voucher, £5 donation to Cancer Research UK, or entry in a £250 prize draw. Offer of an incentive was given in the second and third email prompts (Figure 1).

Participants responding in each incentive arm were sent an email (personally generated by author ZK), which thanked them for their time and contained, as appropriate a unique Amazon.co.uk voucher code and instructions on how to claim; a hyperlink to the charity's website, which detailed the amount donated to Cancer Research UK as a result of participants completing the questionnaires (see Figure 2); and confirmation that they had been entered into a draw with a chance to win £250. Anonymity was maintained by sending the Amazon gift vouchers by email rather than requesting a postal address.

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) flowchart: study 1

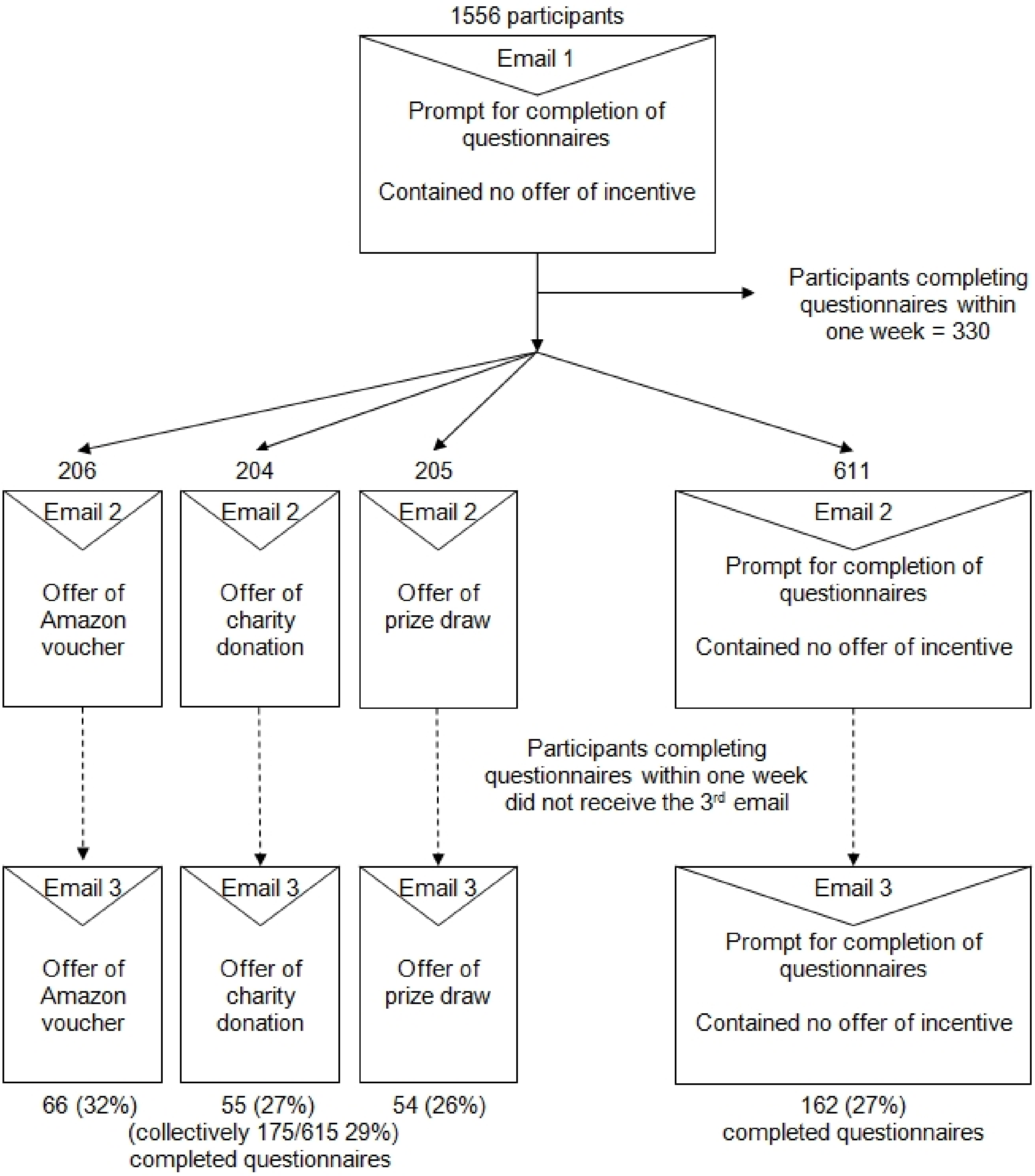
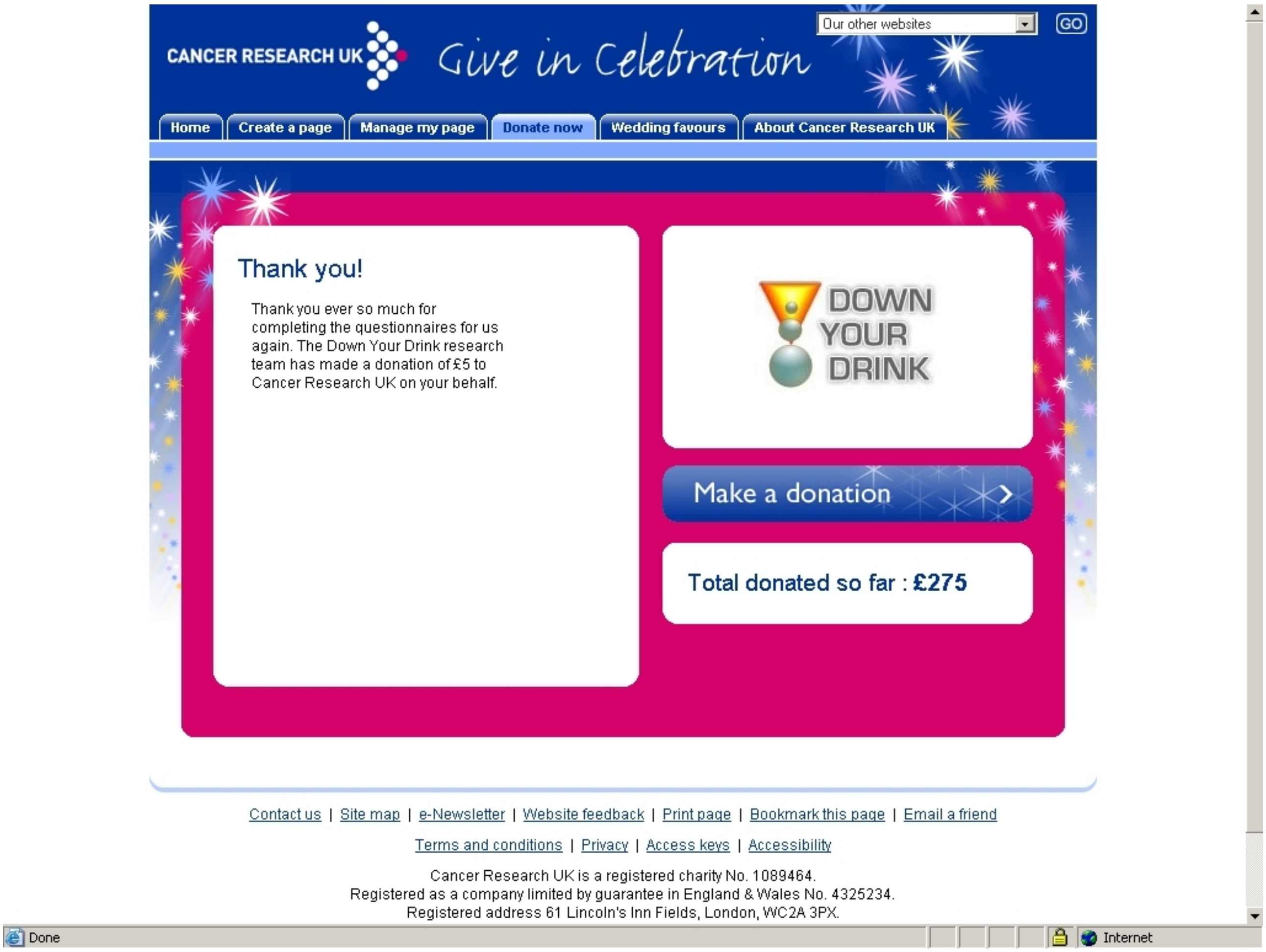


Figure 2. Screen shot of charity donation confirmation page



Thank you!

Thank you ever so much for completing the questionnaires for us again. The Down Your Drink research team has made a donation of £5 to Cancer Research UK on your behalf.

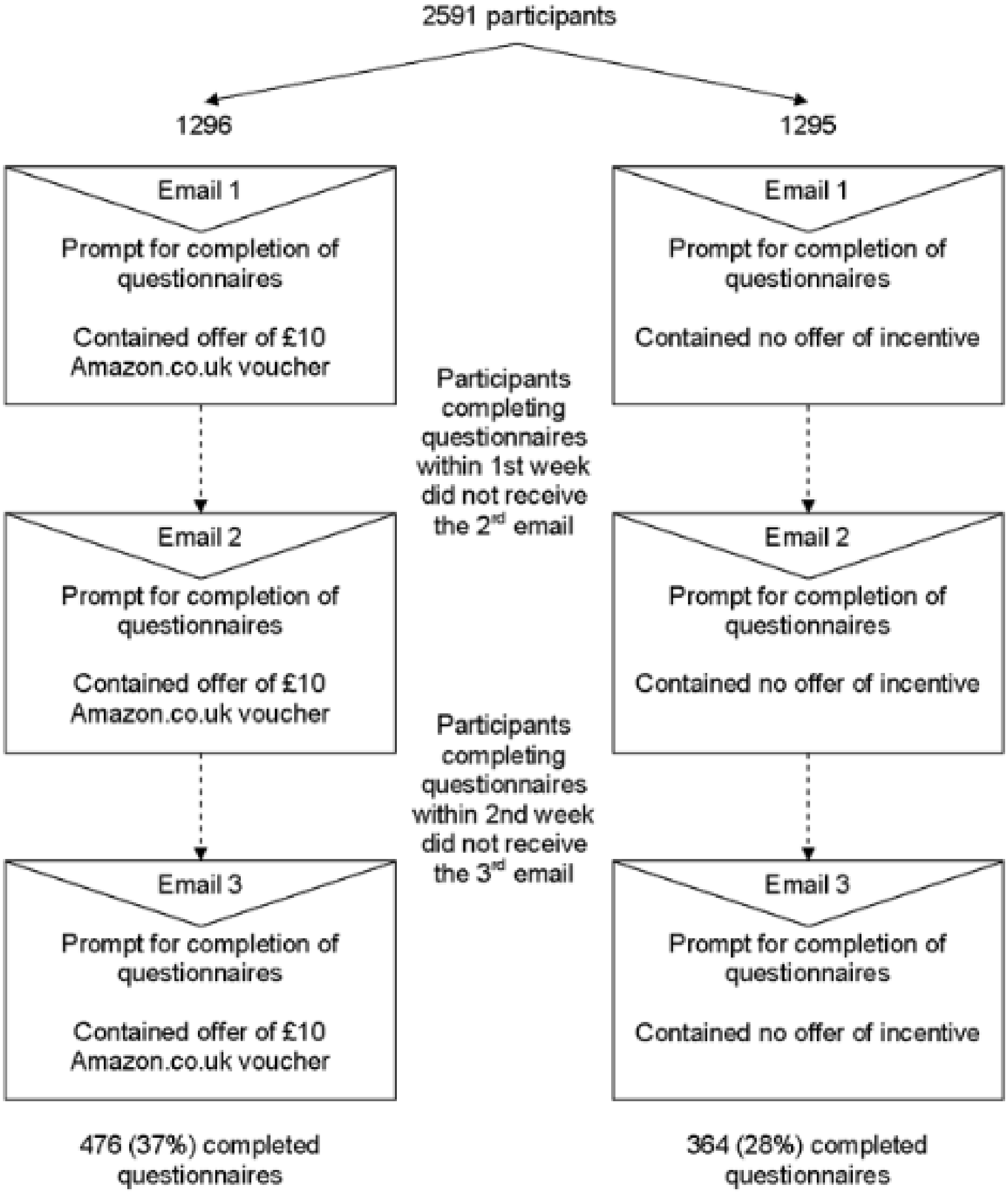
Total donated so far : £275

Cancer Research UK is a registered charity No. 1089464.
Registered as a company limited by guarantee in England & Wales No. 4325234.
Registered address 61 Lincoln's Inn Fields, London, WC2A 3PX.

Study 2

The results of study 1 informed the decision on level and type of incentive in study 2. In study 2, all DYD-RCT participants were randomized to receive either an offer of an incentive (£10 Amazon.co.uk voucher) or no incentive at the first request for data at the final (12-month) follow-up (between November 26, 2008, and September 9, 2009) (Figure 3). All participants received up to 3 email reminders with requests for provision of follow-up data. Each reminder contained a hyperlink to the study questionnaires, stressed the importance of providing follow-up data, and expressed our gratitude to participants. In addition, participants in the incentive arm were informed they would be sent a £10 Amazon.co.uk voucher on receipt of their completed study questionnaires. A further email with a unique Amazon.co.uk voucher code was sent on completion of questionnaires.

Figure 3. CONSORT flowchart: study 2



In both studies, randomization was performed by a computer-generated randomization sequence that triggered automatic emails to participants. Hence, randomization could not be subverted by the study team, and allocation was thus fully concealed. Randomization was stratified by DYD experimental group (DYD intervention vs DYD comparator). The randomization function in Java was used to generate random assignment.

Outcomes

In both studies, the outcome was the proportion of participants who responded, defined as completing the questionnaires within 40 days of the first email reminder after randomization. Additional data already obtained at entry into the DYD trial, including age, gender, baseline weekly alcohol consumption, and DYD experimental group (intervention or comparator) were used to explore possible variability in outcome.

Data gathered for the economic analysis included the costs of developing the database for each study, researcher time in sending personalized emails, and costs of the incentives themselves.

Analyses

For both studies, the sample size was calculated to detect a 6% difference in response rates between incentive and no incentive arms with 90% power at 5% significance level. The response rate in the no incentive arm was assumed to be 11% for study

1 and (building on the results of study 1) 26% for study 2. This gave total sample size requirements of 1468 for study 1 and 2400 for study 2.

The primary analysis compared response rates between the no incentive arm and incentive arm (3 incentive arms combined for the first study). For study 1, secondary analyses explored the differences between incentive types. Statistical significance was calculated using chi-square tests.

Subgroup analyses were conducted for gender, age, and heavy drinking at baseline (> 35 units per week for women and > 50 units per week for men where 1 unit = 8 g ethanol). Interactions between these variables and allocation to incentive in affecting response rates were tested on a risk difference scale using the binreg command in STATA. The statistical analyses were undertaken by authors EK and IW in STATA version 10 (StataCorp LP, College Station, TX).

A simple economic analysis was conducted for both studies. It cost £822 to set up a database for the research for study 1 and £1180 for study 2. Identifying which participants completed the questionnaires and were, therefore, eligible to receive an incentive or not and sending emails to deliver the incentive took 10 minutes per 10 participants at a cost (including overheads) of £0.95 per minute. In practice, offering incentives would involve some but not all of these costs. For example, if all participants were offered an incentive, then some of the selection and computer programming time would be saved. As the purpose of the economic evaluation was to compare the additional costs of incentives compared with the control condition of no incentives, a reasonable estimate of the additional setup costs is 50% of the database costs plus an additional minute of researcher time per incentive offered. The final costs of the scheme are those of the incentive. The cost-effectiveness ratios were calculated as the additional cost per successful additional completed follow-up, that is, the total cost of offering incentives divided by the number of additional responses (see Table 3). The economic analyses were undertaken by authors CG and ZK.

Results

Study 1

A total of 1226 participants were randomized to receive no offer of an incentive (n = 611) or offer of an incentive (n = 615) (Figure 1). The characteristics of participants randomized to each study arm were similar (Table 1). There was no significant difference in response rates of follow-up questionnaires between participants who received an offer of incentive (175/615, 29%) compared with those who did not receive offer of an incentive (162/611, 27%) (difference 2%, 95% confidence interval (CI) –3% to 7%), nor was there any significant difference in response rates between the 3 experimental arms (Amazon.co.uk voucher = 32%, charity donation = 27%, prize draw = 26%; $P = .37$) (Table 2). There were no significant interactions with gender, age, or heavy drinking at baseline (results not shown).

The costs associated with offering incentives in study 1 are outlined in Table 3. The incremental cost per successful follow-up in the incentive arm was £110 (£1432 total cost per 13 additional responses).

Study 2

A total of 2591 participants were randomized to receive no offer of an incentive (n = 1295) or offer of a £10 Amazon.co.uk voucher (n = 1296) (Figure 3). Characteristics of participants randomized to each study group were similar (Table 1). There was a 37% (476/1296) response rate among those participants that received an offer of a £10 Amazon.co.uk voucher compared with a 28% (364/1295) response rate among those who did not receive an offer of an incentive (difference 9%, 95% CI 5% to 12%, $P < .001$) (Table 2). There were no significant interactions with the 3 baseline variables considered.

The incremental cost per successful follow-up in the incentive arm was £52 (£5802 total cost per 112 additional responses) (Table 3).

Table 1. Baseline characteristics of participants in study 1 and study 2

	Incentive	No incentive
Female, %		
Study 1	54	54
Study 2	58	59
Age (years), Mean (SD)		
Study 1	37 (11)	37 (11)
Study 2	38 (11)	38 (11)
Baseline drinking (UK units), Mean (SD)		
Study 1	56 (37)	59 (42)
Study 2	59 (37)	57 (42)
DYD intervention arm, %		
Study 1	51	51
Study 2	50	50

Table 2. Response rates for incentive groups in study 1 and study 2

Incentive Group	Total Randomized	Number of Responses	Response Rate	Difference	95% Confidence Interval
Study 1					
Incentives (collectively)	615	175	29%	2%	–3% to 7%
No incentive	611	162	27%		
£5 Amazon voucher	206	66	32%		
£5 charity donation	204	55	27%		
£250 prize draw	205	54	26%		
Study 2					
£10 Amazon voucher	1296	476	37%	9%	5% to 12%
No incentive	1295	364	28%		

Table 3. Costs associated with offering incentives in study 1 and study 2

	Cost Per Person	Total Cost
Study 1		
Setting up database	£0.67 per person	£411 (50% of total cost)
Time sending confirmatory incentive email (per response to questionnaires)	£0.95 per person	£166
Incentive		
Amazon voucher	£5 (x66)	£330
Charity donation	£5 (x55)	£275
Prize draw	£250	£250
Total		£1432
Cost per extra follow-up response		£110
Total cost per additional responses		£1432 per 13
Study 2		
Setting up database	£0.46 per person	£590 (50% of total cost)
Time sending confirmatory incentive email (per response to questionnaires)	£0.95 per person	£452
Incentive (Amazon voucher)	£10 (x476)	£4760
Total		£5802
Cost per extra follow-up response		£52
Total cost per additional responses		£5802 per 112

Discussion

These trials provide a valuable contribution to the limited literature on the use of incentives for reducing attrition in online trials. Study 1 found that promising a low level incentive (£5 Amazon.co.uk voucher, £5 charity donation, or prize draw for £250) had no significant impact on follow-up rates, whereas in study 2, a higher-level incentive (£10 Amazon.co.uk voucher) improved response rates by 9%. It should be borne in mind, however, that direct comparisons between the 2 studies are limited by differences in the study populations (those not initially responding in study 1 versus all respondents in study 2) and follow-up study time frames (3 and 12 months respectively). Notwithstanding these caveats, the higher incentive was also more cost-effective, in terms of costs per additional response. Researchers should, therefore, not assume that any level of incentive will necessarily improve follow-up rates.

The types of incentives offered in study 1 were comparable to those shown to have a positive impact on improving response rates to postal and electronic surveys [7]. However, collectively the incentives used in study 1 did not improve follow-up. In a trial of a health promotion website, the highest rate of retention was achieved with the highest value of incentive (ie, US $20 or £13) [10]. The findings of study 2 mirror this result. The survey literature suggests that unconditional incentives may be more effective than those conditional on completion of measures [7,9,25]. Our decision to promise an incentive on completion of the questionnaires, rather than unconditionally, was done for 2 reasons. The first was financial: online trials have the potential to recruit large numbers of participants (the DYD trial recruited 7935 people). If incentives were provided unconditionally to the entire sample, there would be substantial cost implications, and without the evidence to support this decision, the expense could not be justified. The second reason was methodological: providing unconditional incentives from the outset of the DYD pilot study might have encouraged multiple registrations for trial entry. In an online trial, with no face-to-face contact with trial participants, re-registration is a relevant concern [11].

Altruism is a commonly cited motive for trial participation [26-28], where participants take part in research for the benefit of others regardless of any benefit for themselves. There is a concern that the use of incentives may undermine altruistic reasons for participation. There is some evidence that altruistic motives are often accompanied by self-interest (conditional altruism), where participants are happy to help others if there is also some benefit for them in taking part in the trial [29-31]. These motivations have not surprisingly also been reported in the limited literature on trial retention, where participants are thought to remain in trials for personal benefit (ie, access to better treatment) as well as commitment to the trial and to help others [32,33]. Altruism is unlikely to have played a major role in the DYD-RCT, where participants were recruited while seeking feedback on, or help to, reduce drinking. Participants were not incentivized to take part in the DYD trial and had consented to complete follow-up questionnaires at study entry. Incentives were offered at follow-up as a “token of appreciation” for completing the questionnaires. Further research is needed to determine motives for entering and remaining in online trials and how this may impact on the use of incentives. Also warranting further exploration is the impact of socioeconomic status on the effectiveness of incentives, possible cultural differences in receptivity, and the underlying reasons for attrition, particularly related to the Internet setting (eg, Over the Internet, is it harder to establish rapport between participant and researcher and to obtain commitment on the part of the participant? What proportion of email reminders are caught in spam filters?).

Our conclusions are strengthened by the large sample sizes employed, the randomized design, and the completeness of the data. We were also able to inform the design of the second study using the results from the first. The £5 Amazon voucher in study 1 resulted in the highest response rate of the three incentive types, although not higher to a statistically significant degree (test results not reported). So, in the second study, participants were randomized to a higher-level incentive (£10 Amazon voucher). Study 2 was undertaken in a population and setting that were similar to study 1, the main differences being that study 1 was conducted among pilot DYD trial participants at 3 months who had not responded 1 week after an email request for follow-up, whereas study 2 was conducted among all main DYD trial participants eligible for 12-month follow-up within a defined time period. Our novel context of online trials is important, since it is likely to be the vehicle for an increasing number of studies of delivering health care and health promotion in the future. A potential limitation of the first incentive study is that it failed to meet its planned sample size because the DYD pilot phase ended slightly earlier than anticipated (due to programming commitments necessary for the commencement of the main DYD-RCT). For this reason and because response rates in the control arm were higher than expected, the results of study 1 were somewhat inconclusive, with a confidence interval including both no difference and the 6% difference in response specified in the power calculation.

This pair of studies has two important implications for researchers. Firstly, researchers should not assume that all levels of incentive would improve follow-up rates; instead, use of incentives for this purpose needs careful consideration and piloting of both level and type of incentive to be offered in a particular study population and setting. The second is that the costs of offering incentives can be substantial, and whether such costs are a good use of research funds needs to be considered. Further research that explores levels of different incentive types, offered and selected in different ways, and other means of reducing attrition in online trials should be prioritized if online health care delivery is to be well informed by strong research evidence.

Acknowledgments

The authors would like to thank Richard McGregor of Codeface Limited for database programming and IT support, Orla O’Donnell for administrative support, and Valerie Brueton for identification of literature on the use of incentives to improve follow-up in trials. These studies were funded as part of the pilot and main DYD-RCT, which was funded by the National Prevention Research Initiative (http://www.npri.org.uk) with support from the following organizations: British Heart Foundation; Cancer Research UK; Chief Scientist Office, Scottish Government Health Directorate; Department of Health; Diabetes UK; Economic and Social Research Council; Health and Social Care Research and Development Office for Northern Ireland; Medical Research Council; Welsh Assembly Government; and World Cancer Research Fund. The funders did not influence any aspect of study design, conduct, analysis, or preparation of the manuscript.

Conflicts of Interest

None declared

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Abbreviations

APQ: Alcohol Problems Questionnaire
AUDIT: Alcohol Use Disorders Identification Test
CONSORT: Consolidated Standards of Reporting Trials
CORE: Clinical Outcomes for Routine Evaluation
DYD-RCT: Down Your Drink randomized controlled trial
LDQ: Leeds Dependence Questionnaire
TOT-AL: total past week alcohol consumption

Edited by G Eysenbach; submitted 28.02.10; peer-reviewed by S Bull, H Christensen, P Wicks, N Zhang; comments to author 27.05.10; accepted 06.08.10; published 02.03.11.

Please cite as:
Khadjesari Z, Murray E, Kalaitzaki E, White IR, McCambridge J, Thompson SG, Wallace P, Godfrey C
Impact and Costs of Incentives to Reduce Attrition in Online Trials: Two Randomized Controlled Trials
J Med Internet Res 2011;13(1):e26
URL: http://www.jmir.org/2011/1/e26/
doi:10.2196/jmir.1523
PMID:21371988

Original Paper

Web-Based Guide to Health: Relationship of Theoretical Variables to Change in Physical Activity, Nutrition and Weight at 16-Months

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Abstract

Background: Evaluation of online health interventions should investigate the function of theoretical mechanisms of behavior change in this new milieu.

Objectives: To expand our understanding of how Web-based interventions influence behavior, we examined how changes at 6 months in participants' psychosocial characteristics contributed to improvements at 16 months in nutrition, physical activity (PA), and weight management as a result of the online, social cognitive theory (SCT)-based Guide to Health intervention (WB-GTH).

Methods: We conducted recruitment, enrollment, and assessments online with 272 of 655 (41.5%) participants enrolling in WB-GTH who also completed 6- and 16-month follow-up assessments. Participants' mean age was 43.68 years, 86% were female, 92% were white, mean education was 17.45 years, median income was US $85,000, 84% were overweight or obese, and 73% were inactive. Participants received one of two equally effective versions of WB-GTH. Structural equation analysis of theoretical models evaluated whether psychosocial constructs targeted by WB-GTH contributed to observed health behavior changes.

Results: The longitudinal model provided good fit to the data (root mean square error of approximation <.05). Participants' weight loss at 16 months was predicted by improvements in their PA ($beta_{total}$ = -.34, P = .01), consumption of fruits and vegetables (F&V) ($beta_{total}$ = -.20, P = .03) and calorie intake ($beta_{total}$ = .15, P = .04). Improvements at 6 months in PA self-efficacy ($beta_{total}$ = -.10, P = .03), PA self-regulation ($beta_{total}$ = -.15, P = .01), nutrition social support ($beta_{total}$ = -.08, P = .03), and nutrition outcome expectations ($beta_{total}$ = .08, P = .03) also contributed to weight loss. WB-GTH users with increased social support ($beta_{total}$ = .26, P = .04), self-efficacy ($beta_{total}$ = .30, P = .01), and self-regulation ($beta_{total}$ = .45, P = .004) also exhibited improved PA levels. Decreased fat and sugar consumption followed improved social support ($beta_{total}$ = -.10, P = .02), outcome expectations ($beta_{total}$ = .15, P = .007), and self-regulation ($beta_{total}$ = -.14, P = .008). Decreased calorie intake followed increased social support ($beta_{total}$ = -.30, P < .001). Increased F&V intake followed improved self-efficacy ($beta_{total}$ = .20, P = .01), outcome expectations ($beta_{total}$ = -.29, P = .002), and self-regulation ($beta_{total}$ = .27, P = .009). Theorized indirect effects within SCT variables were also supported.

Conclusions: The WB-GTH influenced behavior and weight loss in a manner largely consistent with SCT. Improving social support, self-efficacy, outcome expectations, and self-regulation, in varying combinations, led to healthier diet and exercise habits and concomitant weight loss. High initial levels of self-efficacy may be characteristic of Web-health users interested in online interventions and may alter the function of SCT in these programs. Researchers may find that, although increased self-efficacy enhances program outcomes, participants whose self-efficacy is tempered by online interventions may still benefit.

Trial Registration: Clinicaltrials.gov NCT00128570; http://clinicaltrials.gov/ct2/show/NCT00128570 (Archived by WebCite at http://www.webcitation.org/5vgcygBII)

(J Med Internet Res 2011;13(1):e27) doi:10.2196/jmir.1614

KEYWORDS

Internet users; dietary habits; physical activity; psychosocial aspects; self-efficacy; social support; self-regulation

Introduction

As many as 79% of Americans use the Internet, with growing majorities across racial, ethnic, educational, and income groups reporting going online – 73% go online daily. The vast majority of users go to the Internet for information on health topics [1,2]. Internet-based health information has largely been viewed as positive, influencing health decisions and changing the way users think about diet and exercise [3]. With almost universal Internet access and adoption, reach, effectiveness [4], and the function of theoretical mechanisms [5-9] become pivotal issues facing Internet-based public health interventions.

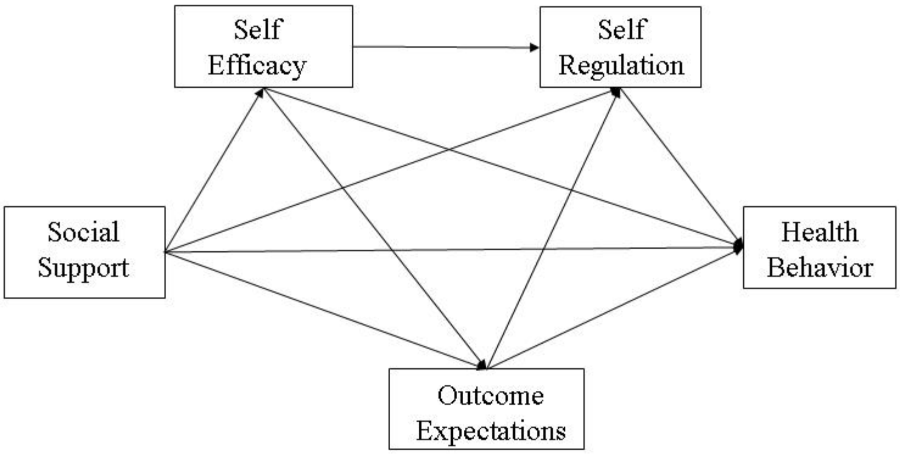
Randomized control trials of Internet-based interventions have largely produced modest, short-term effects [10-17]. Others have shown sustained effects on nutrition and physical activity (PA) for longer periods (ie, 16 months) [18] with results comparable in many ways to results from more intensive, face-to-face interventions targeting lifestyle behaviors [19,20]. None of these trials, however, has recruited participants, delivered programs, and evaluated outcomes entirely online, as is needed to establish the effectiveness of Web-contained interventions.

In addition to limited evidence of long-term effectiveness, attrition is typically high in Internet-based trials (43%-50%) [4], with tentative users who attempt but quickly withdraw from the intervention, short-term users who seem to drop out after using the program for a short time, and stable users who stick with a program over the long term [21]. A presumed advantage of the Internet, however, is the ability to provide a high-fidelity intervention at virtually any dose level, allowing participants to tailor program use to their specific needs and circumstances [4]. Although some suggest that the effectiveness of programs is best reflected in the effects on stable users [21], including short-term users in evaluations provides a more accurate reflection of overall program impacts [22].

The reach of entirely online interventions is defined as the percentage and representativeness of individuals willing to participate [23] from the number of people who arrive at a site either through a search engine or by directly entering the website address. Website use, in combination with username/password entry, allows researchers to capture the number exposed to each component of recruitment, enrollment, and, ultimately, of the intervention [4].

Finally, Internet-based health promotion interventions should be based on theory and evaluated in a way to validate and refine the application of theory within the new delivery environment [5-7,24,25]. Social cognitive theory (SCT; Figure 1) [26,27] suggests that Internet health interventions must help individuals develop a sense of self-efficacy in specific behaviors (such as being physically active and eating nutritiously), which promotes individuals' positive expectations for behavior change and their modification or differential use of self-regulatory skills (ie, planning, self-monitoring, problem solving, and setting self-standards, goals, and self-incentives). SCT further suggests that, as a precursor to self-efficacy, social support enhances the process of behavior change and maintenance.

Figure 1. Social cognitive theory of health behavior



The current study examined the relationship of SCT variables to behavior and weight change in the Web-Based Guide to Health intervention (WB-GTH). An earlier site-based version of GTH suggested that self-efficacy, self-regulation, and social support (and, to a lesser extent, outcome expectations) can mediate the effects of SCT-based health interventions in a manner consistent with theory [28]. It is not clear, however, how such interventions, implemented over a longer period (52 weeks vs 12 weeks) and entirely online with no face-to-face contact with researchers, no on-site computer support, and no direct manipulation of essential environmental support (social and physical), might influence behavior.

The WB-GTH featured online recruitment, screening, consent, assessment, and program implementation with and without enhanced self-regulatory components (basic WB-GTH and enhanced WB-GTH versions). Recruitment into the WB-GTH, described in detail elsewhere [29], included Web-browser advertisements and direct mailings, but was successful largely through newsletters (print and electronic) and listservs of existing organizations. Most participants attracted to the WB-GTH website registered for eligibility screening (85%, [29]). Retention rates from being eligible to providing informed consent and from providing consent to completing baseline were 74%-75% [29].Similar to other efforts [30,31], WB-GTH attracted mostly middle-aged, well-educated, upper-middle-class women. Following study requirements, the sample population was inactive to sedentary and mildly overweight to obese, but otherwise healthy. Psychosocial characteristics of WB-GTH enrollees suggested social support and self-efficacy for behavior change and enhanced self-regulatory skills would be important to developing healthier levels of nutrition and PA [29]. Both basic WB-GTH and enhanced WB-GTH resulted in significant improvements in nutrition, PA, and weight management [32].

The purpose of the current study was to determine whether improvements at 6 months in social support, self-efficacy, outcome expectations, and self-regulation preceded observed behavior and weight change in a manner consistent with SCT [26].

Methods

Recruitment and Participants

The WB-GTH trial was conducted entirely online (baseline assessment from September 2007 to November 2008; 6-month assessment from April 2008 to May 2009, 16-month assessment from February 2009 to March 2010). Of 655 randomly assigned participants, 199 quickly withdrew from the program, logging in to only one or two program modules. Participants who quickly withdrew from WB-GTH were less active, but otherwise did not differ in demographics or behavior from those who engaged with one of the two versions of the WB-GTH (ie, saw at least three program modules; n = 456; [32]). Of these engaged participants, 59.6% returned for the 16-month assessment and were included in the current study (272/655 total randomized participants, 41.5%). Included participants had a mean age of 43.68 (SD 10.39) years, 86% were female, and 92% were white. The sample was well educated with a mean of 17.45 (SD 3.0) years completed, and had a median annual household income of about US $85,000; 84% were overweight or obese and 73% were inactive (ie, <7500 steps/day; mean 6178.15, SD 1825.39). The 184 engaged participants who did not return for follow-up assessment did not differ on demographic or baseline outcome variables from participants included in the current study except that they had slightly higher body mass indexes than included participants (mean 30.36, SD 4.22 vs mean 29.18, SD 3.83).

The WB-GTH Intervention

The WB-GTH program (described in detail elsewhere [32]) ran for 52 weeks with SCT-based modules each consisting of 15-20 Web screens requiring participants to be online for 5-10 minutes each week. Participants logged in as often as once a week with the username/password they created during enrollment. Early modules targeted self-efficacy through gradual behavior change guided by self-regulation. WB-GTH next presented a series of core-content modules [32] that additionally addressed social support and outcome expectations related to behavior change. After 4 months, the WB-GTH focus shifted to behavior-change maintenance with continued self-regulation.

The basic WB-GTH program, used by 51.1% (139/272) of current study participants, provided generic goals for adding steps and minutes of walking to their daily routines (ie, add 400 steps/day each week up to 3000 steps and 5 minutes/day up to 30 minutes, 5 days/week). Other goals included adding fitness walking after reaching 30 minutes of walking 5 days a week, adding fruits and vegetables (F&V) (1/day each week to reach 5-9 for female and 5-10 for male users), adding whole-grain foods and low-fat dairy foods (1/day each week for up to 3 servings a day), and decreasing high-fat and high-sugar foods (no more than 28 servings/week). Participants kept and reported daily logs of steps, minutes walked, enjoyment of and exertion during planned walks, and intake of fruits, vegetables, whole grains, low-fat dairy, and high-fat and high-sugar foods, and they weighed themselves weekly. Each week users of the basic WB-GTH program received general feedback (eg, comparison of current levels and overall goals) with a restatement of generic goals and a prompt for users to plan for the next week. The enhanced WB-GTH program, used by 48.9% (133/272), differed from the basic program by providing users with personalized feedback and tailored goal setting and planning, and by allowing participants to select, report, and receive feedback on specific behavior-change strategies for increasing PA and improving nutrition [32].

Measures

Nutrition

Participants completed the Block 2005 Food Frequency Questionnaire (NutritionQuest, Berkeley, CA, USA) [33] online. We examined the resulting estimates of daily intake in kilocalories, percentage kilocalories from fat and from sugar, and daily servings of fruits and of vegetables at baseline and 16 months and change during the 16-month interval (ie, 16-month assessment minus baseline).

PA and Body Weight

Participants used a pedometer (Digi-walker SW-200, Yamax USA, Inc, San Antonio, TX, USA) and a digital bathroom scale

(Health-o-meter HDL150-01, Sunbeam Products, Inc, Maitland, FL, or Tanita HD-313, Tanita Corporation, Arlington Heights, IL, USA) provided at baseline. Participants wore their pedometers for 7 days and logged the number of steps registered each day. They returned to the WB-GTH website to report daily steps for at least 4 consecutive days. Participants also completed an online questionnaire about the duration, pace, and number of walking, treadmill, jogging, and running sessions they took in a typical week. The metabolic equivalent (MET; ie, the ratio of work metabolic rate to a standard resting metabolic) for each activity was computed and summed across activities to compute walking METhours/week for each participant at baseline and 16 months. Participants used the bathroom scale provided to measure body weight in pounds without clothing just after waking in the morning or before going to bed in the evening. They reported their weight and height online along with their walking log data. We examined mean daily steps (total steps reported divided by days of pedometer use), mean walking METhours/week, body weight in pounds, and change in these variables during the 16-month interval.

Social Cognitive Variables

The Health Beliefs Survey administered online at baseline and 6 months measured change in nutrition- and PA-related social support, self-efficacy, outcome expectations, and self-regulation (see Table 1).

Statistical Analysis

Multivariate repeated measures analysis of variance (MANOVA) evaluated effects of the WB-GTH on SCT variables at 6 months, and nutrition, PA, and body-weight variables at 16 months. Full information maximum likelihood (FIML) latent-variable structural equation modeling (LISREL version 8.81, Scientific Software International, Inc, Lincolnwood, IL, USA) [34] evaluated the relationships among SCT-change variables at 6 months and behavioral and weight-change variables at 16 months. SCT fit was evaluated with root mean square error of the approximation (RSMEA) ≤.05 (*P*-value close fit > .95 or alpha = .05) and FIML chi-square was evaluated with alpha set at .05 or less than 3 times the degrees of freedom (normed chi-square) [35]. With few exceptions, the distributions of measure scores were skewed or displayed unacceptable kurtosis; we normalized measures using the Blom proportional estimate formula in SPSS version 17.0 (IBM Corporation, Somers, NY, USA). Additional variables were similarly normalized to retain a consistent unit of measurement within latent variables. Error variances for single-indicator latent variables (ie, weight change, PA self-efficacy, nutrition negative outcome expectations, and change in daily calorie consumption) were set to sigma^2 × (1 - reliability). Error variances of PA- and nutrition-related SCT variables (eg, PA self-efficacy and nutrition self-efficacy) were allowed to correlate [35]. Error covariances between measured nutrition variables and between theoretically consistent SCT variables were allowed to correlate to improve model fit.

Table 1. Health Beliefs Survey: scale descriptions and internal consistency estimates

Variable description	Subscale	Number of items	Alpha[a]
Food Beliefs Survey			
Social support	Family	11	.90
	Friends	11	.94
Self-efficacy	Eating healthy foods	12	.91
	Avoiding high-fat and high-sugar foods	15	.90
	Planning and tracking intake	10	.96
Positive physical and self-evaluative outcome expectations		10	.90
Negative physical, social and self-evaluative outcome expectations		11	.89
Self-regulation	Planning and tracking	11	.92
	High-fat and high-sugar foods	13	.90
	Healthy food choices	8	.90
Physical Activity Beliefs Survey			
Social support	Family	8	.94
	Friends	8	.96
Self-efficacy		23	.95
Positive outcome expectations	Physical	5	.83
	Affective	5	.66
Negative outcome expectations: physical, social, and self-evaluative		7	.88
Self-regulation	Setting goals and planning activity	9	.91
	Tracking physical activity	5	.85
	Increasing enjoyment	3	.77

[a] Cronbach alpha coefficient of internal consistency.

Results

WB-GTH Outcomes

Participants viewed a mean of 21.33 (SD 17.19) modules: 18% (49/272) viewed only introductory WB-GTH modules (ie, modules 1-5), 37.1% (101/272) also viewed WB-GTH core-content modules (6-16), and the remaining 44.8% (122/272) viewed maintenance modules (>17 modules). Participants viewed similar numbers of modules of each version: basic WB-GTH (mean 22.36, SD 17.51) and the enhanced WB-GTH (mean 20.34, SD 16.87; $F_{1,270}$ = 0.95, *P* = .329).

MANOVA of baseline and 16-month data indicated that WB-GTH participants viewing both versions of WB-GTH made behavioral and weight changes (time: $F_{8,157}$ = 10.02, partial-eta squared = .34, *P* < .001; version × time: $F_{8,167}$ = 1.57, partial-eta squared = .07, *P* = .14). WB-GTH users increased daily steps, METhours/week expended in walking, and intake of fruits and intake of vegetables. WB-GTH users also decreased their intake of fat, sugar-sweetened foods, and calories (see Table 2). Improvements in nutrition and PA did not vary across the number of program modules viewed by participants (time × modules: $F_{16,316}$ = 1.00 partial-eta squared = .05, *P* = .45).

Participants' improvements in behavior and weight at 16 months were preceded by changes at 6 months in social cognitive characteristics related to nutrition (time: $F_{11,235}$ = 42.91, partial-eta squared = .67, *P* < .001; version × time: $F_{11,235}$ = 1.278, partial-eta squared = .06, *P* = .24) and PA (time: $F_{9,237}$ = 90.15, partial-eta squared = .77, *P* < .001; version × time: $F_{9,237}$ = 0.84, partial-eta squared = .03, *P* = .58). Enhanced social cognitive characteristics (see Table 2) included increased dietary social support from family members and friends, self-efficacy for eating healthier foods, and, albeit marginally, self-efficacy for reducing fat and sugar intake; decreased negative outcome expectations; and increased use of self-regulatory strategies related to eating F&V and whole grains, reducing fat and calories, and planning and tracking nutrition. Positive outcome expectations related to nutrition behavior did not change. WB-GTH users also improved perceived PA social support from family and friends and increased their use of self-regulation strategies. Self-efficacy for overcoming barriers to PA, however, significantly decreased as participants used the WB-GTH program. Outcome expectations related to PA did not change.

Table 2. Baseline, 6-month, and 16-month follow-up weight, physical activity, and nutrition-related outcomes of users of the Web-Based Guide to Health intervention

Outcome	Study time point[a]	Mean	SD	F	df[b]	*P*-value	Partial-eta squared[c]
Body weight in pounds	base	176.98	28.03	29.01	1,194	<.001	.130
	16 mo	172.34	28.01				
Nutrition							
Fruit servings/day	base	1.13	0.81	83.34	1,236	<.001	.261
	16 mo	1.66	0.95				
Vegetable servings/day	base	2.97	1.93	55.128	1,236	<.001	.189
	16 mo	3.95	2.36				
Percentage kilocalories from fat	base	36.62	5.86	37.33	1,236	0.00	.14
	16 mo	34.40	6.21				
Percentage kilocalories from sweets	base	14.53	9.32	45.07	1,236	0.00	.16
	16 mo	11.30	8.50				
Kilocalories/day	base	1820.95	700.81	22.36	1,236	0.00	.09
	16 mo	1641.14	510.47				
Family social support	base	2.70	.81	57.193	1,245	<.001	.189
	6 mo	3.07	.83				
Friend social support	base	2.91	.78	29.768	1,245	<.001	.108
	6 mo	3.16	.74				
Self-efficacy for avoiding fat and sugar	base	75.99	17.29	2.875	1,245	.091	.012
	6 mo	77.59	16.81				
Self-efficacy for eating healthy foods	base	73.48	16.80	3.794	1,245	.053	.015
	6 mo	75.59	17.73				
Positive outcome expectations	base	4.32	.61	0.01	1,245	0.95	.00
	6 mo	4.32	.57				
Negative outcome expectations	base	2.90	.73	16.89	1,245	0.00	.06
	6 mo	2.72	.81				
Self-regulation healthy food choices	base	3.11	.82	301.23	1,245	0.00	.55
	6 mo	4.06	.62				
Self-regulation high-fat/high-sugar foods	base	3.01	.75	292.27	1,245	0.00	.54
	6 mo	3.84	.61				
Self-regulation planning and tracking nutrition	base	2.35	.81	376.72	1,245	0.00	.61
	6 mo	3.58	.79				
Physical activity							
Steps/day	base	6252.89	1876.34	40.32	1,177	0.00	.19
	16 mo	7741.47	3247.56				
METhours/week walking[d]	base	2.82	9.70	45.20	1,177	0.00	.20
	16 mo	12.43	18.02				
Family social support	base	2.49	1.03	19.98	1,245	0.00	.08
	6 mo	2.77	1.01				
Friend social support	base	2.88	.98	8.05	1,245	0.01	.03

Outcome	Study time point[a]	Mean	SD	F	df[b]	*P*-value	Partial-eta squared[c]
	6 mo	3.07	.87				
Self-efficacy	base	64.09	19.24	4.06	1,245	0.05	.02
	6 mo	61.28	22.24				
Positive affective outcome expectations	base	16.24	3.92	0.23	1,245	0.63	.00
	6 mo	16.38	4.57				
Positive physical outcome expectations	base	20.49	4.22	2.33	1,245	0.13	.01
	6 mo	20.05	4.81				
Negative outcome expectations	base	10.61	4.84	0.01	1,245	0.93	.00
	6 mo	10.65	5.13				
Self-regulation goal setting and planning	base	1.98	.76	439.28	1,245	0.00	.64
	6 mo	3.47	.94				
Self-regulation tracking activity	base	1.53	.71	604.49	1,245	0.00	.71
	6 mo	3.65	1.19				
Self-regulation increase enjoyment	base	1.79	.84	387.59	1,245	0.00	.61
	6 mo	3.30	1.04				

[a] Baseline (base), 6 months (6 mo), or 16 months (16 mo).

[b] df: degrees of freedom for F test result.

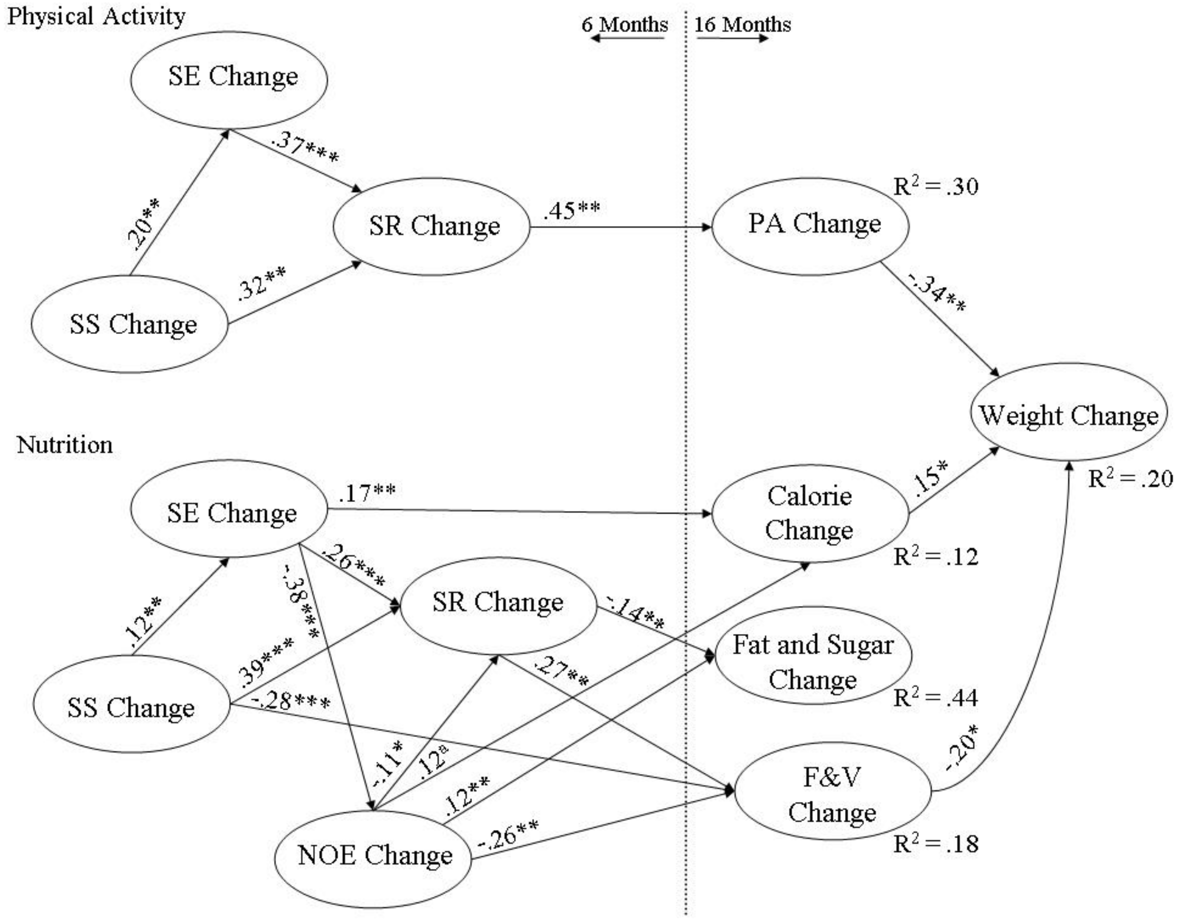
[c] partial-eta squared.

[d] MET: metabolic equivalent.

Social Cognitive Model of Change

A longitudinal, latent variable, structural model incorporated data from SCT variables exhibiting significant change (see Table 2) at 6 months, and nutrition, PA, and weight change at 16 months (Figure 2). The model provided good fit to the WB-GTH change data: root mean square error of approximation (RMSEA) = .05, 95% confidence interval 0.04-0.06; *P* (close fit: RMSEA < .05) = .33; FIML chi-square df = 200, n = 272) = 342.7, *P* < .001; chi-square/degrees of freedom ratio = 1.71). Means, standard deviations, and covariances of measured variables are available from Dr Eileen Anderson-Bill on request.

Figure 2. Social cognitive model of behavior and weight change among users of the Web-based Guide to Health intervention. F&V: fruits and vegetables; NOE: negative outcome expectations; PA: physical activity; SE: self-efficacy; SR: self-regulation; SS: social support. $^{a}P < .10$; $*P < .05$; $**P < 0.1$; $***P < .001$



Physical Activity

Completely standardized significant direct effect coefficients resulting from the structural analysis appear next to their associated paths; the PA portion of the model is at the top of Figure 2 (note: as reported in Table 2, outcome expectations did not change with use of the WB-GTH, and thus were not modeled as predicting change in PA). The associated R^2 values indicated the model explained 30% of the variance of change in PA. Improvements at 6 months in social support, self-efficacy, and self-regulation led to increases in PA at 16 months (social support beta$_{\text{total}}$ = .26, *P* = .04 self-efficacy beta$_{\text{total}}$ = .30, *P* = .01; self-regulation: beta$_{\text{total}}$ = .45, *P* = .004). Within the SCT variables, the indirect effects of self-efficacy (beta$_{\text{indirect}}$ = .17, *P* = .007) and social support (beta$_{\text{indirect}}$ = .20, *P* = .004) on PA provide evidence for the posited meditational roles of self-efficacy and self-regulation. Increased social support at 6 months led to higher PA at 16 months largely by increasing participants' self-efficacy (beta$_{\text{total}}$ = .20, *P* =.002) and self-regulation (beta$_{\text{total}}$ = .39, *P* < .001). Similarly, participants' increased self-efficacy contributed to higher levels of PA by making it more likely that participants would engage in self-regulatory behaviors (beta$_{\text{total}}$ = .37, *P* < .001).

Nutrition

The nutrition portion of the model is at the bottom of Figure 2. The R^2 values indicated the model explained 18% of the variance of change in F&V, 12% of change in calories, and 44% of change in fat and sugar-sweetened foods. Decreased fat and sugar consumption was preceded by improvements at 6 months in participants' social support (beta$_{\text{total}}$ = -.10, *P* =.02), negative outcome expectations (beta$_{\text{total}}$ = .15, *P* = .007), self-regulation (beta$_{\text{total}}$ = -.14, *P* = .008), and, albeit marginally, self-efficacy (beta$_{\text{total}}$ = -.06, *P* = .07). Decreased calorie intake at 16 months was preceded by increased social support at 6 months (beta$_{\text{total}}$ = -.30, *P* < .001). Increased F&V intake was associated with improved self-efficacy (beta$_{\text{total}}$ = .20, *P* = .01), negative outcome expectations (beta$_{\text{total}}$ = -.29, *P* = .002), and self-regulation (beta$_{\text{total}}$ = .27, *P* = .009). The indirect effects of social support and self-efficacy on increased F&V (social support: beta$_{\text{indirect}}$ = .14, *P* =.005; self-efficacy: beta$_{\text{indirect}}$ = .18, *P* < .001) and decreased fat and sugar-sweetened foods (social support: beta$_{\text{indirect}}$ = -.07, *P* =.01; self-efficacy: beta$_{\text{indirect}}$ = -.09, *P* =.005) support meditational roles for negative outcome expectations and self-regulation in the nutrition portion of the model.

Weight Management

The model also evaluated whether participants' weight loss at 16 months related to concomitant changes in nutrition and PA or to psychosocial changes that preceded dietary and PA improvements. The model explained 20% of the variance of change in weight. Participants' weight loss at 16 months was related to increases in PA ($\text{beta}_{\text{total}}$ = -.34, P = .01), which mediated the effects on weight loss of improvements in PA self-efficacy ($\text{beta}_{\text{total/indirect}}$ = -.10, P = .03) and PA self-regulation ($\text{beta}_{\text{total/indirect}}$ = -.15, P = .01). PA self-efficacy also influenced weight loss through its effect on self-regulation ($\text{beta}_{\text{total/indirect}}$ = .37, $P < .001$). Further, weight loss at 16 months was related to improved F&V intake ($\text{beta}_{\text{total}}$ = -.20, = .04) and calorie consumption ($\text{beta}_{\text{total}}$ = .15, P = .04), which mediated the effects of changes in nutrition-related social support ($\text{beta}_{\text{total/indirect}}$ = -.08, P = .03), negative outcome expectations ($\text{beta}_{\text{total/indirect}}$ = .08, P = .03), and, albeit marginally, self-regulation ($\text{beta}_{\text{total/indirect}}$ = -.06, P = .07). Users of the WB-GTH lost weight because of improved diet and PA, which followed improvements in participants' psychosocial characteristics.

Discussion

The WB-GTH is an Internet intervention designed to improve nutrition and PA and prevent further weight gain in overweight to obese, inactive, but otherwise healthy adults. Based on SCT, the WB-GTH was delivered with and without enhanced self-regulatory features to Internet users who were recruited, screened, asked for consent, and assessed entirely online. The 16-month outcomes suggest that WB-GTH users lost almost 5 pounds (~3%) of body weight; increased daily step counts by 24%; made fourfold increases in weekly METS expended in walking; decreased calories from fat by 2%, calories from sweets by 3%, and daily calories by 10%; and increased F&V intake by about 1.5 servings a day. These changes were consistent with those exhibited by users of a site-based version of GTH delivered with enhanced supports [18] and were preceded by improvements at 6 months in social support, self-efficacy, outcome expectations, and self-regulatory behaviors.

A presumed strength of Internet interventions is that they can be highly flexible and personalized based on individual participant data [4]. In WB-GTH, users received program content at a time, pace, and setting determined by the user. Although the WB-GTH was just as effective with less-tailored, generic approaches to planning and feedback [32], the self-monitoring in both WB-GTH versions was quite detailed involving keeping and reporting daily behavioral logs. Bandura's SCT [26,27] posits that adoption of and adherence to healthier eating and PA patterns is largely a matter of self-management; accordingly, SCT-based interventions should influence health behavior by influencing social support, self-efficacy, outcome expectations, and self-regulation of users. The current study provides an estimate of longitudinal effects of SCT variables within a complete theoretical model while simultaneously accounting for error in the measurement of variables. The SCT model provided good fit to nutrition, PA, and weight-management outcome data (RMSEA < .05). Consistent with other research, changes at 6 months in social support, self-efficacy, and self-regulation led to changes 10 months later in PA and, along with negative outcome expectations, in nutrition behavior [28]. In an advancement of previous investigations, weight loss was shown to be predicted by concomitant improvements in PA and nutrition; further, earlier changes in SCT variables contributed to weight loss largely through behavioral changes. In summary, WB-GTH users lost weight as they improved their diet and exercise habits resulting from enhanced psychosocial functioning.

The WB-GTH, like many other Internet programs, ultimately attracted a relatively affluent, predominantly female and white sample [29-31], many of whom declined to participate during the lengthy consent and enrollment process (~50% [29]). Research criteria designed to reduce risk associated with especially vigorous PA limited the external validity of the study by excluding elderly, unhealthy, and morbidly obese adults. Indeed, only about one-third of initially interested Web users qualified for the study [29]. Study exclusionary criteria were reported to have also had differential effects on Web users who were nonwhite [29]. Despite these limitations, the study's inclusion criteria resulted in a sample of overweight or obese participants with step counts generally in the sedentary to inactive range (ie, <7500 steps/day), the vast majority of whom did not meet guidelines for intake of fat, fiber, and F&V [29].

Discussed in detail elsewhere [32], attrition in WB-GTH (59% baseline to 16 months) was associated with a number of tentative users who quickly withdrew from the study [21], with the extended length of the program, and with the extensive assessment component of the research project [32]. The WB-GTH shared early dropout and assessment procedures with the earlier site-based GTH trial that had a much lower attrition rate (22% attrition baseline to 16 months) [18]. Although the retained sample populations in the Web-based and site-based GTH programs were inactive to sedentary overall, dropouts from both versions [18,32] tended to be even less active, suggesting that generalizability of the study findings to the extremely sedentary may be limited. Seemingly differential attrition in the Web-based intervention suggests, however, that a shorter intervention may be more acceptable and face-to-face contact may contribute to higher retention. Internet program users, for example, may benefit from contact with program promoters such as health care providers, employers, clergy, or previous program users. Additionally, determining optimal program length for behavior-change maintenance may be key to retaining short-term and stable users [21].

Finally, although an earlier version of GTH was shown to be effective compared to an untreated control condition [18], there were no differences over time between participants using the two online versions of WB-GTH [32], thus limiting the study's conclusions about the source of changes observed in weight, behavior, and psychosocial functioning. The effectiveness of the WB-GTH is arguably supported by outcomes that were sustained over time and by the limited effectiveness of similar programs in general [32]. Nevertheless, the pattern of psychosocial, behavioral, and anthropometric changes observed among WB-GTH users was consistent with the theoretical foundations of the GTH intervention, lending further credence to its being the source of those changes.

The longitudinal design of the study strengthened the structural equation analysis, but the ordering of the SCT variables was theoretical and not chronological [36]. The ordering, if correct, suggests that SCT interventions may be more effective if they increase social support and self-efficacy, and help participants set goals, plan, and monitor their nutrition and PA behaviors. Improving social support and self-efficacy may be an effective pathway for increasing the use of self-regulatory strategies. Further, improved social support, self-efficacy, and self-regulation may lead to improved PA levels and (along with outcome expectations) nutrition, which contribute to successful weight management among sedentary adults struggling with weight control. High initial levels of self-efficacy among Web-health users interested in online interventions may alter the function of SCT in these programs. The juxtaposition of high efficacy and expectations with low levels of healthy behavior is common. Bandura [26] suggests that self-efficacy for behavior change can be unrealistically high among individuals who lack experience in the desired, healthier behavior. While increased self-efficacy may enhance program outcomes, participants whose self-efficacy is tempered by online interventions may still benefit. After 6 months of using WB-GTH, for example, 51.5% (n = 140) of participants became less confident in their abilities to do the things necessary to be physically active on a regular basis (mean change -16.40, SD 16.61), 18% (n = 49) slightly increased their PA self-efficacy (mean change 4.39, SD 2.87), and 30% (n = 82) made larger improvements (mean change 23.89, SD 11.05). Participants who decreased self-efficacy during 6 months of WB-GTH started with significantly higher self-efficacy than those who gained the most confidence (mean 68.45, SD 18.69 vs mean 57.86, SD 19.27; $P < .001$). Participants at all three levels of change in self-efficacy, however, increased steps/day (mean 1167.05, SD 2854.75 vs mean 1501.61, SD 3851.76 vs mean 1806.88, SD 3253.27) and in METhours/week expended in walking-type activities (mean 7.26, SD 19.15 vs mean 8.73, SD 16.23 vs mean 10.12, SD 20.54).

Although the current study demonstrates how SCT variables can contribute to the effectiveness of online interventions such as WB-GTH, researchers may need to go beyond traditional cognitive and motivational variables in order to explain a larger proportion of behavior change – perhaps, for example, assessing the affective and selective processes delineated in SCT that are associated with behavior change [26]. The WB-GTH, for example, tried to guide users to select social and physical environments that support their new behaviors (eg, finding a walking partner or eating at healthier restaurants) and WB-GTH’s guided mastery approach should have enhanced users’ abilities to anticipate and ameliorate aversive affective states associated with behavior change (eg, help users to like and feel good about their new healthier behaviors), but such effects were not measured in the trial.

The outcomes of WB-GTH suggest that purely Web-based interventions can operate in a manner consistent with underlying theory. Further, despite problems with attrition and a relatively homogeneous reach, Internet programs such as WB-GTH can be effective in guiding users to adopt healthier nutrition, PA, and weight-management habits, which rival changes produced by more intensive, face-to-face interventions.

Acknowledgments

We thank Ashley Dorough, MS for her involvement in piloting and refining the physical activity component of the intervention and Todd Bowden and Shane Moore of PC Resources, Inc. for implementing the web-based components of the study.

Conflicts of Interest

None declared

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Abbreviations

F&V: fruits and vegetables
FIML: full information maximum likelihood
MANOVA: multivariate repeated measures analysis of variance
MET: metabolic equivalent
NOE: negative outcome expectations
PA: physical activity
RMSEA: root mean square error of approximation
SCT: social cognitive theory
SE: self-efficacy
SR: self-regulation
SS: social support
WB-GTH: Web-Based Guide to Health intervention

Edited by G Eysenbach; submitted 14.07.10; peer-reviewed by T Webb, R Cook, N Atehortua, N Zhang; comments to author 14.10.10; revised version received 30.11.10; accepted 20.12.10; published 04.03.11.

Please cite as:
Anderson-Bill ES, Winett RA, Wojcik JR, Winett SG
Web-Based Guide to Health: Relationship of Theoretical Variables to Change in Physical Activity, Nutrition and Weight at 16-Months
J Med Internet Res 2011;13(1):e27
URL: http://www.jmir.org/2011/1/e27/
doi:10.2196/jmir.1614
PMID:21447470

Viewpoint

Supportive Accountability: A Model for Providing Human Support to Enhance Adherence to eHealth Interventions

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Abstract

The effectiveness of and adherence to eHealth interventions is enhanced by human support. However, human support has largely not been manualized and has usually not been guided by clear models. The objective of this paper is to develop a clear theoretical model, based on relevant empirical literature, that can guide research into human support components of eHealth interventions. A review of the literature revealed little relevant information from clinical sciences. Applicable literature was drawn primarily from organizational psychology, motivation theory, and computer-mediated communication (CMC) research. We have developed a model, referred to as "Supportive Accountability." We argue that human support increases adherence through accountability to a coach who is seen as trustworthy, benevolent, and having expertise. Accountability should involve clear, process-oriented expectations that the patient is involved in determining. Reciprocity in the relationship, through which the patient derives clear benefits, should be explicit. The effect of accountability may be moderated by patient motivation. The more intrinsically motivated patients are, the less support they likely require. The process of support is also mediated by the communications medium (eg, telephone, instant messaging, email). Different communications media each have their own potential benefits and disadvantages. We discuss the specific components of accountability, motivation, and CMC medium in detail. The proposed model is a first step toward understanding how human support enhances adherence to eHealth interventions. Each component of the proposed model is a testable hypothesis. As we develop viable human support models, these should be manualized to facilitate dissemination.

(J Med Internet Res 2011;13(1):e30) doi:10.2196/jmir.1602

KEYWORDS

Internet intervention; adherence; computer-mediated communication; accountability; human support; motivation

Introduction

It is widely recognized that eHealth interventions are often plagued by a high rate of attrition [1-3]. While a wide variety of factors such as the design of the eHealth intervention and patient factors have been suggested as potential factors in adherence and attrition [1, 4], support provided by clinicians or coaches, via telephone, email, and chat rooms, has been shown across many treatment targets to enhance adherence [3,5-7].

However, very little attention has been paid to *how* human interaction enhances adherence. The aim of this paper is to propose a theoretical model, which we call "Supportive Accountability," that can serve as the basis for a "science of adherence" [1] for human support. A clear theoretical model would provide intervention developers and researchers with a starting point for future research, as well as the basis for a more structured and manualized approach to design and implementation of human support intervention components.

A few basic definitions must be established, as terminologies may take on subtly different meanings from how they are used in traditional, face-to-face interventions. *Adherence* is defined here as use of the eHealth intervention over time, and has been operationalized in a variety of ways such as number of logins, time on site, number of modules completed, and number of characters typed into the site [3,8]. This definition emphasizes how users of eHealth interventions are assumed to be active patients insofar as they log in to or otherwise access the resource as a period of behavior change is progressing. It should be noted that this definition focuses on adherence to the eHealth intervention, and not adherence to any behavioral prescription. While adherence to behavioral prescriptions is critical to the success of psychological interventions [9], it is beyond the scope of this paper.

Support, in our nomenclature, may be provided by a range of people, including lay persons, students, mental health professionals, and medical professionals. We will use the term *coach* to refer to the support person, as it carries no implications regarding background. Indeed, specific lay coaches may be just as effective as professionals in supporting eHealth interventions [10].

Current Models From Face-to-Face Psychological and Behavioral Treatments

Adherence has been called the paramount issue in psychological treatments [11]. More than 50% of patients receiving psychological interventions in clinical settings have been found to drop out of treatment prematurely [12,13]. Even in structured randomized controlled trials (RCTs) with rigorous patient selection and extra support of research staff, 15%-30% attrition is common [14,15]. Despite such rates, there is little literature on the causes of attrition, and even less on how to prevent it. What research does exist suggests that patients terminate prematurely primarily due to poor therapeutic alliance [16] and patient variables, such as diagnosis of a personality disorder [11,17]. Surprisingly, to the best of our knowledge, there is no overarching theoretical framework for examining adherence. Part of the reason for this may be that for standard face-to-face behavioral treatments, procedures aimed at enhancing adherence are embedded in the treatment itself. This is to say, in face-to-face interventions, the treatment provider offers the core of the intervention while simultaneously coordinating his or her relationship with the patient in a way that will efficiently promote the use of the therapeutic skills and interest to continue in treatment. In contrast, eHealth treatments separate the content of the treatment, which is provided in a standardized manner via a website, mobile device, or other platform, from support provided by humans, which is often intended to increase adherence [18-20].

Constructs generally examined in association with adherence in the face-to-face treatment literature do not adequately explain why such support might improve adherence. For example, emotional bond or therapeutic alliance is nearly universally acknowledged as important for adherence in almost any form of psychological, behavioral, or medical procedure. But these constructs do not elucidate the mechanisms by which bond or therapeutic alliance might lead to increased adherence. Clearly, many treatments, such as motivational interviewing [21], aim to promote adherence. Yet our review of the clinical literature found a dearth of useful theory to apply to the problem of adherence in eHealth interventions.

A broader review of related literature, however, revealed much useful information. Organizational psychology has long examined how to obtain adherence to behavioral instructions among large groups of people. Motivation theory and research, too, provides a rich literature on potential patient-centered factors that might moderate the need for or the effects of interventions. The field of computer-mediated communication (CMC) investigates the effects of communications technologies on communication quality and human relationships.

Based on these three literatures, we have constructed a hypothesized model for the factors that explains how human coaches can influence adherence to eHealth interventions. This model, which we call Supportive Accountability, is depicted in Figure 1. Below we will describe each of these factors.

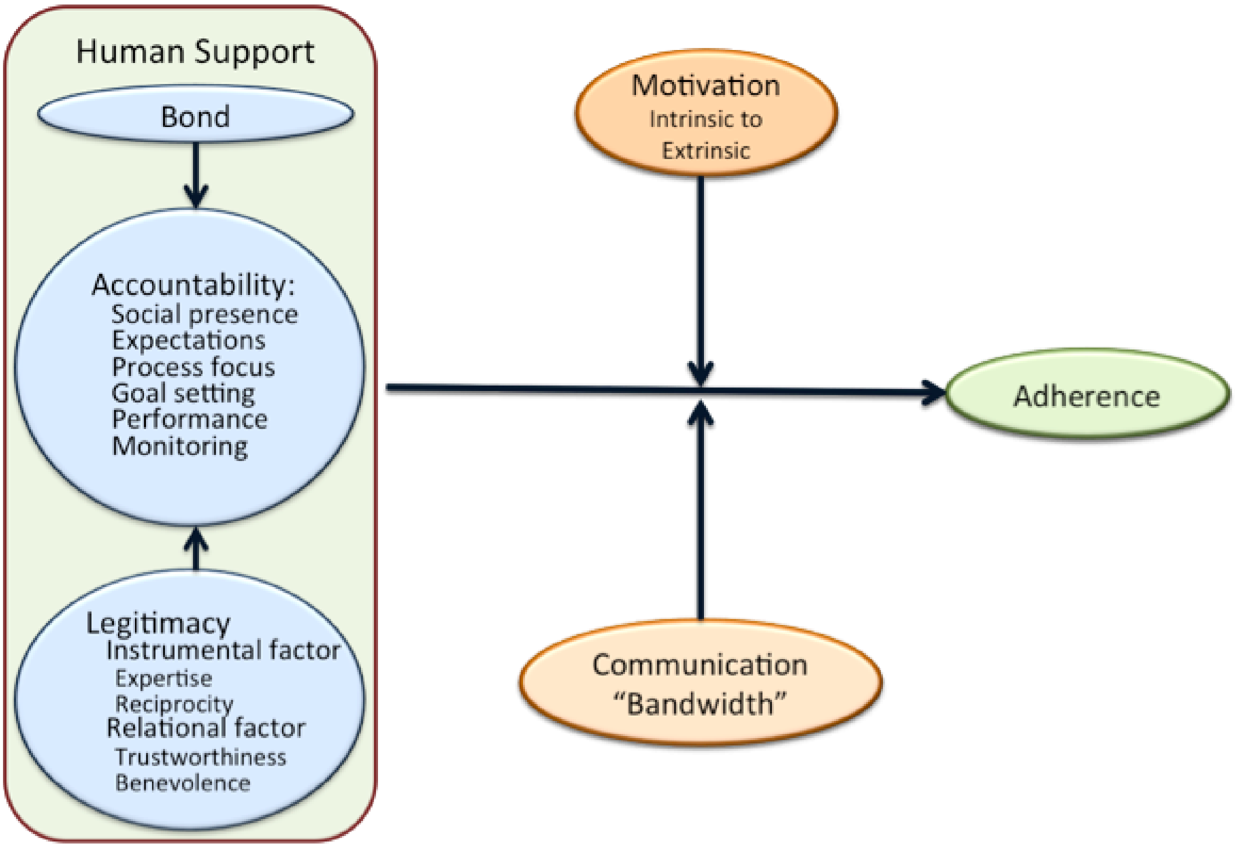
Accountability

Organizational psychology has focused on questions of how to motivate people to engage in specific behaviors. One area that has focused specifically on adherence is the literature on the use and misuse of accountability in encouraging specific goal-directed behaviors. The term *accountability* refers to the implicit or explicit expectation that an individual may be called upon to justify his or her actions or inactions [22]. The literature identifies several factors that are integral to how accountability is cultivated and maintained.

Social Presence

Accountability requires *social presence*—the presence of another human being. This presence can be in person, by telephone, or by email, and may be either synchronous or asynchronous. Although it is true that automated systems that monitor and encourage adherence, such as email reminders, can improve adherence to eHealth interventions, human support enhances adherence to a significantly greater degree [6,23,24].

Figure 1. Model of Supportive Accountability



Expectations

Clarity regarding the *expectations* of patients facilitates adherence. Adherence is not possible when expectations are unknown or unclear. In addition, the reasons for the behavior should be clear. The more that people understand and agree with the underlying rationale for the expected behavior, the greater the compliance [22]. Similarly, in supported e-mental health interventions, when there is agreement between coaches and patients, outcomes are likely to be better [25].

The targets of the expectations can vary. Accountability theory indicates two distinct types of expectations: *outcome* accountability and *process* accountability. For example, outcome accountability for a depression treatment might be defined in terms of depression severity, while process accountability might be defined in terms of completion of thought records or number of logins to a website. Research in accountability fairly consistently finds that process accountability increases completion of the target behaviors, while outcome accountability has primarily detrimental effects, including lower adherence and greater distress. The poor results of outcome accountability are attributed to the effect it has in increasing a desire among people to perform better without respect to the tools and control that could be used to accomplish the goal [22,26,27]. Thus, patients would be much more likely to view feedback from a coach as helpful and rewarding when it is based on the process variables—what they actively do on a session-by-session basis—rather than on a more distal outcome that is not directly under their control.

Another important component of expectations is *goal setting*, which is an important component of many behavioral interventions [28]. However, a review of literature from organizational psychology indicates that goal setting in the context of accountability can have iatrogenic effects in at least two ways [29]. First, goal setting can narrow the focus of behavior onto the specific goals and reduce other behaviors that are useful or important. For example, a clear goal of logging in to an eHealth site 3 times a week may help some patients achieve that goal. However, it may also focus the patient on logging in, leading to perfunctory use of the intervention as opposed to more engaged use. Rigid adherence goals may actually reduce helpful behavior change outside of the narrowly targeted goals of adherence. Adherence goals attached to the patient's larger goals and values may avoid the iatrogenic effects of goal setting. This might link the tools or content of the materials to be reviewed to a larger goal or value that the patient has. Second, if goals are perceived as being set and monitored by the coach, they may be perceived as controlling, producing a boomerang effect in which the goal behavior is reduced. This is not to say goal setting is always detrimental; rather, we raise this to indicate that goal setting can have negative consequences when not managed properly. The role of goal setting and the form it takes in adherence to eHealth interventions remains an area to be explored.

It is important that expectations be set and agreed upon prior to the point of accountability. Cognitive dissonance theory suggests that once people have committed themselves to a decision or a course of action, learning of the need to justify the action will motivate cognitive effort [30]. However, this cognitive effort will be directed toward self-justification rather than to self-reflection. Thus, if someone learns that he or she will be expected to account for an action or inaction at the time one is to be held accountable, accountability will likely prompt “defensive bolstering,” in which they will rationalize their action or inaction. At that point, the opportunity to help the individual engage in self-reflection likely has been lost. This would argue that it is important to be clear about the accountability process prior to its implementation. Additionally, when expectations of individuals’ roles in the intervention have been clearly and explicitly articulated and agreed upon in advance of the point of accountability, they are more likely to engage in preemptive self-examination of contributing factors [31]—that is, to more effectively explore their cognitions and behaviors on tasks likely to be relevant to the presenting problem but not falling directly under the umbrella of adherence-based goals.

Performance Monitoring

A core requirement of accountability is that performance be monitored. Paradoxically, however, performance monitoring and surveillance can reduce compliance and contribute to demoralization [22]. The effects of performance monitoring are particularly damaging if surveillance is perceived as controlling and is not accompanied by adequate explanation [32,33]. These negative effects can be mitigated if a clear explanation is provided in advance, and if it is framed in a benevolent context. It should be made clear that the aim of performance monitoring is to provide feedback, that failure to meet goals provides opportunity for self-reflection and growth, and that there are no negative consequences.

Some clinical populations, such as those with depression or severe mental illness, are at particular risk for deterioration, suicide, or negative outcomes. Coach monitoring procedures should also entail monitoring for signs of these outcomes for the protection of these patients.

Legitimacy

People respond more positively to accountability demands from a coach who is perceived as legitimate [34]. *Legitimacy* stems from patient perceptions about the coach, which dictate that the patient will voluntarily accept the influence of the coach even in the absence of other extrinsic inducements such as reward or punishment. Legitimacy arises from both instrumental and relational factors [34,35].

The instrumental factor has two components. First, legitimacy requires that the patient perceive the coach as having the requisite *expertise*. Perceptions of expertise can be displayed in the interaction by demonstrating knowledge and answering questions, as well as outside the relationship through the display of degrees, certifications, or training [36]. Second, evaluation of the legitimacy of the coach, and adherence that flows from the attribution of legitimacy, rest in part on expectation of *reciprocity*. In its broadest sense, legitimacy rests in part on the expectations of resources to be received and expended in the future, as the relationship develops over time. The contract between patient and coach includes a defined patient role (eg, logging in to a website and performing specific activities), as well as a defined coach role (eg, providing time, attention, and assistance with problems).

The relational component of legitimacy centers on *trustworthiness* and *benevolence* [34]. People seek evidence of integrity, caring, and a sense that the coach has the patient’s best interest at heart when determining legitimacy. The instrumental and relational factors must both be present for coach legitimacy to be established, as well as for adherence to flow from it.

Demands for accountability made by individuals perceived as illegitimate not only fail to produce the desired effects, but may also boomerang [22]. If people perceive that the coach wants to control their beliefs or behaviors, the underlying need for autonomy and freedom of choice is threatened. This activates motivational states aimed at recapturing perceived autonomy, which increases the likelihood of noncompliance with instructions [29,37].

Legitimacy must be both created and sustained. Legitimacy can be cultivated even before the first contact. For example, the credibility of the website may contribute to the creation of coach legitimacy through association. Credibility, which is a characteristic of websites that relies on similar constructs of expertise and trustworthiness [38,39], can be conveyed through the website source (eg, a known university vs an unknown company), presentation (eg, a professional look), names of people associated with the site (eg, recognized experts vs unknown individuals), and design characteristics that are attractive and usable. As we will discuss below, patients likely begin the relationship with a positive bias; however, relatively small negative cues may be overinterpreted, which can quickly undermine coach legitimacy [40]. Coach legitimacy, once created, then must be sustained; this may be accomplished by meeting the agreed-upon expectations for coach behaviors (eg, calling and emailing at the appointed times) or by interacting in ways that consistently convey caring and expertise, among other strategies.

Bond

The conceptualization of legitimacy is similar to Bordin’s seminal model of therapeutic alliance, which emphasizes liking, trust, and respect [41]. However, legitimacy differs from alliance in several ways. First, legitimacy theory relies on the relational and instrumental factors that are tied to the acceptance of influence in order to achieve a desired outcome. In contrast, Bordin’s notion of a healthy alliance does not hinge on the existence of these same factors in establishing legitimacy. The second fundamental difference between legitimacy and therapeutic alliance is that legitimacy models do not necessarily include liking, or bond. This difference may stem in part from the nature of the goals and interpersonal interactions in psychological intervention versus the goals and relationships that are the focus of organizational psychology. Therapeutic bond is an important predictor of outcome in distance treatments (eg, internet or telephone-administered treatments), particularly when those treatments focus on providing skills training [42].

Accordingly, the emotional attachment captured by the notion of bond likely enhances the effects of accountability.

Summary of Human Support Constructs

This model of Supportive Accountability suggests that the potential success of accountability is fragile and must be managed carefully. Our model predicts that adherence to prescribed behaviors will be enhanced when (1) coaches are seen as trustworthy and benevolent, (2) coaches are perceived as having the necessary expertise, (3) coaches frame the relationship as one containing reciprocity, in which the patient can expect to receive definable benefits from the coach, (4) coaches involve the patient in the definition of goals and expectations, (5) outcomes for which the patient is accountable are clear, but are also tied to larger life goals and values, (6) expectations are focused on processes rather than outcomes, (7) negative effects of goal setting, such as limiting desired behaviors or inducing perfunctory adherence, are monitored and minimized, (8) coaches are specific about accountability processes at the beginning of treatment, and (9) performance monitoring is introduced with adequate justification and patient agreement, is framed in terms of benefit to the patient, and is devoid of implied threats of negative consequences.

Motivation

A growing body of data from RCTs shows that adherence to eHealth interventions varies widely [3]. Some percentage of a population is successful and adherent to standalone interventions. Some percentage of a population likely is nonadherent regardless of the quality and amount of support. And the majority likely fall somewhere in between.

Motivation can be defined as that which gives behavior its direction or goals, and determines the strength or energy behind that behavior. Thus, motivation to use an eHealth intervention might be defined by patient and environmental factors that influence whether a person initiates or engages with a website mobile device (goal) and, if so, how frequently he or she uses it (intensity). Self-determination theory is a well-researched theory of motivation that posits that people have innate tendencies for growth and improvement [43]. While self-determination theory focuses on self-determined, intrinsic motivation, it also incorporates extrinsic factors that explain how intrinsic motivation can be modified by external causes. Because self-determination theory sees the determinants of motivated behavior as lying on a gradient from intrinsic to extrinsic, this theory fits well in explaining the variability in adherence seen in supported and standalone eHealth interventions.

Intrinsic motivation refers to autonomous, self-determined action that arises out of an innate propensity to seek out and master challenges, to engage and work toward goals, and to be the agent of one's own life [43]. It arises spontaneously from the individual's psychological needs, personal curiosity, and innate striving for growth.

Patients in face-to-face psychotherapy generally tend to have better outcomes when they exhibit greater intrinsic motivation [44]. However, people with high intrinsic motivation may be able to use information provided without a therapist. Self-guided treatments have been examined for many behavioral and psychological targets, such as depression, anxiety, diet, physical exercise, smoking cessation, and substance abuse. These interventions have been provided using bibliotherapy as well as unsupported eHealth interventions. Recent meta-analyses found a significant, albeit small, effect for self-guided treatments compared to control conditions [5,45], and found that about 1 in every 8 or 9 participants in these interventions clearly benefits from it. Only a small minority of patients have sufficient intrinsic motivation to be able to successfully implement and sustain the use of self-guided material. For most patients, some extrinsic motivation is required.

Extrinsic motivation refers to the motivation that arises from sources external to the individual [43]. Self-determination theory posits that when individuals are more autonomously engaged in a treatment, they are more likely to integrate learning and behavior change, and are more likely to improve. To the extent that people experience their motivation as being a function of external factors, their need for autonomy is threatened and they are more likely to experience conflict and division, and therefore are less likely to comply with the behavioral prescription [37] Furthermore, any change that arises from extrinsic motivation will be unstable and less likely to be maintained once the extrinsic motivators are removed. To cultivate more persistent change, extrinsic motivation must be substituted over time by intrinsic motivation.

The degree to which external motivational factors can be internalized varies along a gradient of autonomy [46]. *External regulation* refers to motivation that is fully extrinsic, such as an external authority that mandates a behavior or compliance with rules, enforced through consequences. *Introjection* refers to esteem-based motivations derived either from seeking social approval or from threats to one's social-self, such as "shoulds," guilt, and shame. *Identification* is more on the intrinsic end of the scale, and involves acting in accordance with one's own values and goals. Pure *intrinsic motivation* is evidenced by activities that are done out of open curiosity, out of interest, or for pure enjoyment. When intrinsic motivation is lacking, motivation to engage in treatment-related behaviors must be enhanced or created, and then it must be sustained. The coach should seek to move the patient along the gradient toward more intrinsic motivation. The more a patient internalizes responsibility for the treatment process, the greater the likelihood of long-term success.

A large body of literature has examined two classes of external motivators: (1) tangible rewards or incentives, and (2) verbal rewards or positive feedback. Tangible rewards such as money may improve outcomes for tasks that are unpleasant, dull, or boring, particularly if the reinforcement is administered variably [47]. However, for tasks that are interesting to the individual, tangible rewards can undermine intrinsic motivation and reduce the maintenance of any behavior change linked to reinforcement for performance of, completion of, or engagement in tasks [48]. One of the reasons that tangible rewards have a negative effect on interesting tasks is that the effect of the reward is mediated by cognitive attributions. That is, the reward itself does not affect behavior; it is the interpretation of the reward that has an effect. Tangible rewards tend to be viewed as indicators that the individual lacks intrinsic motivation or—worse—as controlling and threatening to an individual's autonomy. Thus, for tasks that the patient may have some interest in completing, tangible rewards may undermine performance.

Verbal rewards, on the other hand, have consistently been found to enhance intrinsic motivation in adults (but not in children) under a broad range of contexts [48]. This is particularly true if positive feedback is provided in a way that affirms competence and is not experienced as controlling. The effectiveness of verbal rewards may stem from their often variable form and timing, thus being a form of variable reinforcement. However, if verbal rewards are offered in a controlling manner, they can undermine intrinsic motivation much as tangible rewards do [49].

Summary of Motivational Constructs

Although intrinsically motivated adherence to the immediate goals of an eHealth intervention may be difficult to obtain fully for most people, a coach should aspire to help patients identify with the goals of the intervention. The literature on self-determination theory has several direct implications for coach-supported eHealth interventions [48]: (1) a fundamental requirement for any level of intrinsic motivation is that the eHealth intervention should address a problem that the patient has also identified, and should offer some method of resolving that problem, (2) the eHealth intervention and tasks should be constructed to be engaging and interesting, (3) to the degree that the patient does not find the e-intervention tasks interesting, the coach should seek to increase the patient's level of interest—for example, by increasing the salience of tasks to the patient, helping the patient see the utility and applicability of online tasks to their lives, and enhancing a sense of personal challenge in the completion of tasks, (4) tangible rewards should be avoided, particularly if the targeted activity is interesting to the patient, (5) the patient should be verbally rewarded by acknowledging good performance and good effort, without seeking to control behavior, (6) overt or covert pressure should be avoided, (7) choice regarding how to complete tasks should be provided, and (8) the amount of human support provided by the intervention should be tailored to reflect a patient's individual orientation on the intrinsic-extrinsic gradient.

Self-determination theory suggests two amendments to accountability theory. First, self-determination theory suggests that intrinsic motivation is more effective than extrinsic motivation in achieving desired behavior, and that the resulting behavior will be more durable. For this reason, motivation in Figure 1 is depicted as a moderator. Patients with high levels of intrinsic motivation may have no need of coaching support at all. For the remaining patients, the processes of accountability are more likely to be successful if they are internalized by the patient. This suggests that adherence will be highest if adherence behaviors are self-monitored, with coaches relegated to roles supporting the patient's self-monitoring. In other words, when presented with nonadherence, coaches assist patients by reminding them of their personal objectives, promoting self-reflection and problem solving, and providing the socially facilitative relationship through which these processes can unfold.

The second implication of self-determination theory is that application of support and accountability procedures has a threshold, after which additional support either will not add to improvement or may even reduce adherence. Self-determination theory predicts that, while a patient is struggling with adherence, he or she may perceive social facilitation through accountability as helpful. But once adherence and engagement are achieved, the relational context shifts and the patient would be expected to interpret continued support either as controlling or as an indicator that the coach is concerned about the patient's ability or competence. Thus, patients receiving coaching support after reliably achieving adherence may obtain no further benefit from added support or, worse yet, might show diminished adherence and lower maintenance adherence of therapeutic gains after the removal of the coaching support.

Computer-Mediated Communication

More than 2 decades of research into CMC has examined the influence of communications media on interpersonal relationships. As with much of the literature discussed in this paper, the CMC literature is based on controlled laboratory research outside the clinical arena. One of the earliest and most straightforward approaches, sometimes referred to as *cues filtered out* [50], suggests that bandwidth is the principle feature affecting communication and the experience of social presence in the communication partner. Bandwidth refers to the number of communication cues a medium can convey (eg, verbal content, visual cues, prosody). The assumption was that greater bandwidth would lead to greater ability to complete tasks, better interpersonal relations, and greater social presence. Thus, face-to-face communication, with its full complement of verbal, nonverbal, and contextual cues, could be assumed to provide the richest source of information. The telephone removes visual cues but retains nonverbal information found in prosody. Instant messaging is primarily content, and would be expected to strip away nonverbal information. Texting and email would eliminate the social presence provided by synchronous communication. Thus, as communication media degrade the quality of the interaction, factors such as bond, legitimacy, and the ability to provide supportive accountability would be expected to deteriorate.

However elegant this formulation is, the CMC literature has since suggested it to be overly simplistic. With time, people are able to develop communications that are effective, and emotionally and relationally rich, even in comparatively lean communications media. Indeed, American teenagers now spend almost as much time in text-based communication (text/chat) as they do in face-to-face and telephone communication, suggesting that these media can provide valued forms of communication [51].

One reason that lean media are effective is that people tend to form stronger impressions based on more limited, sometimes stereotyped social and interpersonal cues. Some of these cues may even be independent of the interaction, such as knowledge about the other person's gender, status, or other characteristics available to the person [52]. Early in interactions using lean media, people usually make more positive, idealized attributions of their communication partners. This positive effect is heightened when there is an expectation of future contact [40]. When making attributions about communication partners, people using lean media make attributions based on less detailed information, but their attributions tend to be stronger and more intense than those of people communicating face-to-face [53].

The language that people use in text-based communication may also be different from language used in verbal communication. In general, people tend to be more willing to engage in socioemotional communication in text-based media than in face-to-face communication. For example, CMC users employ more self-disclosure than in face-to-face communications [54]. When using CMC, people are also more willing and more likely to ask personal questions, with those questions involving greater depth; questions asked in face-to-face communication are comparatively impersonal and are marked by more superficiality. Ratings of communication effectiveness are also significantly more positive for CMC than for face-to-face. Thus, while face-to-face communication is richer in the availability of cues, people make much more use of the remaining cues and strategies in leaner communication media.

When people do not have nonverbal cues available, they are quite adaptive in developing new methods of creating impression-bearing, interpersonal cues and strategies. Examples include the use of emoticons, such as ";-)", and abbreviations, such as LOL (laugh out loud), as methods of conveying interpersonal and emotional information. Although people use these frequently to convey such information, findings suggest that they have little effect on a reader's interpretation of a message [40]. However, when two people engaged in communication mirror the use of emoticons and abbreviations, they are more likely to experience high levels of mutual trust [55]. People also use time and date stamps on CMCs as indicators of the quality of the relationship. For example, task-oriented emails sent at night tend to be perceived as expressing dominance, while personal messages sent during the day tend to be perceived as expressing affection [40]. Longer delays in returning mail may also be perceived as expressing lack of affection.

Entrainment, the process of linguistic and paralinguistic mirroring in dyadic communication, has generally been shown to be associated with more positive relational qualities [40]. This is likely in part because people are more comfortable when they perceive others as being like them [56]. When language shows high similarity in content, people are likely to show higher affiliation and trust. Even the use of similar tenses is associated with greater trust [55]. This suggests that coaches should try, within reason and within constraints established by the legitimacy principle, to mirror their clients in content and tone. Thus, a communication about future plans is best met with a question about those future plans. If it is met with questions about the past, it may be more likely to threaten trust. However, there are some limits to entrainment. For example, entrainment in expressions of negative emotions is associated with decreased trust.

While interactions via CMC have the potential to be more emotional, they also have the potential to be more carefully crafted. Users of asynchronous or text-based media often exploit the absence of cues to more purposefully craft their self-presentation [40]. People use more time to consider whether messages reflect the information and characteristics that they wish to convey. Users also may time self-revelations to manage and serve relational goals. Indeed, the very absence of multiple, simultaneous cues from a partner and lack of environmental stimuli can heighten attention to the targeted integration of socioemotional and task-oriented content. Thus, while CMC can allow patients to be more expressive, and potentially more disclosing, it also affords patients greater ability to engage in impression management. Because cues can take on greater significance in lean communications media, subtle indications from a coach could potentially have a strong effect in shaping the information and quality of patient communications.

While much of the research has examined ways in which the "hyperpersonal" effects of leaner communication media can positively influence communication, negative effects have also been noted. The lack of cues in leaner media means that communication is more effortful [40] and thus requires more time. When time is restricted, the likelihood of negatively interpreted responses increases. Furthermore, the positive bias that is present when beginning communication over lean media is coupled with the expectation of future interactions. These positive biases tend to vanish when there is no expectation of future interaction.

Perhaps because the positive bias is supported by greater reliance on less detailed information, the potential for information to affect the relationship negatively is also greater in lean media than in face-to-face communication. Negative communications, or communications that are perceived as not exhibiting sufficient trust, benevolence, and bond, may have a greater negative impact in leaner media than in face-to-face communications. But even cues that simply provide extraneous information have the potential to negatively affect relationships in lean media. For example, providing photographs of pairs of individuals engaged in long-term CMC reduces positive affect, compared to pairs of individuals who do not receive photographs of their communication partners [57].

Of course, people outside of controlled communications experiments are typically not constrained to communicate solely through one medium. Some of the findings described above may be exaggerated, since the experience of psychological closeness is likely to be enhanced when there are no alternatives to communicating via a lean medium, and may be reduced using a lean medium when other richer media are available [58]. People may also prefer some media over others for specific purposes. For example, media with less social presence are often preferred for more conflictual situations. In addition, people may use different media in sequences or combinations to accomplish certain goals. For example, email is often used to raise an issue prior to a telephone or face-to-face meeting. Thus, a choice of medium that is suboptimal by itself may make sense as part of a larger strategy.

Summary and Implications for Coaching

Part of the strength of leaner media appears to be the desire of users to have positive impressions of the person with whom they are communicating, and the ability to selectively manage the information and cues that are conveyed. This is believed to result in a “hyperpersonal feedback” effect, in which an idealizing receiver of a message sends a selectively positive message, which triggers a selectively positive message in return. Users of leaner media easily and naturally tend to behave in ways that meet their partner’s exaggerated interpersonal expectations. This positive bias also appears to rely on the interpolation of positive qualities when cues are absent. When those absent cues are filled with actual information, as in the case of photographs, the effect of the positive bias may be diminished. This suggests that coaches should avoid providing extraneous information or cues that are not carefully designed to meet the aims of the intervention.

The CMC literature provides a number of suggestions for shaping coach-patient relationships, particularly via leaner media such as email. First, people base initial judgments on limited cues, and the impact that these cues have in lean media is stronger than in richer media. Careful consideration of cue presentation prior to and in the initial stages of communication is warranted. Second, people tend to enter CMC with a positive bias toward interaction partners. In the absence of cues, people generally make positive assumptions about others. This suggests that in designing coaching interventions, investigators and developers should be judicious in releasing cues about coaches. Third, people are more willing to convey emotional information and disclose uncomfortable information via lean media than they are via richer media. This can be harnessed to facilitate discussion of difficult topics, and coaches should be made aware of this possible benefit of CMC to make interactions with patients more efficient. Fourth, people search for cues in lean media. Timing can become an important cue. Responses should be timely. Some CMC responses outside of normal working hours may be viewed as expressions of caring. Fifth, people feel more comfortable with people who are like them. Mirroring the content, style, and even tense of patient communications should be used to promote positive relational qualities. Sixth, CMC allows more time to craft messages. Patients will likely craft messages to please the coach. This tendency should be considered in coach communications. Seventh, leaner communications media sometimes require more time and effort to achieve goals. Coaches should anticipate investing their resources in light of this phenomenon. Eighth, if multiple media are used, the overall strategy should be considered. For example, if coaches can use both email and the telephone, it may be strategic to permit potentially difficult or embarrassing information to initially be provided via email, offer a sympathetic response email to underscore bond and the coach’s benevolence, and then follow up by telephone, which can provide greater social presence.

Conclusions

The effectiveness of and adherence to eHealth interventions is enhanced by human support [3,5]. Based on our review of the existing literature from organizational psychology, motivational theory, and CMC, we have developed a framework for understanding and constructing human support components of eHealth interventions. We call this model, displayed graphically in Figure 1, Supportive Accountability. Human factors, such as accountability, bond, and legitimacy, can potentially influence adherence to eHealth interventions. However, we posit that the effect of human factors is moderated by motivational factors, as well as the communications media used. This model is based on basic research, and therefore represents our best guess for what will be effective; however, the components of the model have not been tested in clinical interventions. This model and its components are described so as to be testable, with the aim of developing clearly defined, manualized, evidence-based human support programs. The refinement of such human support models has the potential to enhance effectiveness and adherence to eHealth intervention.

Acknowledgments

This study was supported by research grant R34 MH078922 from the National Institute of Mental Health to David C Mohr, PhD.

Conflicts of Interest

None declared

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Abbreviations

CMC: computer-mediated communication
RCT: randomized controlled trials

Edited by G Eysenbach; submitted 03.07.10; peer-reviewed by N Titov; comments to author 05.11.10; revised version received 05.12.10; accepted 26.01.11; published 10.03.11.

Please cite as:
Mohr DC, Cuijpers P, Lehman K
Supportive Accountability: A Model for Providing Human Support to Enhance Adherence to eHealth Interventions
J Med Internet Res 2011;13(1):e30
URL: http://www.jmir.org/2011/1/e30/
doi:10.2196/jmir.1602
PMID:21393123

Original Paper

Social Cognitive Determinants of Nutrition and Physical Activity Among Web-Health Users Enrolling in an Online Intervention: The Influence of Social Support, Self-Efficacy, Outcome Expectations, and Self-Regulation

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Abstract

Background: The Internet is a trusted source of health information for growing majorities of Web users. The promise of online health interventions will be realized with the development of purely online theory-based programs for Web users that are evaluated for program effectiveness and the application of behavior change theory within the online environment. Little is known, however, about the demographic, behavioral, or psychosocial characteristics of Web-health users who represent potential participants in online health promotion research. Nor do we understand how Web users' psychosocial characteristics relate to their health behavior—information essential to the development of effective, theory-based online behavior change interventions.

Objective: This study examines the demographic, behavioral, and psychosocial characteristics of Web-health users recruited for an online social cognitive theory (SCT)-based nutrition, physical activity, and weight gain prevention intervention, the Web-based Guide to Health (WB-GTH).

Methods: Directed to the WB-GTH site by advertisements through online social and professional networks and through print and online media, participants were screened, consented, and assessed with demographic, physical activity, psychosocial, and food frequency questionnaires online (taking a total of about 1.25 hours); they also kept a 7-day log of daily steps and minutes walked.

Results: From 4700 visits to the site, 963 Web users consented to enroll in the study: 83% (803) were female, participants' mean age was 44.4 years (SD 11.03 years), 91% (873) were white, and 61% (589) were college graduates; participants' median annual household income was approximately US $85,000. Participants' daily step counts were in the low-active range (mean 6485.78, SD 2352.54) and overall dietary levels were poor (total fat g/day, mean 77.79, SD 41.96; percent kcal from fat, mean 36.51, SD 5.92; fiber g/day, mean 17.74, SD 7.35; and fruit and vegetable servings/day, mean 4.03, SD 2.33). The Web-health users had good self-efficacy and outcome expectations for health behavior change; however, they perceived little social support for making these changes and engaged in few self-regulatory behaviors. Consistent with SCT, theoretical models provided good fit to Web-users' data (root mean square error of the approximation [RMSEA] < .05). Perceived social support and use of self-regulatory behaviors were strong predictors of physical activity and nutrition behavior. Web users' self-efficacy was also a good predictor of healthier levels of physical activity and dietary fat but not of fiber, fruits, and vegetables. Social support and self-efficacy indirectly predicted behavior through self-regulation, and social support had indirect effects through self-efficacy.

Conclusions: Results suggest Web-health users visiting and ultimately participating in online health interventions may likely be middle-aged, well-educated, upper middle class women whose detrimental health behaviors put them at risk of obesity, heart disease, some cancers, and diabetes. The success of Internet physical activity and nutrition interventions may depend on the extent to which they lead users to develop self-efficacy for behavior change, but perhaps as important, the extent to which these interventions help them garner social-support for making changes. Success of these interventions may also depend on the extent to which they provide a platform for setting goals, planning, tracking, and providing feedback on targeted behaviors.

(J Med Internet Res 2011;13(1):e28) doi:10.2196/jmir.1551

KEYWORDS

Internet users; dietary habits; physical activity; psychosocial aspects; self-efficacy; social support; self-regulation

Introduction

A high proportion (83% [1]) of Internet users go to the Web for information on health topics [1-3] including exercise (38% in 2008, up from 21% in 2002) and weight loss (33% in 2008). Although community, health system, and workplace health programs have effectively utilized the Internet for a wide array of behavior-change interventions, the reach of the Internet will be realized through the development of theory-based, purely online interventions for Web-health users [4,5]. Much work remains in developing sound methodology for testing the efficacy of programs delivered online [4].

Despite almost universal Internet access and adoption, researchers know little about Web-health users—the adults who go to the Web to find health behavior and behavior change information and who form the likely participant pool for online health promotion and disease prevention research. Overall, Internet users have been equally either male or female and have tended to be somewhat younger, better educated, and to have higher incomes than the general population [2,3]. Web-health users may be more likely to be female than general Internet users, and those going to the Web for health programs may have poor to fair general health [1]. To our knowledge there have been no studies examining the health behavior and related psychosocial characteristics of potential participants of entirely online health interventions.

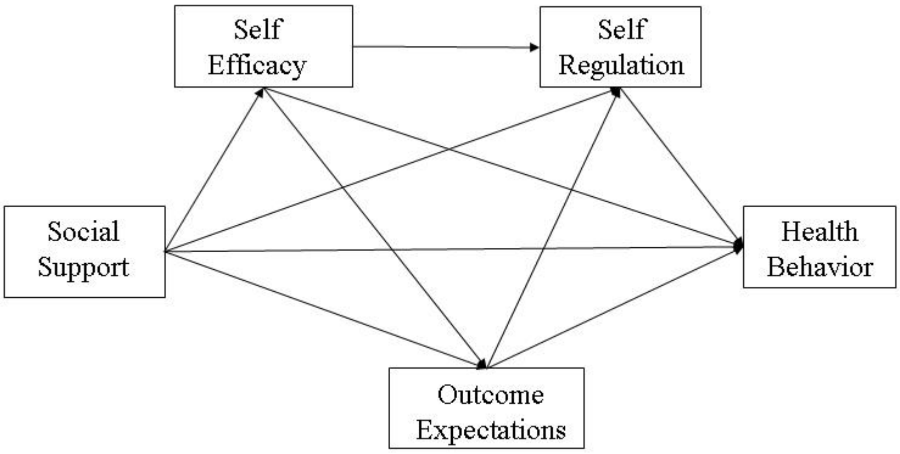
Generally, attrition in Internet-based health programs is high at 43% to 50% [5], but these figures pertain to participants in programs that use the Internet to deliver programs as part of workplace, primary care, or other community-based interventions. Little is known about how participants interact with stand-alone Web-based health programs, that is, programs that recruit, assess, and intervene entirely online, although early studies have suggested that attrition from such studies may be higher [4]. Similarly, Internet interventions in general tend to recruit many tentative users who attempt but quickly withdraw from programs, fewer short-term users who seem to drop out after using the program for a period, and few stable users who stick with a program over the long-term [6]. With some early evidence that rates of recruitment among Web users making contact with online programs may be low (eg, 8% in a study by Murray et al [4]), it is not clear how adoption or adherence patterns apply or if these patterns are related to participants' demographic, behavioral, or psychosocial traits.

In addition to reflecting potential participants' characteristics, Web-based health programs should be theory-based and evaluated to validate and refine the application of theory within the Web environment [7-14]. Social cognitive theory (SCT) [15,16] is widely used as the theoretical basis for health behavior change interventions [12] suggesting Internet health interventions must help individuals develop a sense of self-efficacy in specific behaviors (such as being physically active and eating nutritiously), which stems from physically and socially supportive environments and promotes individuals' positive expectations for behavior change. Higher levels of self-efficacy and expectations of positive outcomes lead to the modification or differential use of self-regulatory skills (ie, planning, self-monitoring, problem solving, self-standards, goals, and self-incentives) essential to maintaining behavior change (see Figure 1 for a schematic representation of SCT). Estimating the initial psychosocial characteristics of users is, therefore, essential to developing effective programs.

In previous research, self-efficacy has been associated with healthy nutrition [15,17-21] and physical activity [20,22,23] habits, as has social support from important others, such as family and friends [22,24-26]. Although outcome expectation has been found to contribute beyond self-efficacy to healthy eating habits [17-20], it has not been a consistent predictor of physical activity [27], with some studies suggesting strong support and others revealing a null effect [20,22]. Among people who desire a healthier lifestyle and who have access to healthy foods and infrastructure for physical activity, SCT suggests their success at maintaining behavior change will be determined largely by how well they set goals, plan, and monitor, that is, self-regulate such changes. Outside the obesity and weight-management literatures, self-regulation of nutrition has received scant attention and has often been poorly defined [28]. Nevertheless, self-regulatory behavior has been associated with healthier eating [10,19,22,29-33] and with promoting healthier activity levels in adults [20,22, 34].

The purpose of the present study was to examine the social cognitive determinants of nutrition and physical activity among Web-health users enrolling in a purely online SCT-based nutrition, physical activity, and weight-gain prevention intervention.

Figure 1. Social cognitive model of health behavior



Methods

Recruitment and Participants

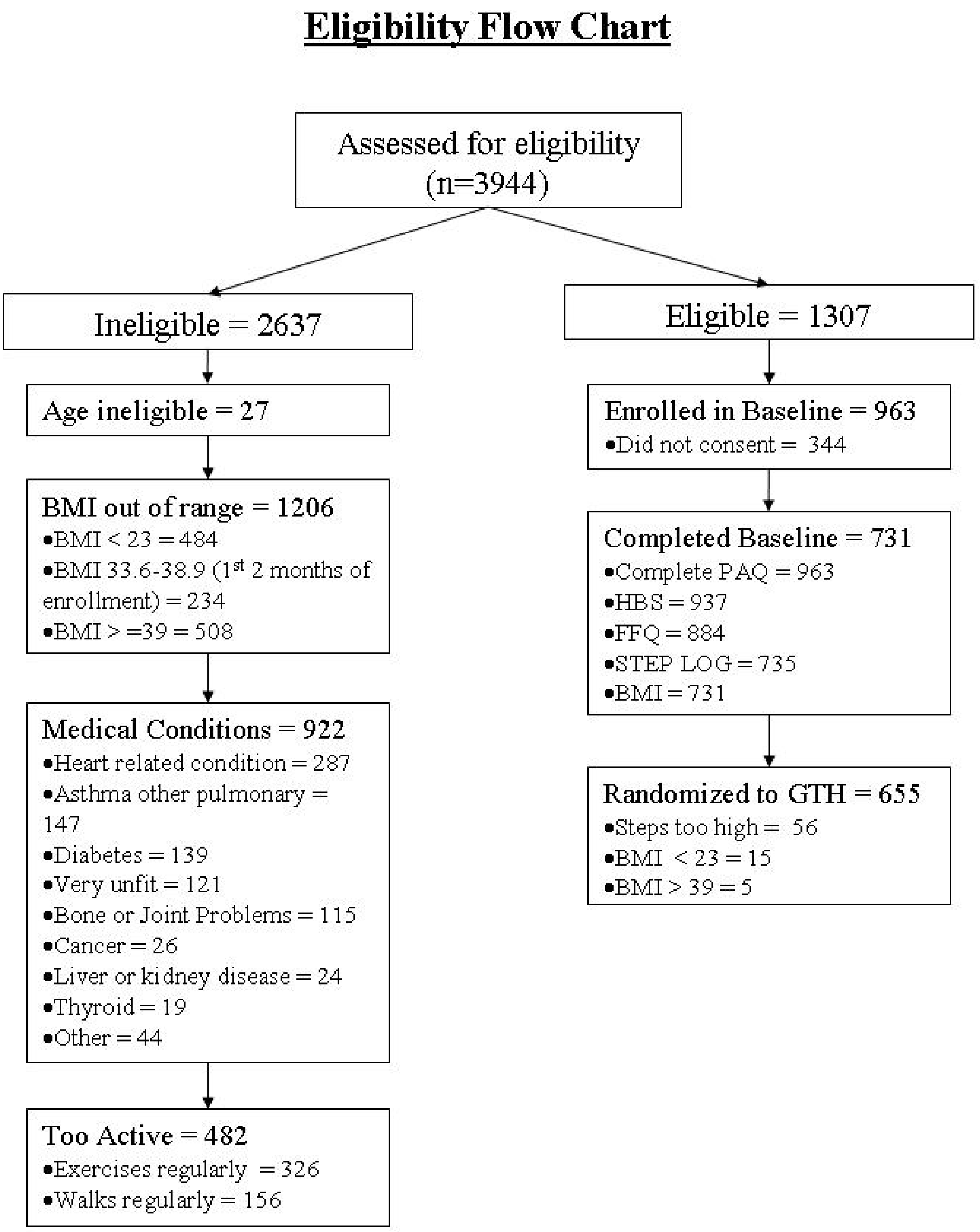
Web-health users were recruited entirely online for a clinical trial of the Web-based intervention called Guide to Health (WB-GTH) (clinical trials identifier NCT00128570). Advertisements in print and online newspapers in the major media markets of Virginia, Virginia Tech alumni publications, and online solicitations through employer and alumni-related listservs during 3 different time periods created 3 waves of recruitment: September 15, 2007 through January 23, 2008; May 8, 2008 through June 15, 2008; and July 9, 2008 through September 19, 2008. One month of Web-browser ads and 2 local direct mailings were used in wave 1 of the recruitment but yielded very few (ie, < 10) visits to the WB-GTH recruitment website. Print and online newspapers yielded some recruits, but the most effective recruitment strategy was through online alumni and employer publications and listservs. Advertisements and solicitations described the need for participants “18 to 63 years old, residing in the United States or Canada, within our weight guidelines, in good health, and not currently active” for an 18-month research project designed to test an Internet program for improving nutrition and physical activity and prevent weight gain. The Internet program was described as including a walking program “designed for you every step of the way,” a nutrition program “tailored to your needs and preferences,” and a “free pedometer and digital scale.” Preventing weight gain (not weight loss) was emphasized. Potential recruits were informed that involvement in the WB-GTH study would require them to log into the Internet program once a week for 18 months and to complete 3 two-hour assessments. Finally, recruitment materials advised potential participants that in order to be screened for study eligibility they would need to select a user id and password and provide an email address.

Approximately 4700 Internet users visited the WB-GTH site to review project information. About 15% (705) progressed no further than the GTH information page, but during the 3 recruitment waves, 3944 individuals registered for screening: 3024 during the first wave of recruitment, 364 during the second wave, and 556 during the third wave. Registering participants had a mean (SD) age of 42.54 years (12.05 years) and a mean (SD) body mass index of (BMI) of 30.81 (7.32) and were predominantly female (3311 or 84%). Based on self-report, of the 3944 individuals who registered, 88% (3454) were white, 6% (240) were African American; 4% (138) were Asian, and 3% (122) were other. In total, 3% (122/3944) reported Hispanic background.

Eligible Web Users

Of screened Web users, about one-third (1307) met eligibility requirements, that is, they were 18 to 63 years of age (or under 65 at the end of the trial), had high normal to obese BMI (ie, BMI 23 to 39, expanded from BMI 23 to 33 in wave 1, which was deemed unnecessarily stringent), were not currently active (ie, they did not exercise at least 20 minutes 3 times a week), but were otherwise healthy (see Figure 2). The WB-GTH program included a fitness walking component that encouraged participants to gradually move into more vigorous levels of walking exertion; hence, individuals with diagnosed coronary, metabolic or pulmonary disease, or coronary artery disease risk factors as specified by the American College of Sports Medicine [35] were excluded from the sample. Eligible participants had a mean (SD) age of 42.17 (11.17) and were predominantly female (1060 or 81%). Based on self-report, 90% (1177) of the 1307 eligible participants were white, 5% (71) were African American, 2% (21) were Asian, and 3% (38) were other. In total, 3% (34/1307) reported Hispanic background. Of the 1307 eligible Web users, 15% (203) were normal weight (BMI 23 to 24.99), 41% (532) were overweight (BMI 25 to 29.99), 33% (433) were mildly obese (BMI 30 to 34.99), and 11% (139) were obese (BMI 35 to 39.99).

Figure 2. Social cognitive model of fiber, fruits and vegetables among web-health users. * $P < .05$, ** $P < .01$, *** $P < .001$



Ineligible Web Users

Of Web users screened for the project, two-thirds (2637/3944) did not qualify. A small proportion had overlooked the age requirements listed on the information webpage and were either too old for the research project (n = 24) or declined to provide their ages (n = 3). Almost half of ineligible users did not meet the study's weight requirements (1206/2637, 46%). The WB-GTH was designed for adults in the high normal to obese weight range so some screened participants were below the weight guidelines (BMI < 23, n = 464), but most who were ineligible were too heavy (n = 742). (As noted above, the BMI cutoff of > 32.9 was modified to BMI ≥ 39 during wave 1 recruitment). A total of 36% (1404/3944) of those who registered were excluded because of medical conditions (n = 922) or because they were too active (n = 482) (see Figure 2 for details). The mean age of ineligible Web users was 42.75 years (SD 12.45 years), similar to eligible users ($F_{1,3942}$ = 2.40, P = .12), but ineligible recruits were more likely to be female (85% vs 81%, χ^2_1 = 11.88, P = .001) and of nonwhite race/ethnicity (13.6% vs 10%; $\chi^2_5 = 26.05$, $P < .001$). Although ineligible users were heavier than those who were eligible with a mean (SD) BMI of 31.36 (8.49) versus a mean (SD) BMI of 29.5 (4.13) ($F_{1,\ 3915} = 62.87$, $P < .001$), the entire range of weights were represented in the ineligible sample, that is, 18% (477) of the 2637 ineligible Web users had a BMI less than 23, 8% (200) had a BMI from 23 to 24.99, 22% (593) had a BMI from 25 to 29.99, 20% (527) had a BMI from 30 to 34.99, 15% (387) had a BMI from 35 to 39.99, and 17% (453) had a BMI ≥ 40.

Measures

Participants completed demographic information, physical activity, and psychosocial questionnaires on the WB-GTH website, requiring about 35 minutes. Next, participants were redirected from the WB-GTH site to the NutritionQuest website where they completed the Block 2005 Food Frequency Questionnaire (FFQ), which required from 30 to 40 minutes. Following each participant's completion of the FFQ, project staff sent the participant a digital bathroom scale and a pedometer for tracking daily steps taken for 1 week, as described below. Participants were sent 2 email reminders after each assessment component if they did not return to complete the next component within 7 days of the possible completion date.

Nutrition

Web-health users completed the Block 2005 FFQ (NutritionQuest, Berkeley, CA) [36] online. FFQ estimates of intake of daily total fat, percent kcal from fat, daily total fiber, daily fiber grams from beans, daily fiber from fruits and vegetables, daily servings of fruits, daily servings of vegetables, and daily servings of fruits and vegetables combined were examined.

Physical Activity

Web-health users used a pedometer (Yamax Digi-walker SW-200, San Antonio, TX) and completed a 7-day walking log provided by the project to record their daily steps taken and their daily minutes walked for exercise. They were to return to the WB-GTH website at the end of 10 days to allow for delivery time and to report at least 4 days of daily steps and minutes walked. The mean (SD) number of days at which participants returned was 15.90 days (6.98 days) excluding 6 participants who began their logs more than 60 days after the logs had been sent. The mean (SD) days of daily steps and minutes walked participants reported at this time was 6.09 days (1.20 days). Mean daily steps and mean daily minutes walked (total steps or total minutes/days recorded) were examined.

Social Cognitive Variables

The Health Beliefs Survey (HBS) [19,20], administered online, measured baseline nutrition- and physical activity-related social support, self-efficacy, outcome expectations, and self-regulation (see Table 1).

Table 1. Health Beliefs Survey: Scale descriptions and internal consistency estimates of social cognitive measures

Variable Description and Subscale	Number of Items	Cronbach Alpha[a]
Food beliefs survey		
Social support		
Family	8	.89
Friends	7	.88
Self-efficacy		
Eating healthy foods	16	.91
Avoiding high fat and high sugar foods	6	.83
Planning and tracking intake	10	.96
Positive physical outcome expectations	7	.89
Negative social outcome expectations	5	.72
Negative self-evaluative outcome expectations	7	.66
Self-regulation		
Planning and tracking	11	.91
High fat and high sugar foods	13	.90
Healthy food choices	8	.90
Physical activity beliefs survey		
Social support		
Family	8	.94
Friends	8	.96
Self-efficacy to face social, emotional, logistical barriers	22	.95
Outcome expectations		
Positive physical outcome expectations	7	.89
Positive self-evaluative outcome expectations	10	.89
Negative social outcome expectations	6	.85
Self-regulation		
Set goals and plan physical activity	9	.91
Track physical activity	5	.85
Increase physical activity enjoyment	3	.77

[a] Coefficient of internal consistency

Statistical Analysis

Latent-variable structural equation modeling (SEM) with LISREL 8.8 (Scientific Software International, Inc, Lincolnwood, IL) [37] assessed the extent to which SCT variables contributed to the nutrition and physical activity behavior of Web users interested in participating in a Web-based nutrition, physical activity, and weight gain prevention intervention. Model fit was evaluated with the Normed Fit Index (NFI) and Nonnormed Fit Index (NNFI) > .90, root mean square error of the approximation (RSMEA) < .05 (*P* close fit > .05). Chi-square was not used in deference to the large sample size. Latent variables were measured with scores from the FFQ, HBS, and the 7-day walk log. With few exceptions, the distributions of measure scores were skewed or displayed unacceptable kurtosis; measures were normalized using the Blom proportional estimate formula in SPSS version 17.0 (SPSS Inc, Chicago, IL). Additional variables were similarly normalized to retain a consistent unit of measurement within latent variables.

Results

Enrolled Participants

Of 1307 Web users eligible to participate in the WB-GTH baseline assessment phase, 963 (74%) consented to become part of the study. Eligible Web users took an average of about 1 day (mean 1.38 SD 4.51) to enroll and to consent to become part of the study, but this ranged from 1 to 52 days.

Of the 1307 eligible users, 26% (344) either failed to complete consent procedures going no further in the online enrollment process (n = 297) or clicked and confirmed the box “I decline to be part of the study” that was available on all pages of the online consent form (n = 47). Participants who did not consent did not differ in age, racial/ethnic background, gender, or BMI from those who did consent to participate in the study (alpha = .05).

Enrolled Web-health participants had a mean (SD) age of 44.40 years (11.03 years), 83% (803/963) were female, and 91% (873/963) were white. The sample was well educated: participants had completed a mean (SD) of 17.08 (3.3) years of education. Participants also had a median annual household income of about US $85,000, 83% (803/963) were overweight or obese, and 69% (507/735) of those completing the 7-day walk log had step counts in the sedentary to inactive range (ie, < 7500 steps/day). The average (SD) number of steps per day among participants was 6480.31 (2350.86). Most participants lived in the United States, but a small number (42) were Canadian residents. Although 51% (488/963) of participants lived in Virginia, the research location, most states were represented in the study (no participants lived in South Dakota, Louisiana, Rhode Island, or Iowa).

Of the 963 Web users participating, 731 completed all components of the baseline assessment in 11 to 135 days. The average (SD) number of days to completion of the baseline assessment was 22.83 (12.62) days. Although the assessment was designed to be completed across 8 days (1.25 hours online, plus the 7-day walking log), only a small percentage followed the prescribed timeline; 95% (694) completed the assessment within 45 days of enrollment. There were no demographic, social cognitive, or nutritional differences between participants with all assessment components and those without, with one exception. Participants who dropped out of the study prior to completion appeared to have slightly lower self-efficacy for making changes in their nutrition behavior that those who completed. Among those who dropped out during the assessment, the mean (SD) self-efficacy score for avoiding high fat and high sugar foods was 67.83 (22.19) versus 71.97 (19.49) among those who did not drop out ($F_{935,1} = 5.06$, $P = .03$) and the mean (SD) self-efficacy score for tracking nutrition was 79.61 (22.63) among those who dropped out versus 82.87 (17.04) among those who did not ($F_{935,1} = 6.79$, $P = .009$).

Nutrition Characteristics of Web-Health Users

Fat, Fiber, Fruit, and Vegetable Consumption

Table 2 contains the means and standard deviations of Web users' consumption of fat, fiber, and fruit and vegetable servings. Overall, Web users' dietary consumption was higher in fat and lower in fruits, vegetables, and dietary fiber than recommended. Most, 56% (494/884), consumed more than the generally recommended 65g of total fat/day, 36% (322/884) reported consuming more than 80g of total fat/day, and almost 20% (172/884) reported consuming more than 100g of total fat/day. Only 13% (115/884) of Web-health users consumed the recommended level of 30% or fewer calories from fat; 78% (690/884) reported getting more than half their calories from fat. Similarly, 13% (115/884) of users met recommended levels of fiber intake (ie, at least 25 g/day); 68% (601/884) reported consuming fewer than 20g of fiber/day. Web-users reported somewhat better levels of fruit and vegetable consumption compared with consumption of fiber and fat with 29% (256/884) of participants consuming the recommended level of at least 5 servings/day and almost half consuming at least 4 servings but the remaining users consuming 3 or fewer servings/day.

Nutrition-Related Social Cognitive Characteristics

Participant means and standard deviations on the Food Beliefs Survey section of the HBS are reported in Table 2. Web-health users' responses to the nutrition social support items suggested that they perceived their family members and friends as being fairly neutral in their support of healthier food choices (ie, scores just under 3 on the 5-point Likert-type scale). Web-health users had positive, but not complete, confidence in their ability to eat healthier foods, avoid high fat and high sugar foods, and keep track of their food choices (ie, scoring 71 to 82 on the 100-point Self-efficacy scale). They seemed to agree that their physical health (eg, weight, blood pressure, and appearance) would improve with healthier food choices (ie, scoring on average 4.3 on a 5-point Positive Physical Outcome Expectations scale). Participants were less concerned (ie, scoring on average approximately 2.9 on each 5-point scale), however, that such changes would result in negative social and self-evaluative outcomes (eg, having less time and energy for others and other activities and dissatisfaction with healthier foods).

Table 2. Nutrition and physical activity behavior and social cognitive characteristics of inactive but otherwise healthy adults enrolling in a Web-based health promotion intervention trial

	Mean	SD	Range
Nutrition characteristics			
Total fat per day	77.79	41.96	19.20 -249.82
Percent kcals from fat	36.51	5.92	17.13 - 60.71
Total fiber g/day	17.74	7.35	1.11 - 44.91
Fiber from beans g/day	2.36	2.04	0 - 18.34
Fiber from fruits and vegetables g/day	6.95	4.12	0.10 - 29.55
Vegetables servings/day	2.95	1.85	0.02 - 12.87
Fruit servings/day	1.08	0.80	0.01 - 4.73
Fruit and vegetables servings/day	4.03	2.33	0.04 – 12.47
Family social support	2.71	0.85	1 - 5
Friends social supports	2.85	0.79	1 - 5
Self efficacy: eating healthy foods	76.18	17.46	9.38 - 100
Self efficacy: tracking nutrition	82.16	18.46	0 - 100
Self efficacy: avoid high fat and high sugar foods	71.06	20.18	11.33 - 100
Positive physical outcome expectations	4.33	0.61	1 - 5
Negative self-evaluative outcome expectations	2.89	0.78	1 - 4
Negative social outcome expectations	2.93	0.84	1 - 4
Self-regulation of eating healthy food choices	2.72	0.83	1 - 5
Self-regulation of high fat and high sugar foods	2.97	0.81	1 - 5
Planning and tracking nutrition choices	1.99	0.86	1 - 5
Physical activity characteristics			
Steps per day	6485.78	2352.54	605.40 - 18,629.43
Minutes walked for exercise per day	13.19	12.80	0 - 70
Family social support	2.43	1.04	1 - 5
Friends social support	2.80	0.96	1 - 5
Self efficacy in face of barriers	64.61	19.57	9 - 100
Positive self-evaluative outcome expectations	17.25	4.69	1 - 25
Positive physical outcome expectations	20.56	4.57	1 - 25
Negative social outcome expectations	10.51	4.93	1 - 25
Set goals and plan physical activity	2.01	0.80	1 - 5
Increase physical activity enjoyment	1.79	0.83	1 - 5
Track physical activity	1.53	0.70	1 - 5

Finally, Web-health users indicated they had never-to-seldom (rated 1 and 2, respectively, on the Self-regulation scale) planned or tracked healthier food choices in the 3 months before the assessment (eg, keep track of high fat snacks or plan to eat fruit for breakfast). They reported that they occasionally (rated 3 on the scale) did things to reduce fat and sugar and increase healthier food choices (eg, drink water instead of sodas or eat fruit for dessert).

Physical Activity Characteristics of Web-Health Users

Daily Step Counts and Minutes Walked

The Web users in the study were selected based on self-reports of exercising less than 20 minutes 3 times a week in the month preceding the assessment.

Daily Steps

Among the inactive participants, average steps logged over 7 days fell within the low active range [38] (see Table 2); 27% (198/735) of the Web-health users took fewer than 5000 steps/day, 42% (309/735) took 5000 to 7499 steps/day, 24%

(228/735) took 7500 to10,000 steps/day, and 8% (56/735) took more than 10,000 steps/day.

Daily Minutes Walked for Exercise

Web-health users logged an average of less than a quarter of an hour in daily walking (see Table 2); 41% (299/735) logged virtually no walking (< 3 minutes/day). On the other hand, 22% of the sample logged 20 minutes or more/day in walking (169/735).

Physical Activity-Related Social Cognitive Characteristics

Participants' means and standard deviations from the Physical Activity Beliefs Survey portion of HBS can be found in Table 2. Web users interested in a program to help them become more active generally did not perceive their friends and family members as taking steps to being physically active themselves (ie, social support scores of < 3.0 on the 5-point scale). Physical-activity self-efficacy scores indicated that Web-health users had some confidence in their ability to increase physical activity in the face of social, emotional, and logistical barriers (ie, the mean score was about 65 on a 100-point scale). Within the self-efficacy items on the Physical Activity Beliefs Survey, however, participants' responses varied. Compared to Web-users' higher mean (SD) score of 80.02 (19.75) on items regarding managing a walking routine (ie, keeping track of walking, making plans to exercise, and resuming walking after a break), their mean (SD) score of 54.75 (23.52) indicated they were less confident in their abilities to deal with the social aspects of becoming more active (ie, finding someone to walk with, exercising when family wanted more time, or socializing only after meeting exercise goals) ($t_{936} = –40.38$, $P < .001$).

Web-health users expected that increasing physical activity would result in health benefits (ie, their mean score was 21 on a 25-point Positive Physical Outcome Expectations scale) and would be good for their mental and physical state (ie, their mean score was 17 on a 25-point Positive Self-evaluative Outcome Expectations scale). Participants were more neutral in their expectations that being more active would interfere with the time they would have for others and other activities (ie, a mean score of 10 on the 25-point Negative Social Outcome Expectations scales).

Overall, Web-health users indicated they had never or seldom (rated 1 and 2 on the scale, respectively) implemented physical activity self-regulation strategies in the 3 months before the assessment (see Table 2). The Web-health users did not track their physical activity (ie, frequency, duration, or intensity of exercise) but were more likely to set goals and plan for being physically active ($t_{936} = 26.66$, $P < .001$)

Social Cognitive Determinants of Web Users' Nutrition and Physical Activity Levels

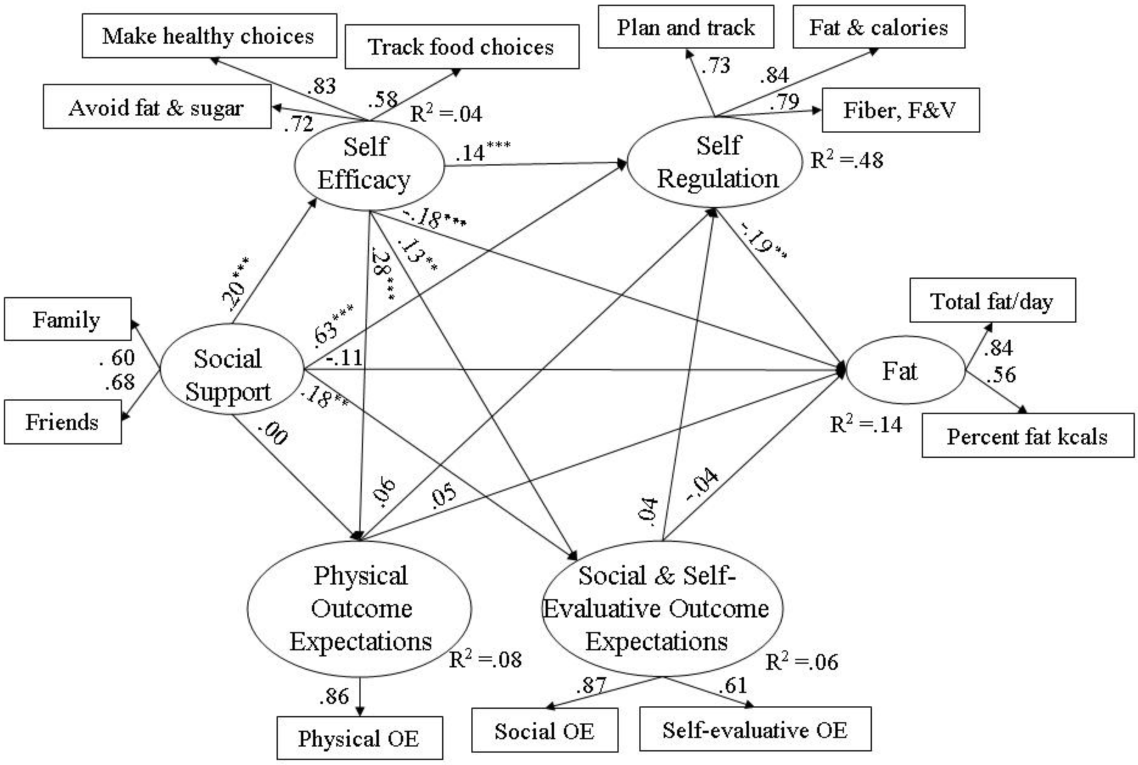
Nutrition Models

Structural equation analyses evaluated behavioral and social cognitive variables simultaneously to determine how well the SCT models of fat (see Figure 3) and of fiber, fruits, and vegetables (see Figure 4) fit the data collected from the Web-health users. Fit was good for each model; specifically, for the fat model, RMSEA = .045 (95% confidence interval [CI] .04 - .05), *P* (close fit) = .80, NFI = .97, and NNFI = .97. For the fiber, fruit and vegetables model fit indicators were RMSEA = .048 (95% CI .04 - .06), *P* (close fit) = .66, NFI = .97, and NNFI = .96. The SCT models differed in the amount of variance each explained, which was 14% of fat intake, 22% of fiber intake, and 36% of fruits and vegetables intake. The completely standardized parameter coefficients associated with direct effects of the latent variables in the models are illustrated in Figures 3 and 4. A variable's direct effect is the portion of its total effect that is independent of other variables in the model; a variable's indirect effect is the portion of its total effect that is dependent on other variables (covariance matrices and factor loadings associated with the analyses are available from author EA).

Social Support and Dietary Intake

Social support from friends and family made a strong contribution (ie, $\text{beta}_{\text{total}} > .20$ [39]) to healthier nutrition: Web users who perceived that important others were attempting healthier eating had lower levels of fat ($\text{beta}_{\text{total}} = -.28$, $P < .001$) and higher levels of fiber ($\text{beta}_{\text{total}} = .25$, $P < .001$) and fruits and vegetables ($\text{beta}_{\text{total}} = .34$, $P < .001$). The total effect of social support on Web-health users' fat intake was largely indirect ($\text{beta}_{\text{indirect}} = -.17$, $P < .001$, indirect/total ratio = .68) through social support's effect on other model variables influencing fat levels (ie, self-efficacy, $\text{beta}_{\text{total}} = .20$, $P < .001$ and self-regulation, $\text{beta}_{\text{total}} = .67$, $P < .001$). On the other hand, the effect of social support on fiber and fruits and vegetables was entirely indirect (fiber, $\text{beta}_{\text{indirect}} = .34$, $P < .001$, indirect/total ratio = 1.36 and fruits and vegetables, $\text{beta}_{\text{indirect}} = .42$, $P < .001$, indirect/total ratio = 1.23) through self-efficacy ($\text{beta}_{\text{total}} = .17$, $P < .001$) and self-regulation ($\text{beta}_{\text{total}} = .65$, $P < .001$). The large positive indirect effects of social support counteracted small, insignificant negative direct effects on fiber, fruit, and vegetable consumption (see Figure 4).

Figure 3. Social cognitive model of fat consumption among Web-health users where * signifies *P* < .05, ** signifies *P* < .01, and *** signifies *P* < .001



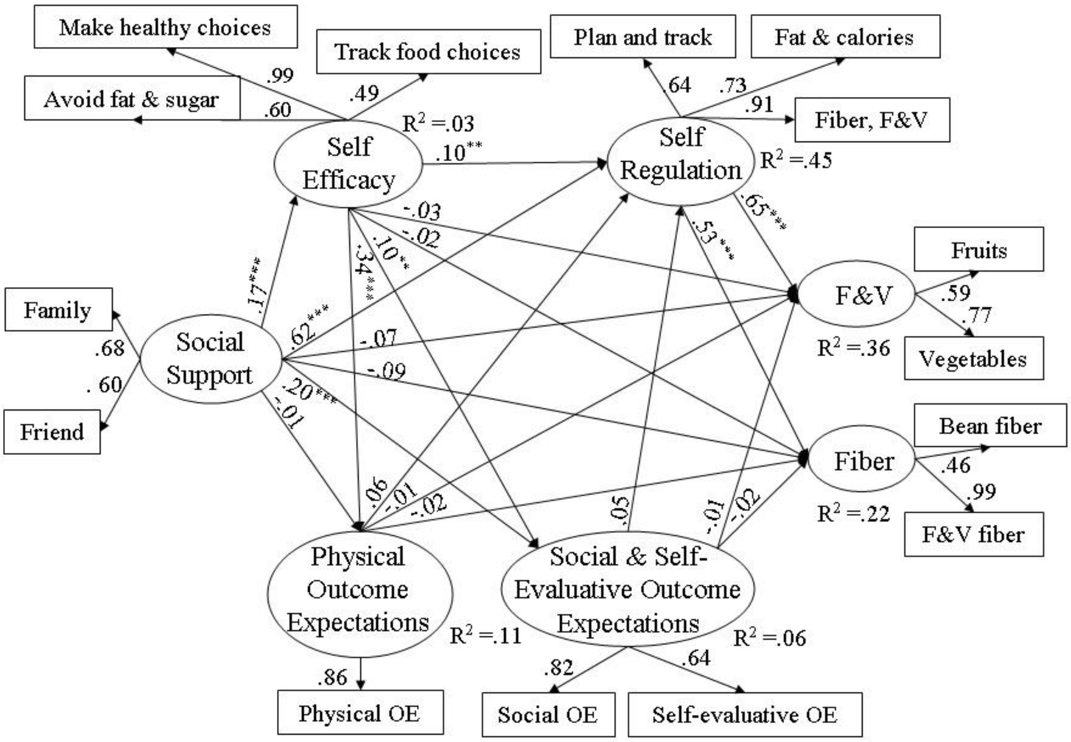
Self-efficacy and Dietary Intake

Fat intake was also strongly associated with self-efficacy; Web-health users with higher confidence in their ability to make healthier food choices, plan and track food intake, and avoid high fat and high sugar foods reported lower levels of fat on the FFQ (beta $_{total}$ = -.21, *P*< .001). Self-efficacy did not influence Web users intake of fiber (beta $_{total}$ = .05, *P* = .27) and fruits and vegetables (beta $_{total}$ = .05, *P* = .23). Although self-efficacy influenced outcome expectations (negative outcome expectations, beta $_{total}$ = .13, *P* = .006; positive outcome expectations, beta $_{total}$ = .28, *P*< .001) and self-regulation (beta $_{total}$ = .16, *P*< .001) in the fat model, the effect of self-efficacy on fat intake was largely direct (ie, beta $_{indirect}$ = -.02, *P* = .25; indirect/total ratio = .10).

Outcome Expectations and Dietary Intake

Negative and positive outcome expectations did not exert total effects on the content of Web users' food intake. This was true for fat (negative outcome expectations, beta $_{total}$ = -.04, *P* = .37; positive outcome expectations, beta $_{total}$ = .03, *P* = .47), fiber (negative outcome expectations, beta $_{total}$ = .01, *P* = .87; positive outcome expectations, beta $_{total}$ = .02, *P* = .59) and fruits and vegetable (negative outcome expectations, beta $_{total}$ = .02, *P* = .66; positive outcome expectations, beta $_{total}$ = .03, *P* = .60). Outcome expectations also did not influence self-regulation as hypothesized by the SCT model (see Figures 3 and 4).

Figure 4. Social cognitive model of fiber, fruit, and vegetable consumption among Web-health users where * signifies $P < .05$, ** signifies $P < .01$, and *** signifies $P < .001$



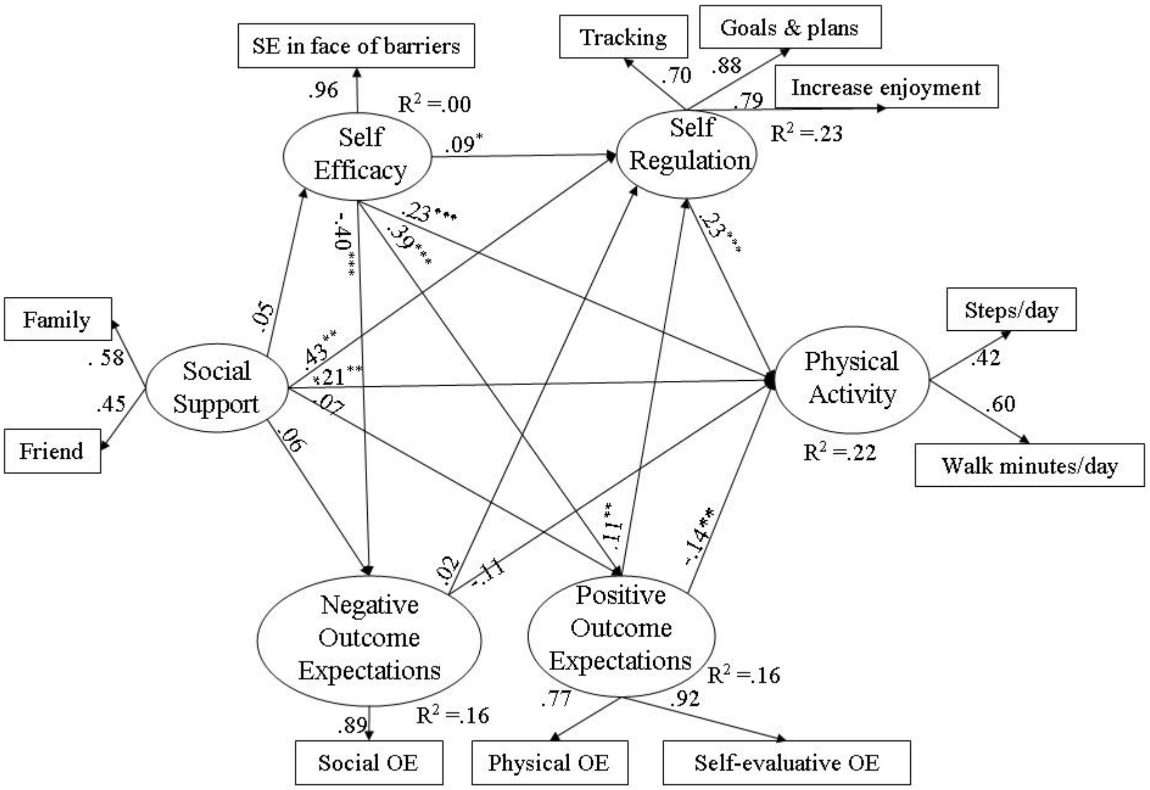
Self-regulation and Dietary Intake

Enactment of self-regulatory behaviors was a moderate (ie, beta = .10 - .19) predictor of Web-health users' fat intake and a strong predictor of fiber, fruits, and vegetable consumption. Planning and tracking and using strategies to increase healthy food choices and to avoid high fat and sugar foods led to lower levels of fat (beta$_{total}$ = -.19, $P = .008$), higher levels of fiber (beta$_{total}$ = .53, $P < .001$), and higher levels of fruits and vegetables (beta$_{total}$ = .65, $P < .001$) in Web-health users' food intake.

Physical Activity Model

Structural equation analyses indicated good fit of the SCT model to physical activity data from Web-health users with fit indicators of RMSEA = .029 (95% CI .01 - .04), P (close fit) = .99, NFI = .98, and NNFI = .99. The SCT model explained 22% of the variance observed in physical activity levels. The completely standardized parameter coefficients associated with direct effects of the latent variables in the models are displayed in Figure 5.

Figure 5. Social cognitive model of physical activity among Web-health users where * signifies $P < .05$, ** signifies $P < .01$, and *** signifies $P < .001$



Social Support and Physical Activity

Social support from friends and family contributed substantially to Web-health users' physical activity levels (beta $_{\text{total}}$ = .30, *P* < .001), an effect that was partly indirect through self-regulation (beta $_{\text{indirect}}$ = .10, *P* < *.001*, indirect/total ratio = .33). Although social support did not influence self-efficacy (beta $_{\text{total}}$ = .05, *P* = .37) or outcome expectations (negative outcome expectations, beta $_{\text{total}}$ = .04, *P* = .48; positive outcome expectations, beta $_{\text{total}}$ = .09, *P* = .10), social support was strongly predictive of whether Web users engaged in self-regulatory behavior (beta $_{\text{total}}$ = .45, *P* < .001). Participants who perceived support from their friends and families for physical activity were more likely to set goals, plan, and self-monitor their own activity levels. The effect of social support on self-regulation was largely direct (beta $_{\text{indirect}}$ = .02, *P* = .10, indirect/total ratio = .04)

Self-efficacy and Physical Activity

Web-health users with greater confidence in their abilities to manage the social, emotional, and logistical barriers to walking on a regular basis were more active; this strong effect was almost entirely direct (beta $_{\text{total}}$ = .25, *P* < .001; beta $_{\text{indirect}}$ = .02, *P* = .49; indirect/total ratio = .08). In addition to physical activity, self-efficacy moderately influenced self-regulation (beta $_{\text{total}}$ = .13, *P* < .001) and was a strong predictor of outcome expectations in the model (negative outcome expectations, beta $_{\text{total}}$ = -.40, *P*< .001; positive outcome expectations, beta $_{\text{total}}$ = .39, *P* < .001). Participants with confidence in their abilities to maintain an active lifestyle were more likely to expect to reap the benefits from becoming more active and were more likely to engage in self-regulatory behavior.

Outcome Expectations and Physical Activity

As in the nutrition models, outcome expectations did not exert total effects on Web users' physical activity (negative outcome expectations, beta $_{\text{total}}$ = -.11, *P* = .09; positive outcome expectations, beta $_{\text{total}}$ = -.11, *P* = .10). Positive outcome expectations (physical and self-evaluative), however, did have a significant but negative direct effect on physical activity (beta $_{\text{direct}}$ = -.14, *P* = .02, which was somewhat counterbalanced by a small, positive indirect effect (beta $_{\text{indirect}}$ = .03, *P* = .06) through positive outcome expectations' effects on self-regulation (beta $_{\text{total}}$ = .11, *P* = .007).

Self-regulation and Physical Activity

Enactment of self-regulatory behaviors was a strong predictor of Web-health users' physical activity. Setting activity goals and making plans, adjusting routines to make activity more enjoyable, and tracking daily activity led to higher levels of walking (beta $_{\text{total}}$ = .23, *P* = .003).

Discussion

Web-health users visiting and ultimately enrolling in an entirely online nutrition, physical activity, and weight gain prevention intervention study (WB-GTH) were generally middle-aged, well-educated, upper middle class women whose poor diet and exercise habits put them at risk of obesity, heart disease, some cancers, and diabetes. Nutrition and physical activity behavior among the Web users when they enrolled was predicted by the support they perceived from others for healthier behavior, the extent to which they used self-regulatory strategies essential to maintaining a healthy lifestyle, and, to a certain extent, their self-efficacy for making healthier choices.

Designed for inactive but otherwise healthy Web users, the WB-GTH website attracted almost 4700 participants over 12 months of recruitment. Participants were directed to the site by advertisements through print and online media and online social and professional networks. A high percentage of those visiting the site (3944 or 84%) registered to see if they were eligible for the study. As observed in a national sample of Web-health users [1], registered WB-GTH users were largely middle-aged, non-Hispanic white, and female. For the parent study, elderly, unhealthy, and morbidly obese adults were excluded from the sample; it appears exclusionary criteria may have disproportionately eliminated non-white participants, perhaps reflecting higher rates of obesity and disease in the African American population [40]. Thus the long-term commitment, evaluation components of the research, and the eligibility criteria required for enrollment in the study limit the external validity of these findings.

The number of eligible registrants remaining in the sample shrank at each step of the enrollment and assessment process consistent with patterns described in earlier studies [4,6]. Among 1307 registrants who met eligibility requirements, about one-quarter (344) declined to participate in the study. Although only minimal information was collected from participants prior to consent, those who did not consent did not differ in age, racial/ethnic background, gender, or BMI from those who did consent to participate in the study. Consistent with the pool of registered Web users, most of the 963 users consenting to participate in the WB-GTH trial and most of the 731 users who completed all assessment components were female and non-Hispanic white. They were also well educated with at least some college education and were upper-middle class with a median annual household income of about US $85,000, consistent with other Web-based nutrition trials [41]. Reflecting the study's inclusion criteria, the resulting sample was overweight or obese with step counts generally in the sedentary to inactive range (ie, < 7500 steps/day). Further, the vast majority did not meet guidelines for intake of fat, fiber, and fruit and vegetables.

In light of their detrimental nutrition and physical activity behaviors, Web-health users exhibited comparatively high levels of self-efficacy for making changes and of expectations that changes would have health benefits. The juxtaposition of high efficacy and expectations with low levels of healthy behavior is common. Bandura [4] suggests that self-efficacy for behavior change can be unrealistically high among individuals who lack experience in the desired, healthier behavior. Similarly, Polivy and Herman [42] have posited a false hope syndrome, which might suggest that recruits for a health-promotion intervention may be unrealistic about the benefits of behavior change (as suggested by the inverse direct relation of high positive expectations and physical activity here). Web users' lower confidence in managing the social aspects of becoming more active, their lower levels of perceived social support for behavior change, more neutral social outcome expectations, and virtual lack of self-regulatory behaviors related to making healthy changes are more consistent with the inactivity and unhealthful diets observed in the sample. This suggests that for Web-health users who may typically have low levels of health-promoting behaviors, SCT-based interventions may temper users' pre-intervention self-efficacy levels.

The SCT-based structural equation models testing the relations among SCT variables and behavior provided good fit to the Web-health users' nutrition and physical activity data (RMSEA < .05). Consistent with other research, perceived social support and engaging in self-regulatory behaviors exerted strong influences on physical activity and nutrition behavior [20,22]. Higher levels of self-efficacy also contributed to physical activity and lower dietary fat but not to higher levels of fiber, fruits, and vegetables among Web-health users. Outcome expectations did not exert a total effect on users' nutrition behavior or physical activity. SCT interventions, then, may be more successful to the extent they help Web-health users garner support for making changes from significant others. Improved social support and subsequent increases in self-efficacy could lead directly to improvements in physical activity and nutrition behavior but would also be effective pathways for increasing the use of self-regulatory strategies essential to healthy levels of activity and food choices. Among Web-health users, even small increases in self-regulatory behaviors could be expected to have substantial impact on dietary and physical activity behaviors. Providing a platform for setting behavioral goals, planning, tracking, and providing feedback would be a considerable strength of automated, self-administered Internet-based health promotion programs.

Acknowledgments

This project was supported by a grant from the National Cancer Institute (1R01CA106250-01A) to Virginia Tech (clinical trials identifier NCT00128570). We thank Ashley Dorough, MS, for her involvement in piloting and refining measurements and Sheila G Winett, Todd Bowden, and Shane Moore of Personal Computer Resources, Inc for programming and managing the Web-based components of the study.

Conflicts of Interest

None declared

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Edited by G Eysenbach; submitted 19.04.10; peer-reviewed by R Cook, A Suppini, D Apap; comments to author 23.06.10; revised version received 25.06.10; accepted 28.07.10; published 17.03.11.

Please cite as:
Anderson-Bill ES, Winett RA, Wojcik JR
Social Cognitive Determinants of Nutrition and Physical Activity Among Web-Health Users Enrolling in an Online Intervention: The Influence of Social Support, Self-Efficacy, Outcome Expectations, and Self-Regulation
J Med Internet Res 2011;13(1):e28
URL: http://www.jmir.org/2011/1/e28/
doi:10.2196/jmir.1551
PMID:21441100

Original Paper

Cancer Survivorship in the Age of YouTube and Social Media: A Narrative Analysis

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Abstract

Background: As evidenced by the increasing popularity of YouTube (www.youtube.com), personal narratives shared through social media are an area of rapid development in communication among cancer survivors. Identifying the thematic and linguistic characteristics of YouTube cancer stories can provide a better understanding of this naturally occurring communication channel and inform social media communication efforts aiming to use personal stories to reach individuals with serious illnesses.

Objective: The objective of our study was to provide an in-depth description of authentic personal cancer stories. Through a linguistically based narrative analysis of YouTube stories, the analysis explicates the common attributes of these narratives.

Methods: Informed by narrative theories, we conducted an iterative, bottom-up analysis of 35 YouTube videos identified by the search terms “cancer survivor” and “cancer stories”. A list of shared thematic and linguistic characteristics was identified and analyzed.

Results: A subnarrative on the cancer diagnosis was present in 86% (30/35) of the stories under analysis. These diagnostic narratives were characterized by dramatic tension, emotional engagement, markers of the loss of agency or control, depersonalized reference to the medical personnel, and the unexpectedness of a cancer diagnosis. The analysis highlights the themes of story authenticity and emotional engagement in this online communication medium.

Conclusions: Internet advances have enabled new and efficient exchange of personal stories, including the sharing of personal cancer experience among cancer survivors and their caregivers. The analytic results of this descriptive study point to the common characteristics of authentic cancer survivorship stories online. Furthermore, the results of this descriptive study may inform development of narrative-based communication, particularly in maintaining authenticity and emotional engagement.

(J Med Internet Res 2011;13(1):e7) doi:10.2196/jmir.1569

KEYWORDS

narrative communication, cancer survivors, social media, qualitative research, linguistics, health communication.

Introduction

A growing body of research points to the importance of storytelling as a cancer communication tool. Through various storytelling contexts, including support groups, patient testimonials, medical encounters, and communication interventions, personal cancer stories have been shown to have a positive health impact for listeners and storytellers alike [1-4]. Survivors’ stories have been used as a vehicle for modeling coping skills, providing social and emotional support, and sharing information and resources [5]. Recently, cancer communication efforts have begun to adapt narratives as a tool for changing health behavior. For example, Kreuter and colleagues have demonstrated that effective use of survivors' narratives increased mammography uptake among African-American women [1,5]. One explanation of narrative's effectiveness is that survivors' direct experience with cancer makes them credible and effective messengers of information conveyed through their personal stories. In this way, narrative communication is seen as offering unique advantages over traditional expository or didactic communication in the context of promoting desirable health behaviors.

Data suggest that individuals with chronic deceases are increasingly using online media to engage in health-related social networking, provide mutual support, and share stories [6,7]. As such, the Internet is an important venue for sharing personal stories about cancer. Paralleling the increased use of social media among cancer survivors, a growing number of cancer control organizations are using patient narratives as a communication device, for a variety of intents and purposes. For example, in its "Survivor Interviews" series, The Lance Armstrong Foundation (ie, LiveStrong) features 200 videotaped cancer narratives of men, women, and caregivers and invites people to watch the survivors' stories "to learn about cancer, to deal with a diagnosis and to hear firsthand about their experiences." The American Cancer Society's "Stories of Hope" series offers a repository of videotaped survivors' stories across different cancer topics, intended to provide "inspiration, hope, and support". The American Legacy Foundation's Legacy for Health "Letters" campaign features farewell letters of four women battling terminal tobacco-related cancers, with the goal of raising public awareness of the dangers of smoking and encouraging people to quit. Many cancer treatment centers also use cancer narratives in their marketing and communications efforts. The Mayo Clinic's "Patient Stories" catalogues videotaped survivors' stories as a window "into our institution, to our model of care, and how the Mayo approach to medicine can change people's lives."

The use of cancer narratives to raise public awareness, provide information and support, and change behavior for people living with cancer has clear instrumental value. However, communication science has not kept pace with the rapid uptake of this new cancer communication medium. Moreover, new-media research can benefit greatly from multidisciplinary approaches, including "a mixture of quantitative and qualitative methodologies appropriate for the specific problem under investigation" [8]. In order to better understand storytelling in new media, such as YouTube, added value can be drawn from qualitative, in-depth descriptive research examining authentic social media discourse to explicate particular attributes and functions of cancer narratives.

Linguistic analysis provides the tools to understand both the form and the function of narrative. Though linguistic methods have long been used to examine other types of illness stories (eg, those of war survivors, psychiatric patients, prisoners), this method has never been applied to cancer narratives [9-11]. A linguistically based narrative analysis can contribute to this inquiry in two ways. First, based on existing theories of narrative, a linguistic approach explicates the storytelling process, going beyond content analysis (*what* is said) to describe the storytelling process (*how* it is said) and identify common characteristics of cancer stories. Moreover, this iterative, bottom-up approach provides a micro-level analytic method to uncover key elements of authentic cancer narratives to yield a better understanding of these stories.

In terms of locating a Web source to conduct social media linguistic analysis, the Internet website YouTube (www.youtube.com) presented an ideal venue, due to its proliferation of user-generated cancer stories. A free video-sharing site created in 2005, YouTube has over 100 million videos, many of which contain personal stories about health and illnesses. With its high accessibility and wealth of user-generated content, the site provides a natural environment in which to conduct an in-depth examination of authentic, patient-generated cancer narratives.

The aims of our analysis were twofold: (1) to identify key characteristics of the naturally occurring survivors' video stories, including linguistic features shared across stories, and (2) to examine the functions of these attributes in the storytelling medium. To address these research aims, our research team conducted a linguistic analysis of 35 YouTube stories posted by cancer survivors, with the primary focus on the posters' verbal construction of the cancer diagnosis experience. The study exemplifies a new and innovative approach to describe online narrative communication. By stepping outside traditional communication research methods and using insights from linguistic research, we are able to obtain insights on the form and function of the narrative attributes in cancer survivors' stories. The results have the potential of informing future research and practice using social media and personal narrative for cancer communication efforts.

Methods

Data for analysis were extracted from the YouTube site (Multimedia Appendix 1). With more than 100 billion views per day, a significant amount of health- and cancer-related content is being shared on the site [12]. We conducted two consecutive rounds of narrative analysis of the English-language YouTube site in October 2008 and January 2009 using the search terms "cancer survivor" and "cancer stories." The research team excluded videos with the primary purpose of entertainment, advertisement, news broadcast, public service announcement, live speech, and artistic expression or those that were highly scripted and elicited by someone other than the survivor.

During round 1 of the data analysis, the top 20 clips rated by the YouTube ranking algorithm as most relevant were extracted. We recorded the selected videos' title, URL, length, number of views and viewer rating (1-5 stars, with 5 being the best) on the day of extraction, author of the video, and the affiliation of the author. All clips were transcribed in their entirety. The research team then analyzed the selected videos to generate hypotheses and to inform the development of a codebook. This open-ended analysis was guided by research aim #1, namely, the identification of key characteristics of survivors' stories. More specifically, the characteristics under analysis included thematic (content-level) as well as discursive (linguistic-level) features. The team of analysts set out to identify and agree on a number of common themes and linguistic features in the data set.

To inform this iterative analytic process, we familiarized ourselves with the narrative analysis literature, particularly the seminal work on narrative syntax by sociolinguist William Labov [13]. The framework posits that naturally occurring personal-experience narratives generally follow a shared *narrative syntax*, consisting of a set of structural elements, including an *abstract*, *orientation*, *complicating action*, *evaluation*, *result/resolution*, and *coda*, each marked by specific linguistic properties. For example, temporally ordered clauses characterize the complication action section of the narrative, moving the events being narrated forward. Based on the narrative syntax, the three coders identified the segments of the first 20 stories and took extensive notes on their direct observations.

After the first round of coding, intercoder reliability was ascertained by having the three coders each code the same set of transcripts to reconcile differences and reach consensus. The project's qualitative framework prompted the use of group consensus building over statistical tests to ensure reliability.

Round 1 provided a hypothesis-generating method and, based on research team discussions, we decided to focus round 2 analysis particularly on the diagnostic narratives. We constructed a coding sheet, using 15 additional YouTube videos identified by the same search criteria. The goal of round 2 was to validate and more accurately describe the observations and hypotheses laid out in round 1. All coded results were entered into ATLAS.ti version 6 qualitative software (ATLAS.ti Scientific Software Development GmbH, Cologne, Germany) for ease of counting and excerpt identification.

Results

Prevalence of Diagnostic Narratives

The analysis revealed that the majority of YouTube posters begin their stories with an abstract ("It's time that I tell my story of surviving cancer"), immediately followed by a set of orientation clauses. Uniformly throughout the data set, this orientation or setup involves recounting the event of finding out a cancer diagnosis. Hereafter, we term these narratives of cancer diagnosis as "diagnostic narratives." The subsequent analysis will describe thematic and linguistic attributes of these diagnostic narratives.

As shown in Table 1, 86% of all stories from rounds 1 and 2 consisted of a distinct segment of a diagnostic narrative.

We found that diagnostic narratives were generally set up with a sense of normalcy, portraying life before the diagnosis as ordinary. They were also found to contain a number of specific linguistic features, including explicit orientations to specific time and space, prevalence of direct reported speech, use of the generic pronoun "you," and depersonalized reference to the medical personnel. Excerpt 1 presents an example of diagnostic narrative, where an ovarian cancer survivor is recounting a seemingly ordinary day with a friend at the mall, when she first suspected that something was wrong.

Excerpt 1

> *One day, my friend J and I we were at the mall, and I had one of those pains and she said what is that, and I said I don't know, and she said well you should really go see your doctor, and I said oh, womanly cramps, she said …*

In this segment, the poster frames the event of diagnosis through orientation clauses, followed by a series of verbal exchange (direct reported speech) between her friend and herself, through which the suggestion of checking it with a doctor is raised and she initially dismisses it. Notice the description suggests an initial lack of suspicion about cancer and a sense of normalcy, implied by the ordinary nature of "womanly cramps".

Excerpt 1 illustrates common thematic and linguistic elements of cancer diagnostic narratives. They can be summarized as fulfilling four narrative functions: the unexpectedness of a cancer diagnosis, dramatic tension with a high level of emotional engagement, absence of control, and finally, the depersonalized reference of medical personnel. Table 2 lists the narrative functions and the linguistic characteristics serving these functions. The last column shows a sample of frequency of occurrence for several of the features coded. Except for temporal/spatial orientation, the linguistic features are counted only in round 2 (n = 14) for purposes of validating the observations made in round 1.

Table 1. Prevalence of diagnostic narratives (DNs) in YouTube survivorship stories

Analysis	Total number of stories	Stories with DNs (% prevalence)
Round 1	20	16 (80%)
Round 2	15	14 (93%)
Rounds 1 and 2 combined	35	30 (86%)

Table 2. Common discursive elements in diagnostic narratives (DNs)

Narrative functions	Representative linguistic features	Frequency of occurrence of selected linguistic features (% of DNs)
Framing of cancer as unexpected and diagnosis as unforgettable	Temporal and spatial orientation clauses	Temporal/spatial orientation, n = 25/30 (83%)
	Prefacing diagnosis with a sense of normalcy	
Dramatic tension and emotional engagement	Direct reported speech/thought	Direct reported speech, n = 10/14 (71%)
	Evaluative languages (eg, negation and emphatic adverbials)	
Marked absence of control	Use of generic pronoun “you”	Generic “you,” n = 4/14 (29%)
	Passive voicing	
	Nonagentive verbs	
Depersonalized reference to the medical personnel	Use of “they”	n = 13/14 (93%)
	Unnamed/unspecified referent	
	Passive voicing	

Cancer as Unexpected and the Moment of Diagnosis as Unforgettable

The first feature of the diagnostic narratives is the presence of orientation framing, typically marked by temporal orientation and description of a sense of normalcy. In other words, these narratives frequently contain explicit mention of time (calendar time such as “November 13, 2004” or time relative to the narrator’s life, such as “the day before my 30th birthday”), space, and memorable life events surrounding the event of receiving a cancer diagnosis. As seen in Excerpts 2 and 3, this orientation framing is hypothesized to create dramatic tension leading up to diagnosis. It also functions to emphasize the speaker’s own vulnerability, as well as the seemingly randomness and the disruptive power of cancer.

Excerpt 2

> *For me life basically consists of basketball, football, soccer, and video games. But in May of 2006 I was diagnosed with cancer in my left arm.”*

Excerpt 3

> *In 2004, things in my life were going great. I looked great, I felt great, and there was never even a hint, never even a whisper that there may be a problem.*

In Excerpt 2, the narrator describes his precancer identities through a list of activities and hobbies. This life was abruptly interrupted—at a specific time (“May of 2006”) by the cancer diagnosis. Similarly, in Excerpt 3, the narrator emphasizes the “great” life she had prior to cancer. The description of normalcy is marked with positive descriptor, repetitions on the adjective “great,” the use of the emphatic adverbials “never even,” and the words “hint” and “whisper,” all implicating the unexpected nature of a cancer diagnosis.

Such explicit temporal and spatial orientation to the event of diagnosis occurred in 83% of the 30 stories (see Table 2). While some merely mention the time, others add evaluations to the receipt of a diagnosis. Excerpt 4 illustrates the poster’s evaluation of the event of finding out that he has cancer.

Excerpt 4

> *Um, January 22nd, that was the day, the worst day of my life when I found out that I had stage four lung cancer of all things. Um, that’s, just wipes you out! Whole family, everybody.You think you’re gonna die.*

The prevalence of the mention of specific time and place of diagnosis and the explicit and often negative comment (eg, “the worst day of my life”) suggests the saliency and unforgettable nature of the event of receiving a cancer diagnosis in the speakers’ construction of cancer stories.

Creation of Dramatic Tension and Emotional Engagement

The YouTube cancer diagnosis stories share a sense of dramatic tension and high emotional engagement. Such sentiment is best illustrated through the frequent use of direct reported speech or thought (n = 10/14, 71%). Also termed “constructed dialogue” by Tannen to reflect the “constructed” nature of such expressions (as opposed to actual verbatim repetition), direct reported speech or thought represents a speaker’s use of voices from a past event during storytelling [14]. Narrative researchers have commonly associated the use of direct reported speech with the creation of a dramatic tension and sense of immediacy to the event being narrated [15-17]. For instance, in Excerpt 5 at the beginning of this diagnostic narrative, the poster describes a conversation with her doctor, where suspicion of breast cancer was raised. Segments containing reported speech are marked in bold type.

Excerpt 5

> *Um, but I said,* ***I think I felt something in the shower. He said, Well you’re young, I’m sure it’s nothing, but let me check it out anyway.***

The use of direct reported speech highlights the immediacy of the interaction between the narrator and her doctor, pulling the audience into the event leading up to learning about a cancer diagnosis. The poster uses the doctor's words to convey the lack of suspicion of breast cancer, echoing the unexpected nature of the diagnosis. In Excerpt 6, we again see the news of a cancer diagnosis narrated through direct reported speech. This time, the speaker animates the doctor's voice to give the cancer diagnosis.

Excerpt 6

> *We scheduled a core biopsy and after the biopsy he came back and said,* ***you have cancer****.*

In Excerpt 6, the bad news is described through a reported speech animating the doctor's voice. As it appears in the video, the direct and blunt style of the statement not only conveys the shock and emotional distress associated with the diagnosis, but also suggests a perceived lack of support from the doctor in navigating the medical world. Both Excerpts 5 and 6 show how direct reported speech helps the posters provide vivid descriptions of interactions between the them (as patients) and their providers, friends, and family members at the time of diagnosis. Serving to temporally move the story forward, this series of back-and-forth exchanges can also be seen as creating a dramatic tension in the narrative, engaging the audience into the plot being narrated.

Similar to reported speech, direct reported thought was also used by posters to recount the time of diagnosis:

Excerpt 7

> *I think the biggest question that ran through my mind was,* ***how could this be happening to me?***

The question ("how could this be happening to me?") represents the narrator's direct reported thought, as is seen within the video by the distinct pause and the shift in intonation immediately prior to this statement. The reported internal monologue suggests his emotional engagement in the storytelling.

In addition to the use of direct reported speech and thought, the analysis revealed a high prevalence of evaluation clauses in the diagnostic narratives. Narrative researchers generally agree on the crucial role of evaluation in storytelling. In fact, evaluative language (operationally defined as clauses that reflect the teller's personal point of value) has been identified as the essential element that turns a series of recounted *events* into a *story* [13,18,19]. In illness narratives, evaluative language helps create a dramatic tension in storytelling. In addition to explicit indication of the tellers' stance toward the events being narrated (known as *external evaluations)*, there are a large number of "syntactic, lexical, and phonological mechanisms embedded within the clauses" to indicate the teller's perspective (known as *internal evaluations*) [19]. These external and internal evaluations can be observed linguistically. For example, in Excerpt 8, a poster comments on her reactions to the cancer diagnosis through a number of linguistic features.

Excerpt 8

> *I couldn't believe that this was happening to me. I have three young, small children. Things were going perfect in my life.*

Marked by negation ("I couldn't..."), perception verbs ("believe"), and emphatic descriptors ("perfect"), this excerpt contains highly evaluative language, contributing to the heightened dramatic tension and emotional engagement during the diagnostic narrative.

Absence of Control

A third narrative function observed in diagnostic narratives is the posters' absence of control. Used interchangeably with the word "agency," control is a theme that has been examined in illness narratives in psychology, linguistics, and anthropology [20-22]. The concept of control (ie, verbal positioning of self as being in control) has been analyzed in a wide range of health discourses, including patient-provider communication, illness stories, and health literacy assessment, and has been linked to coping and the construction of illness identity [22]. In recounting the events leading up to a cancer diagnosis, YouTube posters signal the lack of control through their stories. Linguistic evidence of such lack of control includes the use of passive voicing ("*I was operated on*"), nonagentive expressions ("*They gave me three months to live*"; "*I was diagnosed with lung cancer*"), and, most notably, the switch from the first-person pronoun "I" to the generic second-person pronoun "you."

Consistent with prior research on pronouns in illness narratives, use of the generic pronoun "you" is found in statements where the poster signals a strong lack of control and negative affect [23]. In Excerpt 9, an ovarian cancer survivor uses "you" when describing the experience of being in a "surreal place" upon receiving the news of a cancer diagnosis. The second-person generic pronoun is marked in bold type.

Excerpt 9

> *You find yourself just in a surreal place like* ***this can't really be happening to me, it was a mistake****.*

This statement marks a shift from a narrative dominated by the first-first pronoun "I" to the generic pronoun "you," accompanied by direct reported thought of disbelief at the point where she has lost a sense of control. The pronoun switch can be interpreted as fulfilling two possible functions. The first, consistent with Brown and Gilligan, indicates distance from the narrated event [24]. In both Excerpts 9 and 10, the narrators signal detachment from the news of cancer and death. Secondly, the pronoun shift moves the story from the immediate narrated event to an evaluation of psychological and emotional responses to diagnosis. In Excerpt 10, the shift happens when the narrator juxtaposes a description of coping ("breaking it down") with her feeling of being overwhelmed:

Excerpt 10

> *I'm doing pretty good today and I'm breaking it down. But at the time* ***you****'re overwhelmed by this news. It's just too much!* ***You*** *think* ***you****'re dying you know, according to them. And the way* ***you*** *cough, I felt like it.*

The narrator comments on her receipt of a cancer diagnosis with external evaluation, "It's just too much". Similar to what's found in Excerpt 4 ("...just wipes you out"), this "I" to "you" switch generalizes the reaction to everyone, and may also signal a sense of helplessness, especially the face of one's mortality. In describing her cough, "you" is used to signal one's loss of control to the physical symptoms. Note the sarcasm hinted in the phrase "according to them:" the narrator displays a contrasting attitude toward the diagnosis from the medical professionals. The portrayal of medical professionals is discussed n the next section.

Finally, related to the observation that the generic "you" is used to signal loss of control, this pronoun is frequently used when talking about death and dying. This co-occurrence is illustrated in Excerpt 11:

Excerpt 11

> *I remember one night when I was lying awake at the hospital...shaking, sweating, and not knowing why. But then realizing that* ***you****'re so close to death that* ***you*** *don't know what to do.*

Note the shift from "I" to "you", when the narrator switches from recounting her physical experience of suffering from severe symptoms in the hospital to describing her mental state and a sense of confusion and disorientation facing mortality. This use of "you" in describing one's being "so close to death" and not knowing what to do any further signals the lack of control common in the diagnostic narratives.

Depersonalized Reference to Medical Personnel

In the video narratives, posters generally adopted a neutral or antagonistic stance toward the medical staff (primarily oncologists and surgeons). Regardless of stance, medical personnel were referenced in a highly depersonalized manner, often referred to simply as "they" or "the doctor." The depersonalized reference suggests the tangential role they play in the diagnostic narratives. It further reinforces the survivors' ownership of the cancer experience.

Excerpt 12

> *When I went to see the doctor, they told me it was nothing, they told me it was a fluid-filled cyst and not to worry about it.*

The use of "the doctor" and "they" in Excerpt 12 is typical of the way doctors were portrayed in the stories. In fact, except in videos affiliated with particular organizations (eg, hospitals), medical personnel were rarely given any prominence in the data set. Even when they were described to perform or say something significant, they were not mentioned by name, as illustrated in Excerpt 13:

Excerpt 13

> *Six weeks before my 40th birthday, I was diagnosed with testicular cancer. About three days after that I was on the operating table and the surgeon removed my left testicle.*

While the specific temporal orientation (including the speaker's age at the time of diagnosis and number of days between the news and the surgery) is commonly found throughout the data set, the speaker's lack of personal evaluations here is unusual. However, the lack of emotional evaluation is juxtaposed with deliberate directness and terseness. The speaker describes the surgery following the diagnosis with a matter-of-fact tone of voice. Note that except in this excerpt, his surgeon was not once mentioned throughout his entire video, making the linguistic choice of "the surgeon" highly marked in this context.

In conclusion, the analysis found that in survivor-generated YouTube stories, medical personnel play an insignificant role and are depersonalized when they are referenced. In some cases, the speakers expressed negative emotions or disagreements toward them (such as in Excerpt 10), while in other cases they merely served to complete the narrated event without being given any prominence (such as in Excerpts 12 and 13).

Discussion

Personal narratives hold enormous potential as cancer communication tools, especially as social media continue to transform the way people interact with cancer-related information. However, the particular attributes or functions that make a cancer narrative effective as a communication tool are still not well understood. This information is critically important to cancer control organizations and other developers of cancer messages who hope to use storytelling as a vehicle for raising public awareness about cancer risk, providing information and support to cancer patients, and changing attitudes and behavior. The current study was undertaken to better understand the common linguistic elements of cancer narratives (eg, form) and the functions of these elements in the narratives' ability to reach and engage audiences.

Survivors' stories shared a common narrative syntax, characterized by a set of *orientation* statements describing the experience of being diagnosed with cancer, a series of *complicating actions* describing the events following the initial diagnosis, a variety of evaluation statements attempting to make meaning out of the cancer diagnosis, and, finally, a result or resolution to the diagnosis event. Understanding the syntax of naturally occurring cancer stories is useful, to the extent that narrative communication is most effective when it is perceived as authentic and credible. Cancer communication programs wishing to create narrative content that will resonate with audiences would do well to model their narrative syntax on what is observed here.

Social media approaches to cancer communication that include the use of personal narratives would further benefit from understanding the specific linguistic components that make a cancer narrative effective. Within the overall narrative structure described above, a number of shared linguistic themes and features were identified, which appear to serve important storytelling functions. Orientation statements frequently contained explicit orientations to space and time that conveyed a sense of normalcy prior to the diagnosis. As a storytelling device, this juxtaposition between "before" and "after" helped to establish the cancer diagnosis as unexpected, and the moment of diagnosis as unforgettable. The narratives were also characterized by frequent use of direct reported speech and highly evaluative language. From a storytelling perspective, these linguistic features served to build dramatic tension, increase realism, and induce emotional responses. Because the success of cancer communication efforts depends largely on creating emotional engagement with message content, there is value in understanding how specific linguistic features can be leveraged to create content that will form an emotional connection with the audience.

The information gleaned from the linguistic analysis also provides health communicators, practitioners, and researchers with a window into the cancer diagnosis experience, from the patient point of view. Many of the identified key linguistic attributes reflected patients' own perspectives on the experience with cancer, and this knowledge may shed light on the story posters: as they expressed it in their own words, the YouTube posters generally placed heavy emphasis on the moment of diagnosis, and positioned the news as unexpected and themselves as helpless. Evidence of this lack of agency was observed in the linguistic analysis as the use of passive voicing, nonagentive expressions, and use of the generic second-person pronoun "you." However, over time they moved to construct a coherent account of being a cancer survivor and taking control of their lives, regardless of the prognosis. In contrast, medical staff were found to be infrequently mentioned and depersonalized. One can surmise that the posters, in comparison with other cancer survivors, may display several unique traits; namely, they tended to adjust to the cancer diagnosis and many assumed an activist/advocate role in cancer survivorship.

These insights into survivors' personal perspectives, including common challenges and the process toward better adjustment, have implications in the context of patient counseling. Echoing narrative medicine, which refers to clinical practice fortified by narrative competence, namely, "the capacity to recognize, absorb, metabolize, interpret, and be moved by stories of illness," clinicians working with cancer patients may better understand patients' perspectives and offer better support by listening to their stories [25].

Finally, from a methodological perspective, the analysis illustrates the utility of qualitative linguistic analysis to uncover key elements of cancer narratives: our approach presents to the health communication field a new and innovative analytic method that can be adopted for other types of qualitative health research using data such as from open-ended interviews, focus groups, or patient support groups. In this way, the linguistic analysis of the storytelling process can complement traditional content analysis.

Study Limitations

This study has several limitations. The first is related to sample size. The nature of this in-depth qualitative analysis permitted the use of only a small selection of YouTube videos, therefore making any quantitative analysis uninformative. However, the results of the current descriptive analysis can potentially inform future research on large databases or corpora. Using natural-language processing and computational techniques, a similar type of narrative analysis can be done through a semiautomated coding scheme informed by the study results. For instance, key linguistic features such as reported speech or pronoun shifts can be automatically coded in a large set of survivors' videos, and the results may be correlated with characteristics of illness experience, including prognosis, coping ability, and thoughts about and mention of one's mortality. Adding these quantitative components to a future narrative study can confirm and substantiate existing qualitative observations.

The second limitation has to do with the low generalizability of the YouTube data across the population of cancer survivors. Racial and socioeconomic status disparities in online survivor narratives have been documented; in particular, stories by minorities are underrepresented on the Internet, including on YouTube [26]. The current study confirmed this observation: only 2 of the 35 video stories were posted by survivors of non-European decent. The fact that upper-middle-class Americans of European decent are more likely to post YouTube stories suggests limited generalizability of current results across the population. With more YouTube and other social media data, we will be able to better understand the variation in cancer narratives across racial, ethnic, and cultural groups. Moreover, YouTube posters, as compared with other cancer survivors, tend to be open to sharing personal experience in public and attempting to portray a coherent story, as well as having a more optimistic vision about cancer.

Finally, on a more fine-grained level, we acknowledge that the analysis has excluded some aspects of language, in particular, prosodic features including intonation and pitch. Narrative research has found that prosody has important narrative functions, especially in accentuating the evaluative components of storytelling [27]. For this study, in an effort to focus on readily "codeable" features for the purpose of informing future analyses and designing narrative-based interventions, we left prosody out of the analysis.

Conclusions

This study presents a novel, linguistically oriented approach to analyzing the form and function of patient narratives situated in the discourse of social media. Such an analysis provides a better understanding of how Youtube posters use language to construct the illness experience and specifically the cancer diagnosis through this interactive online medium. The findings on the common attributes shared among Youtube cancer stories have the potential to inform future health communication efforts aiming to use personal narratives and social media.

Acknowledgments

This project has been funded in whole or in part with federal funds from the National Cancer Institute, National Institutes of Health. We would like to thank Vicky Perez of the National Cancer Institute for her assistance in the editorial process.

Conflicts of Interest

None declared

Multimedia Appendix 1

Link list of YouTube videos under analysis

[PDF file (Adobe PDF File), 82 KB - jmir_v13i1e7_app1.pdf]

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Edited by G Eysenbach; submitted 18.05.10; peer-reviewed by P Schulz, L Gibson; comments to author 26.07.10; revised version received 21.09.10; accepted 06.11.10; published 17.01.11.

Please cite as:
Chou WYS, Hunt Y, Folkers A, Augustson E
Cancer Survivorship in the Age of YouTube and Social Media: A Narrative Analysis
J Med Internet Res 2011;13(1):e7
URL: http://www.jmir.org/2011/1/e7/
doi:10.2196/jmir.1569
PMID:21247864

Original Paper

Use of an Online Community to Develop Patient-Reported Outcome Instruments: The Multiple Sclerosis Treatment Adherence Questionnaire (MS-TAQ)

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Abstract

Background: Patients with multiple sclerosis (MS) may face barriers, such as treatment fatigue, memory problems, or side effects, that may influence their adherence to medication.

Objective: The objective of our study was to use an online community to develop a self-report questionnaire to quantify adherence and barriers to achieving adherence, that is specific to MS disease-modifying treatments (DMTs) and predictive of missed doses.

Methods: A review of the scientific literature and analysis of discussions between MS patients on PatientsLikeMe.com were used to generate survey items salient to patients. Cognitive debriefing was used to refine the items. The Multiple Sclerosis Treatment Adherence Questionnaire (MS-TAQ) contains 30 questions in three subscales: Barriers, Side Effects, and Coping Strategies.

Results: MS patients completed an online survey (response rate: 431 of 1209 invited, 35.7%). Between 16% (14/86) and 51% (51/100) of MS patients missed at least 1 dose of their DMT in the previous 28 days, with significant between-treatment differences. The MS-TAQ Barriers scale was positively correlated with the proportion of doses missed ($r = .5$), demonstrating a stronger relationship between adherence and perceived barriers than was found with clinical or demographic variables ($r \approx .3$). The Coping Strategies subscale was negatively correlated with missed doses ($r = -.3$), suggesting that use of more coping strategies is associated with higher adherence.

Conclusions: Online communities can provide domains of interest and psychometric data to more rapidly develop and prototype patient-reported outcome instruments. The MS-TAQ offers patients and clinicians a simple method for identifying barriers to adherence, which may then be targeted through interventions.

(J Med Internet Res 2011;13(1):e12) doi:10.2196/jmir.1687

KEYWORDS

Medication adherence; multiple sclerosis; online communities

Introduction

The World Health Organization estimates an average rate of only 50% adherence for patients with chronic medical conditions [1]. In diabetes the implications for nonadherence are clear; every 10% increase in medication adherence leads to a 0.1% decrease in glycosylated hemoglobin levels [2], and each 1% decrease in glycosylated hemoglobin leads to a 21% decrease in risk of death from diabetes [3]. The mechanisms and consequences of nonadherence to disease-modifying treatments (DMTs) in multiple sclerosis (MS) have attracted less attention, and it remains unclear what level of adherence is required to achieve maximum benefit [4]. Clinicians are without a means of accurately quantifying adherence to DMTs, regardless of the therapy chosen, and patients are without a means of sharing information with their physicians about barriers they experience to being fully adherent.

There is widespread agreement, based on clinical and magnetic resonance imaging assessments, that early DMT use in MS reduces the number of relapses and delays disease progression [5-7]. Following acceptance of therapy, at least two issues impede DMT use. First is DMT discontinuation; around 20% of patients discontinue their DMTs in the first year, usually after the first 6 months on treatment [8]. Reasons for discontinuation include perceived lack of effectiveness, lower levels of disability, injection-site reactions, and other side effects [9,10]. Second is nonadherence or missed doses – that is, taking a treatment less frequently than prescribed or failing to follow prescriber guidance. Adherence can be ascertained through a pill count, lab test, medical chart, self-report, collateral report, or electronic monitor [11]. A recent study comparing the performance of a medication event monitoring system (MEMS) to patient diaries and retrospective self-report found an acceptable correlation between the two (r = .7), though self-report was noted to systematically underreport the proportion of nonadherent patients [12]. The Global Adherence Project (GAP), a large international observational study (N = 2648) that employed retrospective self-report, recently reported that 75% of patients were perfectly adherent to their DMT over 4 weeks [13]. They found that patients who had been on therapy longer, were male, and had longer disease duration were more likely to have skipped at least 1 dose.

Reasons for nonadherence in MS are complex; in an online survey of nearly 800 MS patients [14], the most important factors identified by patients were forgetting to administer the DMT (58%), not feeling like taking the DMT (22%), or feeling tired of taking the DMT (16%). Other factors included skin reactions (5%), pain at injection sites (7%), injection-related anxiety (3%), and needing someone else to administer the injection (4%). Similarly, the GAP study found that 32% of patients provided needle-based barriers as reasons for missing a dose, but that forgetting was still the strongest factor (identified by 50% of nonadherent patients).

Emotional and cognitive issues may also be important; patients with decreased memory function, or increased levels of anxiety or fatigue have lower levels of adherence; patients with a current mood or anxiety disorder were almost 5 times more likely to be nonadherent [15]. In a prospective study, Tremlett et al found a higher number of missed doses among patients with more frequent DMT injections and heavier alcohol use, but found no relationship with side effects resulting from treatment [16]. Using a health beliefs model to understand adherence, Turner et al found that perceived DMT effectiveness, but not barriers to adherence, predicted adherence [4].

In terms of consequences of nonadherence in MS, patients who discontinue treatment are more likely to experience progression of their disability [8]. Furthermore, claims data suggest that gaps in medication availability are associated with a 1.5 to 2 times odds ratio of subsequent admission to hospital [17,18]. The GAP study found that adherent patients had a higher quality of life and lower neuropsychological impairment, although the direction of causality is unclear [13].

Despite relatively consistent barriers to adherence in the literature, scale development in this area has historically focused on injection pain and perceived needle sharpness due to needles or infusions as the means of DMT delivery [19-21]. More patient-centered approaches have been educational in nature or recommended psychosocial interventions, but have been without structured assessment tools [22-24]. A recent editorial pointed out that the “core issue of adherence” is identifying the reasons why patients have decided to be nonadherent, and that much of the literature fails to illuminate the spectrum of behavior between perfect compliance and nonadherence [25].

Online communities may present an opportunity to illuminate unmet patient needs that are outside those identified in the scientific literature or in clinic visits. We sought to build an MS-specific understanding of adherence to DMTs by developing a scale from patients’ own descriptions of their barriers to adherence, called the Multiple Sclerosis Treatment Adherence Questionnaire (MS-TAQ). We hypothesized that perceived effectiveness and barriers to adherence would predict self-reported adherence. We also hypothesized that patients using coping strategies to minimize side effects would have better self-reported adherence.

Methods

Scale Development

PW reviewed the scientific literature in June 2009 in EMBASE and Medline using major and minor headings for the terms multiple sclerosis, compliance, patient compliance, adherence, treatment refusal, non-adherence, and nonadherence. Reference lists were reviewed for additional sources. We identified the following relevant themes as important to adherence: discontinuation, forgetting to take medication, perceived lack of effectiveness, pain, needle phobia/anxiety, adverse reactions, support and patient education, availability of help with injecting, and stigma or reminders of disease.

To further identify relevant themes regarding adherence from the patients’ own discussions, MM and PW conducted a computer-assisted search of the PatientsLikeMe MS community online message board (forum), which as of June 30, 2009 contained 373,345 posts across 23,224 threads, contributed by 4844 unique patients. Patients generate and discuss a range of unprompted topics relevant to managing their condition. PW and MM generated a list of relevant search terms (eg, inject, shot, site reaction, and pain) and applied them to a random sample of 1000 posts; these were reviewed for additional terms and applied to another sample of 4000 post, which were also reviewed for additional terms and refined to eliminate terms that were not discriminating discussions relevant to adherence. For example, the term pain usually referred to symptoms of MS rather than injection-related pain, but sting or soreness normally referred to adherence issues. A final list of 49 terms was reapplied to the original samples (5000 posts) plus additional random samples for a total of 80,000 forum posts. Of these, 6.27% (5019/80,000 posts) contained at least a single mention of one term, but manual review by MM showed that many of these were not relevant (eg, discussions of how to apply for disability insurance rather than discussions of the nature of disability). However, posts with two or more terms in them were almost always relevant to adherence, so we focused on the 1.57% of posts (1254/80,000) that this applied to. The posts containing the most search terms tended to come from long-term patients explaining their own experience to patients with a more recent diagnosis and offering their own advice.

The most obvious themes to arise overlapped those from the scientific literature. For example, a number of studies have found a link between adherence and perceived effectiveness [4,14,15,26-28], and this was a theme readily apparent in patients' forum discussions; for example, one patient wrote "*You never know 'for sure' if they are helping prevent future flares...but I s'pose it[']s not a leap of faith that if you have no flares in the future, it[']s due to the DMTs.*"

However, our qualitative analysis of online community data generated three additional issues not previously described as drivers of adherence in the literature. First, we identified a range of coping strategies being used by patients to modulate consequences of their DMT – for example, "*I take ibuprofen with my injection and sleep through any side effects there may be.*" Second, patients' interpretations of the current severity and impact of their barriers or side effects can be strongly influenced by their previous exposure to other DMTs, which provides a contextual anchoring effect to their current problems. For example, a patient might say "I'm experiencing some side effects on treatment X but they're much less of a problem than what I experienced with treatment Y." Third, we found that patients' experience of some side effects, such as injection-site reactions, waxed and waned over time. While cross-sectional studies might consider them to be present or absent, it was clear that some problems arose some time after treatment commencement while others resolved spontaneously.

On the basis of themes identified in this process, an experienced survey designer drafted question stems and responses. Items were grouped into three subscales, each with a different response format: DMT-Barriers quantifies the extent to which the patient rated 13 barriers to adherence as important reasons for nonadherence (asked only of patients who missed at least 1 dose in the previous 28 days, 4-point scale from "not important at all" to "extremely important" in missing or forgetting a dose); DMT-Side Effects describes the frequency of 10 side effects (asked of all patients, 5-point scale from "never" to "all or nearly all of the time"); and DMT-Coping Strategies is a count of 7 coping mechanisms used by the patient to reduce side effects (eg, using an ice cube on the injection site, asked of all patients, binary yes/no response for "in the past 4 weeks (28 days) did you usually...").

Five female white patients participated in real-world cognitive debriefings after completing a draft version of the questionnaire, according to recommended guidelines [29]. Patients reported that questions were clear and simple, but suggested changing the reference period from "the past 30 days" to "the last 4 weeks (28 days)".

Participants

Patients reporting a diagnosis of MS were recruited from an online community, PatientsLikeMe. The site has been described previously [30-32]. This online system allows patients with serious illnesses to share their symptoms, treatments, and outcome measures of interest (functional disability, weight, quality of life) in an open medical platform. Patients evaluate their perceptions of treatments, including perceived effectiveness, side effects, burden, and adherence, and can also participate in clinical research. The website features a survey tool, PatientsLikeMeLens, which allows selection of participant lists and online administration of surveys.

The following information is provided to comply with the Checklist for Reporting Results of Internet E-Surveys [33]. Patients who had logged on to the site in the preceding 90 days were randomly selected to participate, from an overall pool of approximately 15,000 registered MS patients. On December 21, 2009, six blocks of approximately 200 survey invitations were sent to patients reporting current DMT use on their patient profiles for the following groups: not currently taking a DMT (No DMT), glatiramer acetate (GA; Copaxone, Teva Pharmaceutical Industries Ltd, Petach Tikva, Israel), interferon beta-1a intramuscular injection (IFB-1a IM; Avonex, Biogen Idec, Weston, MA, USA), interferon beta-1a subcutaneous injection (IFB-1a SC; Rebif, EMD Serono Inc, Rockland, MA, USA), interferon beta-1b subcutaneous injection (IFB-1b SC, Betaseron, Bayer Healthcare, Leverkusen, Germany), and natalizumab infusion (Tysabri, Biogen Idec). The invitation was sent as a private message within the PatientsLikeMe community, with a customized research invitation message arriving in members' email inboxes.

New private messages trigger an automated email to patients' email accounts (unless they have opted out of being contacted in this way). Sampled patients had their own password-protected login; they could complete the survey only once, and we have tools to prevent multiple accounts originating from the same location, including account registration, cookies, and internet provider tracing. Therefore, we have more confidence in our denominators than might be found using an "open" survey method. The survey was voluntary to complete and was not mandatory to complete in order to continue using the other features of the site. No incentives were offered; question order was not randomized; certain items only appeared conditional on previous responses (ie, were "adaptive") to minimize respondent burden (see Multimedia Appendix 1); and the total number of questions and screens varied by participants' own responses.

Following initial contact, a reminder message was sent within a week to those who had not yet completed the survey; patients who had only partially completed the survey could reaccess it through the original private message (or reminder message) to complete their survey. Once opened, the survey had a "back" button that allowed participants to change their earlier answers. Only data from completed questionnaires are presented here. The study was approved by Western Institution Review Board

(WIRB), Olympia, WA, USA (Study 1111772). Patients gave informed consent electronically.

Members of PatientsLikeMe join the site with the expectation that they will be participating in research. The recruitment message outlined the purpose of the study and reminded patients that they were under no obligation to participate, that their aggregated results may be published, and that the survey should take about 20 minutes to complete. It was sent from the user account for PW, who can easily be contacted by potential participants from within the PatientsLikeMe system.

User data were protected in accordance with PatientsLikeMe's internal security standard operating procedures, which include password protection, deidentification of locally held data files, regular automated backup, and physical protection of information technology hardware.

Adherence

Patients were asked on how many of the previous 28 days they were supposed to take a dose, whether they missed or forgot any doses, and, if so, how many. For those who missed at least 1 dose, missed dose ratio (MDR) is reported as the number of doses missed divided by the number of prescribed doses over a 28-day period. For example, a patient missing 1 shot of daily GA in 28 days would have an MDR of 0.04, while a patient missing 1 shot of weekly IFB-1a IM would have an MDR of 0.25. For between-treatment group comparisons, MDR is provided for all patients; those who did not report missing a dose were coded as having an MDR of 0.

Survey Items

A complete copy of the questions presented to participants is included in Multimedia Appendix 1. In addition to the MS-TAQ, the survey included demographic information (age, weight, height, sex), MS symptoms (memory, concentration/attention, comprehension, expression, anxiety, depression, vision problems), burden of illness items (ability to work for pay, ability to meet household responsibilities), current DMT, DMT history, perception of side effects, DMT duration, MDR, ability to grasp an injector, method of injection, need for assistance with injection by others, use of manufacturer's support service, expectations and perceptions of DMT effectiveness, and overall satisfaction with DMT.

We included a self-report measure of functional impairment, which has been in use on the PatientsLikeMe site since its launch in 2007. The MS Rating Scale asks patients to rate their current level of disability in seven domains: walking, arm function, vision, speech, swallowing, cognition, and sensation. Response options are "No symptoms or disability in this specific area (0)," "None - Aware of symptoms but no functional disability (1)," "Mild - Mild disability but not requiring help from others (2)," "Moderate - Moderate disability that requires some help from others (3)," and "Total - Total disability and help always required (4)". Summing the responses produces a scale with a range of 0-28, which is normed to 0-100 (higher score represents greater disability).

Statistical Analysis

Statistical analysis was performed using (SPSS) version 17.0 (IBM Corporation, Somers, NY, USA). Group comparisons were assessed using one-way analysis of variance where normally distributed, or Kruskal-Wallis tests where non-parametric. All correlations shown are nonparametric Spearman correlations due to the ordinal nature of the scales. Alpha for significance was set at $P = .05$ (two-tailed). A logistic regression model was used to estimate the net effect of patient factors and behaviors on the odds of missing at least 1 dose. A linear regression model was used to estimate the net effect of factors influencing the MDR. In both cases we used generalized estimating equations, and the Wald chi-square to test model effects.

Results

Participants

In December 2009, survey invitations were sent to 1209 members of the MS community in six blocks of about 200 patients stratified by DMT usage; 41.9% patients responded (507/1209) and complete responses were analyzed for 35.7% (431/1209). We excluded the following from further analysis: 62 patients who did not answer all questions, 3 who were taking mitoxantrone, which was too small a group to analyze, and 11 who provided inconsistent data about their DMT use. Demographics are provided in Table 1. The majority of respondents (311/431, 72.2%) reported a relapsing-remitting form of MS, 10% (45/431) reported that their MS was secondary progressive, 10% (44/431) did not know their MS type, 4% (17/431) reported primary progressive MS, and 4% (16/431) reported progressive relapsing MS. The primary analyses were repeated separately for the relapsing-remitting group and did not materially change the main results of the study; data presented here represent all patient-reported MS subtypes.

There were no significant differences in response rate by sex ($c^2_3 = 4.5$, $P = .02$). There were significant differences for age ($F_{3,1205} = 4.860$, $P = .002$) between responders and nonresponders in the community. Post hoc tests showed that patients who completed the survey were older (mean difference 2.3 years, 95% CI 0.5-4 years, $P = .004$) than those who did not respond.

Table 1. Respondent demographics by disease-modifying treatment (DMT)

	GA (n = 101)[a]	IFB-1a IM (n = 87)[b]	IFB-1a SC (n = 81)[c]	IFB-1b SC (n = 63)[d]	Nat (n = 58)[e]	No DMT (n = 41)	Between-DMT significance	Total average (N = 431)
Mean (SD) age, years	47 (11)	48 (11)	44 (10)	47 (9)	44 (10)	48 (11)	$F_{5,425}$ = 2.230, *P* = .05	46 (10)
Sex, % female	85 (84%)	68 (78%)	61 (75%)	57 (91%)	41 (71%)	30 (73%)	c^2_5 = 10.7, *P* = .06	431 (79%)
Mean (SD) BMI[f], kg/m^2	29 (7)	27 (6)	30 (7)	29 (6)	27 (6)	27 (6)	$F_{5,415}$ = 3.314, *P* = .01	28 (7)
First DMT? n (%)	73 (72%)	73 (84%)	50 (62%)	47 (75%)	3(5%)	NA[g]	c^2_4 = 107.0, *P* < .001	246 (57%)
Median DMT duration, months	25	22	22	25	16	NA	c^2_4 = 19.1, *P* < .001	22
Mean (SD) time since onset, years	10 (9)	11 (10)	7 (8)	11 (10)	15 (9)	14 (8)	$F_{5,418}$ = 5.295, *P* < .001	11 (9)
Mean (SD) time since diagnosis, years	6 (7)	7 (7)	5 (6)	8 (8)	11 (7)	10 (7)	$F_{5,415}$ = 5.870, *P* < .001	7 (7)

[a] GA: glatiramer acetate.

[b] IFB-1a IM: interferon beta-1a intramuscular injection.

[c] IFB-1a SC: interferon beta-1a subcutaneous injection.

[d] IFB-1b SC: interferon beta-1b subcutaneous injection.

[e] Nat: natalizumab infusion.

[f] BMI: body mass index.

[g] NA: not applicable.

To assess biases in our sample we compared the demographics of our sample (Table 1) to the Sonya Slifka MS study by Minden et al [34]. Our populations appeared similar for sex (PatientsLikeMe: 79.3% (342/431) vs Minden et al: 77%) but ours were slightly younger (PatientsLikeMe mean age 47 years, SD 10 vs Minden et al: 51 years, SD 11), and had been symptomatic for less time (PatientsLikeMe mean duration since onset : 11 years, SD 9 vs Minden et al: 18 years, SD 11). Relative to Minden et al, our sample had a higher proportion of patients with relapsing-remitting MS (72.2% (311/431) vs 58%), a lower proportion with secondary progressive MS (10% (43/431) vs 25%), and lower proportion with primary progressive MS (4% (17/431) vs 13%), but similar proportions with progressive relapsing MS (4% (16/431) vs 5%). However, given that we were selecting patients who were using DMTs, the relatively high proportion of patients with relapsing-remitting MS is unsurprising.

Adherence

There were significant differences between the proportions of patients missing a dose in each treatment group (see Table 2). Overall, between 16% and 51% of MS patients missed at least 1 dose of their DMT. Seven patients missed a dose of natalizumab, and open-text responses showed that their physician had changed their dosing schedule to every 6 or 8 weeks in response to safety concerns. Therefore, the 28-day time frame of the original questions is rendered invalid; data on the natalizumab patients was therefore excluded from further analysis related to adherence. Figure 1 shows the distribution of MDR between DMTs across all patients. Figure 2 shows the distribution of MDR between DMTs across only those patients who missed at least 1 dose.

A logistic regression model was constructed to study the net impact of personal and disease factors on the likelihood of having missed a dose of their DMT in the preceding 28 days. Patients were more likely to have missed at least 1 dose in the past 28 days if they had a disease type other than relapsing-remitting (*P* = .002), lower levels of disability (*P* = .03), or a history of taking more than one DMT in the past (*P* = .04). There were no significant associations with age, sex, body mass index, disease duration, time on treatment, or difficulty grasping the injector.

Table 2. Number of missed doses in the preceding 28 days by disease-modifying treatment (DMT)

	GA (n = 100)[a]	IFB-1a IM (n = 86)[b]	IFB-1a SC (n = 81)[c]	IFB-1b SC (n = 63)[d]	Nat (n = 58)[e]	Between-DMT significance
Typical dosing	Daily	Weekly	Every 3 days	Alternate days	Monthly	NA[f]
Prescribed doses, median (range)	28 (0-28)	4 (0-9)	12 (3-16)	14 (7-21)	1 (1-1)	NA
Patients who missed a dose, n (%)	51 (51%)	14 (16%)	25 (31%)	31 (49%)	7, NA[g]	$c^2_4 = 63.0$, $P \leq .001$
Missed doses, median (range)	3 (1-20)	1 (1-3)	2 (1-10)	2 (1-14)	NA	NA
Nonadherent MDR [h], mean	0.16	0.41	0.29	0.28	NA	$c^2_3 = 24.2$, $P \leq .001$
Nonadherent MDR [h], median (range)	0.12 (0.04-0.71)	0.25 (0.22-1.0)	0.17 (0.07-1.0)	0.15 (0.07-1.0)	NA	
All patients' MDR, mean	0.08	0.07	0.09	0.14	NA	$c^2_3 = 19.4$, $P \leq .001$
All patients' MDR, median (range)	0.04 (0.00-0.71)	0.00 (0.00-1.00)	0.00 (0.00-1.00)	0.00 (0.00-1.00)	NA	
Managed to inject 100% of each dose taken?	85 (85%)	83 (97%)	78 (96%)	55 (87%)	54 (93%)	$c^2_4 = 12.2$, $P = .02$

[a] GA: glatiramer acetate.

[b] IFB-1a IM: interferon beta-1a intramuscular injection.

[c] IFB-1a SC: interferon beta-1a subcutaneous injection.

[d] IFB-1b SC: interferon beta-1b subcutaneous injection.

[e] Nat: natalizumab infusion.

[f] NA: not applicable.

[g] Excluded from further analysis due to altered dosing range of 6-8 weeks per transfusion, rendering the 28-day window inapplicable.

[h] MDR: missed dose ratio.

Figure 1. Significant differences in missed dose ratio for all patients in the past 28 days; 0.00 = fully adherent, 1.00 = missed every prescribed dose(circles: outliers >1.5 but <3 interquartile ranges [IQRs]; asterisk: >3 IQRs from nearest edge of boxplot; bolded symbols: >1 point in same place)

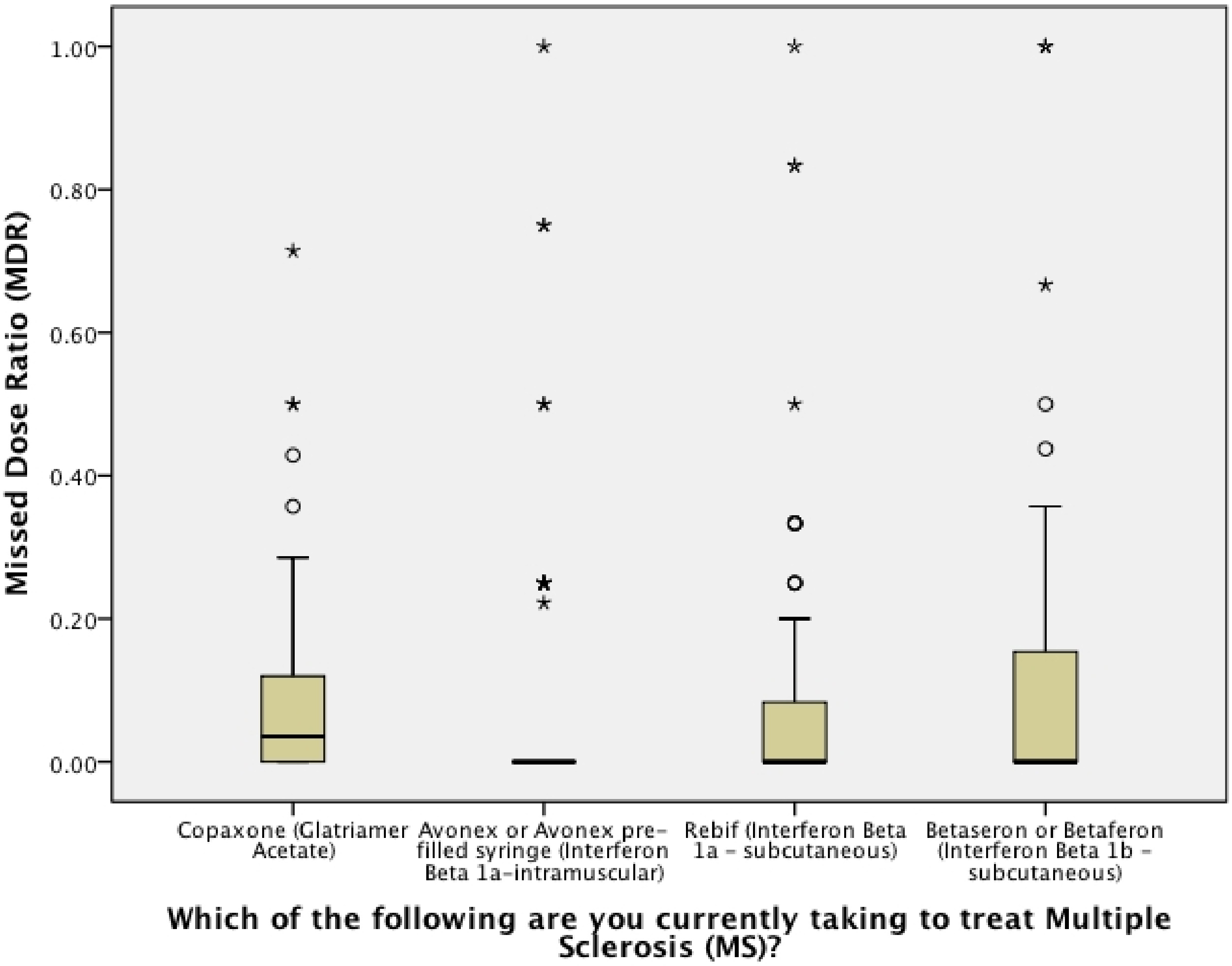
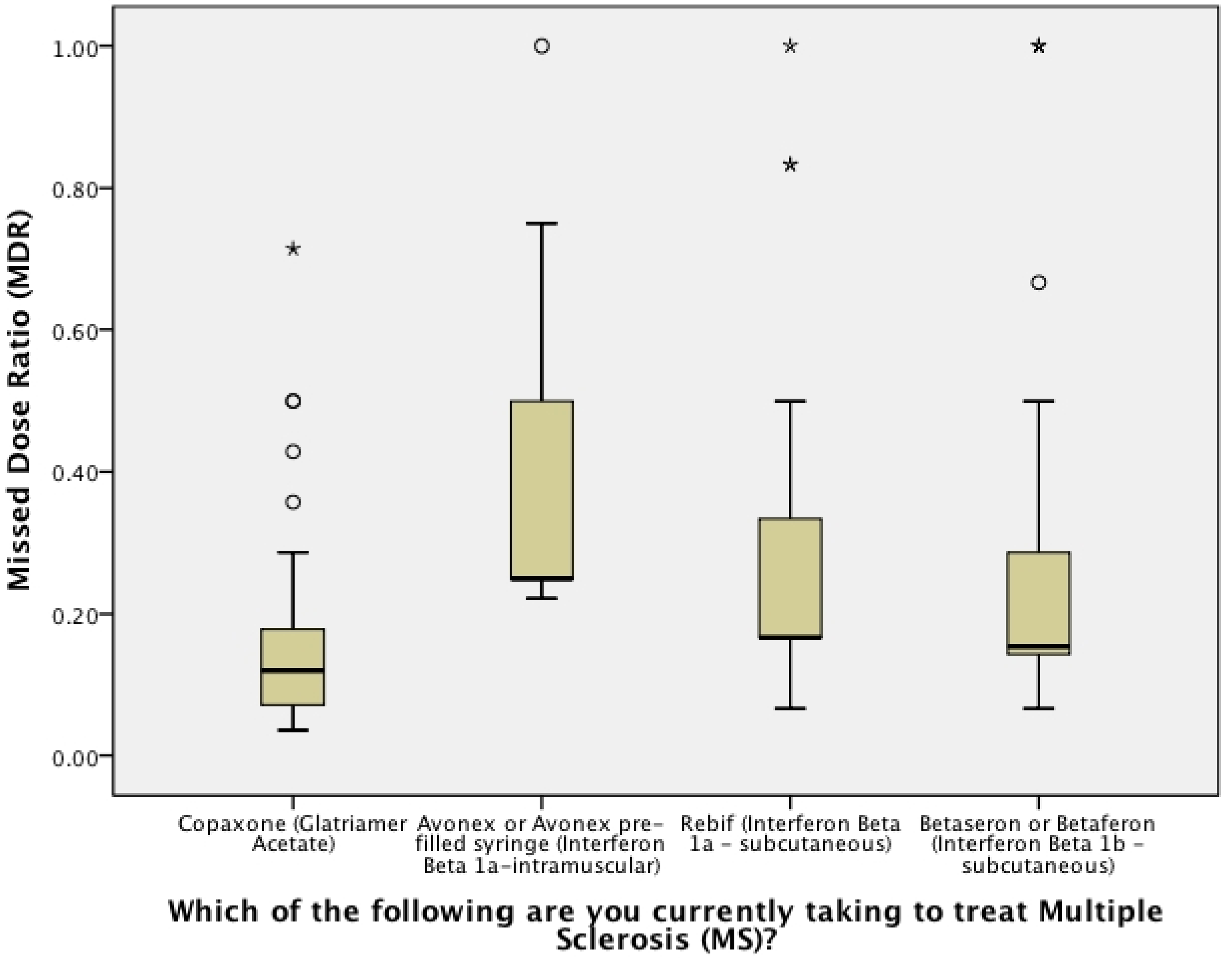


Figure 2. Significant differences in missed dose ratio for patients who reported missing a dose in the past 28 days; 0.00 = fully adherent, 1.00 = missed every prescribed dose (circles: outliers >1.5 but <3 interquartile ranges [IQRs]; asterisk: >3 IQRs from nearest edge of boxplot; bolded symbols: >1 point in same place)



Psychometric Performance of MS-TAQ

Psychometric performance of the MS-TAQ subscales is shown in Table 3. Cronbach alpha was acceptable for DMT-Barriers and DMT-Side Effects but was low for DMT-Coping Strategies; this may have been due to the limited range of the scale and the binary response options.

Table 3. Multiple Sclerosis Treatment Adherence Questionnaire (MS-TAQ) subscale characteristics

MS-TAQ subscale	Number of items	Score		Cronbach alpha	Between-DMT[a] significance
		Mean (SD)	Range		
DMT-Barriers	13	9 (7)	0-39	.82	$F_{3,117} = 1.236$, $P = .300$
DMT-Side Effects	10	12 (9)	0-40	.86	$F_{4,394} = 24.498$, $P < .001$
DMT-Coping Strategies	7	1 (1)	0-7	.40	$c^2_{24} = 101.4$, $P < .001$

[a] DMT: disease-modifying treatment.

Predictors of Missed Dose Ratio in Nonadherent Patients

Among nonadherent patients, a higher MDR was associated with lower DMT convenience ($r = .33$, $P < .001$), lower treatment satisfaction ($r = -.30$, $P = .001$), higher levels of anxiety ($r = .21$, $P = .02$), and higher levels of depression ($r = .21$, $P = .02$). Notably, MDR was not correlated with disease severity as measured by the MS Rating Scale ($r = -.01$, $P = .90$), total symptom severity ($r = .07$, $P = .50$), time since diagnosis ($r = -.004$, $P = .97$), or time since symptom onset ($r = -.08$, $P = .37$). We found no significant correlation between MDR and expectations of effectiveness ($r = -.04$, $P = .66$) or current perceived effectiveness ($r = .17$, $P = .07$), nor with the discrepancy between the two ($r = -.17$, $P = .06$).

However, there was a stronger correlation between MDR and the DMT-Barriers subscale of the MS-TAQ ($r = .50$, $P < .001$). The DMT- Coping Strategies subscale also correlated (negatively) with MDR ($r = -.30$, $P = .003$), suggesting that using a higher number of coping strategies was associated with better compliance. DMT-Side Effects was not significantly correlated with MDR ($r = .10$, $P = .26$).

A linear regression model was used to estimate the net effects of personal and behavioral factors on the MDR. Each point scored on the DMT-Barriers subscale of the MS-TAQ was associated with a 1% *increase* in MDR. Each point change on the DMT-Coping Strategies scale was associated with a 4% *decrease* in MDR.

Discussion

Using qualitative and quantitative data sourced from an online community, we developed the MS-TAQ, a rating scale that quantifies the barriers to adherence, side effects, and coping strategies experienced by MS patients. The Barriers subscale is a more powerful predictor of missed doses ($r = .5$) than an overall satisfaction question ($r = .3$). We confirmed that patients who used more coping strategies to ameliorate side effects were able to take more doses of their medication than those who did not, even if they were still not perfectly adherent.

As in other studies, we identified associations between nonadherence and DMT satisfaction [4,13,14], lower levels of disability [13,35], more barriers to adherence [14], previous history of DMT use [14], and anxiety and depression [14,15]. Like others, we did not find a strong association between adherence and demographic variables [4,12,14,16]. Although side effects in MS DMTs may be associated with discontinuation[8], there does not appear to be an obvious relationship with nonadherence [16]. Side effects are also a common reason for treatment discontinuation in other chronic conditions [36]. The lack of clear relationship in MS may be due to several reasons: first, all DMT options have side effects and it may be a case of learning to live with them; second, we identified that the coping strategies patients develop to live with these side effects were an important predictor of nonadherence; and third, DMTs are widely known to be effective in reducing disease activity and the symptoms of MS are too severe to ignore.

In our study, we observed no association between adherence and self-reported cognitive issues, though this may be because patient self-report may be relatively insensitive to memory problems and we did not use a neuropsychological test battery [15]. Our findings concur with those of Tremlett et al [16], confirmed by the GAP study [13], who found that DMTs with less frequent dosing regimens had better adherence. Tremlett et al found a higher proportion of patients who missed at least 1 dose (73%) than in our study (121/388, 31.2%), but the former was a prospective study with reporting of a 6-month period, whereas ours was 28 days. Their findings suggested an MDR of approximately 0.14 for IFB-1b (vs 0.14 in the current study), 0.13 (vs 0.09) for IFB-1a SC, and 0.06 (vs 0.08) for GA. The GAP study identified a slightly lower proportion of patients missing at least 1 dose in the preceding 4 weeks (25%) [13]. This may reflect methodological differences or, speculatively, could be related to the means of data capture; patients may be more willing to admit to nonadherence online.

Treadaway et al [14] found that, overall, their most frequently endorsed barrier was “forgetting,” but that in the least adherent patients this was lower, with “not feeling like taking injection” and “injection anxiety” being more significant problems. In our nonadherent patients, we also found that the main barriers were “Did not feel like taking my DMT” and “Tired of taking my DMT,” followed by “Memory problems.” This suggests that adherence aids that only provide reminders may still fail to tackle the barriers of patients with the poorest levels of adherence. More work needs to be done to understand how to help patients overcome “treatment fatigue” [35].

Over the preceding 28 days we found that 16%-51% of patients had missed at least 1 dose; there is evidence from the literature to believe the problem might be worse than that. For instance, Tremlett et al’s data suggest that nonadherence in our sample may continue to be a problem; they found that missed doses predict future nonadherence over a 6-month time frame [16]. Furthermore, through their comparison of self-report against passively collected MEMS data, Bruce et al suggested doubling self-report estimates of adherence to arrive at a more accurate estimate [12]. Interestingly, Bruce et al found that some MS patients seemed less likely to be adherent on Fridays and weekends, relative to weekdays [12]. Future research should address the pharmacokinetic consequences of different patterns of nonadherence – for example, skipping a dose every Friday versus not taking 4 doses for consecutive days in a month.

The imminent arrival of oral therapies [37-39] will require further attention to be devoted to measuring adherence in MS patients. The absence of injections and the potential for simplified dosing regimens such as a daily pill should be a significant improvement, but this assumption should be tested. Future research could adapt the MS-TAQ to measure barriers to adherence in oral medications.

As a self-report study conducted in an online population, this study is open to methodological limitations, such as selection bias, response bias, and the difficulty in knowing whether patients self-identifying as patients really do have MS. Similar approaches have been taken by online registries such as NARCOMS (North American Research Committee on Multiple Sclerosis) to answer questions of clinical relevance and real-world validation. Studies have found MS patients’ self-report data to have a high level of validity [40-42]. Our response rate was typical for an online study, and we have described how it differs from both nonresponders and the Sonya Slifka longitudinal study [34], but it is possible that the sample may have been biased in receiving more responses from those with barriers to adherence, which may limit the degree to which the findings can be generalized. We have also been reassured by the relative parity between our findings and those of the larger GAP study [13], which was ongoing at the same time as our own data collection. The use of an MDR with a reference of 28 days proved to be a limitation in measuring adherence to natalizumab transfusions, which may sometimes be spaced at 2-month intervals. The measure may also appear to inflate MDR for treatments with a weekly dosing schedule (as missing a single dose automatically means an MDR of 0.25). The implications for this are unclear, as it is quite uncertain what the exact consequences are for different levels of adherence for each DMT.

A number of studies have identified risk factors for missing a dose of a given medication. A novel aspect of the current study was that we found correlations between patient-generated barriers to adherence and the magnitude of their nonadherence. We also attempted to generate a more positive sense of adherence by identifying supportive coping strategies that may help patients overcome these barriers. It is hoped that the MS-TAQ will be a useful measure of adherence to be applied in MS in future studies, particularly if it can be validated against MEMS. Multimedia Appendix 2 includes a printable version of the MS-TAQ.

Generated by patients' own experiences with adherence, the MS-TAQ can be used by health care professionals as a discussion aid, perhaps administered in the waiting room, in order to identify and overcome barriers to adherence. There is also potential to use online administration and feedback to empower patients to take responsibility for improving their own outcomes through improved adherence. Online communities have the potential to permit rapid development and psychometric validation of patient-reported outcomes.

Acknowledgments

We are grateful to the users of PatientsLikeMe who participated in this study. This study was sponsored by Novartis Pharmaceuticals Corp. and PatientsLikeMe, Inc.

Conflicts of Interest

PW and MM are employees of PatientsLikeMe and own stock options in the company; the PatientsLikeMe R&D department has received research funding from Avanir, Novartis, and UCB. AK and HD are employees of Novartis Pharmaceuticals Corporation.

Authors' Contributions

PW Project design, data collection, statistical analysis, drafting manuscript
MM Qualitative forum analysis, MSTAQ item creation
AK Project design, manuscript review
HD Project design, manuscript review

Multimedia Appendix 1

Copy of the MS-TAQ survey items presented to participants

[PDF file (Adobe PDF File), 79 KB - jmir_v13i1e12_app1.pdf]

Multimedia Appendix 2

Printable version of the MS-TAQ for clinical use

[PDF file (Adobe PDF File), 77 KB - jmir_v13i1e12_app2.pdf]

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Abbreviations

DMT: disease-modifying treatment
GA: glatiramer acetate
GAP: Global Adherence Project
IFB-1a IM: interferon beta-1a intramuscular injection
IFB-1a SC: interferon beta-1a subcutaneous injection
IFB-1b SC: interferon beta-1b subcutaneous injection
MDR: missed dose ratio
MEMS: medication event monitoring system
MS: multiple sclerosis
MS-TAQ: Multiple Sclerosis Treatment Adherence Questionnaire

Edited by G Eysenbach; submitted 22.11.10; peer-reviewed by D Jacobs, P Jongen; comments to author 14.12.10; revised version received 18.12.10; accepted 13.01.11; published 24.01.11.

Please cite as:
Wicks P, Massagli M, Kulkarni A, Dastani H
Use of an Online Community to Develop Patient-Reported Outcome Instruments: The Multiple Sclerosis Treatment Adherence Questionnaire (MS-TAQ)
J Med Internet Res 2011;13(1):e12
URL: http://www.jmir.org/2011/1/e12/
doi:10.2196/jmir.1687
PMID:21266318

Original Paper

Patient-reported Outcomes as a Source of Evidence in Off-Label Prescribing: Analysis of Data From PatientsLikeMe

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Abstract

Background: Evaluating a new use for an existing drug can be expensive and time consuming. Providers and patients must all too often rely upon their own individual-level experience to inform clinical practice, which generates only anecdotal and unstructured data. While academic-led clinical trials are occasionally conducted to test off-label uses of drugs with expired patents, this is relatively rare. In this work, we explored how a patient-centered online research platform could supplement traditional trials to create a richer understanding of medical products postmarket by efficiently aggregating structured patient-reported data. PatientsLikeMe is a tool for patients, researchers, and caregivers (currently 82,000 members across 11 condition-based communities) that helps users make treatment decisions, manage symptoms, and improve outcomes. Members enter demographic information, longitudinal treatment, symptoms, outcome data, and treatment evaluations. These are reflected back as longitudinal health profiles and aggregated reports. Over the last 3 years, patients have entered treatment histories and evaluations on thousands of medical products. These data may aid in evaluating the effectiveness and safety of some treatments more efficiently and over a longer period of time course than is feasible through traditional trials.

Objective: The objective of our study was to examine the illustrative cases of amitriptyline and modafinil – drugs commonly used off-label.

Methods: We analyzed patient-reported treatment histories and drug evaluations for each drug, examining prevalence, treatment purpose, and evaluations of effectiveness, side effects, and burden.

Results: There were 1948 treatment histories for modafinil and 1394 treatment reports for amitriptyline reported across five PatientsLikeMe communities (multiple sclerosis, Parkinson's disease, mood conditions, fibromyalgia/chronic fatigue syndrome, and amyotrophic lateral sclerosis). In these reports, the majority of members reported taking the drug for off-label uses. Only 34 of the 1755 (1%) reporting purpose used modafinil for an approved purpose (narcolepsy or sleep apnea). Only 104 out of 1197 members (9%) reported taking amitriptyline for its approved indication, depression. Members taking amitriptyline for off-label purposes rated the drug as more effective than those who were taking it for its approved indication. While dry mouth is a commonly reported side effect of amitriptyline for most patients, 88 of 220 (40%) of people with amyotrophic lateral sclerosis on the drug reported taking advantage of this side effect to treat their symptom of excess saliva.

Conclusions: Patient-reported outcomes, like those entered within PatientsLikeMe, offer a unique real-time approach to understand utilization and performance of treatments across many conditions. These patient-reported data can provide a new source of evidence about secondary uses and potentially identify targets for treatments to be studied systematically in traditional efficacy trials.

(J Med Internet Res 2011;13(1):e6) doi:10.2196/jmir.1643

KEYWORDS

Off-label; Internet; research; patient platform; methods; online community

Introduction

Off-label prescribing is a legal and common practice in the United States [1]. When a manufacturer develops a new medication for a particular purpose, the US Food and Drug Administration's (FDA's) [2] Center for Drug Evaluation and Research evaluates the drug's efficacy and utility for that purpose before it is brought to market. However, once the drug is on the market, health care providers are free to prescribe the drug for either the FDA-approved purpose ("indication") or any other purpose – a practice referred to as "off-label prescribing." Across all major drug categories, it is estimated that 21% of all prescriptions are for off-label purposes [3].

Off-label prescribing has the potential to be a source of innovation in medicine. Prescribers can discover novel uses for existing medications while monitoring tolerability, safety, and effectiveness. Within their practice they can apply the insight acquired from treating one person to the next case [4]. However, prescribers may not have an adequate number of cases to distinguish between a truly meaningful effect of the drug, and either a placebo effect or the tendency for patients to improve on their own.

Off-label prescribing is often done without supporting medical evidence [1]. For the estimated 21% of prescriptions given off-label, 73% lacked scientific evidence underlying their use [3]. In many cases, patients may be subject to unnecessary, ineffective, and even harmful treatments. In the past, millions of women received prophylactic hormone treatment for the prevention of osteoporosis, for instance. However, systematic evaluation revealed no therapeutic benefit and elevated risks of cardiac damage [5]. Patients are extremely unlikely to be aware that the FDA has not evaluated the safety and efficacy of their treatment for the purpose for which they are using it.

In 2008 the FDA released a guidance document entitled "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices" [2]. This guidance provides advice for industry on circulating journal article reprints that contain information on off-label use, such as for the use of modafinil in treating fatigue in multiple sclerosis (MS) or amitriptyline in treating excessive saliva in amyotrophic lateral sclerosis (ALS). Unfortunately there are a number of limitations to the application of this guidance. First, the quality of the scientific literature and the informal benchmark of acceptability vary dramatically between diseases. The most widely cited paper on the use of modafinil for the treatment of fatigue in MS, for instance, has been cited nearly 250 times but contained only 65 patients at its 9-week end point and failed to find a dose-response effect [6]. Second, the guidance requires industry to provide counterbalancing evidence. Perhaps unsurprisingly, though, there is evidence of selective reporting: many off-label trials are not published, particularly when their finding are not significant [7]. This effect is surely compounded by publication bias; that is, it is easier to publish significant findings than nonsignificant findings. Third, there are inconsistencies among medical conditions in the number of options available; off-label medication use is frequently the only option for "orphan conditions"[1]; and for many medical conditions there is no "approved" treatment. For instance, a study comparing approved drug indications against the *Diagnostic and Statistical Manual of Mental Disorders*, 4th edition, text revision (DSM-IV-TR) found that 89% of all psychiatric disorders lack approved medications for their treatment [8]. Fourth, the regulations apply only to the most visible means of promotion, and fail to address continuing medical education presentations and events, or oral responses to physicians' questions at company-sponsored events, exhibit booths, or in "detailing" visits [9]. Finally, it has been noted that, as the guidance is not legally binding, enforcement is unlikely.

Consequently, there is a need to gather evidence to inform off-label prescribing. Unfortunately, gathering this evidence can be prohibitively expensive. Running a clinical trial, of the type needed to establish the efficacy of a drug for a new purpose, costs US $15,700 for a phase 1 trial and over US $26,000 for a phase 3 trial per patient [10]. If a drug is already being used widely off-label there may be no incentive for manufacturers to evaluate it systematically.

In this paper, we propose a new source of evidence to evaluate off-label use: patient-reported outcomes entered via an online community. An increasing number of patients are going online to access information about their health and talk to other patients about a shared condition [11]. Many patients share advice and details about their treatments and symptoms with one another and with researchers. Clinical trial researchers increasingly use the Internet for recruiting subjects, communicating with participants, and even collecting data [12]. Patient groups like the Life Raft Group for patients with gastrointestinal stromal tumor have successfully mobilized their members to study the effectiveness of investigational treatments [13]. In this work, we suggest how patients, entering outcomes within an online community, could inform how drugs are working for off-label uses by expanding the available evidence base.

To conduct this analysis we examined patient reported outcomes reported on PatientsLikeMe. PatientsLikeMe is a web-based community and research platform where patient members share details about their treatments, symptoms, and conditions, with the intention of improving their outcomes[14,15]. Patients join communities designed specifically for their condition. At the time of writing, there were 11 distinct patient communities and over 70,000 patient members. The site synthesizes members' data into interactive reports for review. Each member sees a graphical representation of their own and others' function, treatments, and symptoms over time and can view reports of aggregated data. The site includes an interactive treatment report for each medication and intervention that patients add to the system. The report includes dosages taken, time on treatment, and evaluations of the treatment, including perceived efficacy, side effects, and burden. These treatment reports can suggest usage patterns and effectiveness rates for drugs across different purposes.

We examined patient data for two medications that are widely prescribed off-label and currently being evaluated for new applications: amitriptyline and modafinil. We documented how patients reported using these drugs and how patient reports could inform broader understanding of these relatively well-understood medications. PatientsLikeMe hosts communities for patients with ALS, MS, depression, Parkinson's disease, fibromyalgia, and chronic fatigue syndrome. Given the high levels of fatigue, pain, excess saliva, and depression presented across these communities, many members of the site could be candidates for treatment of these symptoms.

Amitriptyline (Elavil; Merck & Company Inc, Whitehouse Station, NJ, USA) is a tricyclic antidepressant that was developed by Merck and approved in the United States in 1961. It has FDA approval for the treatment of major depression, clinical/endogenous depression, and involutional melancholia, but it is commonly used off-label for other symptoms ranging from chronic pain to bed wetting. Due to the anticholinergic effects of amitriptyline a primary side effect of the drug is dry mouth. There are 14 clinical trials involving amitriptyline that are recruiting subjects (on clinicaltrials.gov), reflecting an ongoing interest in its use. In neurological conditions such as ALS, amitriptyline has been reported informally as being used by neurologists for the treatment of depression, as well as off-label for excessive saliva, emotional lability, urinary urgency, and insomnia [16], despite an absence of trials supporting its use. Even in its indicated use, for depression, ALS guidelines state “Concerning pharmacological treatment of depression in patients with ALS, there is broad consensus among clinical experts that [selective serotonin-reuptake inhibitors] and [tricyclic antidepressants] are helpful, but there have been no controlled clinical studies of these medications in ALS patients” [17]. Antidepressants like amitriptyline have been highlighted as an important target for future research into off-label drug use [18].

Modafinil (Provigil; Cephalon, Inc, Frazer, PA, USA) is a wakefulness-promoting agent first available in the United States since 1998 for approved purposes related to sleep disorders, including narcolepsy, shift-work disorder, and obstructive sleep apnea. As a wakefulness-promoting agent, it has also been investigated off-label for the treatment of fatigue in conditions including MS [19], fibromyalgia [20], chronic fatigue syndrome [21,22], and Parkinson's disease [23-25]. In the past, promotion of the drug for these off-label purposes by the manufacturer has resulted in warnings and fines from the FDA [2]. A recent review [19] of the MS literature assessing the use of modafinil for the treatment of fatigue in MS considered it a “reasonable therapeutic option” but cautioned that trials to date have been small (total N of the literature = 308 patients), unblinded, and with only short-term follow-up (median follow-up 12 weeks). There were some adverse events, mostly gastrointestinal, but one-third of studies failed to report adverse events at all. Similar methodological problems likewise seriously undermine existing off-label studies in other diseases.

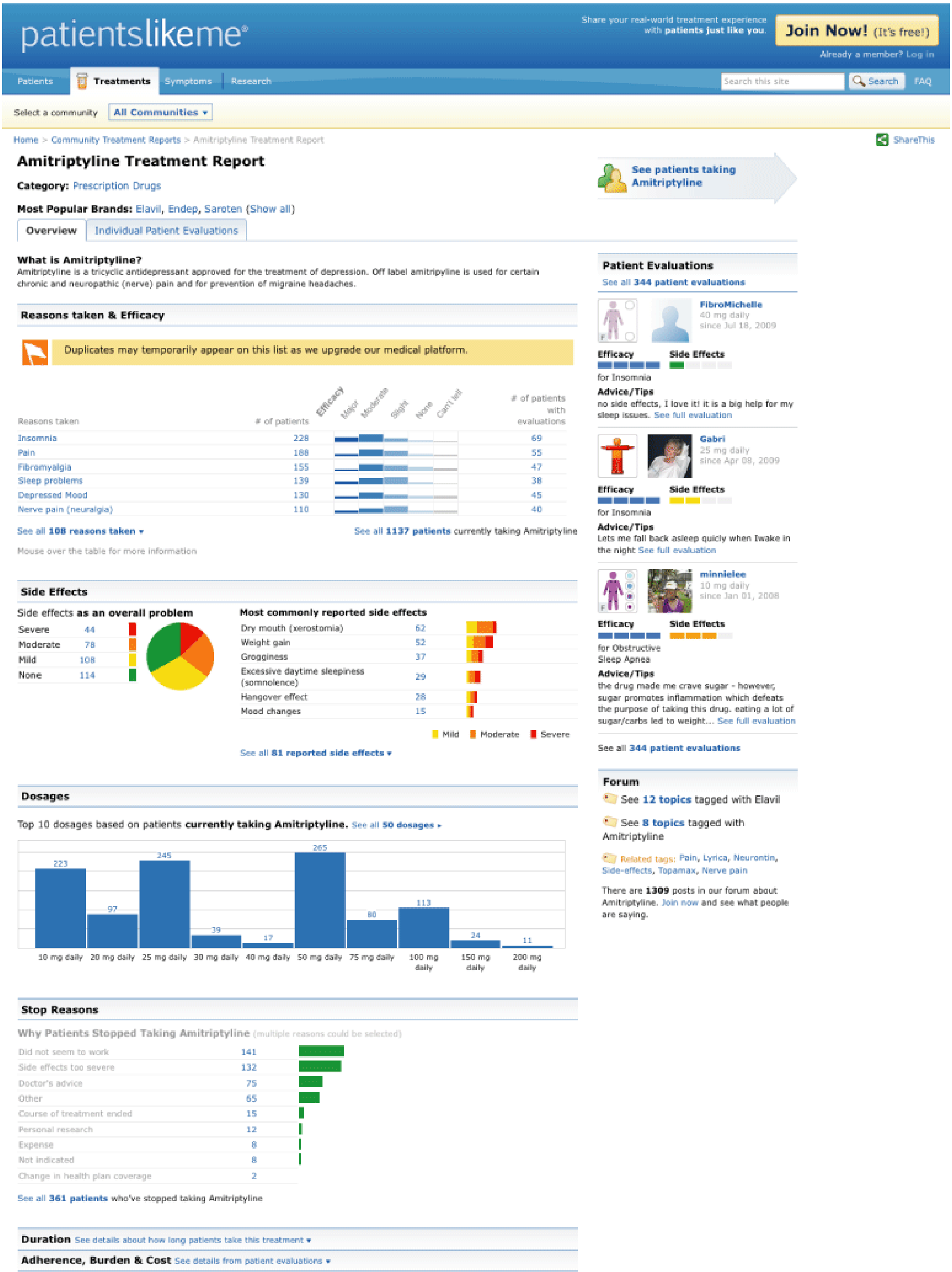
In this study, we conducted a post hoc analysis of the prevalence of on-label versus off-label use, dosing, and perceived effectiveness and side effects for these medications. We looked at prevalence of use across the site and in specific communities. We documented purposes of use by community and the side effects they reported. Lastly, we began to look at how effectiveness varied by purpose to see whether these agents function similarly for on- and off-label indications.

Methods

We analyzed the treatment information entered by patient members about the two drugs of interest, amitriptyline and modafinil, across five condition-based communities: MS, fibromyalgia/chronic fatigue syndrome, ALS, mood disorders (depression, bipolar disorder, and anxiety disorders), and Parkinson's disease. At the time of analysis (May 24, 2010), these communities contained 53,928 members.

Patients complete treatment histories, including start date, the purpose for taking the treatment, dosage (with available dosages according to the Multum database [Cerner Multum, Denver, CO, USA] prompted as the most likely response options), dates of dosage change, and stop date. Members can add more than one treatment history to indicate repeated trials of a treatment. In addition to their treatment history, members may complete evaluations for each treatment, entering side effects, severity of side effects (none, mild, moderate, or severe), burden (difficulty of being on treatment: not at all, a little, somewhat, or very), and perceived effectiveness (can’t tell, none, slight, moderate, or major). In both the treatment reports and the evaluations (See Figure 1), users are prompted to use a curated vocabulary of side-effect and purpose terms, but may enter their own natural language if they wish. In order to aggregate data across the patient-entered vocabulary, patient-generated symptom and side-effect symptom terms were coded using the Medical Dictionary for Regulatory Activities (MedDRA MSSO, Chantilly, VA, USA).

Figure 1. The treatment report for amitriptyline available on PatientsLikeMe. This treatment report was captured after the date of analysis; therefore, the data featured do not match the data reported.



Amitriptyline Treatment Report

Category: Prescription Drugs

Most Popular Brands: Elavil, Endep, Saroten (Show all)

What is Amitriptyline?

Amitriptyline is a tricyclic antidepressant approved for the treatment of depression. Off label amitripyline is used for certain chronic and neuropathic (nerve) pain and for prevention of migraine headaches.

Reasons taken & Efficacy

Duplicates may temporarily appear on this list as we upgrade our medical platform.

Reasons taken	# of patients	Efficacy: Major, Moderate, Slight, None, Can't tell	# of patients with evaluations
Insomnia	228		69
Pain	188		55
Fibromyalgia	155		47
Sleep problems	139		38
Depressed Mood	130		45
Nerve pain (neuralgia)	110		40

See all **108 reasons taken** ▾

See all **1137 patients** currently taking Amitriptyline

Mouse over the table for more information

Side Effects

Side effects **as an overall problem**

Severe	44	🟥
Moderate	78	🟧
Mild	108	🟨
None	114	🟩

Most commonly reported side effects

Dry mouth (xerostomia)	62
Weight gain	52
Grogginess	37
Excessive daytime sleepiness (somnolence)	29
Hangover effect	28
Mood changes	15

🟨 Mild 🟧 Moderate 🟥 Severe

See all **81 reported side effects** ▾

Dosages

Top 10 dosages based on patients **currently taking Amitriptyline.** See all **50 dosages** ▸

Stop Reasons

Why Patients Stopped Taking Amitriptyline (multiple reasons could be selected)

Did not seem to work	141
Side effects too severe	132
Doctor's advice	75
Other	65
Course of treatment ended	15
Personal research	12
Expense	8
Not indicated	8
Change in health plan coverage	2

See all **361 patients** who've stopped taking Amitriptyline

Duration See details about how long patients take this treatment ▾

Adherence, Burden & Cost See details from patient evaluations ▾

Patient Evaluations

See all **344 patient evaluations**

FibroMichelle
40 mg daily
since Jul 18, 2009

Efficacy **Side Effects**

for Insomnia

Advice/Tips

no side effects, I love it! it is a big help for my sleep issues. See full evaluation

Gabri
25 mg daily
since Apr 08, 2009

Efficacy **Side Effects**

for Insomnia

Advice/Tips

Lets me fall back asleep quicly when Iwake in the night See full evaluation

minnielee
10 mg daily
since Jan 01, 2008

Efficacy **Side Effects**

for Obstructive Sleep Apnea

Advice/Tips

the drug made me crave sugar - however, sugar promotes inflammation which defeats the purpose of taking this drug. eating a lot of sugar/carbs led to weight... See full evaluation

See all **344 patient evaluations**

Forum

See **12 topics** tagged with Elavil

See **8 topics** tagged with Amitriptyline

Related tags: Pain, Lyrica, Neurontin, Side-effects, Topamax, Nerve pain

There are **1309** posts in our forum about Amitriptyline. Join now and see what people are saying.

Results

Modafinil

Across the five communities, there were 1948 treatment histories for modafinil: 1316 described current treatment at the time of analysis; therefore, 1316 of 53,928 (2%) of all members reported currently taking modafinil.

Modafinil use was most prevalent in the MS community, where there were 1565 reports for 17,820 members (6%), followed by Parkinson's disease (75/4789, 1%) and mood communities (136/14,483, 1%). Purposes were reported in 1755 of 1948 (90%) modafinil treatment histories (see Table 1, n = 1755). Overall, only 34 of 1755 (less than 1%) of members reported taking modafinil for an approved purpose (narcolepsy and excessive daytime sleepiness resulting from sleep apnea; see Figure 1). Rather, the majority of users reported taking modafinil to treat other issues, including general fatigue (1201/1755, 68%) and excessive daytime sleepiness or tiredness arising from their condition (288/1755, 16%); less common purposes included “brain fog” (61/1755, 3%) a patient vocabulary term for having difficulty concentrating, and cognitive impairment (29/1755, 2%).

When purposes were viewed by MedDRA system organ class (SOC) terminology, modafinil was most commonly used to treat purposes that fall within “general disorders and administration site conditions” (1277/1755, 73%) followed by “nervous system disorders” (415/1755, 24%). No other category accounts for more than 1% of responses.

There were 726 treatment evaluations written about modafinil at time of analysis and 383 side-effect reports. The most common side effects reported fell into the MedDRA SOC “nervous system disorders” (134/383, 35%) and “general disorders and administration site conditions” (100/383, 26%). Looking at individual side effects, jittery feeling (68/383, 18%), dry mouth (60/383, 16%), and anxiety (46/383, 12%) were the most commonly reported.

In these evaluations, most users (532/726, 72%) rated the effectiveness of modafinil in the highest response categories: either “major” or “moderate” (see Table 2). These effectiveness ratings did not vary by purpose. There was a slight tendency to rate the drug as more effective for some off-label purposes, such as a treatment of MS, than for sleepiness. There was only one evaluation in the system for an approved purpose, specifically narcolepsy.

Table 1. Purposes reported by 10 or more users for modafinil

Purpose reported	MedDRA LLT code[a]	Number reporting (n = 1755)	%
Fatigue[b]	10016256	1201	68.43%
Excessive daytime sleepiness[b]	10015595	262	14.9%
Brain fog	10016876	61	4%
Mood	10027945	26	2%
Sleepiness	10041014	26	2%
Cognitive impairment	10009846	29	2%
Narcolepsy and sleep apnea	10028713; 10040975	24	1%
Problems concentrating	10003729	20	1%
Multiple sclerosis	10028245	23	1%

[a] Medical Dictionary for Regulatory Activities lower-level term.

[b] 68% of users reported taking the drug to treat fatigue and another 14% excessive daytime sleepiness, such that most users appear to have taken the drug for related purposes.

Table 2. Effectiveness ratings for modafinil and amitriptyline

Effectiveness rating	Modafinil (n = 726)		Amitriptyline (n = 590)	
	# Reporting	%	# Reporting	%
Can’t tell	30	4%	36	6%
No effect	23	3%	86	15%
Slight	141	19%	167	28%
Moderate	268	37%	201	34%
Major	264	36%	100	17%

Amitriptyline

There were 1,394 treatment reports for amitriptyline: 865 of the total 53,928 patient members reported currently taking the drug (2%).

ALS, although a small community, had the highest rate of use. At the time of analysis, 228 of 4060 (6%) ALS patients in the community reported having taken the drug and 178 of the 4060 (4%) ALS patients stated they were currently taking amitriptyline. In 1197 of the 1394 (86%) treatment reports, patients reported a purpose (see Table 3). Off-label uses were much more commonly reported than the on-label purpose. In 104 of 1197 reports (9%), patients reported taking amitriptyline for the approved use of depression; most commonly, patients reported taking it for insomnia and other sleep problems (321/1197, 27%) or pain (197/1197, 17%). Examining purposes at the SOC level found that members reported using amitriptyline to control complaints in a variety of systems, including nervous system disorders (544/1197, 45%), musculoskeletal and connective tissue disorders (115/1197, 10%), and gastrointestinal disorders (103/1197, 9%). Psychiatric disorders, more broadly, accounted for only 208 (17%) of the 1197 reported purposes. One purpose of note was in ALS, where 88 of 220 (40%) patients took the drug for the purpose of treating a symptom of their condition, excess saliva.

Overall, there were 270 side-effect reports of amitriptyline in the system. The most commonly reported side effects were related to feeling sleepy (reported 126 times in 270 reports, 46%), including “grogginess/sleepiness/drowsiness” (reported 56 times in 270 reports), “daytime sleepiness” (reported 34 times), and “feeling groggy” (reported 36 times in 270 reports). The second most common side effect was dry mouth (reported 78 times in 270 reports, 29%) and third was weight gain (60/270, 22%).

In this example, there were 70 effectiveness ratings for the approved purpose of depression and 520 effectiveness ratings for off-label purposes (see Table 2). The ratings for off-label purposes were higher than for depression: 28 of the 70 (40%) respondents taking it for the prescribed purpose of depression rated it as having either a major or moderate efficacy in comparison to 273 of 520 (52%) taking it for off-label uses.

Table 3. Most common purposes reported for taking amitriptyline: purposes reported by 10 or more users are listed (n = 1197 purpose reports by 1394 users). The reasons people reported taking the drug vary widely.

Purpose reported	MedDRA LLT code[a]	Number reporting (n = 1197)	%
Insomnia/sleep problems	10022437	321	26.8%
Pain	10033371	197	16.5%
Depression	10012378	104	8.7%
Fibromyalgia	10048439	90	8%
Excess saliva	10021677	88	7%
Nerve pain	10029181	83	7%
Emotional lability	10014555	37	3%
Migraine headaches	10027602	37	3%
Anxiety	10002855	36	3%
Headaches	10019211	24	2%
Mood disorder	10027945	21	2%
Muscle pain	10028322	17	1%
Restless legs syndrome	10038741	14	1%
Migraine	10027599	13	1%
Fatigue	10016256	11	1%
Amyotrophic lateral sclerosis	10052889	10	1%
Stiffness/spasticity	10041416	10	1%

[a] Medical Dictionary for Regulatory Activities lower-level term.

Discussion

Using an online patient community, PatientsLikeMe, we identified that only less than 1% of nearly 2000 patients taking modafinil and 9% of nearly 1400 patients taking amitriptyline reported taking each drug for purposes approved by the FDA. In both cases, patients subjectively reported the effectiveness for off-label uses as either higher than or comparable to approved indications. Many patients used some of the most common side effects reported for amitriptyline, including sleepiness, as their purpose for taking the drug, such as the treatment of insomnia.

We were surprised to find that in two relatively well-understood drugs, the vast majority of uses were off-label. Our analysis may indicate that off-label prescribing is even more common in certain patient populations. In terms of patient-reported effectiveness, the data suggest that amitriptyline could be more efficacious for off-label uses than for FDA-approved uses. Further study of newer, less commonly used for off-label purposes, would provide a more complete understanding of the value of patient-reported outcomes in this area.

One advantage of collecting treatment information through an online community is the ability to reach a large population of users at relatively little marginal cost. As the Internet becomes more accessible, an increasingly diverse population is online and joining online communities for support with health problems [11]. By gathering experiences directly from patients, researchers can elicit new types of data not recorded systematically through routine clinical practice, and which would be unlikely to attract funding for traditional clinical trials. In fields of study where self-reported data are acceptable, the Internet offers a unique vehicle to collect vast quantities of data far more effectively than traditional studies permit. This is particularly true for ongoing monitoring of patient safety and serious adverse events. Toward this end, PatientsLikeMe is developing its pharmacovigilance platform to provide a constant stream of safety data to manufacturers and the FDA, which can serve as an ongoing phase 4 study of pharmaceutical products.

However, there are significant challenges associated with collecting patients' outcome data for post hoc analysis. Members of an online community visit the site on their own schedule and contingent upon their own needs. While a website may prompt users for specific information at timed intervals, members ultimately have the choice of when and whether they will add data. Members may add data only when they feel strongly about a treatment, leading to a substantial reporting bias. In this light, unblinded studies like ours might consider different outcome metrics of primary importance and rely on markers of perceived treatment effectiveness such as discontinuation rates, adherence and side effects, rather than self-reported measures of effectiveness, which can be highly susceptible to placebo effects.

Yet there are other limitations. Within the group of registered patients in a community, patients may not report information completely. An unknown proportion may be taking the drug but fail to report it or its effects. Among those who have taken the treatment, only a certain subset completed an evaluation of the drug, and for the most part they evaluated it at only one timepoint. It is hoped that prompts and improved user interface designs, along with more contextual reports and research studies (such as this one), will increase the value to patients and in turn motivate users to enter more information.

In addition, we have a lower level of confidence than in clinical trials that a registered "patient" in our system has had a specific condition diagnosed, that the user is taking the medication as prescribed, or that the patient's experience is tempered by an unreported comorbidity. There is the potential in the future to ask clinicians to verify diagnoses and to use records from the pharmacies or eHealth technology to validate patient-reported behavior, but this will require significant research to address issues of consent and coding requirements to ensure privacy. In the meantime we believe that the scale, scope, and cost to execute such studies outweigh, or at the very least, mitigate, these limitations.

Due to the architecture of the PatientsLikeMe system, we included only a handful of medical communities and possibly incomplete patient experiences. However, plans are underway to significantly expand the number of communities and allow for multiple comorbidities to be collected, thereby increasing the scope, quality, and representativeness of future studies.

Finally, when collecting data from patients online, there is the distinct possibility of more egregious misrepresentation – namely, that users are not who they appear to be. Patients on the site could be falsifying their identities entirely. While this is always possible, certain Internet platforms may be at higher risk for these gross inaccuracies than others. In many websites built specifically to collect medication ratings from patients, users enter minimal information about themselves before entering treatment evaluations, thus lowering the barrier for misrepresentation. PatientsLikeMe, as a community based on ongoing interaction and a reputation built upon a time-based health profile, may be less susceptible to flagrant misrepresentation.

Conclusion

There are stated methodologies to evaluate the safety and efficacy of drugs for a specific purpose before they are brought to market. Once approved, these drugs are being used to treat a wide variety of symptoms and conditions. In many cases, this is a legitimate and ultimately positive use for an existing agent, yet all too often there is no way to establish evidence or monitor patient safety.

At the moment, providers often rely on peer-reviewed literature to inform treatment choice. But critics note that "attempting to use peer-reviewed literature for a purpose for which it is so ill suited is likely not only to fail to adequately regulate off-label use but also to degrade the quality of peer-reviewed literature" [26], suggesting there is a need for other ways to evaluate off-label prescribing. Online patient platforms, as a repository for patient-reported outcomes, provide an opportunity to create new methods to study the effect of these drugs after they have reached the market. Evaluating evidence from multiple sources, including peer-reviewed literature and online communities, could provide converging evidence about effectiveness. Online communities are in the unique position to capture and present information of particular relevance to other patients who are considering taking a drug.

Off-label prescribing is a common practice, but outcomes associated with it are routinely understudied, which sometimes leads to wasteful treatments and even harmful effects. We propose that patients, sharing their data online, can provide relevant, timely information to fill these gaps in knowledge.

Acknowledgments

Thank you to the members of PatientsLikeMe who have contributed the experiences and patient reported outcomes that are analyzed in this article.

Publishers' Note: This article was the winner of the JMIR Medicine 2.0 Award 2009 at the 2nd Medicine 2.0 World Congress on Social Media and Web 2.0 in Health, Medicine and Biomedical Research. Publication fees were partly sponsored by JMIR Publications.

Conflicts of Interest

JF, SO, TV, JH, and PW are paid employees of PatientsLikeMe and own stock and/or stock options in the company. The PatientsLikeMe R&D team has received research funding from Avanir, Novartis, and UCB.

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Abbreviations

ALS: amyotrophic lateral sclerosis
DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders, 4th edition, text revision
FDA: Food and Drug Administration
MedDRA: Medical Dictionary for Regulatory Activities
MS: multiple sclerosis
SOC: system organ class

Edited by G Eysenbach; submitted 10.09.10; peer-reviewed by JT Gussinklo, S Hughes; comments to author 01.11.10; revised version received 06.12.10; accepted 20.12.10; published 21.01.11.

Please cite as:
Frost J, Okun S, Vaughan T, Heywood J, Wicks P
Patient-reported Outcomes as a Source of Evidence in Off-Label Prescribing: Analysis of Data From PatientsLikeMe
J Med Internet Res 2011;13(1):e6
URL: http://www.jmir.org/2011/1/e6/
doi:10.2196/jmir.1643
PMID:21252034

Viewpoint

Review of Extracting Information From the Social Web for Health Personalization

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Abstract

In recent years the Web has come into its own as a social platform where health consumers are actively creating and consuming Web content. Moreover, as the Web matures, consumers are gaining access to personalized applications adapted to their health needs and interests. The creation of personalized Web applications relies on extracted information about the users and the content to personalize. The Social Web itself provides many sources of information that can be used to extract information for personalization apart from traditional Web forms and questionnaires. This paper provides a review of different approaches for extracting information from the Social Web for health personalization. We reviewed research literature across different fields addressing the disclosure of health information in the Social Web, techniques to extract that information, and examples of personalized health applications. In addition, the paper includes a discussion of technical and socioethical challenges related to the extraction of information for health personalization.

(J Med Internet Res 2011;13(1):e15) doi:10.2196/jmir.1432

KEYWORDS

Medical informatics; Internet, information storage and retrieval; online systems; health communication; data mining; natural language processing

Introduction

The use of the Web by health consumers and professionals has changed with the emergence of the Social Web. This phenomenon has been described as Medicine 2.0 [1]. Whereas 10 years ago the Web was coming into its own as an e-commerce engine, the last 5 years have seen an increase in social interaction and content creation platforms that further engage and enmesh individuals in each other’s online lives, increasing the sharing of knowledge. This is especially true and important for individuals seeking health information and interested in finding others with health conditions like their own. Health consumers are socializing, searching for health information [2,3], and creating content about their health in user profiles, blogs, or videos [4]. Sharing experiences and knowledge can go beyond traditional Web content and include structured health data in sites like PatientsLikeMe [5] and 23andMe [6].

The phenomenon of the Social Web would not have been possible without the transformation of Web content from static to dynamic thus providing a much richer interactive Web experience. With the emergence of the adaptive Internet in the early 1990s, websites started to change dynamically, making it possible to provide different Web content for each user. As early as 1994, the system MetaDoc changed the content of technical Web documentation based on level of expertise of the reader [7]. This adaptation of the content for a specific user is known as Web personalization [8] and adaptive hypermedia [9]. Web personalization is making the Web more efficient when accessing information and services. For example, when buying a book at Amazon.com, related recommendations are based on browsing history.

Personalization is also used to adapt Web health information and applications to the needs of each user. As explained in the background section, health education since the 1990s has been personalized and delivered through the Web with positive patient outcomes [10].

One of the main challenges when creating personalized health applications is to capture the information needed for personalization. Traditionally, information capture has relied on input from users (eg, questionnaires), which is time consuming and may undermine the interest of users. A new approach is emerging that consists of using the Web itself as a source of information for health personalization. For example, personal health records (PHRs) integrate many personalized applications, such as the online service TrialX that recommends clinical trials to health consumers based on their PHRs [11]. Content generated by health consumers can also be used for personalization. For example, in the project RiskBot, some methods have been developed for personalizing health information using data from users' profiles in MySpace [12,13]. These are just some of many examples illustrating the different possibilities for extracting information from the Social Web for health personalization.

The objective of this paper is to provide a review of the different approaches for extracting information from the Social Web for health personalization. The paper is structured as follows: the background section provides an introduction to health personalization across different research areas using as an example the case of Tailored Health Education. In the following section, we review approaches to extract information for personalization from different sources of information available in the Social Web. In the discussion section, we address current and future challenges including both technical and socioethical issues. Finally, in the conclusion we summarize the main contributions of the paper.

Methods

In this review, our search strategies were designed to identify relevant research literature that addressed the following aspects of health personalization in the Social Web: (1) studies about the disclosure of health information in the Social Web, (2) techniques to extract that information, and (3) examples of applications. Major scientific databases in computer science (eg, ACM Digital Library) and biomedicine (eg, PubMed) were searched. In addition, we searched through the references of the selected papers, contributions to conferences, and nonresearch literature (eg, websites, books, technical reports). The background section provides an overview of the different research areas where the search was performed.

The multidisciplinary team of authors performed the selection and analysis of the relevant articles. Their backgrounds cover the different domains of the review (eg, information retrieval, computer science, health informatics, and public health). The different studies were analyzed to understand the implications for health personalization, including technical and socioethical aspects.

Background

Personalization

Personalization is a popular term with different meanings across domains. While personalization is the adaptation of something to a certain individual, there is a wide range of things that might be personalized (eg, treatments, websites, educational brochures, advertisements). In addition, personalization can be based on many different characteristics (eg, age, name, and location).

In the Web domain, personalization is the selection and adaptation of websites according to user specific characteristics or behaviors [8]. This is in contrast to “customization” or “adaptable systems,” which refer to systems that are adapted by users themselves, for example, modifying search retrieval preferences or portal settings [9].

In medicine, the term personalization typically refers to delivering health care interventions that are designed for an individual patient (eg, drugs designed for patients with a certain genetic characteristic) [14]. However, the meaning of the word personalization varies within the health domain. In the field of tailored health education, personalization can be as simple as using the patient’s name in the educational material. In that domain, personalization is a subtype of tailoring. Computer tailoring in health education has been defined as “the adaptation of health education to one specific person through a largely computerized process” [15].

For the purposes of this paper, we will use the definition of Web personalization [8] applied to the health domain. Therefore, we define Web health personalization as the adaptation of health-related Web content and applications to characteristics associated with a specific user.

Relevant Research Areas

There are different areas of research within health informatics (see Table 1) dealing with aspects related to the acquisition of information from the Social Web for health personalization. Tailored health education, the next subsection, is of special interest because in that domain, personalized Web applications have been used for more than a decade. In addition, there are relevant research areas in computer science, which are listed in Table 2.

Table 1. Relevant research areas in health informatics

Research Area	Importance for Health Personalization
Tailored health education [10]	Personalization of educational Web content to promote health and modify health behaviors
Personal health records [16]	PHRs are a source of information about users. Personalized applications can be integrated as third party applications inside the PHRs.
Biomedical text mining	Data mining techniques to extract information from text, for example, automatic classification of forum posts [17]
Consumer health vocabulary [18]	Study of the vocabulary used by health consumers and how it maps with medical standardized vocabulary
Computer-aided diagnosis	Analysis of text, audio, and video for diagnosis, for example, speech analysis in neurology [19]

Table 2. Relevant research areas in computer science

Research Area	Importance for Health Personalization
User modeling and personalization	Adaptation of Web systems to users and user modeling [8]
Computer vision	Extraction of information from images and videos, for example, age-group classification from facial images [20]
Affective computing and social signaling	Extraction of information about users emotions [21] and social behavior [22]
Collaborative computing	Use of collaborative techniques to build personalized systems and classify content, for example, tagging of Web content [23]
Web data mining	Extracting information from the Web, for example, the analysis of the links to find relevant websites [24]

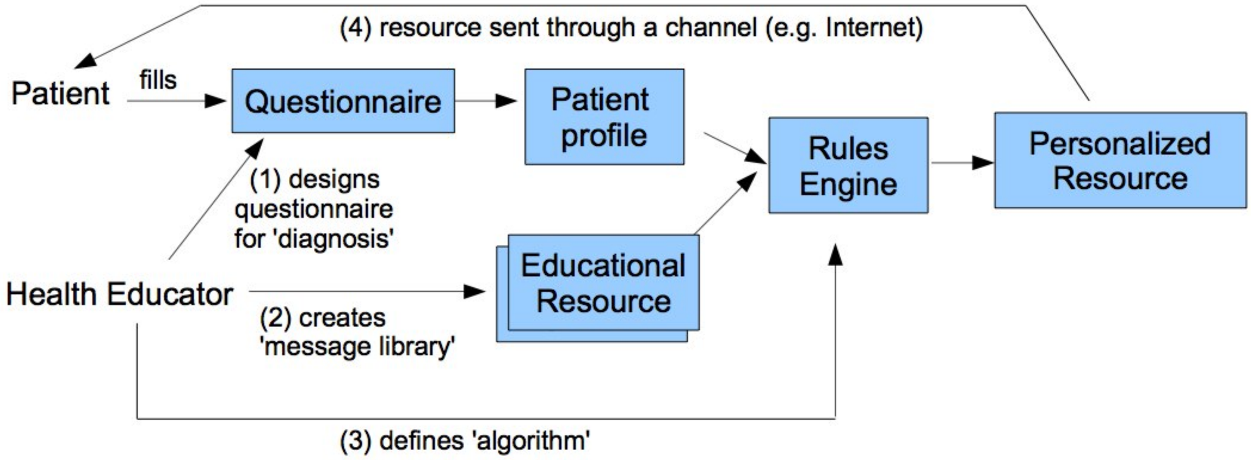
Tailored Health Education

The origin of Web health personalization is found in the field of tailored health education. Computers have been used to personalize health education from the early 1990s, including Web educational content. Detailed reviews of personalized health education can be found in Vries et al [15], Cawsey et al [25], and Kukafka et al [26]. Reviews dealing with Web-based interventions can be found in Lustria [10], Webb et al [27], and in Enwald et al about obesity [28].

According to de Vries and Brug [15], the process of personalizing educational materials (see Figure 1) requires: at least: (1) a “diagnosis” at the individual level of characteristics that are relevant for a person’s health behavior or illness; (2) a “message library” that contains all health education messages that may be needed; (3) an “algorithm,” a set of decision rules that evaluates the diagnosis and selects and generates messages tailored to the specific needs of the individual user; and (4) a “channel.”

Using computer science terminology, the *diagnosis* can be seen as *user modeling* and the *message library* could be seen as the repository with the Web content to personalize. Different adaptations are possible within personalized health education such as selecting which content is to be presented, ordering of content, and adaptation of content itself.

Figure 1. The process of tailoring health education



As described in Figure 1, most personalized health education systems can be seen as expert systems where the expertise of a human health educator is captured to create a personalized intervention (eg, text message or website) based on a set of parameters about the patients and the educational resources. The parameters can be diverse, from basic demographics to complex psychological parameters, depending on the goals of the application. For example, physiological parameters may be more relevant to modify behaviors (eg, smoking) than to provide health information to patients with cancer. In most cases, the parameters about patients are captured using questionnaires, which are time consuming and may decrease the interest to participate. To alleviate that problem, certain parameters (eg, demographics and diagnosis) can be captured from electronic medical records [29].

Adapting the content itself can simply mean adding the patient's name in the appropriate places. It can also mean to adapt content based on behavioral parameters grounded in models such as the transtheoretical model of health behavior change [30]. Personalizing an educational brochure about smoking cessation, for example, may only add the name of the smoker to the educational materials. A more complex personalization will be to provide content with different tips depending on whether the smoker is simply contemplating quitting or has decided to quit but is worried about “side effects” (eg, gaining weight). The adaptation can also be based on demographic information such as age and gender; for example, teenagers may consider quitting smoking mainly because it damages their image (eg, yellowing teeth) and not so much because it increases the risk of cancer.

Extracting Information From the Health Social Web

To create personalized health applications, it is necessary to acquire information about users. The information can be as simple as general demographic data (eg, age, gender, ethnicity, and location) or more complex, such as data acquired through structured questionnaires, health records, and so on. It is equally important to have adequate information about the Web content itself such as topic, language style, and date.

As summarized in Table 3, there are many information sources in the Social Web that can be used to extract information about users and content. The Social Web has facilitated the creation of Web content (eg, blogs, videos, and user profiles). User-generated content can be analyzed to extract information about Web content or users. In addition, user-generated content has been found to contain disclosed personal health information [31,32]. Further, many other sources of information are available such as ratings, links, and Web usage data (eg, click history). Finally, while not necessarily a part of the Social Web per se, personal health records (PHRs), if shared, represent a rich source of health information from which applications and services could be personalized. In the following subsections, we provide a description of different approaches to extract relevant information for health personalization from sources in the Social Web.

Table 3. Main sources of information for health personalization in the Social Web

Sources	Examples of Information That Can Be Extracted for Health Personalization
Personal health records[16]	Personal health information (eg, diagnoses and treatment) Demographic information Genetic information (eg, rare mutations) [33]
Textual content	Textual content is present in most of the Web content, and it can contain information about the authors or about the content itself (eg, description of a video).
User profiles in online communities	Health risk behaviors (eg, smoking) Demographic information [12,13,31] User preferences (eg, topics of interest) [34]
Forum posts and comments	Personal health information (eg, diagnoses and treatments) [32] Emotional/mental status of users [35] Type of content (eg, informational or conversational) [36]
Search queries	User interests [37]
Tags	Topics of tagged content and users interests [38]
Audio	Users emotional status [39,40] Diagnosis (eg, depression) [41]
Facial photos	Emotions [42], gender [43], and age [20]
Videos	Diagnosis (eg, neurological diseases) [44] Characteristics of videos (eg, topic and style) [45]
Ratings	Users preferences and similarities [46]
Social networks and links	Community discovery [47,48] Characteristics of Web content [24,49]
Web usage data	Classification of users based on navigation patterns (eg, clicks and browsing data) [50]

Personal Health Records

Personal health records (PHRs) are lifelong electronic sources of personal health information controlled and managed by health consumers to support decision making [16,51]. The information contained within PHRs is generated by both clinical encounters and patients themselves. Web-based PHRs are becoming increasingly available in the United States [52].

The information contained within a PHR can range from general demographics to clinical visit information, lab test results, and genetic information [16,33]. Many currently available PHRs are beginning to comply with emerging data and interoperability standards like those found with the continuity of care record (CCR), clinical document architecture (CDA) and Health Level 7's (HL7's) PHR functional model. These not only facilitate interoperability with electronic medical records (EMR) but also provide a foundation from which health applications and services can be developed.

As PHRs begin to integrate with third party applications, a larger application ecosystem is fostered, which layers additional functionality provided by the third party applications [53,54]. That approach is similar to the iTunes App Store. For example, in Microsoft HealthVault alone, there are currently upwards of 50 different third party applications [55], a good example of which is TrialX [11]. TrialX uses the data from the PHRs to find possible subjects matching the inclusion criteria in clinical trials. In the PHR Indivo, a clinical trial evaluated the use of PHRs for delivering influenza prevention education [56].

Apart from PHRs, there are patient social networking sites offering users the option to share and visualize detailed and structured personal health information within a community, for instance PatientsLikeMe [5]. However, they have yet to provide application programming interfaces (APIs) for the integration of third party applications. Some researchers are looking into the integration of PHRs with social networking [54,57].

Textual Content

Unstructured free text is one of the most common types of generated content in the Web. As explained in the following subsections, that textual content can be from different sources: (1) user profiles, (2) forums, blogs, and comments, (3) search queries, and (4) tags.

The use of natural language processing (NLP) is the most common approach to extract information from free text. NLP is defined as the use of computer algorithms to process written and spoken human language [58]. Processing text using NLP involves several phases. It includes the extraction of keywords, stop-word removal (eg, removal of irrelevant words), word sense disambiguation and stemming (reduce words to its root). With the extracted terms, different techniques can be used to analyze them, such as terms weighting, semantic networks, and advanced data mining techniques. NLP techniques to analyze text have been enhanced with semantic technologies so that domain knowledge is taken into account in order to alleviate the ambiguity of the extracted terms [59].

Despite the scarce examples where NLP has been used to analyze health content in the Internet, it has been widely used in the biomedical domain. For instance, NLP is used to analyze biomedical text and to create information retrieval applications [60]. As a result of many years of research, several open source frameworks have been developed, such as the Unified Medical Language System (UMLS) Knowledge Source Server [61,62]. This framework provides NLP tools for analyzing biomedical text and semantic networks for matching extracted terms with standardized vocabularies.

The application of biomedical NLP for the analysis of text generated by health consumers is challenged by the gap between the medical vocabulary and the vocabulary used by the health consumers. For example, the common expression “kidney stones” may refer to the medical term *kidney calculi*. It has been found that between 20% and 50% of health consumers' expressions were not represented by professional health vocabularies [18,63]. Nevertheless, these studies imply that nearly half of the free text created by health consumers can be mapped directly to standardized medical vocabularies. Similar results have been found in self-reported symptoms of patients in PatientsLikeMe.com [64] and search queries in the MedlinePlus health portal [65]. In addition, an approach for the identification of new terms has been developed to create a consumer health vocabulary [66]. It consists of the use of NLP to find relevant terms and map them to standardized medical vocabularies. Then, the unmapped terms are classified manually and added to the consumer health vocabulary. Another possible approach to overcome the gap between the vocabularies is to recommend standardized medical terms while typing [67].

User Profiles in Online Communities

Users in social networks and online communities maintain a personal Web site with information about them. Many of these user profiles contain personal information, such as age, gender, and hobbies. Also a significant number of users disclose health information in these profiles. For example, a study found that the majority of the teenagers in MySpace are not just disclosing general demographic information but also information about their health risk behaviors (eg, alcohol abuse) [31]. In health social networks, such as TuDiabetes.com, many users disclose personal health information (eg, type of diabetes or latest blood glucose levels). A special case is PatientsLikeMe [5] where users disclose detailed health information in their profiles.

The automatic extraction of health information from profiles in social networks has been studied in the RiskBot project. In that project, NLP techniques were used to crawl, that is, explore, sex-seeking websites and classify behaviors exhibited on those sites into different risk categories with the intent of using this information to create personalized public health messages [12,13]. The same technique was recently used to extract obesity and its comorbidities from text-based hospital discharge summaries [68].

Outside the health domain, user profiles have been used to extract information about users' interests to provide recommendations and to find users with similar interests [34].

Forum Posts, Blogs and Comments

In addition to user profiles, health consumers are generating significant amounts of textual content through blogs, posts in forums, microblogs, and comments. This content ranges from deeply personal narratives to recommendations and reviews to discrete pieces of health data. Several studies have found disclosed personal health information in different types of content (eg, Twitter [69,70] and YouTube [32]). For example, a simple search in Twitter for "#bgnow" returns tweets that include blood glucose levels. In the studies about Twitter, the extracted information was not used for personalization but was used to study the misuse of antibiotics [69] and to analyze and track sentiments, attitudes, and behavior during a pandemic [70].

Information extracted from content can also be used to gather more information about the content itself. For example, NLP techniques have been used to classify topics of health forums [17]. In this example, the posts in a medical forum were analyzed to extract terms from a predefined set of terms. Then, different data mining techniques were used to categorize the posts.

Web content can also be classified according to emotional parameters, such as intentionality, relying on the fact that the human language provides clues about emotions and intentions. The capture of these clues is being addressed in different research fields, such as affective computing [21] and opinion mining [71]. For example, a blog post can be objective and informative (eg, how to take an insulin injection) or be affective and raising a debate (eg, hate insulin injections). Techniques have already been developed outside the health domain to automatically classify posts depending on their informative nature [36]. In the health domain, similar techniques have been used to classify suicide notes [35] and preliminary work has been done in online suicide notes [72].

Search Queries

Search engines are among the most popular tools to search health information [3]. Many search engines store the text entered by the users to model the previous search queries and personalize the results.

In the health domain, there are only a few examples of health search engines using search queries for personalization. These techniques are mainly used in search engines of research literature [73]. In the health portal MedlinePlus, search queries have been used to analyze the vocabulary of the health consumers [65]. However, that information is used to detect misspellings and topics of interest and not to personalize the search results.

Tags

Nearly one third of Internet users in the United States have already tagged content [23] and 6% of the health information seekers have tagged or categorized Web health information [4]. Prior to the Social Web, many indexing techniques were based on taxonomies created by experts. Today, users are indexing content with their own tags that can be used collaboratively by utilizing new taxonomies of Web resources, known as "folksonomies". In addition to classifying Web content, tagging is also used to capture information about the users. For example, the tagging history of users can be used to model their interests [38]. Health-related examples of tagging are found in platforms such as TuDiabetes.com [74] and GetHealthyHarlem [75], where tags are used to search and recommend content. One of the challenges with tagging is the appearance of ambiguity between tags. The integration of tags with ontologies opens many opportunities for using semantic-enhanced techniques [76], such as giving recommendations of tags based on medical ontologies [67]. It has also been found that nearly half of the tags created by patients for describing symptoms were found in medical standardized vocabularies [64].

Images, Video, and Audio

In the Social Web, users are creating a wide variety of content apart from the text. Video, images, and audio are gaining in popularity as vehicles for sharing experiences and opinions. Extracting information from these file types, while of interest for personalization, has its challenges. The challenges result primarily from increased interpretive ambiguity in visual and audio processing and the computational cost. While the authors are not aware of explicit projects focused on extracting information from video within the Health Social Web, there are examples in other areas of research for instance computer vision, social signaling, affective computing, and computer-aided diagnostics.

Computer vision is concerned with computer systems that extract information from images. Computer vision techniques are used in many different domains (eg, computer-aided diagnostics). There are many examples of applications that extract information from people's facial photos about emotions [42], gender [43], and age group [20].

In social signaling [22], behavioral cues (eg, vocal behavior and hand expressions) are extracted from audio, video, and pictures in order to produce a "social signal" with the meaning of the extracted information. For example, through analyzing the speech in a dialog it is possible to gather information about the emotional status of the speakers and their different roles [39,40].

Social signaling is related to affective computing [21], which aims to create systems and devices that are adapted to human emotions. Affective systems have to recognize emotional information such as the "happiness" of a video [45] or the emotional expressions in a facial photo [42].

Computer-aided diagnostics use video and audio analysis to help diagnose different pathologies. For example, voice has been used to reveal patterns in the voice of patients with depression [41] and speech alterations in neurological disorders [19]. Video has been used to quantify the tremor in patients with Parkinson [44].

Ratings

The ability to rate content is one of the most common types of feedback in the Social Web. It is used in a wide variety of collaborative filtering applications such as recommender systems [46]. The objective of these applications is to provide personalized recommendations based on what the system knows about "you" in conjunction with what it knows about "people like you". As explained in Schafer et al [46], there are two main approaches to giving recommendations based on ratings:

item-based and user-based. Item-based recommender systems will recommend highly rated items similar to those the specific user liked before. In the case of user-based systems, the rating history of a specific user will be used to find users with similar interests. The items with highest ratings among these like-minded users will be recommended. The rationale behind item-based systems is that “people who like x also like y,” while the rationale behind user-based systems is that “people similar to you also like y.”

Some applications are based on ratings in the health domain. For example, the health portal HealthyHarlem integrated a rating-based recommender system of health information [77]. There are also websites with ratings of health-care providers both in the United Kingdom [78] and the United States [79]. Integration of end-user and professional ratings has been explored in the project MedCertain [80] for creating a collaborative health information filtering system.

Social Networks and Links

In many cases, the terms “online communities” and “social networks” are used indistinguishably. However, an online community is a subtype of social network where different users interact virtually, normally sharing specific goals. A social network, in the general sense, can be any network between people, such as family networks. The study of social networks predates the Web, and it has been used in health research [81]. As explained below, social network analysis has influenced how we browse and search the Web.

Similar to human social networks, the Web is a complex network of nodes (eg, websites) that are interconnected using links. The analysis of the “linking” structure among the different websites is a common source of information about websites [24]. A link is an implicit source of information about the “authority” or “prestige” of a website. For example, an outgoing link often indicates conveyance of authority to the linked website. That principle is the basis of many Web search algorithms, such as Google’s PageRank [82].

Link analysis algorithms originated from social network analysis (SNA). SNA has been used for decades as a tool to understand complex human social networks. For example, using SNA and longitudinal data from a population of people over a period of 30 years, Christakis and Fowler found important relationships between health behaviors and health risk as a product of the structure of social networks [81]. SNA has acquired more attention for the analysis of Web social networks since the Internet has become a major social platform where millions of users are establishing relationships of diverse types (eg, friends, fans, and followers).

In the domain of the Health Social Web, SNA has been used to study online communities [83]. In other Web domains, SNA has been used to extract information for personalization. For example, SNA has been used to infer characteristics (eg, centrality, reputation, and prestige) of the members of a community (eg, bloggers) [84]. That information can be used to identify nontrusted users who are more likely to have low quality ratings and content [85,86]. Another feature of SNA is the possibility to detect communities within large social networks [47,48]. The information about the subcommunities can be used for personalization. For instance, a blog about cancer from the community of forensic pathologists may not be the best to recommend to a health consumer.

Furthermore, a social network can be itself a personalization engine where users are spreading content through their friends. Individuals are using information about their friends to spread the Web content in a manual-personalized manner. This new “viral” pattern of distribution of Web content is being used in public health [87-89]. For example, the New York City Department of Health and Mental Hygiene designed an application in Facebook that let users send “e-condoms” as a mean of promoting safe sex for HIV prevention [89]. The analysis of the structure of the social network can be used to increase the dissemination of the information in viral applications by identifying users with higher influence [90].

Web Usage Data

The extraction of Web usage data for Web personalization predates the Social Web, yet it is still widely applied. Web servers store information about users accessing websites, such as version of the Web browser, IP addresses, and clicked links. That information can be used to improve the design of a website (eg, making the most clicked elements more visible) and to personalize the interface (eg, personalizing the layout of the Web based on the size of the screen). Mobasher [50] reviews the wide range of techniques available to extract Web usage data for personalization.

Web usage data is collected in many health-related websites, such as in WebMD [91] and MedlinePlus [92]. In WebMD, Web usage data is used for personalizing the advertisements based on the type of user’s Web browser. Web usage data has also been used to evaluate the impact of public health interventions [93].

Technical and Socioethical Challenges

As explained in the previous section, there are many possible approaches to extracting information for health personalization for the Social Web. However, these approaches have different implications, and how to apply them in personalization will vary depending on the context of the application. In order to decide which approach is the most suitable for a specific application, it is necessary to take into account the main technical and socioethical challenges arising from applying these approaches in health personalization. These challenges are addressed in the following subsections.

Technical Challenges

There is a set of technical challenges associated with the approaches addressed in the previous sections. While it is not feasible to cover all the challenges with each approach, the discussion will focus on what we consider to be the most important ones related to health personalization (Table 4).

Table 4. Main technical challenges of extracting information from the Health Social Web

Challenges	Description
Relevance [94]	To determine which information is relevant for personalization is complex, and it depends on the objectives of the personalization.
Reliability and validity	The reliability and validity of the information used for personalizing is heterogeneous. Users can fake information about themselves [95] or the Web content they create [96].
Integration	Many Health Social Web applications are not integrated. However, some platforms provide open APIs to integrate third party applications [53]. Integration across different platforms can be achieved using semantic technologies [97].
Privacy-preserving extraction of personal information	Preserving privacy while user modeling and data mining [98,99]

Technological levels of maturity vary among the different approaches reviewed in this paper. Some are not only technologically feasible, but are commonly used in health personalization (eg, using PHR data to build personalized applications). Other approaches, such as the use of social network analysis to find communities of users, are technically feasible but not yet applied in health personalization. Other approaches are still experimental or too complex to be applied, such as video analysis.

The extracted information will have different levels of reliability, and whether that information can be used will depend on the application. For example, information extracted from a user profile in MySpace may be reliable enough to target a public health intervention but hardly specific enough to personalize an intervention or find subjects for a clinical trial recommender system. In addition to the reliability of the different techniques to extract information, we have to consider the validity of the sources of information. Many users tend to fake information to protect their privacy. For example, in a study of Facebook profiles, it was found that 8% of the users had fake names [95]. A similar problem is found in Web content, where tags describing content may be fake or spam [96]. The best way to ensure reliability and validity is to have human experts evaluating them. An alternative option is to rely on several data sources. In the example of the health video, it is possible to consider the keywords provided by the author and the viewers, comments, and so on.

There are other technical challenges that are not related to the extraction of information itself, but to the different objectives of the personalization. For example, a personalized recommender system of videos for smoking cessation may suggest a video with a lung cancer x-ray. Although effective, the user may dislike and rate the video as poor. In that case, the relevance and quality of the recommendation depends on clinical parameters and not just ratings, as traditionally recommender systems do. Furthermore, different goals imply different needs of information for modeling both users and resources. A relevant parameter for a personalized application about sexual health, for example, sexual orientation, may be irrelevant in many other applications. The discussion about relevance and quality has been addressed during many years in the field of information retrieval [94,100].

In the Health Social Web, there is a wide range of data sources and applications that are not integrated. Many platforms, such as online communities, don't provide APIs for extracting information or integrating third party applications. The lack of open APIs makes it challenging to extract information for personalization and almost impossible to integrate personalized applications. However, the use of APIs is increasing as exemplified by certain PHRs that can integrate third party applications [53-55]. However, each PHR often comes with a different API, making it hard to integrate applications across different platforms. An approach to address this problem is the creation of APIs that can be used across different platforms. This approach has been applied to integrate data from different social networks platforms [97].

As explained in following subsection, one of the most important ethical challenges is how to preserve privacy while extracting information about users. That concern has motivated the creation of different data mining techniques that preserve the privacy of the “data-mined” users [98,99]. Furthermore, many Web platforms allow the users to define their own privacy preferences.

The Social Web has changed how health information and applications are being disseminated (eg, viral dissemination and collaborative filtering). Users are now relying less on traditional experts and more on guidance from fellow users within their social networks. This phenomenon, which has been termed “apomedation” [101], is already affecting personalized health applications. For example, an increasing number of applications are relying on users to be disseminated throughout their social networks [89]. This approach has implications in the evaluation of these viral applications since it may be impossible to control who uses them. One possible solution for that problem is to extract information about impact of these applications from the social network itself [93,102].

Socioethical Challenges

While we consider ways to use available personal information to make Web content and applications more useful, we must be mindful of related ethical challenges in doing so. First and foremost among them is privacy. There is a continuum of personal information that is captured, logged, left, and made available in the Social Web. Personal health records, for example, are by definition likely to contain highly sensitive personal information and, as such, the majority of PHR providers have varied privacy and confidentiality policies as part of their terms of use. Third party applications that make use of PHR content will need to conform to stated privacy policies.

However, this will not be easy as there are no standards for PHR privacy policies. As such, it will be difficult to create a single application that could be of use across different PHRs.

Existing on the other end of the continuum are those who are intentionally disclosing personal information about themselves or loved ones within blogs (eg, blogging about family genetic risks and the health of their children) [103,104]. In these contexts, privacy and confidentiality policies rarely exist, as individuals are simply free to publicly write about whatever is on their minds. When using techniques that extract user information, it is important to maintain a proper balance between the public and private nature of the content. Researchers should be mindful about common research principles, such as informed consent for using extracted information, and may consider poststudy interventions such as those used by Moreno et al [105]. Such principles can be seen in applications that first ask users if it is appropriate to use identifiable information, such as the ability to use current location to receive “geo-located” relevant content. As Wang and Kobsa suggested, there is a need to tailor privacy to the constraints of each individual user [106]. Mayer-Schonberger, on the other hand, has argued for the important historical role “forgetting” has played in society. He extends this idea to the Web in the form of expiration dates for information [107]. This deceptively simple idea would allow the erasure of certain kinds of information from the ubiquitous and eternal memory of the Web.

Another ethical issue regarding privacy is the extracting of information about minors because they are especially vulnerable to misuses of personal information. Unfortunately, disclosure of personal health information in social networks is rather common among teenagers [31]. There are different approaches to reducing it. For example, some researchers have approached minors disclosing health information on MySpace suggesting they reduce their disclosure of sensitive information by sending them emails to their profiles [108]. These messages sent to the teenagers reduced the disclosure of personal health information, but such emails may have been seen by some teenagers as spam. To avoid the risk of being seen as spammers, one possible approach is to rely on users to disseminate the intervention through their friends.

Many personalized applications within the Social Web intend to enhance socializing and sharing of knowledge between users. Unfortunately, in the health domain, there are some scenarios where the desired goal may be the opposite, since there are online communities promoting unhealthy behaviors, such as communities promoting anorexia and bulimia as “lifestyles” [109-111]. Facilitating the sharing of “proanorexic” knowledge and socializing can be harmful. However, the approaches presented in this paper can be used to identify these communities to reduce their impact (eg, parental software filtering proanorexia communities).

The integration between different data sources in the Web is partially a technical issue, but to achieve complete interoperability, there are also other barriers to be addressed. The terms of use of many Web services and APIs are complex to understand for both users and developers. In addition, these terms are normally framed within regional or national legislation, and many users may reside in locations with different legislation. For example, consumers of a company providing online direct-to-consumer genetic services, such as 23andMe, may receive online genetic counseling, which is illegal or not regulated in many countries. In addition, the laws enforcing privacy are different in each country and this affects the development of personalized applications [112]. What can be legally extracted and stored about users changes across the different countries; thus, a personalized health application may be doing something illegal while extracting information about their users depending on their residence.

Conclusions

The Web has largely become a social platform where millions of health consumers are accessing and sharing knowledge about health [1,4]. Health consumers are not just socializing and accessing information on the Web, but are also using an increasing number of Web applications (eg, search engines and PHRs) to improve their perceived understanding of health issues. Many of these Web health applications are personalized to each user. One key aspect of health personalization in the Social Web is to extract information about users and resources. As reviewed in this paper, the Social Web offers many possibilities for the extraction of information about users and resources. It can be as simple as extracting information about age or as complex as extracting information about emotions. These techniques can be used not only for creating personalized applications but also for public health (eg, health surveillance) as part of the emerging discipline of “infodemiology” [113].

The adaptation of online intervention methodologies [114] to the context of personalization and the Social Web is an area for further research and beyond the scope of this paper. Critical issues need further exploration such as the scope and boundaries of effective online interventions, the role of trust in online health social networks and communities, and the ethical implications of research with publicly disclosed personal health information. The development of the techniques reviewed in this paper leads to new research questions: How to use the extracted information to influence health behavior in online contexts? How can we move techniques beyond individuals to groups, communities, and populations? In addition, more research is needed to determine the intrusiveness of these techniques. We need to be mindful of the issues raised in this paper, but the challenges cannot be an excuse not to develop more dynamic and personalized health applications. Outside the health domain, Web applications are becoming increasingly personalized; thus, health consumers will expect a more personalized experience in Web health applications.

The use of different approaches reviewed in this paper can catalyze the emergence of new applications adapted to the specific needs of the users without posing the traditional burden of filling in questionnaires and forms. However, in Web personalization “one size does not fit all,” so in order to decide which techniques are suitable for a specific application, we have to bear in mind the goals of the application and the personal preferences of users.

Acknowledgments

We would like to thank the reviewers and our colleagues for their very useful comments, which helped to improve this paper. This project belongs to the Tromsø Telemedicine Laboratory cofunded by the Research Council of Norway, project 174934.

Conflicts of Interest

None declared

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Abbreviations

API: application programming interfaces
CCR: continuity of care record
CDA: clinical document architecture
EMR: electronic medical records
HL7: Health Level 7
NLP: natural language processing
PHR: personal health records
SNA: social network analysis
UMLS: Unified Medical Language System

Edited by G Eysenbach; submitted 18.12.09; peer-reviewed by K Mandl, R Halkes; comments to author 20.02.10; revised version received 20.07.10; accepted 28.07.10; published 28.01.11.

Please cite as:
Fernandez-Luque L, Karlsen R, Bonander J
Review of Extracting Information From the Social Web for Health Personalization
J Med Internet Res 2011;13(1):e15
URL: http://www.jmir.org/2011/1/e15/
doi:10.2196/jmir.1432
PMID:21278049

Viewpoint

Wikipedia: A Key Tool for Global Public Health Promotion

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Abstract

The Internet has become an important health information resource for patients and the general public. Wikipedia, a collaboratively written Web-based encyclopedia, has become the dominant online reference work. It is usually among the top results of search engine queries, including when medical information is sought. Since April 2004, editors have formed a group called WikiProject Medicine to coordinate and discuss the English-language Wikipedia's medical content. This paper, written by members of the WikiProject Medicine, discusses the intricacies, strengths, and weaknesses of Wikipedia as a source of health information and compares it with other medical wikis. Medical professionals, their societies, patient groups, and institutions can help improve

Wikipedia's health-related entries. Several examples of partnerships already show that there is enthusiasm to strengthen Wikipedia's biomedical content. Given its unique global reach, we believe its possibilities for use as a tool for worldwide health promotion are underestimated. We invite the medical community to join in editing Wikipedia, with the goal of providing people with free access to reliable, understandable, and up-to-date health information.

(J Med Internet Res 2011;13(1):e14) doi:10.2196/jmir.1589

KEYWORDS

Internet; Wikipedia; public health; health information; knowledge dissemination; patient education; medical education

Introduction

The Internet allows unprecedented opportunities for patients and the general public to retrieve health information from across the globe. Surveys have shown that online health information retrieval is both common and increasing [1-4]. Population-based studies have shown that 61% of American and 52% of European citizens have consulted the Internet for health-related information on at least one occasion [1,4]. Similarly, numerous cross-sectional surveys in patient populations have shown variable but considerable rates of eHealth activities [5-10]. Physicians frequently report that patients have searched the Internet regarding health issues [11,12], although patients do not always discuss these online activities with their doctors [13,14]. Among American e-patients, 44% said this information had a minor impact and 13% said it had a major impact on their decisions about health care [4].

Websites offering medical information differ widely in their quality [15]. While physicians should reasonably view trustworthy information as useful, some have voiced concerns that Internet information may undermine their authority and lead to self-treatment [13]. Furthermore, incorrect medical information could result in patient harm. Indeed, about 3% of users of health care information feel that they or someone they know has been seriously harmed by Web-based information [4]. A potential solution for these drawbacks is that physicians direct online health information seekers to quality resources. This so-called Internet prescription has been evaluated in a few randomized trials, which showed that it increases use of the recommended websites [16-18]. Despite concerns over the quality of health websites, the 2005 Health On the Net survey found that medical Internet users value information availability and ease-of-finding more than accuracy and trustworthiness [13].

General search engines, of which Google is the market leader in Western countries, appear to be the most common starting point for laypeople seeking health information, despite the existence of eHealth quality labels and special search engines to explore health information [4,10,13,19,20]. Search engines commonly lead seekers to Wikipedia [21]. In the 2009 Pew Internet survey on health information, 53% of e-patients had consulted Wikipedia (not necessarily related to health information) [4]. This paper examines the role of Wikipedia as a provider of online health information.

Wikipedia: An Internet Heavyweight

Core Features of Wikipedia

Wikipedia is a freely accessible, multilingual, Web-based, free-content encyclopedia that is written collaboratively by volunteers from countries around the world. It is the largest reference website and the most prominent example of a wiki, with over 3.3 million articles in English alone accrued between its inception in January 2001 and May 2010. Wikis allow anyone reading a particular page to also alter it using relatively simple editing commands. Wikipedia maintains a public record of all previous changes to improve collaboration between multiple editors. Everyone is invited to edit, with most changes appearing immediately after submission. Wikipedia is supported by a nonprofit organization, the Wikimedia Foundation, and is free of commercial interests and advertisements. It is one of the most commonly used websites on the Internet, attracting around 362 million visitors monthly as of January 2010 or 29% of global Internet users, making it the sixth most popular website on the Internet [22,23]. The multimedia content used across all Wikimedia projects is stored in a central repository (Wikimedia Commons), which hosts more than seven million freely licensed media files.

Content Creation and Maintenance

Wikipedia's open editorial policy is a departure from the traditional encyclopedias written exclusively by experts. Its editors often write using a pseudonym with no easy way to verify their credentials or expertise. The lack of vetting by identifiable experts has led to the critique that the editorial process favors consensus over credentials [24]. Additions to articles are judged based upon their verifiability, and information added without references may be challenged or removed. The development of Wikipedia's articles has been described in evolutionary terms; that is, each phrase and sentence is subject to scrutiny and review over and over again, so that eventually "only the fittest" of these will survive, while unsustainable sections will be eliminated [25]. Fitness is determined by verifiability, ease of understanding, and completeness. The goal is an easy-to-read, thoroughly referenced article that is broad in scope. Such an article is less subject to major edits unless there are changes in the subject matter itself. As articles are improved, editors can nominate them for quality labels. Promotion to Good Article status requires independent review by one editor. A common next step would be Wikipedia's peer review process, whereby an article is subjected to closer scrutiny from a broader group of editors. The highest-quality articles are Featured Articles, a label that is applied only when there is consensus that the article exemplifies Wikipedia's best work.

Articles can be damaged in a number of ways, including deletion of information, insertion of misinformation or nonsense, use of offensive language, and addition of spam defined as advertisements or nonuseful links [26]. People who are unaware of Wikipedia's quality control measures may find it surprising that Wikipedia's content is not compromised more frequently. However, multiple layers of quality control are in place to prevent or revert spurious additions or removals. These include the following:

- Watchlist: People with an interest in a particular subject can be notified when edits are made to articles they are following.
- Recent changes: Volunteers judge the merits of each change throughout Wikipedia through a list of recent changes (with or without the help of vandalism-fighting software).
- Bots: A system of automated computer scripts, developed by volunteers, fixes a range of problems such as common grammatical and spelling errors, simple vandalism, and copyright violations.
- Page protection: Pages that are highly likely to attract vandalism or controversy can be partly or fully protected from editing by less-established editors.
- Edit filter: Certain edits can be prevented by built-in filters, such as removing references or large sections by new editors. This can also be applied to sensitive medical information: for example, when a filter was established to prevent removal of the Rorschach ink blots [27].
- Blocking and banning: Both anonymous and logged-in editors who demonstrate noncontributory or disruptive editing (eg, page blanking, spamming) can temporarily or permanently have their editing privileges removed.

Some of these maintenance tools (eg, page protection and blocking) are operated by trusted, established editors called administrators. Although it is impossible to guarantee the validity of every Wikipedia article, as no one person is ultimately responsible for the content, the development of an elaborate antivandalism system explains the paradox of how quality can be sustained in a radically open editing system. In one study, 42% of damaged articles were repaired within one viewing and thus had no impact, while 11% were still present after 100 viewings [26]. This shows that, while the system is surprisingly effective, there remains room for improvement.

As of June 2010, Wikipedia is experimenting with a system of Flagged Revisions or Pending Changes, whereby the edits of anonymous and new users (those with fewer than 200 edits) require a sign-off by an established editor before they are made visible. This system has been in use on the German-language Wikipedia since May 2008, and other-language Wikipedias (eg, Russian and Polish) have followed since. Another system under investigation is WikiTrust, which color codes article content that is unstable and possibly unreliable based on the credibility of content and reputation of the author [28]. Registered users can already modify their settings so that article quality information from assessments is displayed in color at the top of the article. Another proposal includes specifically protecting critical health-related information. We believe that these are examples of a trend toward more control over the editing process.

Who Writes Wikipedia?

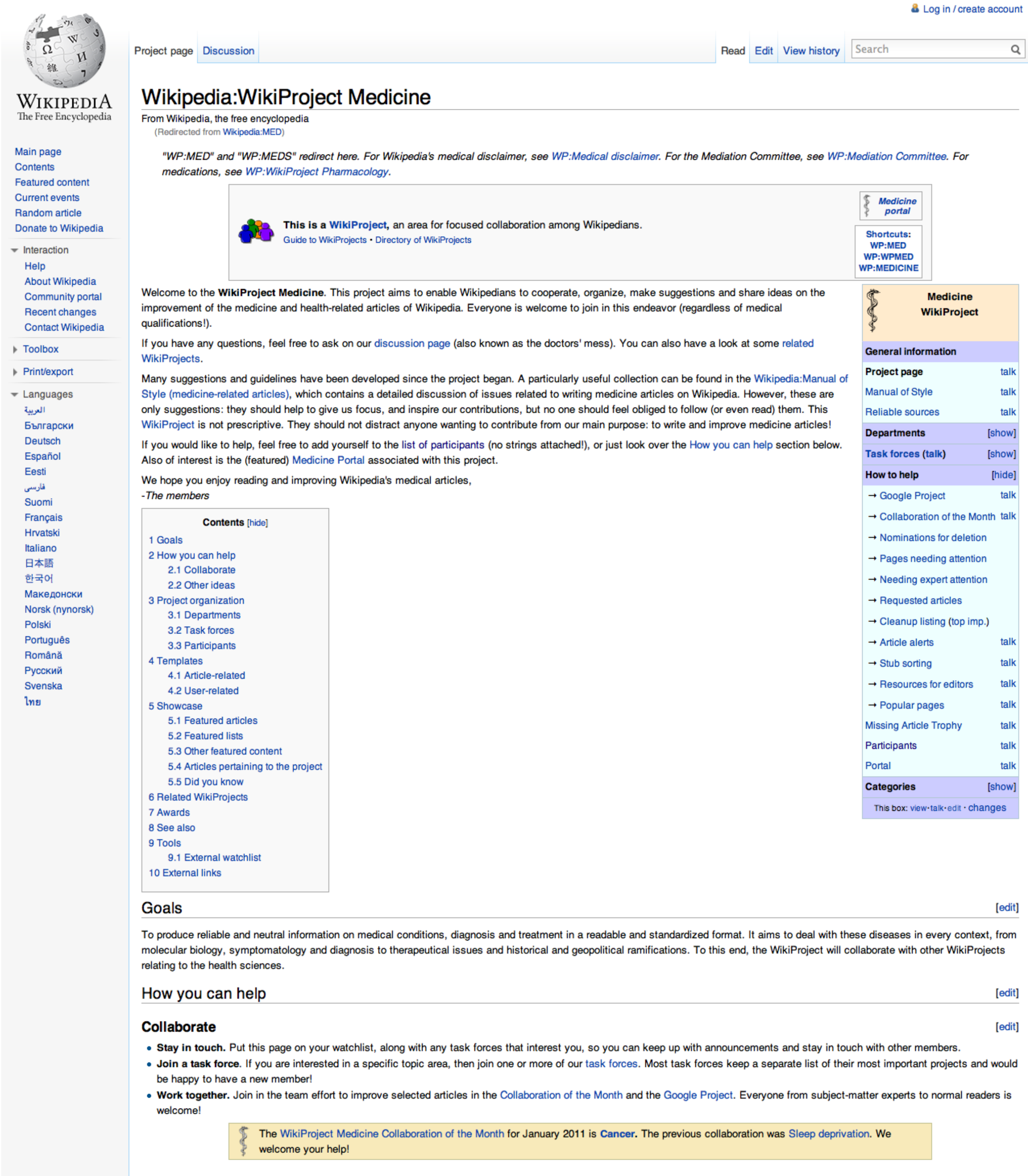
Wikipedia has attracted a few thousand prolific and dedicated editors plus a large number of both registered editors (>12 million) and anonymous visitors who make edits less frequently (the so-called long tail) [29,30]. About 0.1 % of editors contribute nearly half of Wikipedia's value as measured by words read [26]. However, all contributors are needed to improve article content and quality.

WikiProject Medicine

Groups of editors interested in a certain field of knowledge can collaborate through so-called WikiProjects. WikiProject Medicine (Figure 1) was founded in April 2004. It has more than 200 listed participants as of 2010, many of whom discuss Wikipedia's biomedical content at the virtual "doctor's mess" [31] (Figure 2) (the authors of this paper are all members of the group). Membership does not require any credentials, but most members are doctors, medical students, nurses, scientists, patients, or laypeople with an interest in specific medical topics. Project members have been responsible for creating a style manual that provides specific guidance on writing health-related articles, including the naming of articles, avoidance of jargon and eponyms, and a standard outline for articles on diseases and medications (in collaboration with WikiProject Pharmacology). Another guideline drafted by WikiProject Medicine participants deals with finding and selecting high-quality references. In accordance with its guideline on verifiability, Wikipedia lends itself very well to evidence-based medicine. Notably, it automatically recognizes PubMed Identifier (PMID) codes (for example, the text "PMID 11720967" would automatically be converted into an external link to the corresponding article's abstract in Medline).

Wikipedia articles are graded by WikiProjects according to defined quality measures, similar to peer review. Wikipedia contains more than 20,000 health-related articles and more than 6200 articles related to drugs and pharmacology (with an overlap of roughly 700 articles), based on article assessment data from WikiProject Medicine and WikiProject Pharmacology [32,33]. Other activities of WikiProject Medicine include a periodic collaboration on a specific article (the Collaboration of the Month) and Task Forces focusing on different specialty topics (eg, cardiology, dermatology).

Figure 1. WikiProject Medicine. URL: http://en.wikipedia.org/wiki/WP:MED



Wikipedia:WikiProject Medicine

From Wikipedia, the free encyclopedia
(Redirected from Wikipedia:MED)

"WP:MED" and "WP:MEDS" redirect here. For Wikipedia's medical disclaimer, see WP:Medical disclaimer. For the Mediation Committee, see WP:Mediation Committee. For medications, see WP:WikiProject Pharmacology.

This is a WikiProject, an area for focused collaboration among Wikipedians.
Guide to WikiProjects • Directory of WikiProjects

Medicine portal

Shortcuts:
WP:MED
WP:WPMED
WP:MEDICINE

Welcome to the **WikiProject Medicine**. This project aims to enable Wikipedians to cooperate, organize, make suggestions and share ideas on the improvement of the medicine and health-related articles of Wikipedia. Everyone is welcome to join in this endeavor (regardless of medical qualifications!).

If you have any questions, feel free to ask on our discussion page (also known as the doctors' mess). You can also have a look at some related WikiProjects.

Many suggestions and guidelines have been developed since the project began. A particularly useful collection can be found in the Wikipedia:Manual of Style (medicine-related articles), which contains a detailed discussion of issues related to writing medicine articles on Wikipedia. However, these are only suggestions: they should help to give us focus, and inspire our contributions, but no one should feel obliged to follow (or even read) them. This WikiProject is not prescriptive. They should not distract anyone wanting to contribute from our main purpose: to write and improve medicine articles!

If you would like to help, feel free to add yourself to the list of participants (no strings attached!), or just look over the How you can help section below. Also of interest is the (featured) Medicine Portal associated with this project.

We hope you enjoy reading and improving Wikipedia's medical articles,
-*The members*

Medicine WikiProject

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Manual of Style	talk
Reliable sources	talk
Departments	[show]
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Goals [edit]

To produce reliable and neutral information on medical conditions, diagnosis and treatment in a readable and standardized format. It aims to deal with these diseases in every context, from molecular biology, symptomatology and diagnosis to therapeutical issues and historical and geopolitical ramifications. To this end, the WikiProject will collaborate with other WikiProjects relating to the health sciences.

How you can help [edit]

Collaborate [edit]

- **Stay in touch.** Put this page on your watchlist, along with any task forces that interest you, so you can keep up with announcements and stay in touch with other members.
- **Join a task force.** If you are interested in a specific topic area, then join one or more of our task forces. Most task forces keep a separate list of their most important projects and would be happy to have a new member!
- **Work together.** Join in the team effort to improve selected articles in the Collaboration of the Month and the Google Project. Everyone from subject-matter experts to normal readers is welcome!

The WikiProject Medicine Collaboration of the Month for January 2011 is **Cancer**. The previous collaboration was Sleep deprivation. We welcome your help!

Figure 2. The doctor's mess at the WikiProject Medicine. URL: http://en.wikipedia.org/wiki/WT:MED. Questions about editing medicine-related Wikipedia articles or joining WikiProject Medicine may be posted here.

Wikipedia talk:WikiProject Medicine

From Wikipedia, the free encyclopedia
(Redirected from Wikipedia talk:MED)

Welcome to the **Medicine WikiProject**! **There are only a few rules:**

Shortcut: WT:MED

- **This page is a place to discuss issues related to Wikipedia's medical articles and related policies.**
- If other topics are brought up, it's likely that they will be moved to the relevant sections of Wikipedia. Unless they're really interesting.
- **We are not able to provide any medical advice**; please see your local health professional. Questions about medical subjects in general should be asked at the reference desk.
- Don't shout, remain civil and treat each other with respect.
- Please add new sections at the end of the page.
- Threads older than 10 days are automatically archived.
- Please wash any cups you use and clean up.
- The 7 o'clock news always has priority on the tv, except when The Simpsons are on.

WikiProject Medicine **Archives:** Index, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21

Search archives

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Medicine WikiProject

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12 Access to article
13 Langenbeck's Archives of Surgery
14 Year 10 English (as used in Australia)

A few more eyes [edit]

This editor User:Harrygouvas edits Wikipedia using primarily papers he himself has written. They are not generally review articles. Help getting some of the papers he has worked on inline with policy would be appreciated. Have provided him some feedback. **Doc James** (talk · contribs · email) 16:40, 11 January 2011 (UTC)

Adoptee [edit]

Would anyone be willing to adopt User:Quantumash? They've left a request at my talk page, but this isn't my area of expertise.Smallman12q (talk) 23:07, 12 January 2011 (UTC)

> Predictive medicine? This is futuristic stuff which will never come to pass as it is a misunderstanding of Chaos theory --**Doc James** (talk · contribs · email) 23:31, 12 January 2011 (UTC)

Article request [edit]

Would someone be willing to add a stub on short anagen syndrome? ---My Core Competency is Competency (talk) 01:42, 13 January 2011 (UTC)

> I have made a start. I only found 16 references on Pubmed. **Axl** ¤ [Talk] 10:28, 13 January 2011 (UTC)
>
> > Thank you so much! ---My Core Competency is Competency (talk) 18:56, 13 January 2011 (UTC)

Pott's fracture [edit]

Working in german medical WIKI on ankle fracture (my edit), patella, osteochondritis etc I started correcting potts Fraktur in german. Looking for better versions I found yours in englisch. I would like to commend on that. nomen49--78.54.118.139 (talk) 07:57, 13 January 2011 (UTC)

Wikipedia as a Source of Health Information

A Prominent Resource

Wikipedia contains a large amount of health information, which is accessed extensively by both the lay public and health care providers. Studies have found that 70% of junior physicians use Wikipedia in a given week, while nearly 50% to 70% of practicing physicians use it as an information source in providing medical care [34-36]. The junior physicians used Wikipedia more frequently than all other websites excluding Google [34]. Of pharmacists who responded to a questionnaire, 35% admitted using it [37]. The medical articles on Wikipedia receive about 150 million page views per month, with the top 200 most-visited medical articles each receiving more than 100,000 views per month and the top 500 each receiving greater than 60,000 views per month [38]. While some of the most popular articles are of featured or good quality (eg, Asperger syndrome, schizophrenia, and tuberculosis), many other popular articles require improvement. In 2008 the English Wikipedia had the highest average search engine ranking for health terms in comparison with other health resources such as MedlinePlus, WebMD, and

NHS Direct. It was ranked among the first 10 Google search hits for medical keywords obtained from various indexes in greater than 70% of cases, being first place in 25% to 33% of cases [21]. The higher a website is ranked among search engine results, the more likely it is that (inexperienced) searchers will view it, with an exponential decay after the first page of results [19,20]. With the importance of search engines such as Google for people who seek health information, we believe that Wikipedia's global reach gives it a vast and underestimated potential as a tool for medical knowledge translation.

Wikipedia's Strengths and Weaknesses

Wikipedia's approach has proven to be remarkably successful as evidenced by its scope and popularity. The main criticism focuses on the open nature of the editing process, which inherently poses risks of inaccuracies. One commentator summarized the situation as follows: "Wikipedia is both phenomenally successful and, in the eyes of some critics, fundamentally flawed" [39]. A reader can never be absolutely certain that information is not corrupted but, as we have discussed earlier, elaborate quality control mechanisms are in place, and are likely to expand in the future. Another drawback of Wikipedia is that in the intermediate-quality articles, the writing by many different editors may give articles an uneven, choppy quality [40].

Some people use Wikipedia's articles to advance their personal beliefs, and so the encyclopedia has been criticized for hosting fringe theories, quackery, and unbalanced views [41]. When editors hold conflicting views regarding the content of an article, an elaborate process exists for dispute resolution, guided by Wikipedia's core policies of verifiability and neutral point of view. Each article has an associated discussion page where multiple editors can coordinate their efforts and resolve any editing controversies. If this route fails, editors can request assistance from experienced editors, solicit comments from a wider part of the community, and request informal and formal mediation and, ultimately, arbitration. As Wikipedia has grown, the rate of creation of new articles and content has decreased, while levels of maintenance and indirect work (including coordination and conflict resolution) are increasing [42]. Some editors avoid editing in controversial areas, which is perfectly acceptable since plenty of noncontroversial areas need substantial improvements. Wikipedia has a strict policy against personal threats in discussion, although in extremely rare instances online editing controversies can have consequences in real life (for example, the first author of this article was investigated based on his Wikipedia editing [43]). As long as editors keep in mind their professional obligations while contributing, we believe that editing Wikipedia poses fewer dangers than social media websites, for example [44,45].

A strength of Wikipedia is its ability to be updated swiftly, whereas traditional peer-reviewed articles in rapidly evolving fields can be outdated even before they are published [46]. Prominent examples of Wikipedia's capability to update almost instantaneously are articles on disease outbreaks, such as the 2009 influenza pandemic.

Empirical Studies on Wikipedia's Medical Content

Wikipedia articles have occasionally been cited in scientific articles, although this remains controversial [47]. Between 2004 and 2009, it was among the referenced works in the ISI Web of Science 263 times, while the Encyclopædia Britannica was only cited 10 times [48]. Wikipedia's reliability has been tested in a number of studies, notably in a favorable comparison with Britannica [49]. Wikipedia articles increasingly contain references, with high impact factor medical journals such as the *New England Journal of Medicine*, *The Lancet*, the *Journal of the American Medical Association*, and the *British Medical Journal* among the 10 most frequently cited science journals in Wikipedia in 2007 [50].

Empirical studies evaluating Wikipedia's medical content have recently started to emerge. In a study examining drug information, Medscape Drug Reference provided answers to 82.5 % of predetermined questions, while Wikipedia could answer only 40% [51]. While there were few factual errors, Wikipedia articles were often missing important information, like drug dosages, interactions, and contraindications. However, the authors failed to acknowledge that the Wikipedia style manual for drug articles specifically discourages mentioning dosages, as such information is rarely within the scope of a general encyclopedia and corruption of this information could result in serious harm. The authors did point out that drug company representatives have been caught deleting information from Wikipedia entries that make their drugs look unsafe [51]. A study that looked at Wikipedia articles pertaining to the most commonly performed inpatient surgical procedures found that, while these pages were accurate, they still had critical content omissions [52]. Another paper comparing the appropriateness of articles in Wikipedia with those in UpToDate, eMedicine, and AccessMedicine for medical student use found that Wikipedia was the easiest to use and access; however, it lacked the depth and accuracy of the other three traditional online medical resources [53]. An analysis of the suitability of Wikipedia for nursing students found that the average medical article contained 29 reputable sources [54].

A recent evaluation found Wikipedia accurate enough to include parts of it in a laboratory observations database [55]. Another Web-based study found that Wikipedia had entries on 82.8% of gastroenterological conditions selected from the *International Classification of Diseases*, 10th revision [56]. Of these articles, 65% were substantiated with at least one peer-reviewed reference, and the average number of references per article was 6.8. The median Flesch-Kincaid reading level was above high school grade (13.7 years). Another analysis presented at the 2010 Annual Meeting of the American Society of Clinical Oncology, based on 10 articles dealing with cancer, found that errors "were extremely rare on Wikipedia" (<2%) but information was less easy to understand than that in the US National Cancer Institute's PDQ (Physician Data Query), a peer-reviewed cancer database [57]. An assessment of the scope of Wikipedia's coverage of pathology informatics in 2010 found that 90% of terms in the Association for Pathology Informatics curriculum had a corresponding Wikipedia page. The contents of the pages were deemed comprehensive, of high quality, current, and useful for both the beginner and advanced learners [58].

The main conclusions that can be drawn from these studies are that the medical information on Wikipedia is found in articles on many topics that contain few factual errors, although the depth of individual articles and the ease of understanding need to be improved substantially. Nevertheless, Wikipedia's medical disclaimer warns that articles may contain inaccuracies, and Wikipedia's article on its own reliability states that it can be a valuable starting point when researching a topic, but that users should take care – as with all general reference works – to check facts and be aware that mistakes and omissions do occur.

Comparison With Other Medical Wikis

Wikipedia is but one of many free online encyclopedias with medical content that allow user contributions. At least 70 medical wikis have been cataloged [59]. Some of them are devoted to medical specialties (such as Radiopaedia.org and WikiSurgery.com), while others deal with medicine in general (such as Ganfyd.org and Wikidoc.org). Health topics are also part of Web-based encyclopedias attempting to cover all human knowledge (such as Wikipedia and Citizendium.org). Several specialized medical wikis offer the benefit of verification of the editors' credentials, and specific topics can be dealt with more elaborately than in a general wiki (even Wikipedia encourages moving overly specific content to dedicated wikis if it falls outside the scope of a general encyclopedia). On the other hand, being a general encyclopedia, Wikipedia has the advantage that topics indirectly related to medicine (eg, concepts of physics or chemistry underlying medicine) are presented in detail in the same encyclopedia.

To achieve sustainability and to guarantee a minimal editing rate, wikis need to establish a critical mass of contributors. A selection of wikis and competing websites is shown in Table 1, which demonstrates the unique and dominant position of Wikipedia in terms of access, breadth, and reach (note that although Google Knol is compared with other websites in this table, it is not a wiki). Nevertheless, depth and quality need improvement, as more than 80% of the 20,000 medical articles are still in the earliest developmental stage (Stub- or Start-class articles on the Project Assessment scale), while only 90 articles are Good Articles and 70 are Featured Articles or Lists, approximately.

Table 1. Comparison of selected wikis containing medical information

Encyclopedia	Year	Content license[a]	Scope	Number of English articles	Ranking (percentage) of global Internet traffic[b]	Contributors	Number of editors	Languages
Wikipedia.org	2001	cc-by-sa	General	>3.3 million; >20,000 medical, >6000 drug related	6th (13.0%)	Anyone	>12 million registered	271
Radiopaedia.org	2005	cc-by-nc-sa	Radiology	~4000	642,225 (0.00022%)	Registered users	3800	1
Wikidoc.org	2005	cc-by-sa	Medicine	~71,500[c]	191,463 (0.00105%)	Registered users	>2000	8
Ganfyd.org	2005	medical-by-nc-sa[d]	Medicine	>8000	665,248 (0.00027%)	Medical	450	1
Askdrwiki.com	2006	cc-by-nc-sa	Medicine	>2000	1,199,394 (0.00014%)	Medical	1100	1
Citizendium.org	2006	cc-by-sa	General	~13,900	52,188 (0.00209%)	Registered users	>9000	1
Knol.google.com	2008	As per contributor	General	>100,000; >5900 medical	Unknown	Registered users	Unknown	12
Medpedia.com	2009	cc-by-sa	Medicine	>10,000	43,869 (0.00233%)	Medical	~2600	1

[a] Abbreviations used: cc = Creative Commons license, by = attribution required, nc = non commercial use, sa = share-alike, reproduction under the same license.

[b] Visitors between March and June 2010, according to Alexa, Inc.

[c] Many of Wikidoc's articles are derived from Wikipedia.

[d] Ganfyd has its own specific license, which does not allow altering, transforming, or building upon the content unless the editor is a registered medical practitioner within the United Kingdom, Australia, New Zealand, Canada, Switzerland, or the United States.

A Unified Platform for Disseminating Medical Knowledge

Traditionally the medical community has relied on an authoritarian “push” model to disseminate information. Yet with the rapid growth of the Internet as a source of health information, the question is not how we can encourage people to use a particular set of reliable health resources (as with an Internet prescription), but how we can best provide the global community with accessible, free, up-to-date, easy-to-understand, and comprehensive information. Wikipedia already has a worldwide audience for disseminating health information and its format has proven to foster mass collaboration. Why not adopt Wikipedia as the platform for the global medical knowledge database proposed at the dawn of the Medicine 2.0 age [60]? Instead of each creating their own health information website, patient groups, foundations, charities, professional societies, hospitals, and medical journals could all participate in and contribute to a reference work where most are likely to look first. To quote Peter Frishauf, the founder of Medscape [46]:

> *In Wikipedia you read one living article written by many, continually updated by many. Who needs 50 articles on avian flu when one will do?*

Increased participation of the medical community is important to improve article quality and will benefit the larger audience of e-patients and health care providers. Physicians will benefit as they can use the free-content articles for patient education. Non-English-speaking patients can be given information in their native languages if these pages are available and satisfactory, or the English article could be translated into one of the more than 250 languages in which Wikipedia exists.

A Call to Action

Why Contribute?

Of American physicians who use Wikipedia about 10% edited one or more articles [35]. A study in Germany looked at motives for editing Wikipedia and determined that participants had a high degree of intrinsic motivation, enjoyed their autonomy when contributing, found their work to be of significance, and accepted the time and effort needed to invest in this activity to derive these benefits in return [61]. Studies have not examined why health professionals would participate in editing and organizing medical articles on Wikipedia. This requires much time and effort and, contrary to scientific publications, Wikipedia articles have no direct authorship, thus the prestige of authorship so typical for scientific articles is not attained. An attempt at recognition of authorship can be found more explicitly in competing websites such as Google Knol or Medpedia. However, the high search engine ranking of Wikipedia led Peter Frishauf to conclude [46]:

> *For writers, Wikipedia offers neither authorship, recognition, reward, nor punishment. Articles aren’t indexed, but with Google and Yahoo!, who needs it? The motivation for writing is love of information and a desire to share it.*

We propose that physicians may contribute to Wikipedia for several reasons:

- It may be personally satisfying to provide an important educational service for individuals looking for health information, and to see articles grow that one created or improved.
- While not having a high scientific impact, Wikipedia’s articles have a high social impact due to its broad readership. In the experience of the authors, a newly created article can often be found among the top Google results within a day, often outperforming review articles in highly regarded medical journals.
- Editing or adding information helps contributing students or professionals master the subject matter and learn more about the evidence underpinning it.
- Translating complex ideas into accessible concepts and language is an interesting intellectual challenge, which can help in everyday nontechnical communication with patients.
- Writing for Wikipedia teaches modern online communication.
- WikiProject Medicine offers participation and recognition in a Web-based international community.

Wikipedia can be used as an education opportunity for both students and physicians. Medical schools should challenge their students not only to read Wikipedia’s articles critically, but also to rewrite, discuss, critique, and improve them. The experiences of a group of graduate students editing Wikipedia was described in a 2009 publication as “extremely valuable as an exercise in critical thinking and communication skills” [62].

Several options exist to create direct incentives for health professionals and biomedical scientists to contribute to Wikipedia. WikiProject Medicine members are applying to get recognition as a continuing medical education (CME) opportunity, so that professionals could get credits for editing medical content. Authorship of Wikipedia could also be counted similarly to a scientific publication for people requesting grants or funding. Scientific journals could couple traditional publishing with contributions to Wikipedia. An example of this is the scientific journal *RNA Biology*, which requires authors on a series of review articles on RNA families to also update or create the relevant Wikipedia entry [63]. Similarly, medical journals could enhance their “social impact factor” [64] by requiring submitting authors to review a related Wikipedia entry, or by releasing a key figure or clinical image under a free-content license so that it can be incorporated into Wikipedia.

Examples of Collaborations

Recently the US National Institutes of Health have started an initiative to encourage its scientists to contribute to Wikipedia. This is a recognition of Wikipedia’s global reach and an effort to strengthen Wikipedia’s scientific underpinnings [65]. A collaboration of the RNA WikiProject with the Rfam database, a collection of RNA families, has allowed mutual data exchange and community annotation of the Rfam database [66]. Google.org, the philanthropic arm of Google that uses information and technology to address global challenges in areas such as health, poverty, and the environment, is reviewing and translating medical articles [67]. Wikipedia's open access model makes it ideally placed for health education in developing and developed countries alike. For example, Wikipedia articles are used for humanitarian purposes in the One Laptop per Child Project and the CD selection for SOS Children UK, and so its medical articles could assist in providing health care information for all [68-70].

Conclusion

Wikipedia's goal is to give the world free access to the sum of all human knowledge. Pursuing this, Wikipedia has evolved into an important medical resource for the general public, students, and health care professionals. While it has attracted a sizable number of experts that are enlarging its medical content, its potential to improve health may not yet be fully appreciated. While some authors have called for a variant of Wikipedia for medicine [46,71], many wikis have until now failed to attract the required long tail of editors. We believe that duplicate efforts will hurt the quality of available online information because the scarce number of active contributors is spread thinly over multiple resources. Furthermore, we hope Wikipedia will expand quality control measures in the future. Collaborations with other organizations should be set up to provide direct incentives for experts to contribute (such as coupling Wikipedia editing with article publication, with CME credits, or with funding).

In conclusion, we invite the medical community to join us in editing Wikipedia, with the goal of promoting health by providing readers worldwide with free access to reliable, understandable, and up-to-date health information.

Conflicts of Interest

All authors are members of the English Wikipedia's WikiProject Medicine and have contributed to Wikipedia and various other wikis. Michael F Martone is involved in the development of an iPhone application that may in the future integrate Wikipedia content. Tim Vickers is Director of the Molecular and Cellular Biology WikiProject. Dr Bertalan Meskó is the founder and managing director of Webicina.com, a company providing web 2.0 services to medical professionals and patients.

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Abbreviations

CME: continuing medical education
PMID: PubMed Identifier

Edited by G Eysenbach; submitted 21.06.10; peer-reviewed by D Giustini, B Hughes, J Friedlin, R Ward, R Dellavalle, L Osborn, J Mohit; comments to author 12.07.10; revised version received 16.08.10; accepted 27.08.10; published 31.01.11.

Please cite as:
Heilman JM, Kemmann E, Bonert M, Chatterjee A, Ragar B, Beards GM, Iberri DJ, Harvey M, Thomas B, Stomp W, Martone MF, Lodge DJ, Vondracek A, de Wolff JF, Liber C, Grover SC, Vickers TJ, Meskó B, Laurent MR
Wikipedia: A Key Tool for Global Public Health Promotion
J Med Internet Res 2011;13(1):e14
URL: http://www.jmir.org/2011/1/e14/
doi:10.2196/jmir.1589
PMID:21282098

Original Paper

Seeking Support on Facebook: A Content Analysis of Breast Cancer Groups

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Abstract

Background: Social network sites have been growing in popularity across broad segments of Internet users, and are a convenient means to exchange information and support. Research on their use for health-related purposes is limited.

Objective: This study aimed to characterize the purpose, use, and creators of Facebook groups related to breast cancer.

Methods: We searched Facebook (www.Facebook.com) using the term breast cancer. We restricted our analysis to groups that were related to breast cancer, operated in English, and were publicly available. Two of us independently extracted information on the administrator and purpose of the group, as well as the number of user-generated contributions. We developed a coding scheme to guide content analysis.

Results: We found 620 breast cancer groups on Facebook containing a total of 1,090,397 members. The groups were created for fundraising (277/620, 44.7%), awareness (236, 38.1%), product or service promotion related to fundraising or awareness (61, 9%), or patient/caregiver support (46, 7%). The awareness groups as a whole contained by far the most members (n = 957,289). The majority of groups (532, 85.8%) had 25 wall posts or fewer. The support oriented groups, 47% (27/57) of which were established by high school or college students, were associated with the greatest number of user-generated contributions.

Conclusions: Facebook groups have become a popular tool for awareness-raising, fundraising, and support-seeking related to breast cancer attracting over one million users. Given their popularity and reach, further research is warranted to explore the implications of social network sites as a health resource across various health conditions, cultures, ages, and socioeconomic groups.

(J Med Internet Res 2011;13(1):e16) doi:10.2196/jmir.1560

KEYWORDS

Internet; Facebook; breast cancer; supportive care; peer support; health promotion; fundraising

Introduction

Online communities present a convenient means to exchange information and support with people in similar circumstances and are increasingly being used for health purposes [1], particularly by breast cancer survivors [2]. One of the most popular and perhaps most successful online communities, if success is based on sheer numbers of registered users, is the social network site Facebook (www.Facebook.com). Just over 5 years since its launch, Facebook became the second most visited website in the world (second only to Google) [3], with over 500 million active users (those who returned to the site within the last 30 days) worldwide [4]. While young adults are still more likely to use social network sites [5], the fastest growing demographic of Facebook users is women 55 years and older [6], which corresponds to the average age of onset of breast cancer [7]. Although recent studies indicate that Facebook groups are used for health purposes [8], little is known about how this resource is used by people affected by breast cancer.

Online communities are “virtual social space(s) where people come together to get and give information or support, to learn or to find company” [9]. They tend to be characterized according to the activity (eg, support) or the people that they serve (eg, breast cancer survivors), or the communication technology that supports them (eg, message board) [10]. Initially, online communities were supported by mailing lists, and asynchronous and synchronous message boards. More recently online communities have formed around blogs, wikis, and social network sites, commonly referred to as Web 2.0 social media applications [11]. Social network sites are differentiated from other online communities based on their ability to enable users to display their social networks. Their backbone consists of visible user profiles that display an articulated list of friends who are also users of the system [12]. While other online community platforms enabled users to create a list of friends, these networks were not displayed or accessible to other users. This unique feature of social network sites is hypothesized to result in connections between individuals that would not otherwise have been made [12].

Research on online communities for health purposes has primarily focused on the use and effects of mailing lists and message boards by breast cancer survivors, who have been shown to be one of the groups most likely to seek support from peers on the Internet [2]. Qualitative studies have revealed that these types of online communities provide breast cancer survivors with a safe, relatively anonymous space to communicate about sensitive and potentially stigmatizing topics [13], reduce feelings of isolation and uncertainty regarding prognosis and ambiguous painful symptoms [14], and enable them to become more informed and better prepared for their interactions with the health system [15]. Randomized controlled trials have shown that professionally moderated mailing lists and message boards for breast cancer survivors can reduce depression, stress, and cancer related trauma, and can enhance social support [16-18].

Relatively little is known about the use of social network sites for health purposes. Keelan and colleagues [19,20] examined the use of YouTube videos and Myspace blogs as a source of information on immunization and found a subcommunity of users critical of or with divergent views about vaccines. Research by Scanfeld and colleagues has demonstrated that Twitter has been used to share information on the use and side effects of antibiotics [21]. To our knowledge, there is only one study of the use of Facebook for health purposes. Farmer et al [8] examined noncommunicable disease groups and found a considerable number of patient and caregiver support groups related to malignant neoplasms. Surprisingly, breast cancer groups were notably absent from their analysis.

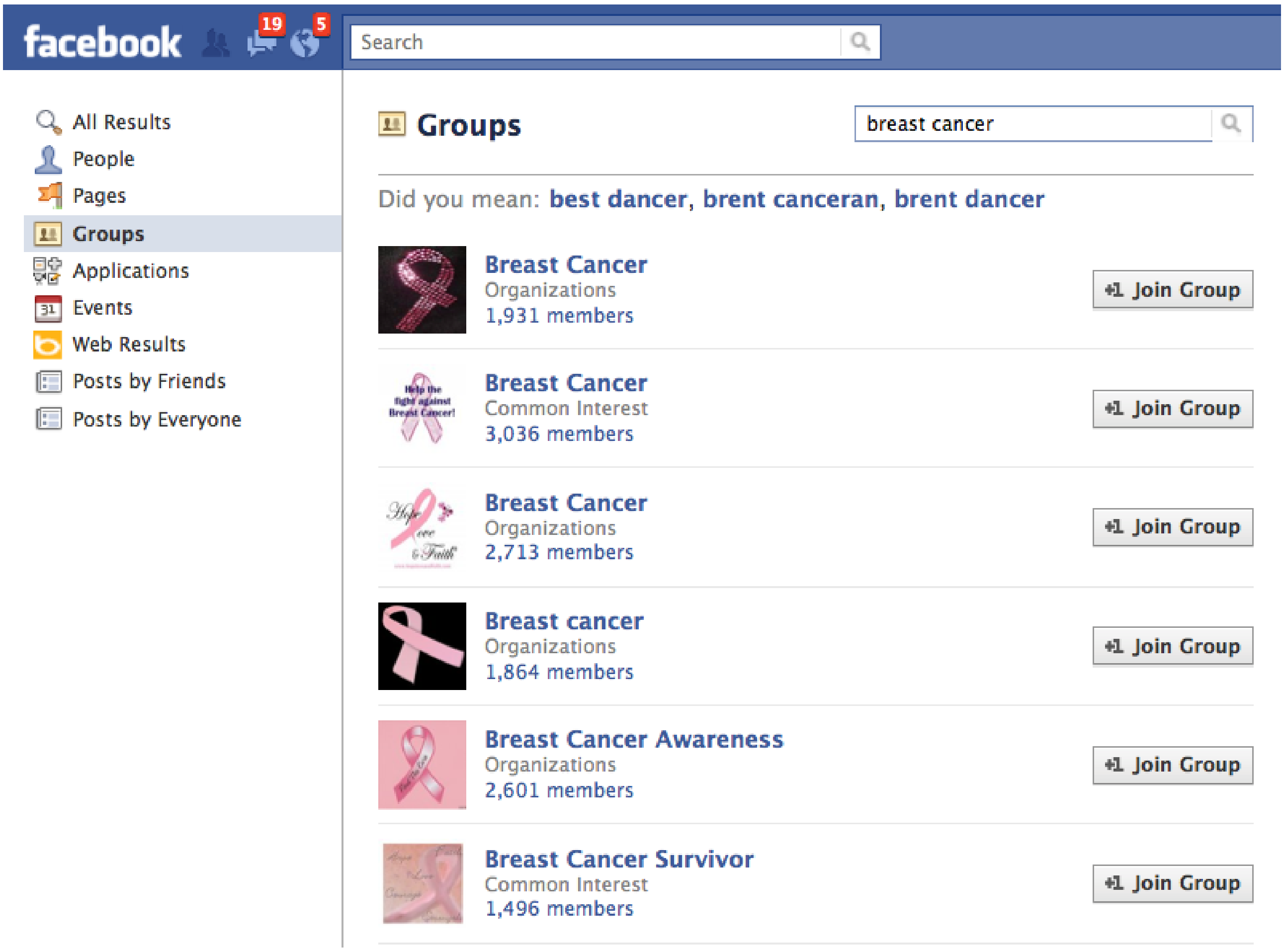
Breast cancer is the most common cancer among women worldwide [22], and thanks to advances in detection and treatment, women affected by this disease form the largest group of female cancer survivors [23]. However, the posttreatment period carries numerous physical and psychosocial needs that often go unaddressed by professional health care services [23]. Addressing the needs of this growing population of cancer survivors has been identified as supportive care’s new challenge [23,24]. Social network sites could provide breast cancer survivors with a convenient means to connect with a diverse network of peers, thus facilitating access to a wider array of supportive information and services. In fact, some have questioned the utility of government-funded personal health care solutions, when social network sites provide users with the tools to create and share health resources on their own [25]. Little is known about how people affected by breast cancer use social network sites. This study attempted to fill some of the gaps by presenting a characterization of the purpose, patterns of use, and creators of Facebook groups related to breast cancer.

Methods

Search Strategy

On November 19, 2008 we searched Facebook using the platform’s built-in search engine and the keyword breast cancer (Figure 1). We restricted our analysis to Facebook groups that were related to breast cancer, operated in English, and were publicly available to anyone with a Facebook account to view and join. Pages for individual members, organizations, events, and applications were excluded.

Figure 1. Sample Facebook search result restricted to group pages



Data Extraction

Two of us (JLB and MCJM) independently reviewed the resulting set of eligible groups and extracted information on the following: (1) general characteristics (eg, group name, purpose, creator, and URL), and (2) membership and user-generated content (eg, number of members, discussion posts, wall posts, photos, and videos).

Data Analysis

We determined the purpose of each group based on a content analysis of, and in order of priority (if available), the title of the group, the description of the group, the information in the Recent News section, the discussion posts, and the wall posts. (The content analysis of the discussion and wall posts was restricted to those displayed on the main page of the group.)

We began by analyzing the content of the first 100 groups to develop a coding and classification scheme that could be applied to the entire set. This initial step led to the identification of four main types of breast cancer groups:

- Fundraising groups: created to attract financial resources for breast cancer through an event, product, or service. Visitors to these groups were asked to donate money, or to purchase a product or ticket to an event. Instructions were typically provided regarding how or where to donate the funds.
- Awareness-raising groups: created to bring attention to the importance of breast cancer in general, or to promote a charitable organization, a fundraising event, or screening or research program.
- Support groups: created to meet the informational and emotional needs of breast cancer survivors or affected family members or friends.
- “Promote-a-site” groups: created to increase the prominence of an external website raising funds or awareness for breast cancer through the sale of products or services.

After independently classifying the general purpose of the groups using the above coding scheme, we resolved any differences. Next we generated a second-tier coding scheme to subclassify and more specifically describe the purpose of each group.

We also developed and independently applied a coding scheme to classify the approximate age and geographic location of the creators of the support groups. We restricted our analysis of the creators to the support groups, because we were primarily interested in the role of Facebook groups as a source of supportive care.

Lastly, we calculated descriptive statistics using SPSS version 17 (IBM Corporation, Somers, NY, USA) to summarize and compare the size (in terms of number of members) and amount of user-generated contributions of each type of group (in terms of wall posts). Most data were expressed as medians with interquartile ranges (IQRs) because the number of group members and user-generated content varied considerably and did not follow a normal distribution. We used chi-square tests to compare categorical data across groups.

This study was a component of a larger research study for which ethical approval was obtained. However, it should be noted that this study met the exclusion criteria of the (Canadian) Tri-Council Policy Statement as to what studies require review by an institutional research ethics board, because all information was publicly available.

Results

The search of Facebook on November 19, 2008 yielded 637 groups. As shown in Figure 2 620 groups were included in the final analysis. We excluded one group because it was not related to breast cancer, three groups because they were not in English, and 13 groups because they were “closed.” Figure 3 shows an example of a breast cancer support group on Facebook at the time the study was conducted. Since then, the platform has undergone revision, including changes to the way information is displayed on the group pages and the addition of new features (eg, group chat). Figure 4 shows an example of the current layout of a breast cancer awareness group on Facebook.

Figure 2. Flow diagram of group selection process

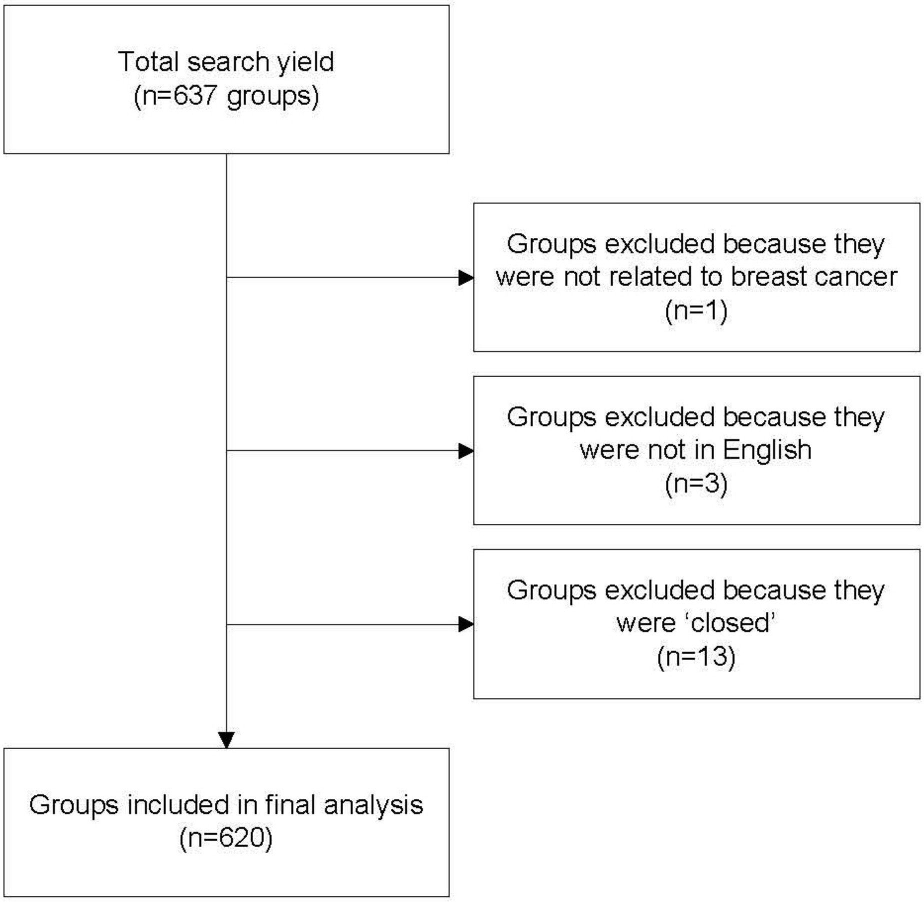


Figure 3. Sample breast cancer support group on Facebook in 2008

1,000 strong for my mom and her fight with breast cancer

Global

Basic Info

Name:	1,000 strong for my mom and her fight with breast cancer
Category:	Common Interest - Health & Wellness
Description:	My mom was diagnosed the 7th of August '08, help her defeat cancer.

Recent News

we are now sure it is breast cancer. she will go through radiaton therapy, then a surgery to get rid of the cancerous cells. and she will probably have to lose her hair. thanks for joining and thanks again for all the support :)

today is the first day of the start of 20 weeks of chemo

you guys are all wonderful :]
we are kinda almost at the half way point... if everyone invites two people we will reach our goal

Members

Displaying 8 of 847 members See All

The Wall

Displaying 5 of 43 wall posts. See All

Dee Jay McKenzie Miller wrote
at 1:35am on June 24th, 2009

Hi Paige. I lost my mom to breast cancer 5 years ago. She was my best friend. I have grown a lot since then and also know some things now that I wish I knew then. First of

Figure 4. Sample breast cancer awareness group on Facebook in 2010

Breast Cancer

Basic Info

Name: Breast Cancer

Category: Organizations - Non-Profit Organizations

Description: a group that will show you just how serious this cancer is to those of any age.

Privacy Type: Open: All content is public.

Recent News

News: i recentlly found out that one of my friends has cancer. along with her mother. i have known this girl for many long years, and she deserves the best.

Information

Category: Organizations - Non-Profit Organizations

Description: a group that will show you just how serious this cancer is to those of any age.

Privacy Type: Open: All content is public.

Admins

- Alison J. Jones (Guelph Collegiate Vocational Institute) (creator)

Members

6 of 1,932 members

Group Purpose

As shown in Table 1, the majority of groups (513/620, 82.7%) were created for fundraising or awareness purposes. In total, 44.7% (277/620) were created to raise funds for breast cancer, 38.1% (236/620) to raise awareness about breast cancer and related events, 10% (61/620) to promote an external website raising funds or awareness for breast cancer through the sale of products or services, and 7% (46/620) to generate support for people affected by breast cancer. A minority of groups (9%) were classified as having an additional purpose, 34% (19/55) of which related to fundraising or support, 27% (15/55) to raising awareness, and 4% (2/55) to supporting an external website. As shown in Table 2, the three most common types of breast cancer groups on Facebook, which comprised 69% of the total sample, were (1) groups created to raise funds for a fundraising walk associated with a charitable organization in the United States or Canada (239/620, 38.5%), (2) groups raising awareness about a specific fundraising event (95/620, 15%), or (3) groups promoting the importance of breast cancer in general (94/620, 15%).

Table 1. General purpose and size of Facebook breast cancer groups

Group	Sample group description	n (%)	Members			
			Total	Median (IQR)[a]	Minimum	Maximum
Fundraising	*My mom is a 11 yr cancer survivor and i [sic] am walking for her and encouraging friends and family to join me in this walk for a cure for breast cancer.*	277 (44.7)	51,307	151 (92)	1	2623
Awareness	*October is Breast Cancer Awareness Month. Share Beauty...Spread Hope ...Think Pink!!*	236 (38.1)	957,289	270 (389)	2	772,815
Promote-a-site	*This doesn't cost you a thing. Their corporate sponsors/advertisers use the number of daily visits to donate a mammogram in exchange for advertising.*	61 (10)	64,861	373.5 (932)	116	16,769
Support	*For anyone who knows someone who has survived, is battling, or has died of breast cancer. For congratulations, hope and [in] memoriam.*	46 (7)	16,940	235.5 (237)	2	2995

[a] IQR: interquartile range.

Table 2. Specific purpose and frequency of Facebook breast cancer groups

General purpose	Specific purpose	Primary purpose, n	Secondary purpose, n
Fundraising (n = 277)	1. Charity fundraising event	239	2
	2. Personal fundraising event	11	14
	3. Product promotion	17	0
	4. Charitable organization	7	2
	5. Noncharitable organization event	3	0
	6. Service promotion	0	1
Awareness (n = 236)	1. Breast cancer in general	94	7
	2. Fundraising event (eg, walk)	95	6
	3. Charitable organization	23	1
	4. Awareness event	10	1
	5. Research project	5	0
	6. Political advocacy	4	0
	7. Risk factors	3	0
	8. Planning an event	2	0
Promote-a-site (n = 61)	1. Product promotion	43	2
	2. Political advocacy	16	0
	3. Awareness	1	0
	4. Research recruitment	1	0
Support (n = 46)	1. For anyone affected by breast cancer	22	10
	2. For oneself or loved one with breast cancer	22	3
	3. For fundraisers	2	6
Total		620	55

Group Size

We identified a total of 1,090,397 Facebook users who were members of one or more of the 620 breast cancer groups. The awareness groups contained by far the most members (957,289, 87.8%), followed by the promote-a-site groups (64,861, 5.9%), fundraising groups (51,307, 4.7%), and support groups (16,940, 1.5%). The groups ranged in size from 1 to 772,815 members and had a median of 196.5 members (IQR 214.7). Most groups (612/620, 98.7%) contained 5000 or fewer members and 70.8% (439/620) contained 101 to 500 members. On average, the promote-a-site groups had the greatest median number of members (median 373.5, IQR 932), followed by the awareness groups (median 270, IQR 389), support groups (median 235.5, IQR 237), and fundraising groups (median 151, IQR 92) (Table 1).

User-Generated Contributions

A user can contribute content to a Facebook group in various ways, such as posting messages to the “wall,” news section, or discussion board, or uploading multimedia such as photos or videos. As Table 3 shows, the most frequently used communication feature was the wall. Although wall posts ranged in number from 0 to 8614, the groups contained a median of 5 wall posts (IQR 11). The majority of groups (532/620, 85.8%) had 25 wall posts or fewer. The support groups had the greatest median number of wall posts (median 16, IQR 38), followed by the awareness groups (median 6, IQR 19), promote-a-site groups (median 4, IQR 9), and fundraising groups (median 4, IQR 7). The difference in median number of wall posts across the groups was statistically significant (c^2_3= 52.0, $P < .001$).

Table 3. User-generated content on Facebook breast cancer groups, median (interquartile range)

Group	Wall posts	Discussion posts	Photos	Videos
Support	16 (38)	1 (4)	3 (12)	0 (0)
Awareness	6 (19)	1 (3)	3 (11)	0 (0)
Fundraising	4 (7)	0 (1)	0 (6)	0 (0)
Promote-a-site	4 (9)	2 (2)	0 (1)	0 (0)

Support Groups

Nearly half (32/65, 49%) of the support groups were created to generate support for anyone affected by breast cancer. A typical purpose statement for these types of groups was “For anyone who knows someone who has survived, is battling or has died of breast cancer. For congratulations, hope and [in] memoriam.” An additional 38% (25/65) of the support groups were established to obtain support for the creator of the group or a loved one affected by breast cancer and 12% (8/65) were created as a forum for information sharing among people participating in a fundraising walk (Table 2). Interestingly, a minority of the groups that were created “for anyone” affected by breast cancer (6/32, 19%) were initiated by individuals with an afflicted family member or friend, even though the explicit purpose of the group was not to gain support for the creator of the group or a loved one in particular. In the remaining 26 of these groups, the motivation of the group creator was not explicitly described. A small percentage of the support groups (5/65, 8%) were also serving in memoriam of a loved one who had died of breast cancer.

Support Group Creators

We also examined the creators of the support groups for anyone, oneself, or a loved one affected by breast cancer (excluding groups created as a support forum for people participating in a fundraising walk, because we were primarily interested in breast cancer-related support). All but one of the creators of the support groups (n = 57) restricted the visibility of their personal profile pages to members within their networks. However, in 47% (27/57) of the support groups the academic institution of the creator and their expected graduation date either was included on the group page itself or was available in the search result content, and in 86% (49/57) of the support groups the geographic location of the creator was also available. Of the groups with available information on the approximate age of the group creators, 56% (15/27) were college students, 37% (10/27) were high school students, and 7% (2/27) were recent college graduates. None of the support group creators appeared to be health care professionals or associated with a health care organization. Of the groups with available information on the geographic location of the support group creators, 57% (28/49) were located in the United States, 41% (20/49) in Canada, and 2% (1/49) in Australia.

Discussion

We found a large number of breast cancer-related groups on Facebook (n = 620) with over one million members. Unlike most disease-specific online communities, the majority of breast cancer groups on Facebook were created for fundraising and awareness purposes, rather than supportive care. The awareness groups as a whole contained by far the most members (n = 957,289), while the support groups were associated with the greatest number of user-generated contributions. Many of the individuals who did create the groups for supportive care purposes were adolescents and young adults, and the majority appeared to be living in the United States or Canada. None of the support group creators appeared to be health care professionals or associated with a health care organization.

Unlike in our study, Farmer et al [8] found patient (47.4%) and caregiver support groups (28.1%) to be more common than fundraising groups (18.6%). However, Farmer et al did not include breast cancer groups in their sample. Of relevance, the authors did include lung, stomach, and colorectal cancer as search terms, and found considerably fewer groups (n = 55) and members (n = 77,832) associated with these neoplasms, than we found associated with breast cancer (620 groups with 1,090,397 members). This difference is largely due to the greater number of fundraising and awareness groups we found associated with breast cancer, which is not surprising given that the breast cancer fundraising movement is one of the largest and most successful survivor-driven social movements, which other disease groups seek to emulate [26]. However, we also found more support groups for breast cancer (n = 47) than Farmer et al found for lung, stomach, and colorectal cancer combined (n = 32). Although breast cancer is the most common neoplasm in women, lung, stomach, and colorectal cancers are the three neoplasms associated with the greatest morbidity and mortality among both men and women worldwide [22]. Hence, the difference in the number of support groups on Facebook associated with these cancers cannot be attributed to their relative prevalence, and may instead reflect a greater tendency for people affected by breast cancer to join online communities than people affected by other conditions [2].

In contrast to breast cancer-specific online communities, which are used primarily to meet treatment information, symptom management, and emotional support needs [27], breast cancer groups on Facebook were not primarily used for supportive care purposes. One of the frequently reported advantages of breast cancer-specific online communities, which to date have focused on mailing lists and message boards, is the relative anonymity and privacy that they provide, which allows users to communicate about personal and socially stigmatizing topics [13]. Although Facebook groups provide facilities for discussion forums based on shared experiences, the visibility of user profiles and personal networks reduces the relative anonymity of the encounter and, if open to the public, which all groups in this study were, they have the potential to attract a much wider audience. This core functionality of social network sites, which gives users access to a more diverse and extensive network, makes them ideally suited for fundraising and awareness-raising purposes, as this study has demonstrated, but may make them less suitable for support-seeking related to topics that are embarrassing or socially stigmatizing [2].

Many of the individuals who did create the groups for supportive care purposes were adolescents and young adults, and the majority appeared to be living in the United States or Canada. These findings reflect the site's user demographics at the time study was conducted. In the fall of 2008, the largest demographic of Facebook users was 18-24 years old [5], the United States reported more Facebook users than any other country, and Canada had the highest penetration of Facebook users per capita [28]. While some support groups were created for a loved one affected by breast cancer (perhaps a less technology-savvy parent), many young people established Facebook groups to obtain support for themselves.

Adolescents and young adults can experience significant distress when a loved one has cancer [29,30], and research suggests that their unique needs are often poorly met both within and outside the family [31]. Social network sites such as Facebook could provide this group with a convenient and familiar means to accumulate coping resources. Use of these sites is associated with greater levels of *bridging social capital*, or access to information and resources through a diverse set of acquaintances, and *bonding social capital*, or emotional support from close friends [32]. Both of these, according to the theory of stress and coping, can promote coping efforts and lessen negative appraisals of events, in turn reducing or buffering anxiety [33]. Furthermore, Ellison et al [34] have shown that college students who are active on Facebook experience higher levels of both forms of social capital, and Burke and colleagues [35] have confirmed that these findings generalize to older users and English speakers outside the United States.

Notwithstanding the large number of members that the breast cancer groups attracted, there were relatively few user contributions overall, and in the fundraising, awareness, and promote-a-site groups in particular. These findings support the consistently reported observation that online communities attract significantly more lurkers (visitors who do not post messages) than posters [36]. However, the fundraising, awareness, and promote-a-site groups were not created to stimulate discussion but rather to promote a message, event, product, or service. Although activity, which is often judged by the number of posts, is a key determinant of a successful online community [37], posting messages in online health communities is not necessary to obtain the empowering effects from participating in them [38]. Likewise, it may be possible to benefit from joining a Facebook group without contributing content, depending on the purpose of the group or the motivation of the joiner. According to a study by Park et al [39], college students join Facebook groups not just to socialize, but also to obtain information about events, to seek self-status, and to find entertainment. In addition, Park and colleagues found that those who joined Facebook groups for information purposes were more likely to participate in civic and political activities, suggesting that Facebook groups may play an important role in facilitating youth engagement.

Practice Implications

The findings of this study are valuable because they provide information on the health-related use of the most widely popular social network site in existence. They indicate that Facebook groups are being used by a considerable number of people affected by breast cancer for fundraising and awareness purposes, and to a lesser extent supportive care. That being said, our findings should not be interpreted to imply that Facebook is rarely used for supportive care purposes, given that several ways to solicit or provide support on Facebook were not examined in this study, including private messages, wall posts on personal profile pages, and status updates. These findings do suggest that Facebook may play an important role in facilitating public engagement in health promotion and fundraising activities, particularly among youth.

Limitations

This study has important limitations. First, we were unable to collect demographic information on 53% (30/57) of the support group creators due to their use of privacy settings. However, this finding suggests that users of Facebook not only are becoming aware of the public nature of their online activities, but also are activating the privacy measures offered. In fact, all but one of the support group creators in our sample restricted their personal Facebook profiles to their networks, whereas a study of Facebook users conducted in 2005 found that only 0.06% of college students restricted the visibility of their profiles to members within their networks [40]. Since then, significant changes made to the platform and user base of Facebook might in part explain the increased use of privacy settings by this sample, such as the launch of the NewsFeed feature, which provides updates on the activities of friends [41], the introduction of third-party-developed applications [42], and the expansion of registration to anyone.

Another related limitation was our reliance on user self-reported data (that were available on the group page itself or in the search result content) to infer the approximate age and geographic location of the support group creators. This information is possibly incorrect or fabricated. In addition, we could not determine the exact number of unique individuals affiliated with a particular type of breast cancer group on Facebook, given that a single user could be a member of multiple groups. Therefore, the total number of members affiliated with each type of breast cancer group could be inflated. At the same time, the total number of breast cancer groups identified in this study is likely only a portion of the total number of breast cancer groups on Facebook, given that we restricted our study to groups in English, while Facebook is available in more than 70 different language versions [4].

Lastly, we encountered numerous challenges while investigating the nature of breast cancer groups on Facebook that were primarily related to its limited functionality as a search tool. The search bar yields an imprecise yield (eg, “>500 groups”), the order of the search results is inconsistent and unclear, and the search is limited to the title of the group. Since the time we conducted our study the search tool has been enhanced but, to our knowledge, these specific issues have yet to be resolved. We contacted Facebook to notify them of these technical issues and obtained an encouraging response. Collaboration with platform owners would certainly facilitate future research in this area.

Research Implications

Further research is warranted to understand the implications of participating in health-related groups on Facebook. While other researchers have examined site activities that lead to higher levels of social capital [34,35], no known studies have examined the impact of participating in a health-related group on Facebook. It is also unknown whether general social network sites such as Facebook are as effective as disease-specific online communities in providing health-related information and support, and for whom. Given the importance of anonymity in facilitating disclosure in online breast cancer communities [13], research is warranted to examine breast cancer survivors’ perceptions of social network sites as a source of supportive care in comparison to other sources. Lastly, a better understanding is needed of the privacy implications of sharing personal health information on public social network sites, which has raised concern [25], leading some to advise against disclosing personal information on these sites [8].

Conclusions

Facebook groups have become a popular tool for awareness-raising, fundraising, and support-seeking related to breast cancer, attracting over one million users by the end of 2008. Given their popularity and reach, further research is warranted to explore the implications of social network sites as a health resource across various health conditions, cultures, ages, and socioeconomic groups.

Acknowledgments

This work is a component of JLB’s PhD thesis at the University of Toronto. JLB wishes to acknowledge the guidance of her PhD thesis committee: LE Ferris PhD CPsych LLM (ADR) LLM (Admin Law), J Katz PhD CPysch, and AR Jadad MD DPhil FRCPC.

Conflicts of Interest

None declared

Authors' Contributions

JLB conceived and planned the study with support from ARJ. JLB and MCJM collected and analyzed the data. JLB drafted the manuscript. ARJ and MCJM reviewed and contributed to the manuscript. JLB is guarantor.

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Abbreviations

IQR: interquartile range

Edited by T Houston; submitted 06.05.10; peer-reviewed by D Mayer, E Black; comments to author 20.06.10; revised version received 31.12.10; accepted 31.12.10; published 04.02.11.

Please cite as:
Bender JL, Jimenez-Marroquin MC, Jadad AR
Seeking Support on Facebook: A Content Analysis of Breast Cancer Groups
J Med Internet Res 2011;13(1):e16
URL: http://www.jmir.org/2011/1/e16/
doi:10.2196/jmir.1560
PMID:21371990

Viewpoint

Open Source, Open Standards, and Health Care Information Systems

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Abstract

Recognition of the improvements in patient safety, quality of patient care, and efficiency that health care information systems have the potential to bring has led to significant investment. Globally the sale of health care information systems now represents a multibillion dollar industry. As policy makers, health care professionals, and patients, we have a responsibility to maximize the return on this investment. To this end we analyze alternative licensing and software development models, as well as the role of standards. We describe how licensing affects development. We argue for the superiority of open source licensing to promote safer, more effective health care information systems. We claim that open source licensing in health care information systems is essential to rational procurement strategy.

(J Med Internet Res 2011;13(1):e24) doi:10.2196/jmir.1521

KEYWORDS

Health Care Information Systems

Introduction

Doctors, patients, and policy makers are increasingly aware of the significant improvements in patient safety, quality of patient care, and efficiency that health care information systems (HIS) have the potential to bring [1-3]. This has led to significant investment in HIS. Investment has also been motivated by a desire to capitalize on the global market for HIS, estimated to be worth US $53.8 billion by 2014 [4], by developing HIS for export. In the United Kingdom, contracts were negotiated in 2004 for a National Health Service (NHS) National Programme for Information Technology (NPfIT) with a budget of £12.4 billion over 10 years. This makes it an information technology (IT) project unprecedented in terms of cost and scale [5]. Furthermore, the current US administration has recently displayed the political will for wider adoption of HIS by committing US $19 billion to develop and encourage the implementation of HIS as part of the American Recovery and Reinvestment Act of 2009 [6,7].

However, difficulties have been experienced in the United Kingdom delivering the NPfIT on time and within budget [8]. Additionally, concern has been expressed that a lack of clinical engagement threatens the success of the project [5,9-12]. While some progress has been made with networks, hardware, and software, many promised benefits such as single-point data entry (“With IT, information can be captured once and used many times” – Downing Street 2002 NHS IT Briefing [13]) are still eagerly awaited by practicing UK clinicians [14]. In the United States, excepting the Veterans Administration (VA) hospitals’ HIS, uptake of HIS has been poor [7]. While it is too early to assess the results of the fiscal stimulus, concern has been expressed that the procurement process, standards, and certification will be biased in favor of software vendors who operate closed development models and sell their software with proprietary licenses. Furthermore, this may be to the detriment of rapid widespread adoption, and meaningful usage, of effective HIS [15].

We believe that open source software (OSS) licensed HIS provide a key opportunity for the promotion of effective systems by enhancing clinical engagement in software development, fostering innovation, improving system usability, and reducing costs, and should therefore be central to a rational HIS procurement strategy.

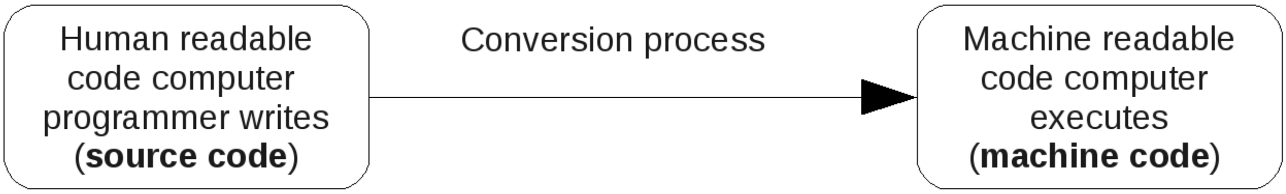
Background

Approaches to Software Development and Licensing: Proprietary Software and Open Source Software

In terms of software development and licensing, there are broadly two kinds of software: (1) proprietary software, such as Microsoft Internet Explorer Web browser, and (2) OSS, such as Mozilla Firefox Web browser.

The major difference between the two is the availability of the source code. This is the code computer programmers write, which is turned into the machine code computers execute (Figure 1).

Figure 1. The programmer writes source code, which is converted to the machine code that the computer runs



OSS is software where the end user can access and modify this source code, because of their rights under the licensing arrangement, to make new machine code and redistribute it. With proprietary software the source code is secret and the end user can access and execute only the machine code.

In fact, the reality of OSS is more complex. We use OSS in this paper to refer to both Free/Libre, as in the sense of the French “libre”, software and open source software. This is also sometimes referred to as free and open source software. Whichever term is used, OSS refers to a large number of different software licenses that have certain requirements for source code openness in common [16]. The Free Software Foundation and the Open Source Initiative act as arbiters of these licenses.

Free software and OSS movements disagree on aspects of commercialism and licensing but agree on many fundamental principles such as the availability of the source code and the ability to modify and distribute it freely. Specifically, most free software licenses are less permissive. They forbid both contamination of source code with proprietary code, and later closure of source code previously released under an open license [17].

It is crucially important to realize that the quality of the software and source code is not inherently affected by the nature of the license. The application of a license to a piece of source code does not affect the code per se, but the type of license does affect the development of source code and has long-term implications for the purchaser.

Open Standards Facilitate Competition Between Open Source Software and Proprietary Software

Having defined open *source* it is expedient to examine open *standards*, since it is often suggested that they, and not open source, should be required by a purchaser in order to promote competition between proprietary software and OSS.

Usage of the term *open standard* varies considerably. There is agreement upon what constitutes a standard, but disagreement on what is required for a standard to be considered open.

Standards may be classified according to their openness. Cerri and Fuggetta [18] give a useful system of classification, which we have adopted here.

1. Closed: the standard is owned by a company and is kept secret (eg, the Skype communication protocol).
2. Disclosed: the standard is owned by a company but is made available to other companies and users (eg, Adobe PDF format).
3. Concerted: there is a consultation on a new standard, but admission to the consultation process and management of the process is controlled by a company (eg, Sun Microsystems Java programming language).
4. Open concerted: there is an open participation in the process through which the standard is defined and managed (eg, World Wide Web Consortium [W3C] HTML).
5. Open de jure: the standards are owned and managed by official international or national standardization bodies (eg, the Digital Imaging and Communications in Medicine [DICOM] standard).

An open standard is developed through methods 4 or 5 and must fulfill all of the following requirements [18]:

1. The standard specification document must be publicly available, either free of charge or at a nominal fee.
2. The standard must be owned and managed by an official standardization body or by an open group or consortium. It must not be owned or controlled by a single party, and no single party must have special rights to it.
3. The standard must be defined and managed according to an open process. Every interested party must be able to join the standardization process, which must be based on an open decision-making procedure (eg, consensus).

4. The standard must be free to implement for all interested parties, without any royalty fee. Any patented technologies included in the standard must be licensed with royalty-free nondiscriminatory terms.
5. It must be possible to extend and reuse the standard in other open standards.

Evolution of the computer industry has been driven by the emergence of standardized platforms that allow, and even encourage, modular substitution of complementary components such as software and hardware. Briefly, this evolution charts the shifts in business strategies of the Big Four: Apple Computer, IBM, Sun, and Microsoft. With time, vertically integrated proprietary platforms such as early IBM mainframes gave way to horizontally specialized strategies of personal computers and servers. More recently, the emergence of OSS has necessitated further refinement of business strategy. Three of the Big Four have developed hybrid OSS and proprietary platforms and now emphasize selling services and support rather than software alone [19].

Standards matter to businesses, who are keenly interested in establishing dominant standards where possible, ensuring that their products interoperate with the dominant standard where not, and in any case influencing and using standards for their own benefit. This is why compatibility issues are frequently encountered when one tries, for example, to open a Microsoft Word 2007 document on a computer not using a Microsoft operating system, or even a computer not using the same version of Microsoft Word.

The aim of open standards is to have competing implementations of the same standard, rather than competing platforms, in order to benefit consumers. The rationale is that open standards lower entry barriers and encourage competing implementations of the same standard, which in turn tends to foster innovation and lower costs to the consumer. The consumer is empowered to change products without losing data or facing significant conversion costs, thereby preventing lock-in. Further, together with antitrust laws, open standards help to protect consumers from monopolies [18,19].

Open Standards Need Open Source Software Implementations

Proper development and maintenance of an open standard requires a balance between not allowing extension, which may prevent evolution of the standard and stifle innovation, and allowing proprietary extensions, which can lead to the subversion of a standard [19].

An open standard can also be subverted where adoption of proprietary standard is sufficiently widespread for it to become a de facto rival standard. For example, Internet Explorer has introduced an array of proprietary extensions to many of the standards, such as HTML (maintained by the main international standards organization for the World Wide Web, the W3C). Consequently, webpages that make use of these proprietary extensions appear broken even in standards-compliant Web browsers, introducing the need for a “quirks mode” in standards-compliant Web browsers to allow rendering of these noncompliant elements.

A successful open standard achieves and maintains the aim of having competing implementations of the same standard, making the substitution of alternative components possible in reality, not just theory. This essential state of affairs is much more likely where an open source implementation exists, for the following reasons [20,21]: (1) an open source implementation acts as a reference implementation, revealing standard specifications that are unnecessarily hard to implement or contain specification flaws, and (2) OSS tends to enjoy wide diffusion and dissemination, facilitating adoption of the standard.

Having an open source implementation of a standard therefore means both that the standard is more likely to be of high quality and that the standard is much more likely to become widely adopted. In fact, it has been observed that all successful open standards have OSS implementations [20]. Therefore, when creating or choosing a sustainable open standard it is very unwise to create or choose a standard without at least one open source implementation.

Contemporary Health Care Information Systems Procurement Strategies and Standards

In the United Kingdom, the government chose to procure HIS centrally and implement them locally via five separate local service providers, who in turn were able to choose and change subcontractors [5]. The software being developed for use under NPfIT is proprietary. The government created an output-based specification [10], which was then tendered to interested contractors who employ programmers to write software that meet the specifications. Unfortunately, compared with OSS, this development model is often more expensive, less responsive to users, less secure, and more vulnerable to lock-in. In lock-in, a software purchaser loses the ability to switch software products because of the use of proprietary data formats or restrictive licensing conditions [22-24].

The United States has already developed an excellent HIS, the VA VistA hospital system, which directly serves or forms a core part of the software serving almost 30 million Americans [25]. Unfortunately, outside of the VA network of hospitals, uptake of HIS has been poor [7], the use of proprietary software is commonplace, and there has been a paucity of high-quality, affordable, and interoperable HIS [26]. Adoption of a VistA-derived OSS HIS platform and reference implementation allows competition to be based on service and support, reducing licensing costs while also providing an inclusive environment where creativity, innovation, and flexibility are not stifled by platform barriers [16]. Perhaps unsurprisingly, some observers are already predicting OSS HIS adoption will soon become widespread [27].

There is a power asymmetry between vendors and purchasers of proprietary software comparable to that of vendors and purchasers of used cars, which is a so-called “lemon market.” In this comparison there are two main points. First, the typical purchaser of a used car is in a weak position because he or she lacks knowledge about the technical fitness of the product, is blind to everything but price, and has no way of identifying poor-quality used cars, the “lemons.” Second, ongoing maintenance costs depend on the car’s design. If the car is designed in such a way that a specialist garage is required and generic replacement parts are hard to come by, the maintenance costs are high. A shrewd buyer may reduce this asymmetry by taking a warranty or having a mechanic look under the hood and inspect the car before buying. Such a buyer would also prefer more standard designs and generic parts, all else being equal, since these will tend to lower maintenance costs. Incidentally, there is one very important difference between the car market and the HIS market, which we will return to below. Namely, drivers are usually buyers in the car market but end users are not usually buyers in the HIS market.

In HIS procurement, purchasers are in a stronger position if they inspect, and allow others to inspect, the quality of the code; if they ensure that the programming code will be easily maintainable and that the data are stored in an established open format so that it will be cheap to get the data out and switch software when needed; and, finally, if they acquire the rights to the code, including the right to take it to another programmer or software company. In general, then, purchasers will be in a stronger position when they buy OSS rather than proprietary software.

There are a plethora of competing standards in HIS. Against this background DICOM stands out as a stunning success, and DICOM conformity is a standard part of just about every radiology product, software, or hardware. However, despite promising developments such as the US Nationwide Health Information Network [28], for most standards, open and closed alike, widespread conformity has not yet been achieved and this is to the detriment of interoperability.

The Pros and Cons of Certification

Certification of standards in HIS has been mooted as essential to ensure interoperability and because of the safety-critical nature of HIS. The Certification Commission for Health Care Information Technology (CCHIT) is charged with certifying that American electronic health record systems meet standards in order that they qualify for Recovery and Reinvestment Stimulus Bill funds. Concern has been expressed that certification fees and other aspects of the process of certification, such as handling of versioning and a preference for comprehensive rather than modular systems, is a barrier to entry for OSS [28]. There has also been some controversy surrounding CCHIT's relationship with vendors [29].

Certification of implementations of a standard is a choice. While it provides assurance to purchasers and users that a particular standard is met, the cost of certification must be borne and is often passed on to software developers. Despite being one of the oldest and most successful open standards bodies, the W3C does not have a certification process. In part this is because of the risk of alienating part of the industry or the Web community by adopting what could be seen as a policing or commercial role. It is also because of a concern that true vendor neutrality in certification is unachievable.

Certification may also restrict physicians in their own personal use of HIS. It has been observed that many physicians already use hand-held HIS and that psychological ownership is important for acceptance. Certification may undermine this [30,31].

It would be ironic if a healthy respect for the safety-critical nature of health care and the desire for interoperability leads to the proliferation of insufficiently open standards and to certification processes that close out OSS and stifle the development of effective HIS.

Prerequisites of an Effective Health Care Information System

General Prerequisites of Successful Information Systems

Three major reasons for IT project success across all sectors of the economy have been identified [32]: (1) extensive, informed, and continuing user involvement, (2) senior and executive manager support, (3) a clear and accurate requirements modeling strategy. Sadly, however, a common finding in software projects is that “significant budget and time-line overruns, under-delivery of value, and the outright termination of a project before completion are all forms of failure” [33,34].

Budget overspending and failure to deliver key features have plagued recent HIS projects, and cost remains a major issue for would be HIS purchasers [7,34].

Prerequisites of an Effective Health Care Information System

In the first instance, we need a conservative or status quo HIS that mirrors, facilitates, and supports our current best practices. A system that demonstrably helps with the clinical workload in a reliable fashion is likely to have high spontaneous adoption rates. But as we would not wish our current clinical practices to be set in stone, so we should not wish our HIS to be static. Clinical acceptance is important and more likely to occur if significant process change is not required at the outset but instead is introduced after initial acceptance is secured, and in a stepwise fashion [9,25].

Returning to the major difference between car and HIS markets mentioned above, one might argue that better cars, from a driver perspective, result from driver choice. The driver is not compelled to buy a particular brand of car, and so car manufacturers have an incentive to make desirable cars – we leave unanswered what makes a desirable car. In the health care setting, choosing noncoercive implementation of an HIS could be an acid test of whether an HIS is of sufficiently high quality. Furthermore, employees may be permitted, and encouraged, to use rival but compatible HIS components, to promote desirable HIS. The assumption here is that health care professionals desire HIS that is usable, efficient, and helps to improve patient care.

We also need an affordable HIS software platform to be established to help coordinate and focus efforts on health transformational goals. The iPhone has been cited as a model successful platform [35] but a better model might be software, with Firefox or VistA as an example because these are less restrictive and more flexible platforms [36]. The implementation of an open source HIS platform will help to define and secure an open standard, as argued above [19,20]. This will make the addition and substitution of components possible, since modularity is an inherent feature of open source development.

It will help to create a healthy market [35], as well as facilitating systems' evolution, flexibility, and functional creativity [37].

Physician use of hand-held HIS should be encouraged as a means of making the end user the buyer and/or chooser of the HIS used, since this will tend to improve HIS. Therefore, smooth integration of hand-held HIS with hospital HIS should be a priority. Integration will be facilitated by an OSS HIS platform. Allowing individual physicians the freedom to choose the software that best suits them may help to drive meaningful use and innovative computer-aided practice [38].

Why Open Source Software? Characteristics of Open Source Software and its Advantages

General Argument

The major single argument is that OSS empowers purchasers of software by making it easier for a given purchaser to change software products and/or software development teams, thus preventing lock-in and driving down costs [28]. However, important differences between the typical open source development model and proprietary development models provide a number of important additional arguments (Figures 2, Tables 1).

The arguments for OSS may be summarized as follows: (1) stronger position for purchaser, therefore lower costs, (2) software is superior (eg, usability, security, reliability) because of superior development model, quality of code can be checked, users can contribute, and contributors have many motivations (attracting highly motivated people to contribute “for free” is possible), and (3) facilitates open standards, encouraging competing implementations, strengthening the purchaser's position, and leading to superior software.

In OSS development, there may or may not be a purchaser. A project may consist entirely of unpaid user-developers and users. If there are purchasers, they may employ core developers or a software company to write and release software to foster the formation of a community of user-developers. Existing specifications are usually adapted to meet user needs. Development benefits hugely from the involvement of the users.

This contrasts with proprietary development, in which there must be a purchaser. Either the software company creates a user specification for an imagined purchaser and then writes and markets the software to this purchaser, or it is paid to write software that meets a particular purchaser's specification. Creating a comprehensive and accurate specification from scratch is costly. Users do not have access to the code so cannot contribute to it, and so any latent development skill possessed by users cannot be tapped. While a product continues to sell, the software company has little incentive to respond to individual user requests.

Figure 2. Open source software development process

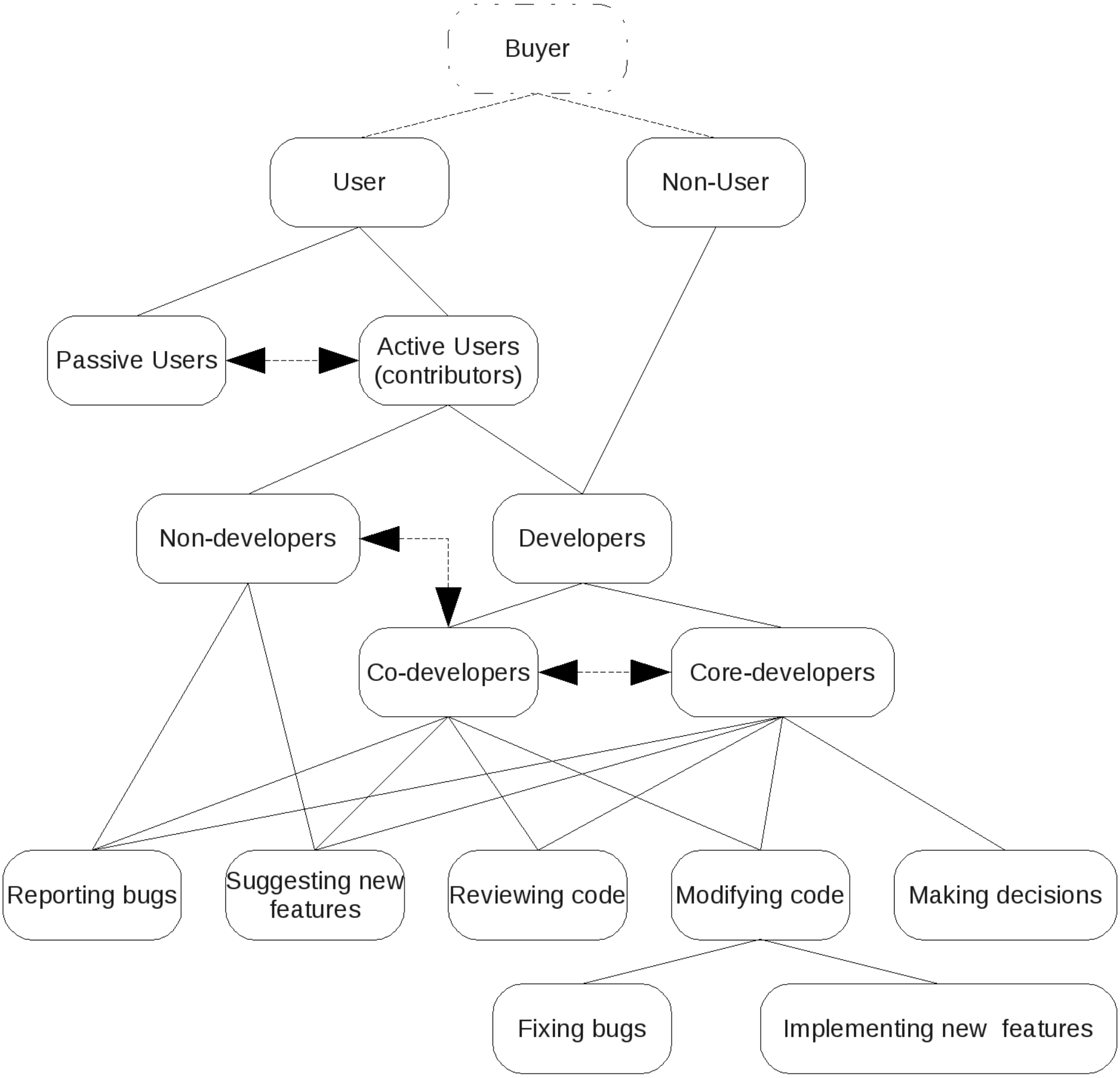


Figure 3. Proprietary software development process

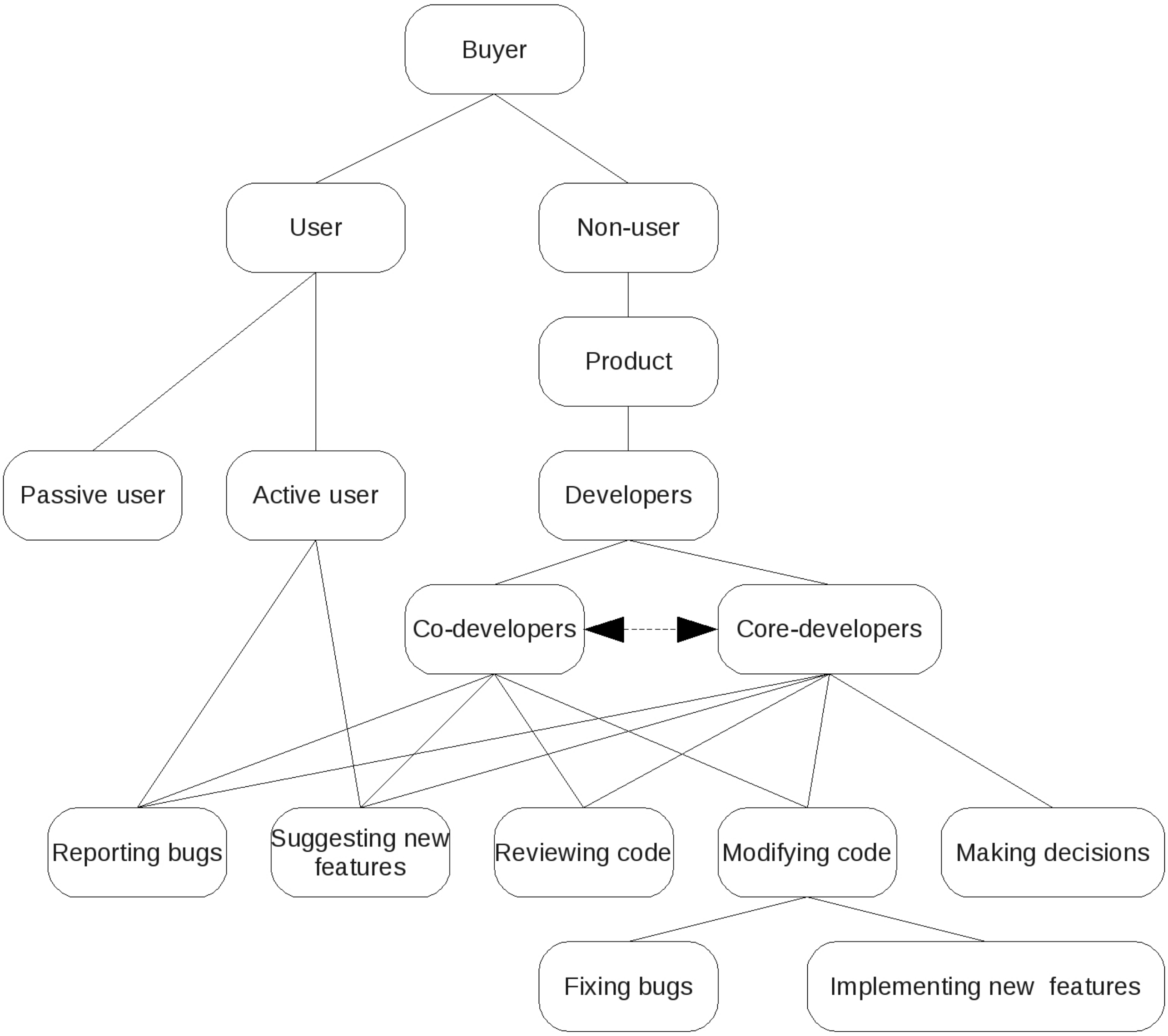


Table 1. Comparison of proprietary and open source software development methods

Aspect	Proprietary software	Open source software
Software owner	Company, shareholders	Community, citizens
Foundations of product	Other products on market with a few distinct changes (analogy: me-too drug)	Existing tested code base (analogy: generic drug)
Pricing model	What the market will bear	Cost recovery
Development team	Professional programmers isolated from user base	Mix of professional and amateur programmers, often including users
Development team strategy	Cut and run, lock in to proprietary code	Code reuse, continuing quality improvement
Development team dynamics	Small, centralized, managed	Large, decentralized, meritocratic
Developer incentives	Salary, internal promotion	Community, recognition, contribution to application area ± salary & promotion
Method to test and assure quality	Internal synthetic test cases, team integrity	Real cases, user testing, open inspection by community
Driver to respond to user needs and requests	Market share	Community-prioritized need
Intellectual input	Small team, distorted by team dynamics	Wisdom of crowds

Successful OSS projects tap into the skills of the community that forms around them to suggest new features, report bugs, and modify the source code accordingly. A nascent developer community must have something testable to play with but, once formed, open source communities can put skilled time of much greater orders of magnitude into a problem [39]. The central argument to OSS development is that when everyone can inspect the source code, the software gets more scrutiny and more corrective feedback than a single development team can provide, leading to better software [40]. Reasons why this is so hinge on the characteristics of OSS and are multifactorial, but include [17,41] the following:

- Economic: a single proprietary software development team does not usually have the staff comparable to the size of the distributed communities involved in development of large OSS projects. OSS removes the need for duplication of programming effort (although it may occur anyway). Lock-in is prevented, leading to better long-term code security.
- Psychological: there is plurality of motivation, as members of an OSS community include individuals who may be more highly motivated [24] because they contribute for complex personal, rather than primarily financial, reasons such as peer recognition, as well as corporations motivated by financial gain.
- Social: OSS communities tend to be fluid, have a strong meritocratic culture, and foster creativity and innovation. OSS community meritocracies do break down in the usual human ways, but the licenses allow others to carry on through mechanisms such as “forking” (where a group of developers splits to form two groups and continue development along separate lines).
- Managerial: OSS projects tend to free community members from conventional managerial and bureaucratic constraints, facilitating innovation.
- Computer science/design related: Open source products have a high degree of modularity (necessitated by the distributed nature of development) and a high degree of interoperability.

Table 2. Implications of the differences in proprietary and open source software development methods

Aspect	Proprietary software	Open source software
Cost drivers	Competitors, value added	Development costs
Typical upgrade frequency	When competing products or serious bugs threaten – annual	When new release tested and robust – bimonthly
Use of proprietary tools, data formats	Frequent	Discouraged
Consequences of developer, company abandoning area	Catastrophic (even if source code deposited in escrow)	Not applicable
Software selling points	“Creeping featurism”	Robust, tested, user-centered software
Suitability for safety-critical applications	Only if relevant development and testing methods followed	Only if relevant user and developer community engaged
Risk of monopoly	Low to medium	Low
Ability of purchaser to influence quality, cost, upgrades	Low to medium	Medium to high
Training issues	Applications distinctive, specific training usually needed	Less training: generic look and feel so applications resemble one another
Process for tailoring to local needs	Pay remote software developer and wait	Ask local member of developer team and wait

Barriers to the Adoption of Open Source Software

General Barriers to Adoption of Health Care Information Systems

The major reported barrier to the adoption of HIS is cost [7]. Other barriers include physicians’ resistance to health care software because of the time cost of learning something new, fear of lawsuits, risk of data breaches, fear of automation and deprofessionalization, and poor track record of existing HIS [34,38,42].

Particular Barriers to Adoption of an Open Source Software Health Care Information Systems

Lack of awareness and understanding of, and familiarity with, OSS is a major barrier to the adoption of OSS HIS [28], although this may be changing with the increasing recognition of the success of VistA and the adoption of VistA-derived OSS HIS platforms [27,36].

In many countries there is a lack of clear governmental support for OSS HIS, which may be attributable to a lack of awareness of the proven merits of OSS, the significant power wielded by lobby groups representing commercial or proprietary software developers and vendors, or a wish to protect tax revenue and employment generated by existing proprietary HIS markets. A number of myths have also circulated in the past about OSS such as it being more expensive, less secure, or riskier in terms of liability, which are debunked here and elsewhere [26].

It has been claimed that the total cost of ownership is often higher for OSS because of implementation costs. Lack of expertise and business drawbacks, including training investments and finding the right staff or the right business to outsource implementation and support, do have the potential to negatively influence total cost of ownership. However, many businesses in the service sector find that lower licensing costs and escape from vendor lock-in outweigh this [43-46].

It has been argued that OSS is inherently less secure than closed proprietary software. Arguments have included the claim that because the code is public in OSS an attacker can more easily find and exploit vulnerabilities. This is the “security through obscurity” argument, that systems that hide their inner workings from potential attackers are more secure. Security through obscurity alone completely fails when code is disclosed or otherwise discovered using tools such as debuggers or dissemblers [47].

Worse, it has been suggested that the cloak obscurity provides tends to encourage poor-quality code. Opening the source allows independent assessment of the security of a system, makes bug patching easier and more likely, and forces developers to spend more effort on the quality of their code [47].

The idea that using OSS is inherently riskier because one automatically become liable for any failings of the software is false. Typically a large organization will pay a contractor for an OSS implementation and support package. Many contractors providing OSS implementation and support offer legal indemnity to clients in exactly the same way as proprietary vendors [46].

Particular Reasons to Adopt Open Source Software Health Care Information Systems

The general arguments for OSS previously summarized are that it (1) puts the purchaser in a stronger position, therefore lowering costs, (2) generates superior software (eg, usability, security, reliability) – because of the superior development model, quality of code can be checked, users can contribute, and contributors have multiple motivations (attracting highly motivated people to contribute “for free” is possible), and (3) facilitates open standards, encouraging competing implementations, strengthening the purchasers position, and leading to superior software.

These arguments obtain particularly for OSS HIS. In summary this is because (1) large sums of money are spent on HIS, which makes it easier for the purchaser to lever the advantages of OSS HIS, (2) OSS HIS development can benefit hugely from an existing large, talented, and highly motivated user base, and (3) existing proprietary HIS have not delivered as claimed, and an absence of OSS reference implementations has led to an absence of successful open standards, and in turn an absence of competing implementations.

Health care systems have large, highly trained technical work forces (there were 633,000 employed surgeons and physicians alone in 2006 in the United States [48], and there are approximately 1.3 million full-time workers in the UK NHS). Within these workforces are large numbers of individuals who will report software bugs and request new features in an environment where developers are responsive to this [16,28]. Even though a smaller number of individuals, perhaps one in a thousand, will be motivated and able to fix such bugs and implement new features, this still amounts to a critical mass of several hundred physicians and surgeons. These individuals are immersed in the nuances and intricacies of clinical practice and much better placed than external developers to make software that complements their work [16,23,28,49].

A team of paid core developers could ensure key features are delivered in a timely fashion, building on existing [40] open source medical software projects and preventing duplication of effort. Indeed, Ubuntu Linux, a highly successful open source operating system with over 6 million users, already follows a similar model.

The long-term security of the code base could be protected with a licensing arrangement that specifies that the code remain open and without restriction, allowing the government to readily employ a different team of programmers or businesses to continue development of the code should the need arise.

The complex personal motivation and values within OSS communities, such as healthy rivalry and respect for demonstrated excellence, are a useful match with those found in the medical profession and academia. Together with the informatics talent already demonstrated within the medical profession [50], health care systems can provide fertile ground for the growth of an OSS community. Such a community will facilitate clinical engagement with software and foster creativity [49], innovation, the development of IT skills within a health care system, and an HIS that fits with the needs of clinical users and workflows [22].

A high degree of modularity, together with openness, will help ensure the dependability of the safety and security-critical systems within health systems. Indeed, OSS is already used in a number of safety and security-critical systems, such as German traffic light controllers and American spaceships [22,51-53].

Several mature and function-rich exemplar OSS HIS already exist, including VistA, an electronic health record programmed by Federal (US) employees working for the VA. Development began in the 1970s and in its present form VistA serves approximately 30 million Americans and now is a de facto standard for HIS. VistA has been hailed as “the aspirin of electronic health records” [26], and its success can be attributed to the decentralized distributed team development model initially used. This model has been seen as a precursor to OSS development. The public domain VistA code base already serves as the basis for a number of both commercial and noncommercial leading OSS HIS, such as WorldVista and ClearHealth [16,25,26,28,54,55].

Public and professional awareness of OSS successes is limited because differences in the commercial model mean that OSS software is less often marketed to the general public. However, industrial-grade OSS successes include the Apache Web server, which represents 50% of the world’s Web server market and is supported and distributed by a number of large corporations including IBM and Oracle [40]. In fact, without realizing it, millions of people use Linux everyday when they surf the Internet, use Google, or use a host of other systems with embedded Linux, ranging from washing machines to automated teller machines.

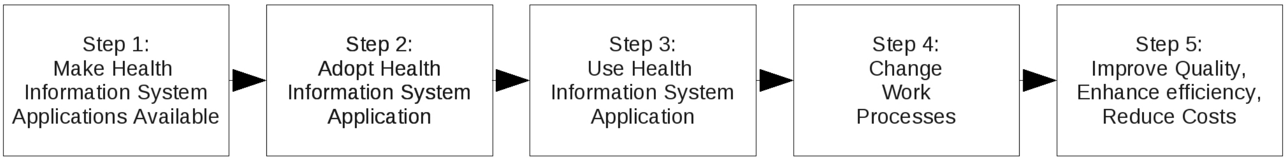
Internationally, governments and businesses are more keenly aware of the benefits of OSS and the threat it poses to the existing US-dominated proprietary software market. The American Center for Strategic and International Studies tracks governmental policies on the use of OSS, and its July 2008 report describes 275 open source policy initiatives to date, 135 of which are within Europe. EU Commission policy recommends that OSS should be promoted among public administrations in terms of efficiency, productivity, and quality of their services and provides funding for the use of OSS in e-government and e-business solutions [53].

In 2004 the UK government announced that it will consider OSS solutions alongside proprietary ones in IT procurement, will only use products with open standards, and will seek to avoid lock-in to proprietary IT products and services [56].

Since 2003 the official US Department of Defense policy is that OSS solutions should be given equal consideration alongside proprietary ones in IT procurement. The US Navy has gone further and in 2007 recognized OSS as key to operational effectiveness [57,58]. Both organizations value safety, interoperability, and cost effectiveness in their IT systems, as do health care providers.

The complexity of evaluating HIS and the lack of a good evidence base for the implementation of HIS have been noted. However, it has been recognized that for HIS to produce benefit it is first necessary that applications be available, adopted by institutions, and supported and used by clinicians (Figure 4) [21,59].

Figure 4. An illustration of the steps necessary before an HIS produces benefit [21]



Rational HIS must aim to improve the quality of patient care, enhance efficiency, and reduce costs. This model emphasizes the importance of clinical engagement for the successful diffusion of HIS [9]. The rapid diffusion of OSS has been noted [24]and gives rise to the conclusion that OSS will benefit patients and professionals, and support the planned reforms of the health care system.

The particular suitability of OSS for HIS has already been mentioned briefly in the *British Medical Journal* [50] and, more recently, in an American Medical Informatics Association White Paper [25]. OSS continues to gain ground outside the health care setting, and in view of its manifest benefits, efforts to include it within the health care setting, and within HIS procurement strategies, must be renewed in order to maximize return on significant HIS investment.

In the future those who choose to invest in OSS HIS platforms, encourage individual physicians to use their own interoperable personal HIS, and take care not to create barriers to entry through regulation will be the first to fully realize the benefits of investment in HIS.

Conflicts of Interest

Neither of the authors receives any material benefit from software standards organizations or from software development, either commercial or open source.

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Abbreviations

CCHIT: Certification Commission for Health Care Information Technology
DICOM: Digital Imaging and Communications in Medicine
HIS: health care information systems
IT: information technology
NHS: National Health Service
NPfIT: National Programme for Information Technology
OSS: open source software
VA: Veterans Administration
W3C: World Wide Web Consortium

Edited by G Eysenbach; submitted 26.02.10; peer-reviewed by I Valdes, N Ernst, H Oh, Y Zhang; comments to author 27.05.10; revised version received 29.11.10; accepted 08.12.10; published 17.02.11.

Please cite as:
Reynolds CJ, Wyatt JC
Open Source, Open Standards, and Health Care Information Systems
J Med Internet Res 2011;13(1):e24
URL: http://www.jmir.org/2011/1/e24/
doi:10.2196/jmir.1521
PMID:21447469

Original Paper

Acceptability of a Clinician-Assisted Computerized Psychological Intervention for Comorbid Mental Health and Substance Use Problems: Treatment Adherence Data from a Randomized Controlled Trial

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Abstract

Background: Computer-delivered psychological treatments have great potential, particularly for individuals who cannot access traditional approaches. Little is known about the acceptability of computer-delivered treatment, especially among those with comorbid mental health and substance use problems.

Objective: The objective of our study was to assess the acceptability of a clinician-assisted computer-based (CAC) psychological treatment (delivered on DVD in a clinic-setting) for comorbid depression and alcohol or cannabis use problems relative to a therapist-delivered equivalent and a brief intervention control.

Methods: We compared treatment acceptability, in terms of treatment dropout/participation and therapeutic alliance, of therapist-delivered versus CAC psychological treatment. We randomly assigned 97 participants with current depression and problematic alcohol/cannabis use to three conditions: brief intervention (BI, one individual session delivered face to face), therapist-delivered (one initial face-to-face session plus 9 individual sessions delivered by a therapist), and CAC interventions (one initial face-to-face session plus 9 individual CAC sessions). Randomization occurred following baseline and provision of the initial session, and therapeutic alliance ratings were obtained from participants following completion of the initial session, and at sessions 5 and 10 among the therapist-delivered and CAC conditions.

Results: Treatment retention and attendance rates were equal between therapist-delivered and CAC conditions, with 51% (34/67) completing all 10 treatment sessions. No significant differences existed between participants in therapist-delivered and CAC conditions at any point in therapy on the majority of therapeutic alliance subscales. However, relative to therapist-delivered treatment, the subscale of Client Initiative was rated significantly higher among participants allocated to the BI ($F_{2,54}$ = 4.86, P = .01) and CAC participants after session 5 ($F_{1,29}$ = 9.24, P = .005), and this domain was related to better alcohol outcomes. Linear regression modeled therapeutic alliance over all sessions, with treatment allocation, retention, other demographic factors, and baseline symptoms exhibiting no predictive value.

Conclusions: Participants in a trial of CAC versus therapist-delivered treatment were equally able to engage, bond, and commit to treatment, despite comorbidity typically being associated with increased treatment dropout, problematic engagement, and complexities in treatment planning. The extent to which a client feels that they are directing therapy (Client initiative) may be an important component of change in BI and CAC intervention, especially for hazardous alcohol use.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12607000437460; http://www.anzctr.org.au/trial_view.aspx?ID=82228 (Archived by WebCite at http://www.webcitation.org/5ubuRsULu)

(J Med Internet Res 2011;13(1):e11) doi:10.2196/jmir.1522

KEYWORDS

computerized cognitive behavior therapy; brief intervention; comorbidity; depression; alcohol use problems

Introduction

Although mental health problems are highly prevalent, the gap between need for effective treatment and treatment received is large, particularly for counseling interventions [1]. The World Health Organization reported that this gap is 56% for depression and 78% for alcohol abuse and dependence [2,3]. Comorbidity, or the co-occurrence of two or more disorders such as depression and alcohol abuse/dependence, is the rule rather than the exception in clinical practice [4,5] and compounds the difficulties in treatment access [6].

Comorbidity has largely been ignored in research and policy, especially depression and alcohol/other drug (AOD) use comorbidity, and treatment services do not generally provide well for people with multiple disorders [7]. Many general practitioners and specialist clinicians lack the confidence or skills to screen and assist patients with comorbid mental disorders and AOD use problems, and clients are often reluctant to discuss these issues with their health care providers [8]. As a result, treatment may not be accessed until the problem is severe, if at all. Thus, improving access to effective treatments for high-prevalence, treatable disorders such as depression and AOD use is an important health care priority.

Brief interventions (BIs) have been widely implemented in the AOD field with a view to extending the reach of interventions, especially for alcohol problems [eg, 9]. It has been suggested that BIs are most appropriate for people with less severe drinking problems and are best combined with more intensive, longer treatments for people with moderate to severe problems [10]. Accumulating evidence supports the effectiveness of BIs for people with comorbid depression and AOD use problems [eg, 11-13].

The increased availability and use of computerized or internet-based programs as a supplement to health care is also a potential solution to accessibility problems [14]. A recent systematic review of e-therapy for mental health problems identified 14 randomized controlled trials supporting the efficacy of computer- or internet-based treatments for depression, panic disorder, chronic tension/migraine, trauma, insomnia, obesity, complicated grief, and eating disorder [3]. This mode of delivery is also supported by a recent randomized controlled trial of internet-based self-help for alcohol use problems [15].

We recently reported the results of the (to our knowledge) first randomized controlled trial of clinician-assisted computer-based (CAC) psychological treatment for depression and AOD use comorbidity [16]. Therapist-delivered treatment was directly compared with a BI and CAC treatment. BI was shown to be beneficial for problem drinking among this depressed sample over the short term. No significant differences were found between the CAC and therapist-delivered treatment modalities, with significant improvement across a range of depression, AOD, and quality-of-life outcomes at the 12-month follow-up assessment. Therapist and CAC treatments produced effect size differences in depression and functioning of greater than 0.25 standard deviations relative to the BI at 12-month follow-up. The BI and CAC intervention were associated with moderate to large effect sizes for alcohol consumption at 12 months, with CAC participants reporting significantly better overall substance use outcomes than the other conditions, and were five times more likely than BI participants to report a 50% reduction in hazardous substance use days [16]. Intention-to-treat analyses confirmed each of the above findings. Clinician assistance provided in the computer condition was on average 12.5 minutes of generic contact per session (eg, compliance checking, mood, and AOD use assessment).

A central component in the uptake and success of any treatment is acceptability to patients, particularly when translating results from clinical trials to clinical practice. This is especially relevant for different modes of treatment delivery, such as computerized therapy, which offers alternatives to traditional, face-to-face treatment. However, a recent review reported that very little attention has been paid to the acceptability of computerized psychological treatment, notably cognitive behavior therapy (CBT), compared with traditional approaches [17]. This is also true of the BI literature. Treatment acceptance, or readiness to accept help, may be the determining factor in whether or not clients make changes to their life circumstances.

The present study aims to address this gap, by reporting on the acceptability of CAC CBT for comorbid depression and AOD use problems relative to an equivalent therapist-delivered CBT treatment and BI. As suggested by Kaltenthaler and colleagues [17], proxy criteria for patient acceptability of treatment include treatment participation and retention, and questionnaires or surveys that cover patient acceptability or satisfaction with treatment. In this study, treatment attendance and patient-rated therapeutic alliance throughout the treatment period were used as proxies for treatment acceptability, and these indices were compared for therapist-delivered versus CAC treatment. Therapeutic alliance associated with BI is also reported.

Methods

The methods and study design have been reported in detail elsewhere [16]. Eligibility criteria were as follows: (1) current depressive symptoms (score of 17 or greater on the Beck

Depression Inventory, BDI-II [18]), (2) current problematic use of alcohol (ie, consumption above recommended drinking levels as suggested by the National Health and Medical Research Council of Australia) or cannabis (at least weekly use), (3) absence of a brain injury, organic brain disease, and/or significant cognitive impairment, and (4) ability to understand English.

Participants were recruited across New South Wales, Australia. Referral to the project was via a range of sources, most commonly via self-referral in response to television interviews conducted with the investigators (39/97, 40%), or newspaper articles promoting the study (53/97, 55%). A comparatively small proportion of participants were recruited via local mental health outpatient clinics (3/97, 3%) and AOD outpatient services (2/97, 2%). Following initial assessment, participants received one face-to-face session with a therapist comprising feedback, case formulation, and initial goal setting. Upon completion of this session, participants were randomized to no further treatment (BI only), nine weekly sessions of combination CBT and motivational interviewing (MI) delivered exclusively by a therapist, or nine sessions of CAC CBT/MI with weekly brief check sessions (approximately 12.5 minutes) delivered face to face by a therapist. Check-in sessions were generic in nature, comprising a check to ensure completion of the module, review of homework set for the coming week, and a mood/AOD assessment. The computerized component of CAC was DVD-based, and delivered via computers located at the study clinics. The DVD program was text-based, with interactive components including video vignettes, printable worksheets and handouts, and options for tailoring content to the participant's stage of change or area of need. All text contained in the CAC intervention was presented by a voiceover to accommodate people with reading difficulties. Follow-up occurred 3, 6, and 12 months following baseline. Three-month (posttreatment) outcomes are reported here because of their temporal proximity to the treatment attendance and alliance indices.

Measures

The following instruments are relevant to the analyses reported below:

1. *Demographic information*: using subscales of the Diagnostic Interview for Psychosis (DIP) [19], basic demographic information was collected (including age and gender).
2. *BDI-II* [18]: a 21-item self-report questionnaire screening for the presence of depressive symptoms over the previous 2-week period. Items cover the range of symptoms listed in the Diagnostic and Statistical Manual of Mental Disorders, 4th revision [20] for major depressive disorders. The questionnaire has been validated with adult and adolescent populations, and is used to screen for depressive symptoms among people with AOD use problems [21].
3. *Opiate Treatment Index* (OTI [22]: addresses the quantity and frequency of use across 11 substances, including alcohol and cannabis. Each drug type is assessed individually, and clients report on their last three using occasions in the month prior to assessment, estimating the amount of drug consumed on each of these occasions. An average use index for the previous month is calculated for each drug.
4. *Hazardous Use Index*: an aggregate global AOD use score was calculated for all participants that estimated, using the OTI, the number of day equivalents in the previous 28-day period that participants used a range of 10 drug types at harmful levels (range 0-280).
5. *Beck Hopelessness Scale* (BHS) [23]: a 20-item self-report instrument that measures optimism about the future and indirectly estimates suicide risk. Participants complete the scale by providing true/false responses to 20 statements related to their thoughts about the future over the previous 2-week period.
6. *Readiness to Change* [24]: a questionnaire based on the stage-of-change model [25]. Participants completed one questionnaire for each drug they were using at baseline (alcohol, cannabis) and rated their agreement with 15 statements relating to their baseline AOD use according to a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree). The scale is divided into three subsections that relate to the following stages of change: precontemplation, contemplation, and action. Scores are totaled for the items particular to each subsection, and the subsection with the highest total score is the baseline stage of change for that drug. For the purposes of this analysis, stage of change was dichotomized into precontemplation versus not (ie, contemplation or action).
7. *Agnew-Davies Relationship Measure* (ARM) [26]: a measure of therapeutic alliance containing 28 self-report items regarding client- and therapist-based domains and impressions of the client-therapist relationship. Each item is rated according to a 7-point Likert scale, with higher scores indicating more positive perceptions of alliance. Five subscales are derived from item ratings [26]: (1) Bond, which represents the friendliness, acceptance, and understanding felt by the client in the therapeutic relationship (eg, "I feel accepted in therapy", "I feel friendly toward my therapist"), (2) Partnership, which concerns the extent to which the client feels that he or she is working jointly on therapeutic tasks with the therapist (eg, "my therapist follows his or her own plans", "my therapist and I agree about how to work together"), (3) Confidence, which concerns the extent of optimism and respect for the therapy in which the client is engaged (eg, "I feel critical of or disappointed in my therapy", "I feel optimistic about my progress in therapy"), (4) Client Initiative, which examines how well the client takes responsibility for the direction of therapy (eg, "I take the lead when I'm in therapy", "I am expected to take responsibility rather than be dependent on therapy", "I look to my therapist for solutions to my problems"), and (5) Openness, which concerns the extent to which a client feels free to disclose personal issues and worries in therapy (eg, "I can discuss personal matters I am ordinarily ashamed or afraid to reveal", "I am worried about embarrassing myself in therapy").
8. *Treatment attendance*: A record of attendance was kept for each participant to determine the number of treatment sessions they attended during the course of therapy. The maximum possible attendance for participants in the BI

was 1, with CAC and therapist-delivered participants having access to a maximum of 10 sessions.

Statistical Analysis

Data were analyzed using the Statistical Package for Social Sciences version 17.0 (SPSS Inc, Chicago, IL, USA).

Baseline Characteristics

Exploratory data analysis was performed on all measures relevant to the current study.

Treatment Attendance and Follow-up Participation

Chi-square analysis examined the proportion of treatment sessions attended (full complement vs not) for therapist-delivered and CAC condition participants. One-way analysis of variance (ANOVA) was used to examine the average attendance for the active treatment groups. For therapist-delivered and CAC condition participants, a dichotomous variable was also created to indicate whether an adequate dose of treatment had been received (yes/no). An adequate dose of treatment was considered to be attendance at 6 or more of 10 possible sessions, given that this exposed them to the majority of CBT/MI strategies included in the treatment program. Chi-square analysis was used to compare CAC and therapist-delivered condition participants on this new variable. Chi-square analysis also compared participants who completed the 3-month follow-up assessment with those who did not on gender and treatment attendance at the required number of sessions, and one-way ANOVAs examined completers and noncompleters on age, baseline levels of depression, alcohol and cannabis use, and total scores on the ARM.

Therapeutic Alliance

Four subscales were calculated from participant responses to the ARM (Bond, Confidence, Openness, and Client Initiative). A total score was also calculated for each session (1, 5, and 10). One-way ANOVA compared scores on these subscales and total scores at each administration with treatment allocation. Change scores were created, representing the change in ARM total scores between sessions 1 and 5, sessions 1 and 10, and sessions 5 and 10, with positive scores indicating an increase in therapeutic alliance. Data were substituted with a change score of 0 when participants did not provide alliance ratings at sessions 5 and 10. Changes in ARM total scores using these variables, according to treatment allocation, were examined using one-way ANOVAs, and only for participants allocated to the therapist-delivered or CAC conditions. Power calculations were performed on the outcomes of these analyses using G*Power (Version 1.3.2, Franz Faul, Universitat Kiel, Kiel, Germany).

An average alliance total score and subscale scores were calculated for each participant, comprising the average of available ratings for each subscale or total score (n = 55). Within this dataset, Pearson correlations examined associations between average therapeutic alliance total and subscale scores and changes in depression, alcohol use, cannabis use, and hazardous use indices at the 3-month assessment relative to baseline. One-way ANOVA examined associations between alliance total scores, gender, treatment allocation, and retention. Multiple linear regression was used to predict alliance total score, using a set of predictors that included either alcohol or cannabis use variables (baseline use and stage of change), and a range of symptom (BDI-II, BHS) and treatment (allocation, adequate treatment) variables. G*Power (version 1.3.2) was used to estimate the power associated with each linear regression.

Results

Detailed descriptions of the sample at baseline have been reported elsewhere, along with the impact of the interventions on key symptoms over a 12-month follow-up period [16].

Baseline Characteristics

Table 1 displays the baseline sample demographics and Table 2 the presenting symptoms relevant to the current analysis.

Treatment Attendance and Follow-up Participation

As indicated in Table 2, 35 participants (36%) were randomized to therapist-delivered treatment, and 32 (33%) were allocated to the CAC condition, following the BI session. Only three therapist-delivered participants (9%) and one CAC participant (3%) failed to return for any additional sessions following randomization (χ^2_1 = 0.7, P = .40). In these active therapy conditions, 51% (34/67) of participants attended the full complement of 10 therapy sessions, including 54% (19/35) of therapist-delivered participants and 47% (15/32) within the CAC condition (χ^2_1 = 0.4, P = .54). Therapist-delivered and CAC condition participants attended an average of 7 of their allocated 10 sessions (mean(therapist) 7.4, mean(CAC) 6.9, $F_{1,66}$ = 0.39, P = .53). Two-thirds (44/67) attended an adequate dose of therapy (6 or more sessions): 69% of therapist-delivered (24/35) and 63% (20/32) of CAC treatment participants (χ^2_1 = 0.3, P = .60).

Table 1. Baseline demographics of participants in a randomized controlled trial of clinician-assisted computerized cognitive behavior therapy for coexisting depression and alcohol/other drug use problems (N = 97)

	Participants	
	Mean	SD
Age (years)	35.37	10.21
Baseline levels of depression (BDI-II total score)[a]	31.93	9.55
Baseline levels of alcohol use (standard drinks/day)[b]	5.05	5.67
Baseline levels of cannabis use (use occasions/day)[b]	10.00	15.06
Hazardous alcohol/other drug use index[c]	40.34	18.21

[a] Beck Depression Inventory II (BDI-II).

[b] Opiate Treatment Index (OTI) q score.

[c] Estimated day equivalents in the previous month that participants used a range of 10 drug types at harmful levels (range 0-280).

Table 2. Baseline presenting symptom profiles

	n	%
Males:females	45:52	46:54
Allocated to treatment		
Brief intervention - control	30	31
Therapist-delivered therapy	35	36
Clinician-assisted computer-based therapy	32	33
Alcohol status		
Abstinent	16	16
Using - below threshold	29	30
Using - above threshold	52	54
Cannabis status		
Abstinent	27	28
Using - below threshold	1	1
Using - above threshold	69	71
Stage of change – alcohol use		
Precontemplative	27	28
Contemplative	34	35
Action	20	21
Maintenance/abstinent	16	16
Stage of change – cannabis use		
Precontemplative	10	10
Contemplative	39	40
Action	21	22
Maintenance/abstinent	27	28

Completion of follow-up assessments was 85% (82/97) for 3-month postbaseline, 81% at 6 months (79/97), and 85% (82/97) at 12 months. In total, 67 participants (69%) completed all phases of assessment (baseline, and 3,6, and 12 months), with no significant differences between treatment groups in follow-up participation (BI: 21/30, 70%; CAC: 23/32, 72%; therapist: 23/35, 66%; $\chi^2_2 = 0.7$, $P = .70$).

In addition, no significant differences existed between participants who completed the 3-month follow-up assessment versus those who did not in terms of age ($F_{1,96} = 1.25$, $P = .27$), gender ($\chi^2_1 = 0.3$, $P = .59$), or attendance at the required number of treatment sessions ($\chi^2_1 = 1.9$, $P = .17$). Completers and noncompleters were also not significantly different on baseline measures of depression ($F_{1,96} = 0.46$, $P = .50$), alcohol use ($F_{1,96}$

= 1.46, *P* = .50), or cannabis use ($F_{1,96}$ = 0.03, *P* = .86), or on the total scores of the ARM following session 1 ($F_{1,54}$ = 0.23, *P* = .63), session 5 ($F_{1,29}$ = 0.36, *P* = .56), or session 10 ($F_{1,16}$ = .10, *P* = .92).

Therapeutic Alliance

Table 3 displays the mean and standard deviations for each of four subscales of the ARM.

Table 3. Mean subscale scores on the Agnew Relationship Measure (ARM) [26][a] for people participating in a study of treatment for coexisting depression and substance use disorders (and their treating clinician), according to treatment allocation[b]

	Subscales of the ARM				Total Score
	Confidence	Client Initiative	Openness	Bond	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Session 1 [c]					
BI (17/31, 57%)	6.13 (0.65)	4.16 (0.90)	5.60 (1.12)	6.21 (0.81)	22.10 (2.64)
Therapist (14/35, 40%)	6.10 (0.80)	3.13 (1.03)	5.44 (1.45)	6.29 (0.63)	20.96 (2.73)
CAC[d] (24/32, 75%)	6.14 (0.78)	3.52 (0.92)	5.36 (1.58)	6.64 (0.49)	21.66 (2.49)
Session 5 [c]					
Therapist (10/35, 29%)	6.26 (0.43)	3.95 (0.37)	5.58 (0.70)	6.45 (0.37)	22.24 (1.66)
CAC[d] (20/32, 63%)	6.10 (0.64)	4.60 (0.62)	5.54 (1.04)	6.55 (0.66)	22.78 (1.90)
Session 10 [c]					
Therapist (5/35, 14%)	6.51 (0.46)	4.05 (0.89)	5.44 (0.99)	6.80 (0.21)	22.80 (1.45)
CAC[d](12/32 38%)	6.18 (0.53)	4.69 (0.71)	6.03 (0.73)	6.56 (0.49)	23.47 (1.88)

[a] Increasing scores indicate increasing levels of therapeutic alliance.

[b] Brief intervention (BI) – control participants did not complete these measures across all assessments given their treatment program comprised one session only.

[c] Rates of completion of the ARM at each session are provided as a proportion of the total number of participants allocated to each condition.

[d] Clinician-assisted computer-based condition (CAC) - this included therapist assistance of approximately 10 minutes per session.

As indicated in Table 3, very few differences were evident in therapeutic alliance as a function of treatment modality. At the conclusion of session 1, participants in the BI rated themselves significantly more highly on Client Initiative than did participants allocated to the therapist-delivered condition ($F_{2,54}$ = 4.86, *P* = .01), with no differences existing between the BI and CAC conditions. At session 5, participants in CAC treatment rated themselves significantly more highly on questions relating to Client Initiative than did their counterparts receiving therapist-delivered treatment ($F_{1,29}$ = 9.24, *P* = .005). This difference had disappeared by session 10 ($F_{1,16}$ = 2.48, *P* = .14).

Change scores were calculated for the change in ARM total scores between sessions 1 and 5, 1 and 10, and 5 and 10 for participants allocated to the therapist-delivered and CAC conditions. Data for participants who provided alliance ratings at session 1 but did not provide ratings at any other timepoint were substituted with a change score of 0. On average, alliance scores increased over the treatment period (mean(1 vs 5) -1.01, SD 2.48, mean(1 vs 10) 0.92, SD 1.85, mean(5 vs 10) 0.04, SD 1.21). One-way ANOVAs indicated that no significant differences existed between therapist-delivered and CAC participants in the amount of change in alliance between sessions 1 and 5 ($F_{1,37}$ = 0.02, *P* = .96) and sessions 1 and 10 ($F_{1,37}$ = .13, *P* = .72), with both treatment groups reporting increases in alliance between sessions 1 and 5 (mean(therapist) 1.04, mean(CAC) = 1.00) and sessions 1 and 10 (mean(therapist) 0.78, mean(CAC) 1.00). No significant differences existed in the amount of change in alliance scores between sessions 5 and 10 according to treatment allocation ($F_{1,37}$ = 1.29, *P* = .26); however, therapist-delivered participants reported a small decrease in alliance between these sessions, while CAC participants reported a small increase of the same magnitude (mean(therapist) -0.25, mean(CAC) 0.21). Parallel analyses were conducted, without substituting data for noncompleters, and provided the same pattern of results.

Predicting therapeutic alliance

Of the total sample, 55 (57%) provided alliance ratings following session 1, 30 provided session 5 alliance ratings, and 17 provided session 10 alliance ratings. For sessions 5 and 10 alliance ratings, this corresponded to 45% (30/67) and 25% (17/67) of eligible participants allocated to either therapist-delivered or CAC treatment (see Table 3). Given the missing data associated with completing therapeutic alliance ratings at sessions 5 and 10, alliance ratings were averaged over the available timepoints to produce an average score for each participant on each subscale and the total ARM score, providing a dataset of 55 for this analysis.

Associations with therapeutic alliance

No significant correlations existed between any of the subscales of the ARM or the total alliance score and age, change in depression (BDI-II) scores, hopelessness (BHS) scores, and cannabis use between baseline and 3-month follow-up. This was also true for baseline levels of depression, hopelessness, and cannabis and alcohol use. A significant modest positive correlation existed between scores on the subscale of Client Initiative and change in alcohol use between baseline and 3-month follow-up (Pearson $r = 0.21$, $P = .05$), with reductions in alcohol use during this time being associated with improved alliance ratings on this subscale.

One-way ANOVAs indicated no significant differences in alliance total score and subscale ratings and gender, stage of change for alcohol use, stage of change for cannabis use, and whether participants attended an adequate number of treatment sessions. There was a trend for treatment allocation to be associated with the subscale of Client Initiative ($F_{2,54} = 4.07$, $P = .05$, power = 0.90), with post hoc analysis indicating that ratings on this subscale were significantly higher for participants in CAC treatment than in the therapist-delivered intervention. Power to detect differences in alliance subscales and total scores was low to moderate, and of the order of 0.6 for Bond, 0.08 for Confidence, 0.05 for Openness, and 0.78 for the total score.

Linear Regression Analysis: Modeling Therapeutic Alliance

Two linear regression models were used to predict the average alliance total score, using models that included either the alcohol or cannabis use variable, and a range of symptom and treatment variables. Predictor variables included baseline depression (BDI-II total score), hopelessness (BHS total score), cannabis or alcohol use at baseline (OTI score), and stage of change for alcohol/cannabis (precontemplation vs contemplation/action, or nonuse), treatment allocation, and whether adequate treatment was received (yes/no). This combination of predictors did not significantly predict alliance total scores in either the alcohol ($F_{6,46} = 0.60$, $P = .73$, power = 0.29) or cannabis model ($F_{6,38} = 0.33$, $P = .92$, power = 0.20).

Given the associations between treatment allocation, change in alcohol use, and the subscale score for Client Initiative, a third linear regression model examined average Client Initiative scores, using the predictor variables of change in depression, change in hopelessness, change in alcohol use, treatment allocation, adequate treatment received, and baseline stage of change for alcohol use. This model did not significantly predict scores on the Client Initiative subscale ($F_{6,46} = 0.86$, $P = .54$). Power for this regression, calculated post hoc, was low at 0.34 (calculated using G*Power, version 1.3.2).

Discussion

This study compared treatment acceptability, in terms of treatment dropout/participation and therapeutic alliance, of therapist-delivered versus CAC psychological treatment for comorbid depression and AOD use problems. Results indicated that both modes of treatment delivery were of equivalent acceptability to participants. This was also true for participants who received a BI. This suggests that people with comorbid depression and AOD use problems, despite the engagement, retention, and treatment difficulties characteristic of this population, can develop strong attachment with a computer-delivered treatment program and commitment to complete an adequate dose of treatment with minimal therapist input. These results are discussed in detail below.

Treatment Attendance

All participants were randomly assigned to therapist-delivered versus CAC treatment following one face-to-face session. Take-up rates of both modes of treatment were high following randomization, with 91% (32/35) of therapist-delivered and 97% (31/32) of CAC treatment participants returning for at least one session. Over the 10 sessions of active treatment, no statistically significant differences were evident between the treatment groups in patterns of treatment attendance. Therefore, according to this index of acceptability, it is reasonable to suggest that people in the CAC treatment found this mode of delivery as acceptable as a therapist-delivered alternative. In a recent review of the acceptability of computerized CBT for depression [17], mean percentage dropout over treatment (ranging from 1 to 33 sessions) was 32% (SD 16.52, range 0%-75%). Take-up rates of computerized treatment reported in the same review ranged from 3% to 25%, although it was likely that these rates also reflected reluctance to enter the trial, not just participation in computerized CBT [17]. Studies of face-to-face CBT for depression have reported dropout rates of up to 38%, with 27%-30% dropout reported in medication trials of antidepressants [17]. These rates are comparable with those reported in this study.

Therapeutic Alliance

Results relating to the second criterion of acceptability, therapeutic alliance, also suggested equivalence in outcomes between therapist-delivered and CAC treatments, and, for session 1, a BI. Participants rated therapeutic bond, confidence in therapy, ability to direct therapy, and client openness highly across the treatment conditions at sessions 1 (all conditions), 5, and 10 (therapist-delivered and CAC treatments). It is of note that Client Initiative was rated significantly higher by participants in the CAC condition at session 5, relative to the therapist-delivered condition. Although this difference had disappeared by session 10, it suggests increased empowerment and enhanced problem-solving skills potentially associated with the “self-help” nature of computer-based treatment. As a similar result regarding Client Initiative was obtained for the BI relative to the therapist-delivered alternative after session 1, similar alliance mechanisms may be operating in the BI and CAC conditions among this comorbid group. Over the course of treatment, total alliance scores increased by 2 points from session 1 to session 10, with no significant differences evident between the therapist-delivered and CAC treatment groups. In addition, therapeutic alliance scores (total and subscale scores) across all time points were not predicted by treatment allocation, nor by any of the models tested in the regression analysis.

No previous study has reported on therapeutic alliance among people completing therapist-delivered versus CAC treatments for depression and AOD use problems; however, studies of computerized CBT for other mental health conditions have generally reported patient satisfaction and acceptability of this mode of delivery [17]. For example, in a large-scale randomized controlled trial conducted in the United Kingdom, Proudfoot and colleagues [27] compared an eight-session computerized CBT with treatment as usual among 274 people with depression or anxiety-related conditions. Average satisfaction with treatment was over one and a half times higher in the computer group relative to controls who received treatment as usual [27]. Attrition rates were comparable with those encountered in face-to-face therapies, with around 35% of computer participants not completing their full complement of sessions.

The real-world implications of these results are potentially important. Namely, a group of people with moderate and severe levels of comorbid depression and AOD use problems, who are challenging to engage and retain, and are regarded as complicated to treat effectively [28-30], participated in computer-based treatment with reduced therapist input over 10 sessions with equivalent dedication and attachment to a face-to-face therapy. This engagement occurred with a computer-delivered program, requiring only 12.5 minutes per session of generalist therapist input over the treatment period [16]. Our previous research has also indicated that CAC treatment was as effective in improving depression, AOD use, and functioning outcomes as the therapist-delivered equivalent [16].

Early alliance ratings (session 5 or earlier) have generally demonstrated higher predictive value, in terms of symptom reduction and other posttreatment outcomes, than later-therapy alliance and/or average alliance [31-33]. Although this was generally not true for our sample, changes in alcohol use were associated with higher levels of Client Initiative across therapy. Individuals in the BI (after session 1) and CAC interventions (after session 5 and overall) rated Client Initiative significantly and consistently higher than the therapist-delivered treatment. The implication of these results for early alliance is that treatments requiring less therapist contact may be more effective at enhancing self-directedness and responsibility for directing treatment and change, and in this context this may have translated into improved alcohol use outcomes. Therapists involved in ongoing contact with clients may need to attend more to encouraging Client Initiative for change early in treatment, with this taking precedence over technical interventions in the beginning of therapy [34]. It may also be that more time spent on motivational approaches is important in this context [32].

Limitations

There are several limitations to this study, not the least of which is the small sample size and participant attrition in relation to therapist alliance ratings. In substituting data for participants who did not complete the session 5 and session 10 ARM ratings, we assumed no change, when alliance may have deteriorated. This may have inflated the improvement observed in therapeutic alliance over the treatment period reported in relation to Table 3. Further, in predicting therapeutic alliance, and in examining the associations between treatment allocation and therapeutic alliance, power to detect differences between therapist-delivered and CAC groups was low to moderate (range 0.1-0.63). Looking at the data, actual differences between these treatment groups in alliance measures was 0.08-0.15 for Bond, Confidence, and Openness, with the largest differences in alliance observed for Client Initiative (0.59) and the total alliance score (1.28) in favor of higher scores for CAC participants. Therefore, we remain cautiously confident in our assertion that there was little notable difference in alliance ratings and acceptability of CAC versus therapist-delivered treatments offered in our study. However, replication is required to further explore these results. In addition, the extra benefit of the brief check-in sessions conducted with all CAC participants cannot be quantified in this study and may well have influenced the equivalence in therapist-delivered versus CAC outcomes. However, significantly reduced therapist time was used in the CAC condition, and the content of this interaction was generalized and could reasonably be applied by professionals working in mental health, AOD, and primary care settings [16]. Previous computer experience was not assessed among the CAC participants, nor was preference for a particular mode of treatment delivery. These variables may have affected on the results. It is also possible that the self-referral nature of study recruitment attracted and retained participants with high motivation to attend and complete treatment, manifesting in a high propensity for strong alliance. Results may be different with a less-motivated sample, although a reasonable proportion of participants did report being in the precontemplative stage of change for their AOD use. Anonymous therapeutic alliance data collection did not allow the therapist to monitor completion of the therapeutic alliance measure. A better monitoring system involving the administrative staff might be more successful in encouraging participants to complete the forms in further studies. Kaltenthaler et al [17] suggested that several other components were important in considering acceptability of treatment in this context. These include reasons for dropout, patient satisfaction questionnaires, and expectations of therapy. These domains were not measured in the current study, and it remains important for future research to include measures of these issues. Notwithstanding these limitations, the results support the acceptability of computerized CBT treatments for people with depression and AOD use comorbidity.

Summary and Conclusions

No previous research has examined the acceptability and therapeutic alliance of CAC therapy among a group with comorbid depression and AOD use relative to a BI or therapist equivalent, nor with a sample reporting severe levels of depression at baseline and concurrent heavy use of alcohol or cannabis. The results indicate that people with this comorbidity find CAC treatment as acceptable, in terms of treatment dropout and therapeutic alliance, as an equivalent therapist-delivered treatment program. This robust finding was demonstrated across a range of potentially confounding demographic and symptom domains. Rates of dropout in both treatment modalities were equivalent to other treatment trials among people with depression, and among those participating in trials of CBT, despite the study population having current and severe comorbidity and being stereotypically difficult to attract, retain, and treat effectively.

The extent to which client characteristics and alliance may work together to moderate posttreatment outcomes still needs to be determined. Symptom and functioning outcomes of CAC versus therapist-delivered treatment have been reported elsewhere [16];

however, short-term change in depression, alcohol, or cannabis use in this study was not associated with changes in therapeutic alliance, with the exception of Client Initiative and hazardous alcohol use. Both the BI and CAC interventions, which required less therapist contact, were associated with significantly elevated Client Initiative relative to therapist-delivered treatment. This suggests that initiative may be an important element in nontherapist-directed change.

The promising results regarding the acceptability of CAC treatment to a complex comorbid group are important, considering that the computer-delivered intervention used an average of 12.5 minutes face-to-face clinician time per session compared with approximately 1 hour of face-to-face therapy among the therapist-delivered equivalents. In Australia, 67% of people with mental health problems do not access treatment for their conditions [35,36]. Together with evidence that the majority of people prefer to manage on their own, including a substantial proportion with comorbid conditions [37], the potential for computer-based self-help treatments is promising. For people with comorbid depression and AOD use problems in particular, who report increasing difficulties accessing treatments when sought, computer-based therapy means easier access to evidence-based treatment [38]. Computer-based therapy could result in more people seeking treatment for their condition, or receiving treatment in an earlier phase of their disorder. Potentially, this could prevent conditions such as alcohol misuse, other problematic substance use, and depression from becoming more chronic and disabling, relieving the disease burden on mental health services and the community [38]. The self-help nature of the BI and CAC interventions offered in this study was associated with superior Client Initiative to face-to-face treatment, and may better empower people to become more actively involved in their own health care. Clinician contact in the computer condition was generic in nature, and could potentially be delivered via telephone, email or other modalities rather than face to face. In addition, this generic contact could be provided by many generalist health and primary care professionals, not necessarily those with specialist psychological or comorbidity-specific training. Clearly, access to BIs and computer-based health care stands to be a key driver of improved mental health and general health outcomes for this highly comorbid group within the community.

Acknowledgments

The authors wish to acknowledge the involvement of the study participants without whom this research would not be possible. The study was funded in part by the Alcohol-related Medical Research Scheme (Australian Brewer's Foundation), and a bequest from Ms Jennie Thomas on behalf of her late husband Philip Emlyn Thomas via the University of Newcastle, Australia. In addition, a National Health and Medical Research Council (NHMRC) public health postgraduate scholarship supported the primary author. The research team remained independent from the funding bodies.

This study was carried out in accordance with the National Health and Medical Research Council of Australia's Statement of Ethical Conduct of Research among Human Participants. Ethics approval was gained from the relevant Human Research Ethics Committees (HAREC Approval No: 02/03/13/3.16, HREC Approval No: H 307 0502).

Conflicts of Interest

None declared

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Abbreviations

ANOVA: analysis of variance
AOD: alcohol/other drug
ARM: Agnew-Davies Relationship Measure
BDI-II: Beck Depression Inventory II
BHS: Beck Hopelessness Scale
BI: brief intervention
CAC: clinician-assisted computer-based
CBT: cognitive behavior therapy
MI: motivational interviewing
OTI: Opiate Treatment Index

Edited by G Eysenbach; submitted 28.02.10; peer-reviewed by K Griffiths; comments to author 27.05.10; revised version received 14.07.10; accepted 20.08.10; published 27.01.11.

Please cite as:
Kay-Lambkin F, Baker A, Lewin T, Carr V
Acceptability of a Clinician-Assisted Computerized Psychological Intervention for Comorbid Mental Health and Substance Use Problems: Treatment Adherence Data from a Randomized Controlled Trial
J Med Internet Res 2011;13(1):e11
URL: http://www.jmir.org/2011/1/e11/
doi:10.2196/jmir.1522
PMID:21273184

Original Paper

Using Metrics to Describe the Participative Stances of Members Within Discussion Forums

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Abstract

Background: Researchers using forums and online focus groups need to ensure they are safe and need tools to make best use of the data. We explored the use of metrics that would allow better forum management and more effective analysis of participant contributions.

Objective: To report retrospectively calculated metrics from self-harm discussion forums and to assess whether metrics add to other methods such as discourse analysis. We asked (1) which metrics are most useful to compare and manage forums, and (2) how metrics can be used to identify the participative stances of members to help manage discussion forums.

Methods: We studied the use of metrics in discussion forums on self-harm. *SharpTalk* comprised five discussion forums, all using the same software but with different forum compositions. *SharpTalk* forums were similar to most moderated forums but combined support and general social chat with online focus groups discussing issues on self-harm. Routinely recorded time-stamp data were used to derive metrics of episodes, time online, pages read, and postings. We compared metrics from the forums with views from discussion threads and from moderators. We identified patterns of participants' online behavior by plotting scattergrams and identifying outliers and clusters within different metrics.

Results: In comparing forums, important metrics seem to be number of participants, number of active participants, total time of all participants logged on in each 24 hours, and total number of postings by all participants in 24 hours. In examining participative stances, the important metrics were individuals' time logged per 24 hours, number of episodes, mean length of episodes, number of postings per 24 hours, and location within the forum of those postings. Metric scattergrams identified several participative stances: (1) the "caretaker," who was "always around," logged on for a much greater time than most other participants, posting but mainly in response to others and rarely initiating threads, (2) the "butterfly," who "flitted in and out," had a large number of short episodes, (3) two "discussants," who initiated many more discussion threads than anybody else and posted proportionately less in the support room, (4) "here for you," who posted frequently in the support room in response to other participants' threads, and (5) seven "people in distress," who posted many comments in the support room in comparison with their total postings and tended to post on their own threads.

Conclusions: Real-time metrics may be useful: (1) by offering additional ways of comparing different discussion forums helping with their management, and (2) by identifying participative stances of individuals so allowing better moderation and support of forums, and more effective use of the data collected. For this to happen, researchers need to publish metrics for their discussion forums and software developers need to offer more real-time metrics facilities.

(J Med Internet Res 2011;13(1):e3) doi:10.2196/jmir.1591

KEYWORDS

Online communities; metrics; discussion forums; self-harm; moderation; participative stance

Introduction

Many health-related discussion forums combine the roles of supporting their members while offering the possibility of discussing general issues. The emphasis between focus group discussion and mutual support may vary. For vulnerable groups such as young people who self-harm (YPSH) the support element may be very important. If discussion forums have formal research aims, then the way participants contribute may be as important as the content of the discussion. In either case, moderators and forum owners may have to make decisions about the safety of continuing a forum and about the management of the forum. This study retrospectively explored the use of metrics, asking whether they might be useful in the management of a forum or in the analysis of contributions to a discussion.

In 2001, Preece [1] argued that “Little attention has focused so far on evaluating the success of online communities.” She suggested various metrics such as the number of participants in a community, the number of messages per unit of time, members’ satisfaction, and some less obvious measures such as amount of reciprocity, the number of on-topic messages, trustworthiness, and several others, but warned that these should be triangulated with qualitative data. In 2004, Phippen [2] suggested that the evaluation of virtual community usage and user behavior had its roots in social science approaches such as interview, document analysis, and survey, but that little evaluation had been carried out using traffic or protocol analysis. Since then Web analytics has gained huge commercial importance with methods such as Google Analytics having global use [3-5]. Although Syme [6] argues that “metrics for social media is in its infancy stage,” much has been written about social networking metrics. For example, a case study [7] of the analysis of 10 months’ Facebook data for UNICEF-USA assessed the impact of their efforts to get users to make online contributions. This included analysis of metrics such as visitor sessions, unique visitors, click-throughs to the main site, and percentage of the traffic on the main site generated by Facebook. In their study the key metric was the rate (1.8%) of conversion from Facebook visitor to donor (the key goal for UNICEF). Although similar to studies measuring the use of social networking for marketing, and those using metrics to gain insight into the health status of whole online populations [8,9], our study was concerned with the facilitation of an online focus group discussion within a safe environment.

Most studies of online communities tend to take a qualitative approach or use surveys among users (eg, [10-13]), although some have used a combined approach. For example, Rao et al [14] classified participants as lurkers or posters according to metrics and then used survey methods. Toral et al [15,16] used social network analysis to explore social interactions in a task-oriented community of Linux users. They included the use of various network maps and use of the Gini coefficient. The Gini coefficient is a measure of dispersion more usually known in presentations of inequalities in income, but Toral et al [16] used it to describe inequalities in contribution to a discussion forum.

Can metrics help us compare one discussion forum with another, and do they add to what can be found using other methods of forum analysis such as online surveys, and thematic or discourse analysis? Strijbos et al examined roles and participative stances in the context of collaborative learning [17-20] mainly using qualitative methods. Can metrics tell us anything new about forum participants? If so, should different metrics be made easily accessible to allow moderators and forum owners to monitor and adapt their forums in real time?

The aim of this study was to examine and report metrics in five different versions of an online forum on self-harm, and to assess their usefulness for (1) describing and comparing forums and (2) describing the participative stances of individuals within forums.

Metrics are likely to depend on how and why a forum was set up, and its interface, functionality, and size. We compared five different forums, all with the same interface and purpose, set up as part of a single project on self-harm, known as *SharpTalk*. If metrics from these five forums help to explain our findings from other methods of analysis, they may have wider use in comparison of discussion forums or as a moderation tool.

Methods

Setting

SharpTalk

The *SharpTalk* project [21] was set up to explore the potential of online communities to facilitate engagement and shared learning between health care professionals and YPSH. We used the forum as an online focus group [22-24] to observe how health care professionals and YPSH interacted and to provide a supportive online environment for the duration of the study (final report available from authors).

Recruitment

Announcements on existing online self-harm forums were used to recruit 77 YPSH. We recruited 18 National Health Service (NHS) professionals and final-year students in health/social care disciplines by emails and advertisements in two universities, three NHS Trusts, and on the national websites of relevant professional bodies. One researcher (SS) was responsible for email contact. All participants were anonymous and known only by a chosen username.

Forums

Participants were initially allocated to one of three separate forums, made up as follows (phase 1):

- Forum 1: 34 YPSH

- Forum 2: 26 YPSH + 5 health care professionals
- Forum 3: 17 YPSH + 13 health care professionals.

Each forum had three rooms: support/crisis, discussion/debate, random/off-topic.

Team Roles

Six of the authors (EH, RJ, TE, JS, BS, TF) acted as moderators, while two (SS, CO) were known as researchers and introduced topics and facilitated discussions.

Reconfiguration of the Forums

By the start of the third week, only two health care professionals had posted more than once; 12 out of 18 had not posted at all. The third forum therefore had few active members and little support was available for those in crisis. Although the moderators were offering support and taking on a more extensive role than simple policing, it was felt that the situation was not safe for participants. Following consultation with *SharpTalk* participants, the Ethics Committee, and funders, we therefore reconfigured the forum compositions, reallocating all participants to two instead of three forums with the aim of achieving a more even distribution of active participants (phase 2). These were made up as follows:

- Forum 4: 39 YPSH + 6 health care professionals
- Forum 5: 38 YPSH + 12 health care professionals.

These two discussion forums ran for a further 10 weeks, until research and funding considerations required them to end.

Forum Characteristics

As in most discussion forums, participants could see who else was online in their forum. There was also a private messaging facility. Participants could post or respond to messages at any time and were encouraged to post on-topic for the relevant room. Posts were saved with time and date.

Differences Between SharpTalk and Other Discussion Forums

SharpTalk was set up to explore whether and how health care professionals and YPSH would interact online. It therefore combined peer support and general social chat with focused discussion and debate. Discussion topics were introduced by the researchers, as in an online focus group, or by participants, or sometimes by moderators. The failure of health care professionals to participate actively in the forum resulted in the moderators taking on a much more involved role than is usual, acting almost like proxy health care professionals.

Metrics and Other Data

Data Recorded by the Forum Software

The forum software recorded data in four sequential files. (1) Pages viewed: each record comprised a time stamp, user ID, page code, and URL for every page viewed by users. Pages included menus as well as messages, so the data provide an estimate of activity rather than an exact count of messages viewed. (2) New nodes: information on each thread or node was recorded as it was started (node ID, node title, user ID, name, and time stamp). (3) Postings: each record comprised a posting ID, node ID, user ID and name, user name, the actual post, and time stamp. (4) Users' file: user ID, user name, and forum.

Derived Data

The four source files listed above were merged and manipulated to derive other data such as episodes (Table 1). An episode was defined as a period in which the participant's name is showing on the logged-on list. In these forums, users who did not look at a new page for 15 minutes were removed from the logged-on list; when they started looking again it was counted as a new episode. Episodes were not specifically recorded but were imputed from the time between time stamps on page views. By examining sequential time stamps for individuals from the pages-viewed file, if a gap of more than 15 minutes was found, or a time stamp was the last page viewed, we assumed an end of episode (rounded up by 1 minute). Once the episodes were identified we calculated the length of episodes in minutes. Staff (moderators and researchers) had access to all forums and could move from one to another. As a result, it was not possible to allocate staff viewings and postings to specific forums.

Table 1. Metric definitions

Metric group	Definition	Source or definition
Participants	(1) Total number of participants, (2) number of active participants (ie, those who at some time logged onto the discussion forum), (3) number of participants who never posted	Total number from those registered on forum; active participants from user IDs listed at least once on pages-viewed file; those who never posted from users who never had ID listed in postings file
Episodes	(1) Total number of participant episodes, (2) total number of participant episodes per 24 hours, (3) mean number of participant episodes per 24 hours, (4) average length of episodes	Episodes were imputed from time between time stamps on pages-viewed file, to correspond with the way the forum software removed a participant's name from the logged-on list if the participant did not actively do something for 15 minutes; 24-hour metrics were based on whole calendar days from recorded data
Time	(1) Total minutes logged on, (2) total participant minutes per 24 hours, (3) mean minutes per participant per 24 hours	The total minutes logged on was the sum of the episodes; 24-hour metric based on whole calendar days
Posting	(1) Number of messages posted per forum per 24 hours, (2) number of messages posted per person per 24 hours, (3) for individuals, location of postings (own thread, somebody else's thread), (4) for individuals, location of postings (different sections of the forums: support room, discussion room, random/off-topic room)	Number of postings from postings file, analyzed by date, forum, and individual; location of postings derived by combining new nodes file (node ownership) and postings files
Reading	(1) Number of pages viewed per forum per 24 hours, (2) number of pages viewed per person per 24 hours	Derived from pages-viewed file; a page might be either an index (ie, list) of message headings, or the actual message

Other Sources of Data

As part of the registration process, all participants completed an online questionnaire that included demographics and information on Internet use and self-harming behavior. In the last few weeks of the forums, all participants were invited to give their views by rating statements about *SharpTalk* or about discussion forums in general. Finally, we have the views of participants, moderators, and researchers as recorded in the discussion forum messages.

Analysis

A Priori Hypothesis

Our hypothesis was that forum 3 would show significantly less activity than forums 1 and 2, and that there would be no difference between forums 4 and 5, but that even the less active of these two would be significantly more active than forum 3.

Comparison of Characteristics of Forums

We compared the three forums in phase 1 and the two forums in phase 2 for various metrics. We derived total figures from all activity in phase 1 (447 hours) and phase 2 (1884 hours). To derive standard deviations and 95% confidence intervals, we restricted analysis to time that the forums ran, which was 18 calendar days in phase 1 and 79 calendar days in phase 2 (ie, excluding the first and last partial days and counting the changeover day in phase 2). The four 24-hour metrics were compared between the 3 forums in phase 1 and the 2 forums in phase 2 by analysis of variance (ANOVA), and between those forums in each phase that we perceived to be the quietest (forum 3 in phase 1 and forum 4 in phase 2) using an independent-sample t test. As we have made four F tests and four t tests, there is minimal scope for familywise error; nevertheless, we report only those results that have $P \leq .001$.

We also compared the metrics with our views of the forums from our involvement in moderation and in discussion threads, and with views polled from members at the time, and in a subsequent online questionnaire.

Identification of Different Patterns of Usage in the Forums

We examined the logging on and posting habits of members, identifying different patterns of online behavior by plotting scattergrams and visually identifying outliers and groups using seven metrics per 24 hours: (1) mean number of episodes, (2) mean number of postings, (3) mean number of topics started, (4) mean number of replies made on other people's threads, (5) mean number (percentage) of posts made on own thread (ie, a measure of how much participants responded to topics initiated by others compared with how much they were focused on their own topics), (6) total time online, and (7) pages viewed. No statistical tests were carried out.

Results

Baseline Description of Participants From Registration Questionnaire

In total, 95 people registered: 77 young people aged 16-25 years (with 47/77 aged under 20) all of whom had self-harmed (YPSH), and 10 health professionals and 8 health care students aged 18-45 years. Among the YPSH, 54 (70%) had self-harmed in the last 4 weeks but four had not self-harmed for more than a year. All 77 had cut themselves at some time. Other frequent forms of self-harm were as follows: not eating (50/77), overdosing (48/77), burning (44/77), biting (35/77), using alcohol or drugs (35/77), binge eating (34/77). Six of the health care professionals had histories of self-harm. All but three participants used the Internet every day.

Comparison of Forums

Comparison of Metrics with Other Data

It was the view of the moderators and researchers during phase 1 that forum 3 was not viable and provided insufficient support for members. These views were largely supported by participants' views given in a survey in the last few weeks of the study. For example, one survey respondent said "*The earlier* *groups were a bit too small and resulted in few posts. Meaning you didn’t feel very involved especially if you aren’t confident about making new topics and being very active.*” Moderators, researchers, and participants thought that the reformed forums (4 and 5) in phase 2 were viable and safe. We then asked whether, in retrospect, the metrics confirm the view that forum 3 in the first phase was not viable and, if so, whether these levels could be of use in comparison with other discussion forums.

Participation Numbers

There were 95 registered participants who were allocated to three forums in phase 1 and two forums in phase 2. The proportion of inactive participants was higher in phase 2 than in phase 1 as inactivity became cumulative; that is, nearly all participants who did not participate in phase 1 did not participate in phase 2, plus some further participants dropped out. The number of participants, number of active participants, or number of participants who at some time posted did not differ between forums 1,2, and 3 in phase 1, or between forums 4 and 5 in phase 2 (Table 2). We did not look for differences between forum 3 and forum 4.

Table 2. Period of study and numbers of participants

	Forum 1	Forum 2	Forum 3	Forum 4	Forum 5
Period of study	5 pm June 15, 2009-8 am July 4, 2009			9:45 am July 4, 2009-9:45 pm September 20, 2009	
Total hours	447	447	447	1884	1884
People					
Registered participants (YPSH[a])	34	31	30	45	50
Staff (HCPs[b])	8	8	8	8	8
Type of participation					
Inactive: participants who never read any messages	3 (9%)	8 (26%)	4 (13%)	17 (38%)	21 (42%)
Active participants	31 (91%)	23 (74%)	26 (87%)	28 (62%)	29 (58%)
Participants who never posted any messages	4 (12%)	11 (36%)	12 (40%)	23 (51%)	29 (58%)

[a] YPSH: young people who self-harm.

[b] HCPs: health care professionals (National Health Service professionals and final-year students in health/social care disciplines).

Episodes

In phase 1, ANOVA showed that the three forums had significantly different total numbers of participant episodes each day ($F_{2,51} = 43.3$, $P < .001$). The 95% confidence intervals show that forum 3 had fewer participant episodes than forum 2, and forum 2 had fewer than forum 1. But as Table 3 shows (confirmed by a *t* test), forum 3 and phase 2 forum 4 had a similar number of participant episodes.

Table 3. Comparison of episode metrics for five discussion forums, including 24-hour metrics (calculated excluding partial calendar days; see methods)

	Forum 1	Forum 2	Forum 3	Forum 4	Forum 5
Total number of participant episodes in study period	1053	761	458	1847	3489
Total number of participant episodes per 24 hours (95% CI[a])	56.2 (50.8-61.6)	40.1 (36.5-43.7)	23.7 (18.5-29.0)	23.4 (20.4-26.4)	44.2 (40.5-47.9)
Mean number of episodes per participant per 24hours	1.66	1.32	0.82	0.52	0.89
Based on	18 days	18 days	18 days	79 days	79 days
Number of staff episodes	451	451	451	1041	1041
Mean episodes per staff per 24 hours	3.03	3.03	3.03	1.66	1.66

[a] CI: confidence interval.

Time

The total time spent by participants on the discussion forum in 24 hours was less for forum 3 than for forums 1 and 2 (ANOVA: $F_{2,51} = 35.2$, $P < .001$) but not significantly less than for forum 4 (*t* test) (Table 4).

Table 4. Comparison of time metrics for five discussion forums, including 24-hour metrics (calculated excluding partial calendar days; see methods)

	Forum 1	Forum 2	Forum 3	Forum 4	Forum 5
Total participant minutes	24527	15608	4199	23672	53390
Total participant minutes per 24hours (95% CI[a])	1277 (1042-1512)	820 (647-993)	212 (121-303)	300 (235-365)	676 (558-794)
Mean minutes per participant per 24 hours	38.7	27.0	7.5	6.7	13.6
Based on	18 days	18 days	18 day	79 days	79 days
Staff minutes across forums 1-3 in phase 1 and forums 4-5 in phase 2	13593	13593	13593	21069	21069
Mean minutes per staff per 24 hours across forums 1-3 in phase 1 and forums 4-5 in phase 2	91.2	91.2	91.2	33.5	33.5

[a] CI: confidence interval.

Postings

The total postings each 24 hours was less for forum 3 than for forums 1 and 2 ($F_{2,51} = 27.3$, $P < .001$) and less than for forum 4 ($t_{81.9} = -3.3$; $P = .001$) (Table 5).

Table 5. Comparison of posting metrics for five discussion forums, including 24-hour metrics (calculated excluding partial calendar days; see methods)

	Forum 1	Forum 2	Forum 3	Forum 4	Forum 5
Total participant postings	793	1469	198	1797	1784
Total participant postings per 24hours (95% CI[a])	36.6 (28.9-44.3)	75.9 (56.0-95.8)	9.3 (5.0-13.6)	22.0 (15.9-28.2)	21.6 (17.1-26.1)
Based on	18 days	18 days	18 days	79 days	79 days
Mean postings per participant	23.3	47.4	6.6	39.9	35.7
Mean postings per participants who read any pages	25.6	63.9	7.6	64.2	61.5
Total staff postings across forums 1-3 in phase 1 and forums 4-5 in phase 2	708	708	708	1095	1095
Mean staff postings per 24 hours across forums 1-3 in phase 1 and forums 4-5 in phase 2	38.0	38.0	38.0	13.9	13.9
Mean postings per staff member in phase 1 (forums 1-3) and phase 2 (forums 4-5)	88.5	88.5	88.5	136.9	136.9

[a] CI: confidence interval.

Reading

The number of pages viewed by all participants in 24 hours in forum 3 was less than in forums 1 and 2 ($F_{2,5} = 21.4$, $P < .001$) but, with this sample size, not quite significantly less than in forum 4 (Table 6).

Table 6. Comparison of reading metrics for five discussion forums, including 24-hour metrics (calculated excluding partial calendar days; see methods)

	Forum 1	Forum 2	Forum 3	Forum 4	Forum 5
Pages viewed by participants	26844	25906	5378	36022	71488
Mean participant page views per 24 hours (95% CI[a])	1378 (1095-1661)	1352 (996-1708)	265 (164-366)	456 (350-562)	909 (741-1077)
Based on	18 days	18 days	18 days	79 days	79 days
Mean participant page views per participant	790	836	179	800	1430
Pages viewed by staff across forums 1-3 (phase 1) and forums 4-5 (phase 2)	20237	20237	20237	30226	30226
Mean staff page views per 24 hours across forums 1-3 (phase 1) and forums 4-5 (phase 2)	1087	1087	1087	385	385
Mean staff page views across forums 1-3 (phase 1) and forums 4-5 (phase 2)	2530	2530	2530	3778	3778

[a] CI: confidence interval.

Overall forum metrics may mask where within a forum activity is taking place. Table 7 shows in which rooms postings were made, showing that forum 2 had a very lively random/off-topic room. This table also offers evidence that the change in forums was beneficial. Staff postings in the first period made up 29% (260/894) of postings for support and 18% (556/3013) of all postings. In phase 2, staff postings made up a smaller proportion of support postings (425/1746, 24%) but a slightly greater proportion of all postings (960/4541, 21%). This suggests (a view expressed by moderators) that the reconfigured forums required less intensive input from moderators but that they then joined in elsewhere in the forums. This has implications in terms of the size of forums that are designed to provide meaningful support to participants.

Table 7. Total postings in discussion, off-topic, and support rooms (excludes some postings to a general room by participants and postings to the moderator room by staff)

Room	Phase 1					Phase 2			
	Forum 1	Forum 2	Forum 3	Staff	Total	Forum 4	Forum 5	Staff	Total
Discussion	270	612	86	206	1174	312	471	338	1121
Off-topic	127	709	19	90	945	799	678	197	1674
Support	396	147	91	260	894	686	635	425	1746
All	793	1468	196	556	3013	1797	1784	960	4541

Both off-topic rooms were quite active in phase 2, with the most posts on any one thread being 267 on “the or game part 2” (a game played by participants) in group 4, running from July 4, 2009 to August 5, 2009. In total, 46/424 posts or threads (11%) had no replies; that is, they were threads of the first post only (this includes threads in the moderator room). In total, 35% (147/424) of threads were started by the research team and 65% (277/424) by the participants.

Metrics per participant are perhaps less useful for comparing forums because of the impact of denominators. A number of participants who only read a few messages in the first phase then dropped out, so that the proportion of nonparticipants in forums 4 and 5 (phase 2) was higher (38% and 42%) than in the three forums in phase 1 (9%, 13%, and 26%, respectively). However, we have used participant-based metrics to identify participative stances within forums.

Participative Stances in the Discussion Forums

Participant-based metrics were used to identify outliers and specific types of participants. These participants were named as follows.

Caretaker

Figures 1 and 2 show that one person (marked CT on both figures) was logged on for a much greater time than most other participants. This person had relatively few episodes but was logged on for very long periods of time. While logged on, she or he reviewed numerous pages but, given the amount of time online, posted fairly infrequently. This person had all of the 32 longest episodes. CT did post, but rarely started topics. Figures 3 and 4 illustrate well this person’s online behavior: CT viewed the page to start a new topic 13 times but started only two new topics. For the other 81/95 participants who viewed at least one page, the mean time per episode ranged from 2 to 36 minutes, whereas CT had a mean time per episode of 134 minutes. In total, the 82 participants had 7611 episodes, 17% (1330/7611) of which were 1 minute or less, but with a long tail going to 1254 minutes (21 hours). We named this type of use of the forum as *Caretaker* to suggest being always around and being watchful, participating to some degree but not initiating many threads. The Caretaker was in forum 1 and then forum 5.

Butterfly

The person we characterised as *Butterfly* (marked B on Figure 5) spent a lot of time online but his or her main characteristic was the large number of episodes (1024), with a relatively short mean episode length of 10 minutes. That is, this person's usage pattern was to log on very frequently, have a quick look around, and log off again. Butterfly was in forum 3 and then forum 5.

Discussant

This stance was adopted by two people (marked D1 and D2 on Figures 5). D1 initiated many more discussion threads than anybody else. Although not as extreme as D1, D2 also initiated a large number of threads but dropped out of *SharpTalk* before the end of the project. The *Discussants* posted proportionately less in the support room (Figure 6) and more in the discussion room (Figure 7). D1 was in forum 2 and then forum 5. D2 was in forum 2 and then forum 4.

Here For You

The person marked HFY (*Here for you*) on Figure 8 posted the most comments but initiated far fewer threads. HFY posted a lot in the support room in response to other participants' threads. HFY was in forum 2 and then forum 4.

Figure 1. Number of episodes versus total time logged on to the discussion forum for all participants. This shows Caretaker (CT) (with over 25,000 minutes logged on) and Butterfly (B) (with many short episodes) as outliers, as well as Discussant 1 (D1), Crisis-oriented 1 (C1), and Here for you (HFY)

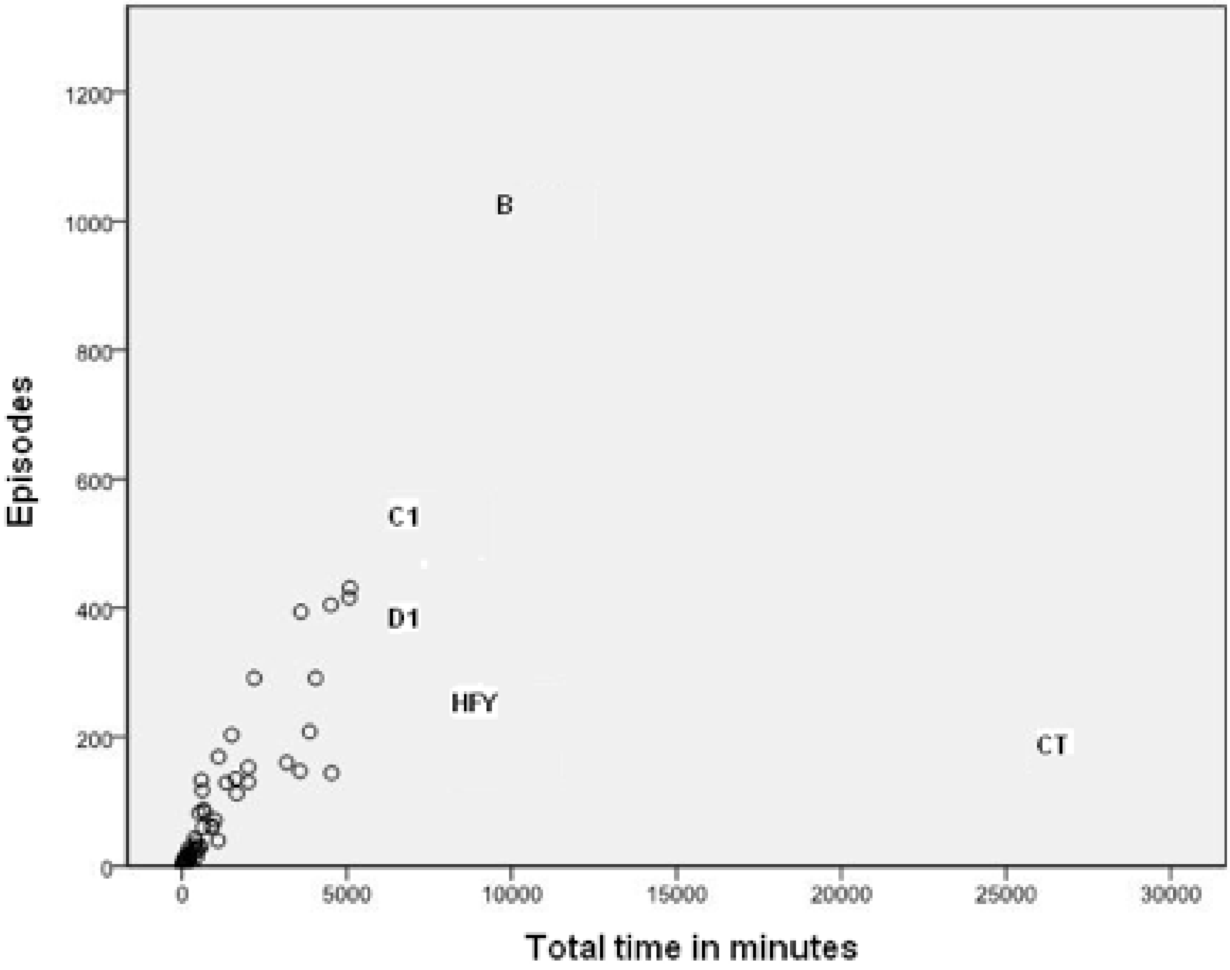


Figure 2. Number of pages viewed versus total time in minutes for all participants. This shows the Caretaker (CT) (with over 25,000 minutes logged on and over 40,000 pages viewed) as an outlier

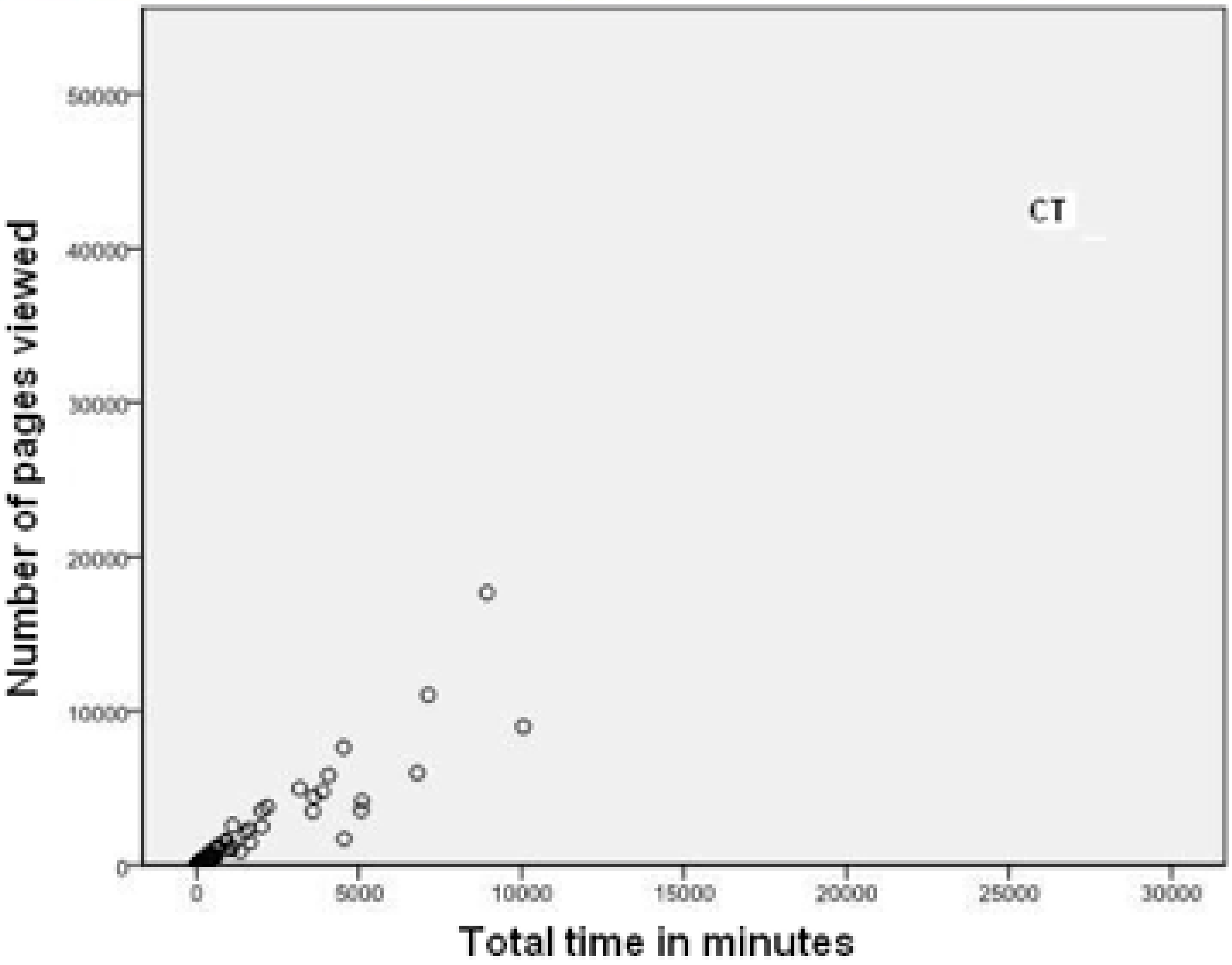


Figure 3. Number of topics started by each participant versus number of times they viewed the page from where new topics could be started. This shows two outliers: Discussant 1 (D1), who started many topics, and Caretaker (CT)

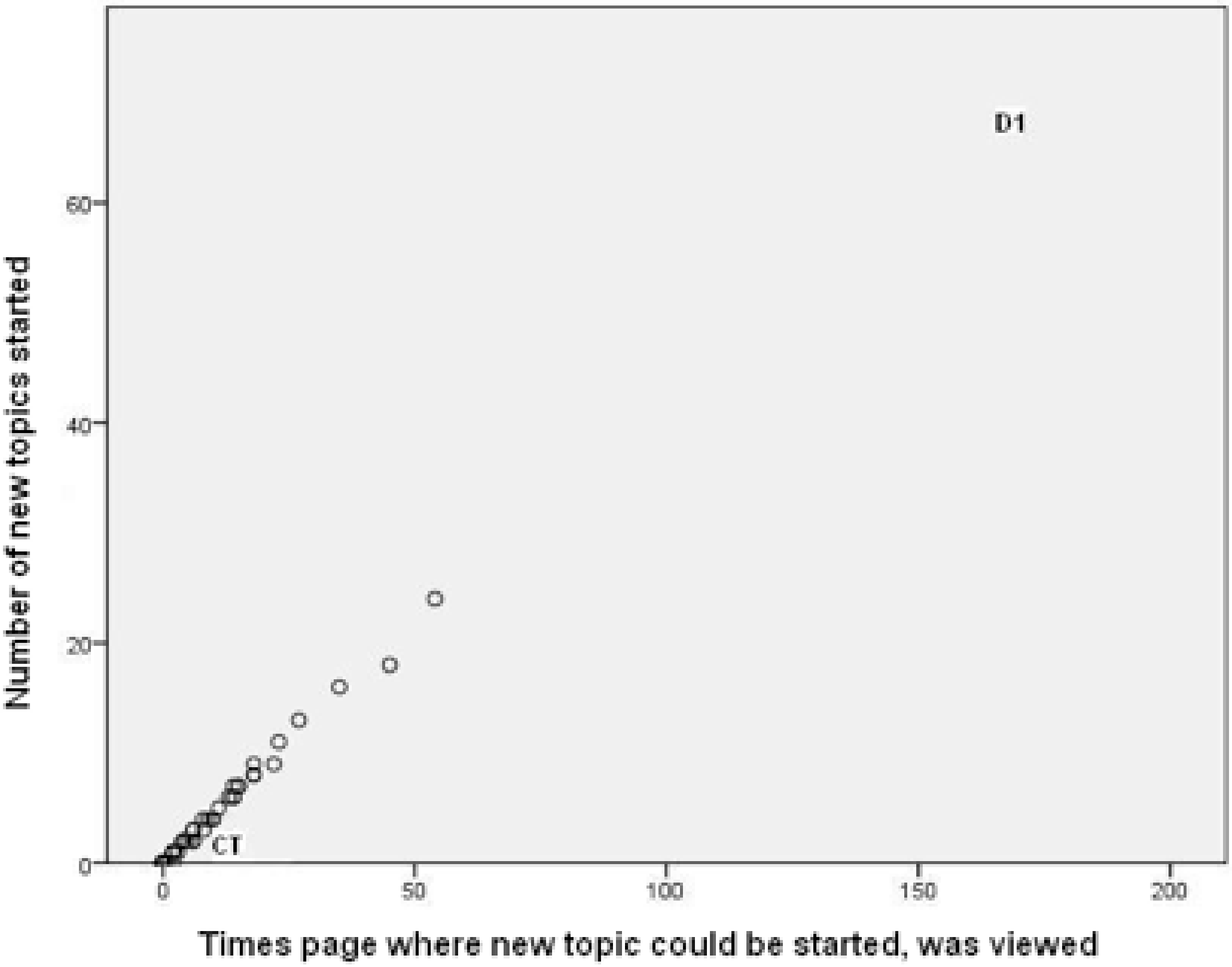


Figure 4. Detail from Figure 3, showing Caretaker (CT) as outlier, having viewed the page from were new topics are started many more times than she or he started new topics

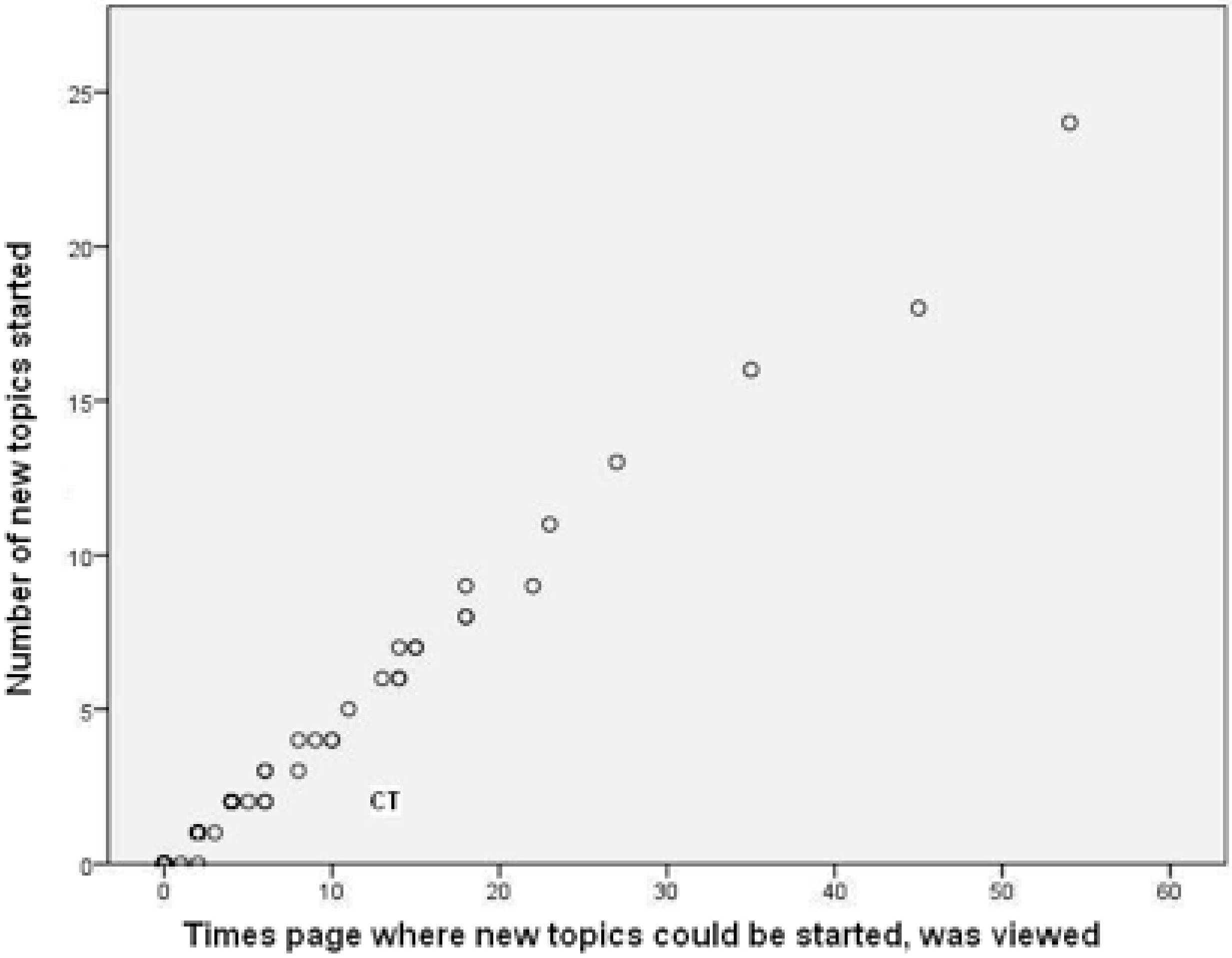


Figure 5. Number of topics started versus total number of comments (postings) showing Discussant 1 (D1), Discussant 2 (D2), and Here for you (HFY) as outliers

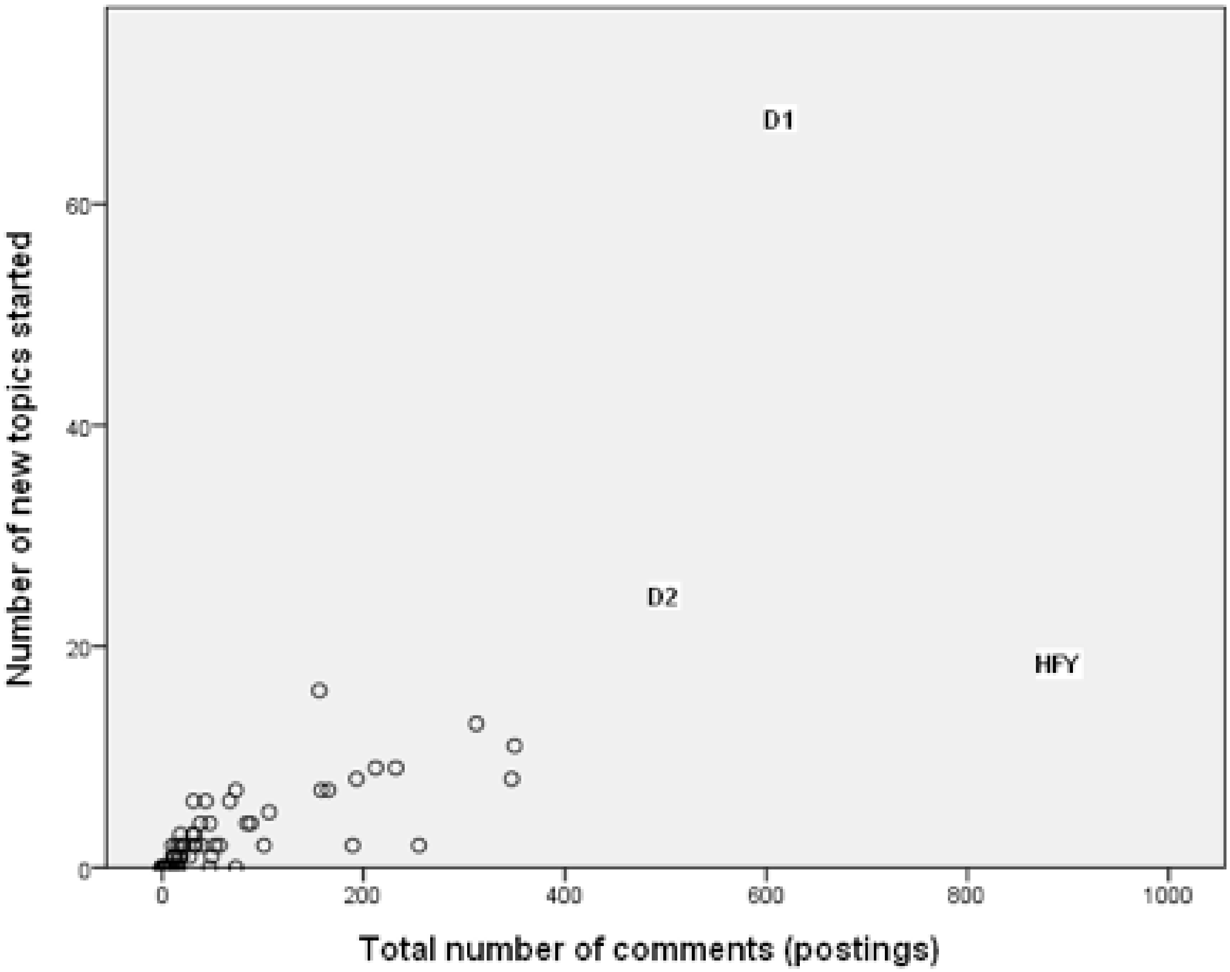


Figure 6. Total number of comments (postings) made in the support room versus total number of postings, showing Here for you (HFY), Discussants 1 and 2 (D1 and D2), Butterfly (B), and Crisis-oriented 1-6 (C1 to C6)

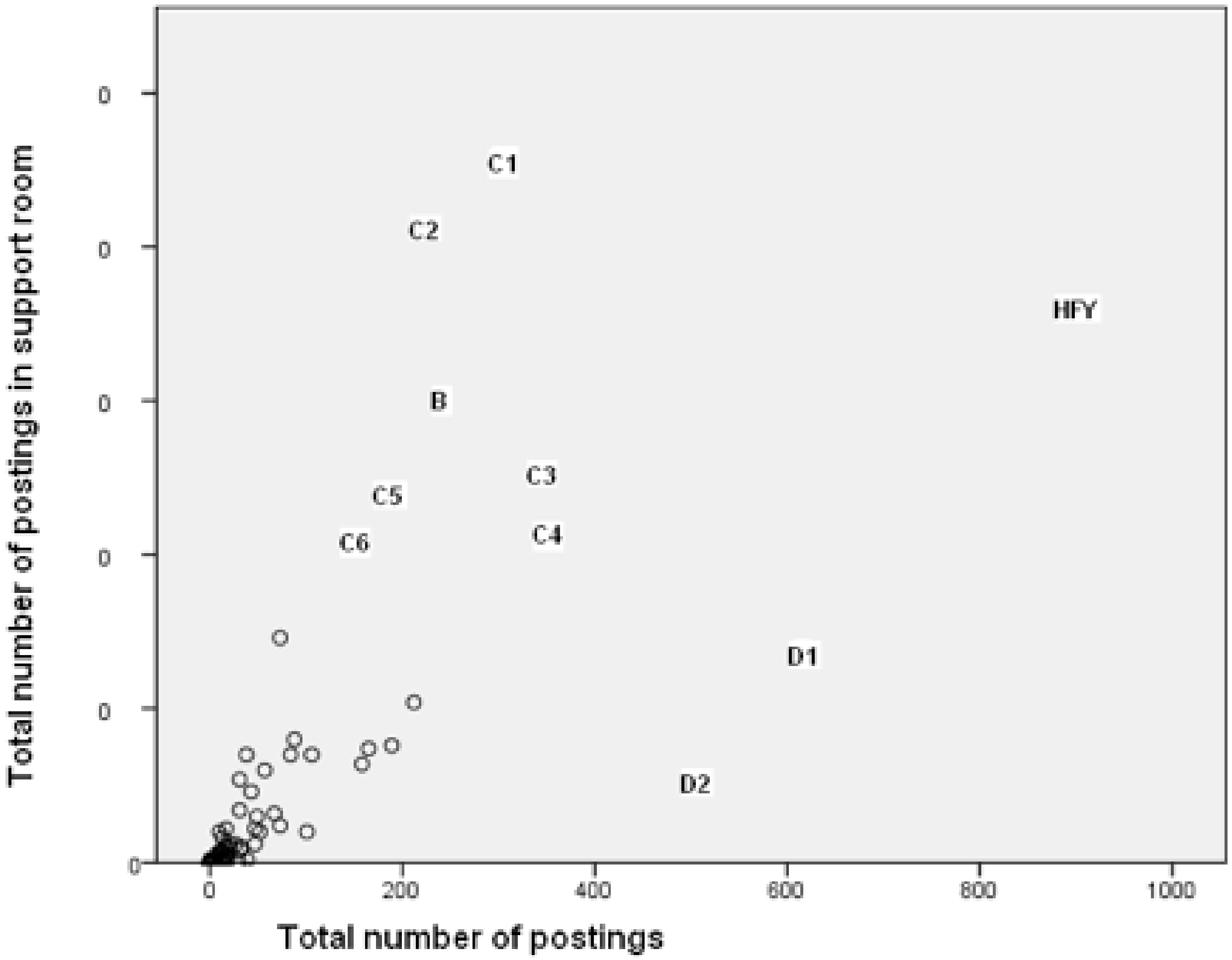
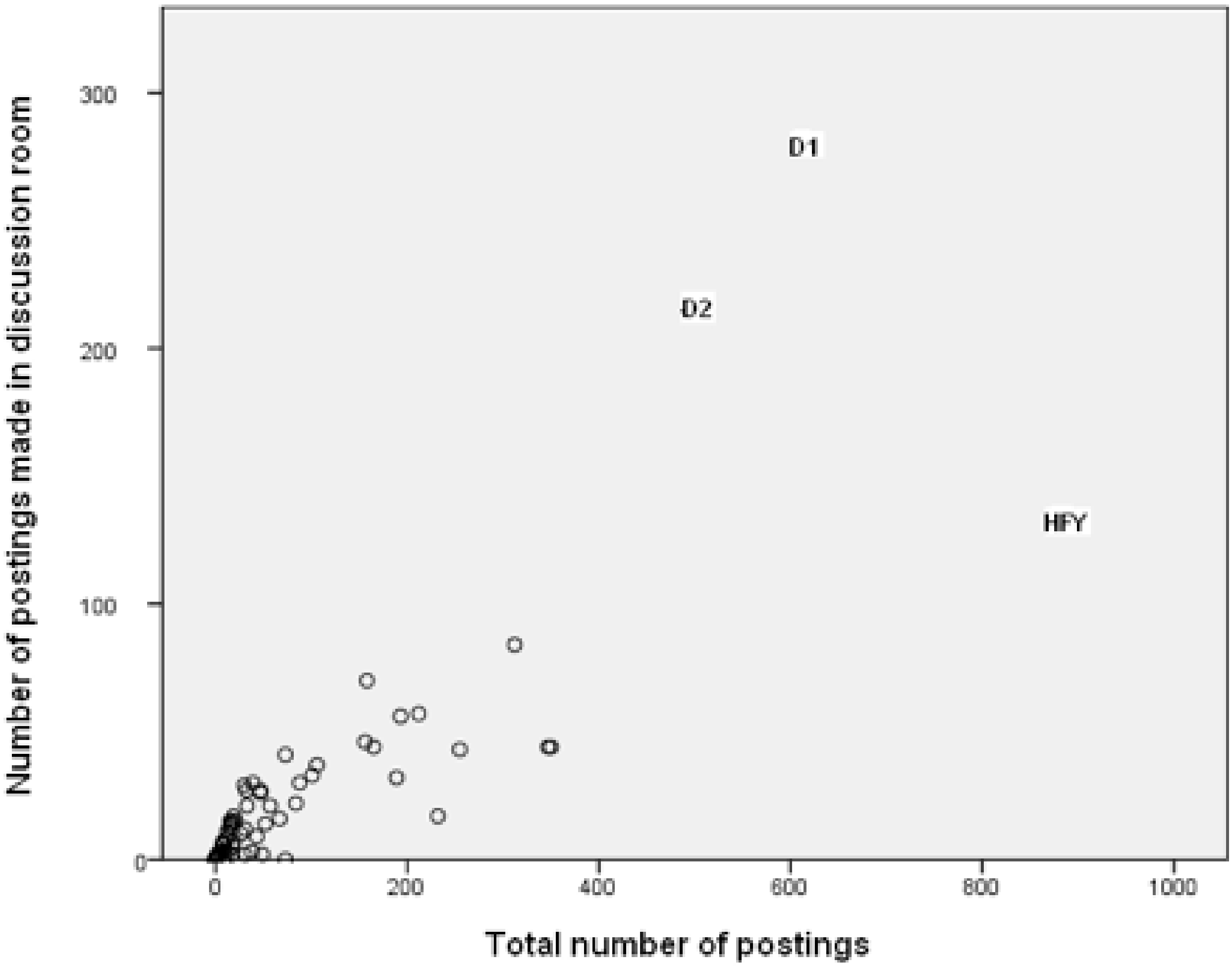


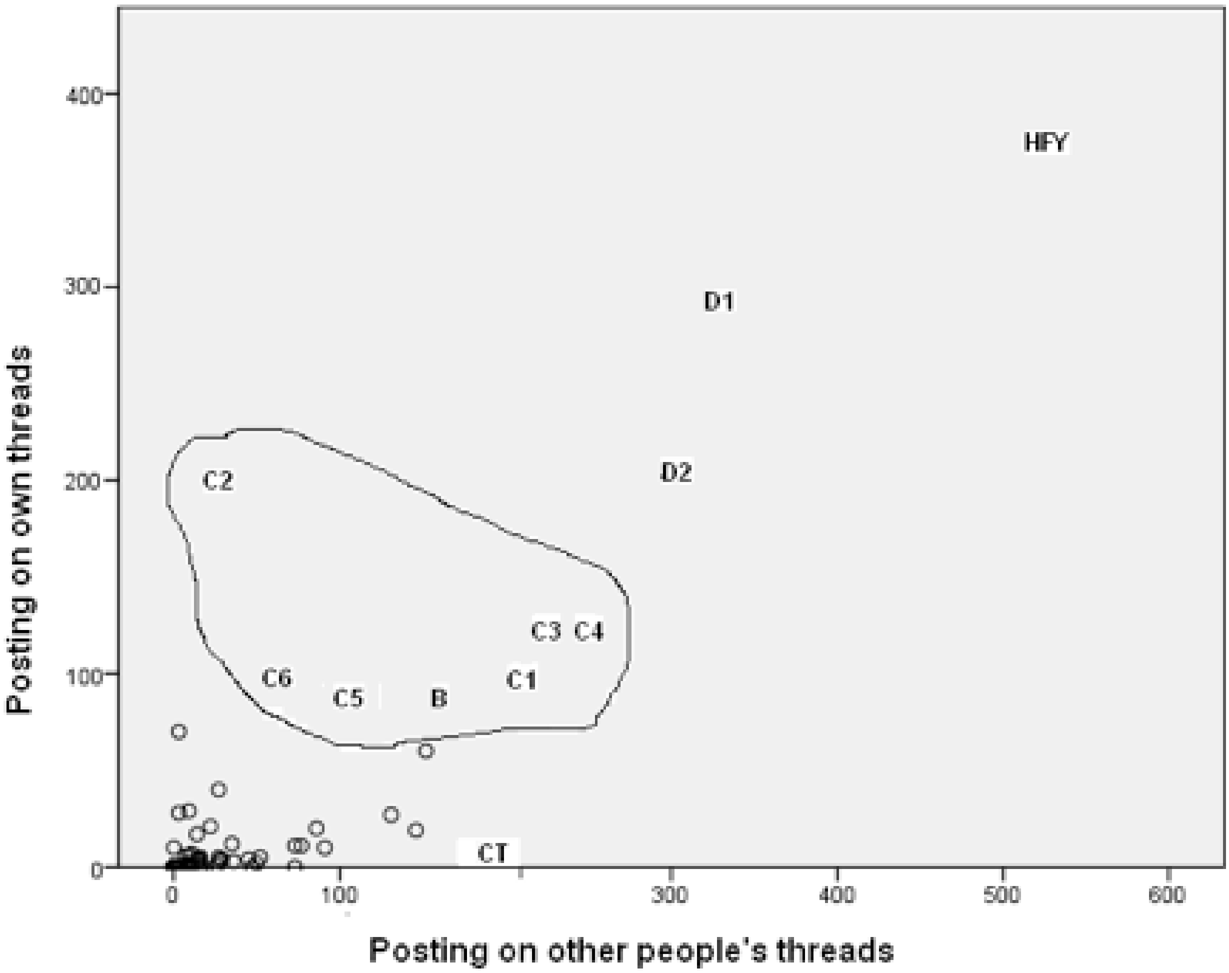
Figure 7. Comments (postings) made in the discussion room versus total number of postings, showing Discussants 1 and 2 (D1 and D2) and Here for you (HFY) as outliers



Crisis-Oriented Individuals

Figure 6 shows seven people (C1, C2, B [Butterfly], C3, C4, C5, C6) who were crisis oriented insofar as most of their posting activity took place in the support room. These same seven people are shown on Figure 8. These simple metrics do not allow us to see whether these were people in crisis who were requesting support or were responding to others' distress. However, we see that one individual in particular (C2) posted mainly on their own threads and relatively infrequently on those of others. In comparison, we can see Caretaker (CT), who posted nearly 200 comments but started only three threads in the support room. Our knowledge of the actual content of these postings confirms that these seven people were often in crisis.

Figure 8. Number of postings on their own threads versus postings on other people's threads showing Here for you (HFY), Discussants 1 and 2 (D1 and D2), Butterfly (B), Caretaker (CT), and Crisis-oriented 1-6 (C1 to C6)



Discussion

How useful is analysis of various metrics from log data in helping to understand and describe the characteristics of an online community? Can such metrics, as an additional method to qualitative methods, help us compare one discussion forum with another, and do they have validity when compared with other methods of forum analysis such as online surveys, and thematic or discourse analysis? Do they tell us anything new about the ways in which participants behave in a forum – to use Strijbos's term, their "participative stance" [17-20]? If so, should metrics be further developed and used to allow moderators and forum owners to monitor and adapt their forums in real time?

Our study suggests that the routine provision of metrics to owners and moderators of discussion forums could help them in two ways.

Comparison of Forums

Metrics could provide a second opinion as to whether action is needed to change a forum that is not working well, or guidance on target recruitment numbers for a sustainable forum. We made a judgment, based on the postings that we saw, that forum 3 was not safe as a support community, whereas all other forums were providing adequate support for members. We might hypothesize, from our experience, that similar forums to *SharpTalk*, with less than 300 participant minutes, fewer than 15 participant postings, or fewer than 300 participant page views per 24 hours, are likely to be too small to be viable.

Others setting up small discussion forums with the intention of using them as support groups or online focus groups need to estimate how many participants are needed to make them viable. In face-to-face focus groups, group sizes of 6-8 are typical. Online focus groups are likely to need many more, perhaps 35-40 active members, but further work based on metrics of traffic would be worthwhile as a guide.

Clearly our one case study may be atypical in terms of its participants and activity, but if metrics that seem to distinguish between failing and viable forums were routinely available for more forums, they would provide guidance on whether some change to a forum is needed. These metrics will depend on the functions of the forum. In an educational setting, for example, small group learning may suffer from forums being too big, and numbers of 3-6 may be more appropriate [25].

Managing or Moderating a Forum

In face-to-face focus or therapeutic groups, the facilitator can watch the body language of the participants and can identify individuals who need extra help or encouragement to be drawn into the discussion. Metrics may help in trying to plug that gap but will only be of use if they are available in real time. They could provide contextual information to moderators of online focus groups who may wish to take action on the basis of the participative stances of members, as judged by metrics, where the actual postings may not tell the whole story.

In online collaborative learning, for example, Strijbos and De Laat [19] recently described various participative stances. They reviewed the literature on classifying online learners and published their own ideas, including nametags such as Captain, Over-rider, Free-rider, Ghost, Pillar, Generator, Hanger-on, and Lurker [19]. However, there are two major differences between that strand of work and the current study. First, that work was done with student groups who were task oriented and collaborating on a specific piece of work. While some of the ideas are relevant, it may not be appropriate to use names such as Lurker, which have become disparaging, in the support group setting. Even in the community discussion forum setting, others have challenged the view that Lurkers are “selfish free-riders” [26]. Secondly, and more important, their classifications have been based on transcript analysis rather than metrics.

By exploring the behaviors of outliers, we were able to identify and characterize the participative stances of our members. The categories that we identified may be unique and special to this group of young people, but the approach, if available at the time, could support moderators by giving a fuller picture of forum activity. It is possible that forums will stand a better chance of being successful if they contain certain key characters such as the Discussants and possibly the Caretaker. It is possible that increasing forum size will increase the chance of someone behaving in that way; alternatively, people may be more likely to take on these roles in smaller forums where they perceive their input to make a difference. Both of these statements are conjecture and need further study.

How much is the character of a forum determined by outlying behaviors within the forum? If the Caretaker had been moved to a different forum, would it have changed the dynamic of that forum significantly, or simply changed the average metrics? All participative stances are context dependent but, in our experience, moving the most proactive Discussant (D1) seems likely to have changed the dynamic of the forums, but we have no evidence to support that. Teachers running small group work know which students will work well together from observation. More study is needed of how the same people may take different stances in different forums, but metrics could be calculated and presented in real time, thus offering information that might enable better management of forums.

Developments Needed

Producing the metrics presented in this paper from the raw data required extensive analysis and data processing. If these metrics are thought to be useful, the implication is that discussion forum software could include the facility to produce metrics to provide rapid feedback. Dimitracopoulou and Bratitsis [27-29] have been developing and evaluating new ways of offering participants, in online learning environments, visualized representations of appropriate interaction analysis indicators in real time, so that they are aware of, and can regulate, their behavior. Such indicators would have been useful for our project, but even simpler approaches than interaction analysis, such as the metrics as presented in our paper, might be useful in many situations.

Limitations and Generalizability

SharpTalk had two major differences from many discussion forums. First, its membership was recruited for a fixed period of study. This is typical of an online focus group [22-24] but not of open discussion forums, in which new members are added to a continuing dialogue. Second, although *SharpTalk* was set up mainly as an online focus group, it also functioned as a *support group* for people with specific health behaviors and needs (self-harm). So the metrics used to compare forums, or at least the values of those metrics, may not be typical of other forums. Similarly, some of the unusual participative stances may not be found frequently in other forums. Nevertheless, the approach, particularly that of plotting scattergrams to identify key outliers, appears generalizable to other online focus groups and worth further study.

This paper is descriptive in that we had hypotheses only about the activity levels in the forums, not the participative stances that we would find. We have conducted eight statistical tests (four ANOVAs and four t tests) in this analysis. While this is not a huge number compared with other studies, readers should remember that 1 in 20 statistical tests will be significant at a level of $P = .05$ just by chance alone. In our opinion, the number of statistical test is insufficient to warrant adjustment for multiple testing, and we think it unlikely that chance alone explains all the findings that reached the conventional measure of statistical significance, but it may explain some of them. The robustness of our findings can be tested only by replication by other groups, who will be able to use the findings of the current study to generate testable hypotheses.

Conclusion

Our post hoc analysis and construction of metrics suggest that (1) by offering an additional way of comparing different discussion forums, metrics may help with their management, and (2) by identifying participative stances of individuals, metrics may allow better moderation and support of forums, and more effective use of the data collected. However, our analysis was time consuming and post hoc, and there was no body of published metrics for other discussion forums. For metrics to be useful, researchers need to publish metrics for their discussion forums and software developers need to offer more real-time metrics facilities.

Acknowledgments

This project was funded by the National Institute for Health Research under the Research for Innovation, Speculation and Creativity (RISC) program. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research, or the Department of Health.

We acknowledge the help of the following: Jayne Clarke, Peter Aitken (supported by the NIHR CLAHRC for the Southwest Peninsula), Fraser Reid, Matthew Gibbons, Priscilla Alderson, Nicola Madge, and Mary Gilhooly. In particular, we thank the young people who were participants in the *SharpTalk* project. We also thank Andy Phippen and Maged Kamel Boulos from the University of Plymouth, who read and commented on the manuscript.

Conflicts of Interest

None declared

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Abbreviations

ANOVA: analysis of variance
HCPs: health care professionals
NHS: National Health Service
YPSH: young people who self-harm

Edited by G Eysenbach; submitted 23.06.10; peer-reviewed by T Hong, D Keeling, A Hart, K Heaton; comments to author 14.07.10; revised version received 22.11.10; accepted 20.12.10; published 10.01.11.

Please cite as:
Jones R, Sharkey S, Smithson J, Ford T, Emmens T, Hewis E, Sheaves B, Owens C
Using Metrics to Describe the Participative Stances of Members Within Discussion Forums
J Med Internet Res 2011;13(1):e3
URL: http://www.jmir.org/2011/1/e3/
doi:10.2196/jmir.1591
PMID:21239373

Original Paper

The Characteristics and Motivations of Online Health Information Seekers: Cross-Sectional Survey and Qualitative Interview Study

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Abstract

Background: Most households in the United Kingdom have Internet access, and health-related Internet use is increasing. The National Health Service (NHS) Direct website is the major UK provider of online health information.

Objective: Our objective was to identify the characteristics and motivations of online health information seekers accessing the NHS Direct website, and to examine the benefits and challenges of the health Internet.

Methods: We undertook an online questionnaire survey, offered to users of the NHS Direct website. A subsample of survey respondents participated in in-depth, semistructured, qualitative interviews by telephone or instant messaging/email. Questionnaire results were analyzed using chi-square statistics. Thematic coding with constant comparison was used for interview transcript analysis.

Results: In total 792 respondents completed some or all of the survey: 71.2% (534/750 with data available) were aged under 45 years, 67.4% (511/758) were female, and 37.7% (286/759) had university-level qualifications. They sought information for themselves (545/781, 69.8%), someone else (172/781, 22.0%), or both (64/781, 8.2%). Women were more likely than men to seek help for someone else or both themselves and someone else (168/509 vs 61/242, $\chi^2_2 = 6.35$, $P = .04$). Prior consultation with a health professional was reported by 44.9% (346/770), although this was less common in younger age groups (<36 years) ($\chi^2_1 = 24.22$, $P < .001$). Participants aged 16 to 75 years (n = 26, 20 female, 6 male) were recruited for interview by telephone (n = 23) and instant messaging/email (n = 3). Four major interview themes were identified: motivations for seeking help online; benefits of seeking help in this way and some of the challenges faced; strategies employed in navigating online health information provision and determining what information to use and to trust; and specific comments regarding the NHS Direct website service. Within the motivation category, four concepts emerged: the desire for reassurance; the desire for a second opinion to challenge other information; the desire for greater understanding to supplement other information; and perceived external barriers to accessing information through traditional sources. The benefits clustered around three theme areas: convenience, coverage, and anonymity. Various challenges were discussed but no prominent theme emerged. Navigating online health information and determining what to trust was regarded as a "common sense" activity, and brand recognition was important. Specific comments about NHS Direct included the perception that the online service was integrated with traditional service provision.

Conclusions: This study supports a model of evolutionary rather than revolutionary change in online health information use. Given increasing resource constraints, the health care community needs to seek ways of promoting efficient and appropriate health service use, and should aim to harness the potential benefits of the Internet, informed by an understanding of how and why people go online for health.

(J Med Internet Res 2011;13(1):e20) doi:10.2196/jmir.1600

KEYWORDS

information seeking behaviour; information seeking behaviour; internet; patient-provider communication; health services research

Introduction

In the United Kingdom, in 2009, 70% of households had Internet access [1]. With this rise has come an increase in health-related Internet use. The proportion of UK Internet users using online information on health matters increased from 37% in 2005 to 68% in 2009 [1,2]. A survey in seven European countries in 2005 found that 71% of all adults reported using the Internet for health information [3], and in the United States this figure is 61% [4]. Furthermore, public perceptions of the importance of the Internet as a source of health information have risen dramatically [5].

The National Health Service (NHS) Direct website is the main health advice and information website for patients and the public in the United Kingdom. It was launched in December 1999, and in 2009, there were 18 million visits to the website, compared with 1.5 million visits in 2001 [6]. At the time of this research it provided health advice (through symptom checkers, a health encyclopedia, and an online enquiry service), information on local health services, articles regarding healthy living and fitness, and many other features, including a pregnancy planner, support for long-term conditions, and access to information about health care abroad. Since mid-2009 it has worked with the NHS Choices service, and some of the features described above have migrated to other parts of the NHS Choices platform.

There is limited information describing how and why people use online health information, or the effect of this on health status, although this literature base is growing [6-11]. In this study we used a mixed-methods approach to investigate the characteristics and motivations of online health information seekers in England. In theory, the Internet offers certain advantages as a health information resource. In particular, it provides convenient and anonymous access at any time, from any location, to a wide range of expert sources; and through virtual communities it can provide peer support and social interaction [12]. Health-related use of the Internet has been hailed as a tool to support the emergence of the informed and empowered health consumer, and a shift in the balance of power between patient and professional [13]. At the same time, concerns have been raised about the quality of information, the potential for unhelpful peer-to-peer interactions, and the exclusion of individuals who experience barriers to access [14,15]. In Table 1 we have summarized the main characteristics and potential public health benefits and challenges that have been proposed for health-related Internet use [12,16,17]. In this paper, by exploring the expressed reasons for seeking online health information, we hope to assess the extent to which the theoretical benefits and challenges of the health Internet are being realized in practice.

Table 1. Theoretical characteristics and potential public health benefits and challenges of health-related Internet use

Characteristics of the health Internet	Potential public health benefits	Potential challenges to public health
• Vast quantity of information • Unregulated • Always on • Accessible from anywhere • Interactive • Information can be captured, archived, and retrieved • Content from both expert sources and user-generated sources • Content can be free or paid for • Users can organize in virtual communities	• Public education • Public empowerment supporting informed consumers engaged in their own care • Connect people with others who have similar problems • Online social support • Reduce barriers (time, location, and cost) to accessing information and services • Avoid the stigma of real-world consultation for certain problems • Deliver interactive interventions, as well as information • Integrated health services such as shared electronic records • Reduced travel and carbon emissions	• Misinformation leading to harm • Misuse of accurate information or services such as e-pharmacy • Exacerbation of inequalities in health caused by the digital divide • Challenges to the authority of health professionals • Disruptive behavior in virtual communities • Social isolation of users • Internet addiction of users • Ergonomic effects of computer use and reduced physical activity

Methods

Design

A combination of questionnaire survey and semistructured interviews was used. A self-administered, open, cross-sectional survey of visitors to the NHS Direct website was undertaken using a link placed on the home page of the website. It was therefore a web-based opt-in survey of a convenience sample. Cookies prevented multiple submissions from one computer. Consent was given by participants entering an email address to be sent the link to the survey. There were no incentives to participation. The questionnaire had two aims: first, to identify the characteristics and motivations of users of the website; and second, to recruit potential participants for a qualitative interview study. The questionnaire included 15 questions (one question per screen) covering demographic and health status characteristics, reasons for using the website, and questions related to information-seeking behavior. There was no adaptive questioning or manipulation of item order. In the final part of the survey, the respondents were asked for consent to be contacted at a later date for an interview. The questionnaire was developed based on previous work. The instrument is included as an online appendix.

Interview participants were selected by maximum variation sampling with respect to demographic and health status characteristics of gender, age, ethnicity, those seeking help for acute and chronic illnesses, and those seeking help for themselves or for others. To minimize recall bias, while allowing sufficient time for participants to act on the information they had found, interviews were conducted within 1 to 2 weeks of use of the site. These semistructured interviews were undertaken via telephone, email, or instant messaging. Interviews were conducted by two interviewers, who were members of the research team (JP and NI). Anonymized interview transcripts were used for analysis. We used open-ended questioning and determined the order of questioning by the direction taken by each interview participant. Each interview usually began with a brief description of the interviewee's last visit to the NHS Direct website and went on to explore their online health-related information needs and their information-seeking behavior under the following headings: motivation for using the NHS Direct website, the NHS Direct website itself, facilitators and barriers to online health seeking, role of the Internet compared with other sources of information, and consequences of using online health information. Demographic characteristics of each participant were also recorded (age, gender, ethnicity, educational attainment, and current or most recent occupation). The interview topic guide is included as an online appendix. Survey and interview data were held in password-protected files on password-protected computers. NHS ethics committee approval was obtained for both elements of this study.

Analysis

Questionnaire results were analyzed to provide summary descriptive statistics and cross-tabulations for which chi-square statistics were calculated to examine differences in proportions by demographic characteristics. No statistical corrections such as weighting were used, but nonresponders to individual questions were excluded from the analysis of those questions. All interview transcripts were read by three investigators (JP, NL, and JR), who familiarized themselves with the data through reading and reflection, and each independently undertook open coding of all transcripts [18]. Constant comparison was used to refine emerging conceptual categories, including a search for deviant cases. The investigators met to agree on a series of thematic codes that described a number of categories and subcategories. These agreed-on codes were reapplied to the transcripts, using NVivo software (version 8, QSR International Pty Ltd, Southport, UK).

Results

Questionnaire Survey

A total of 792 respondents completed at least part of the survey accessed via the homepage link. Results are presented as a proportion of the total number of responses to each question (the denominator therefore varies according to the individual question response rate). As can be seen from Table 2, 71.2% (534/750) of respondents were aged under 45 years, 67.4% (511/758) were female, and 37.7% (286/759) had a university degree or higher qualification. With respect to personal general health, 61.7% (474/768) rated it as good or very good (compared with a general population figure of 76%) [19]; 42.6% (322/755) reported having a long-standing illness, disability, or infirmity (very similar to the general population figure of 42%) [19].

Regarding reasons for seeking help, 69.8% (545/781) reported looking for information for their own health issue, while 22.0% (172/781) reported looking for information for someone else (8.2% were looking for both, 64/781). These proportions differed by gender, with women more likely than men to report seeking help for someone else ($\chi^2_2 = 6.35$, $P = .04$; 33% of women, 168/509, versus 25.2% of men, 61/242, reported seeking information for someone else or for both themselves and someone else). There was a significant difference by age group for women, which was predominantly due to a higher number of women in the 56- to 65-year-old age group reporting looking for help for someone else compared with women in other age bands ($\chi^2_7 = 22.89$, $P = .002$). There was no difference by age group for men ($\chi^2_7 = 10.65$, $P = .15$).

Of all respondents, 47.5% (366/770) reported seeking help for a new health issue, while 19.6% (151/770) reported seeking help for a long-standing issue; 17.1% (132/770) reported seeking help for both new and long-standing issues, and 15.7% (121/770) for neither. The commonest category of user was a person who reported seeking help for a new health issue, regarding their own health (257/770, 33.4%). A total of 44.9% (346/770) reported having already consulted a health professional (such as a general practitioner or nurse) about the problem for which they were using the NHS Direct website, and 6.1% (47/770) had previously consulted the NHS Direct telephone service about the issue they were currently looking up online. There were no significant differences in this previous consultation behavior by gender ($\chi^2_1 = 0.625$, $P = .43$). Users in younger age groups (<36 years) were less likely to report having had prior consultation with a health professional before using the website ($\chi^2_1 = 24.22$, $P < .001$); 35.9% (143/398) of those aged up to 35 reported having consulted prior to using the website, compared with 53.9% (186/345) of those over 35.

Table 2. Survey responses by gender (missing data reported because partially completed surveys were included in the analysis). Total respondents N = 792

	Female	Male	Missing data
Age group (years)			
Under 25	184	56	1
26-35	109	47	3
36-45	91	41	2
46-55	59	38	3
56-65	40	34	1
66-75	17	10	0
Over 75	2	12	0
Missing data	9	9	24
Highest qualifications			
None	57	36	4
O levels or equivalent	119	46	3
A levels or equivalent	108	33	2
University degree or equivalent	181	100	5
Other	36	27	2
Missing data	10	5	18
State of general health (self-reported)			
Very good or good	306	153	15
Fair	150	64	1
Bad or very bad	50	25	4
Missing data	5	5	14
Looking for information for			
Myself	341	181	23
Someone else	120	49	3
Myself and someone else	48	12	4
Missing data	2	5	4
Looking for information on			
New issue	243	109	14
Long-standing issue	88	59	4
Both a new and long-standing issue	93	39	0
Other	80	34	7
Missing data	7	6	9
Had previously consulted a health professional about this same issue			
Yes	230	103	13
No	274	139	11
Missing data	7	5	10

Interview Sample

Twenty-six (20 female, 6 male) participants aged 16 to 75 years were recruited from a total of 265 who had indicated their willingness to take part in an interview on the questionnaire. They were interviewed either by telephone (n = 23) or by instant messaging/email (n = 3). Twenty-one described their ethnicity as white British, and five belonged to other ethnic groups. At the time of recruitment the participants were looking up information for themselves (n = 15), for someone else (n = 10), or for both themselves and someone else (n = 1). The participants rated their health as very good (n = 2), good (n =

6), fair (n = 14), bad (n = 1), or very bad (n = 3). Participant characteristics are summarized in Table 3.

The range of health topics searched for was broad, with the most popular being musculoskeletal problems (6/26), mental health problems (3/26), and dermatological problems (3/26).

Table 3. Characteristics of interview participants (n = 26)

	Female (n = 20)	Male (n = 6)
Age group (years)		
16-25	4	0
26-35	2	0
36-45	4	2
46-55	4	1
56-65	4	3
Over 65	2	0
State of general health (self-reported)		
Very good or good	7	1
Fair	9	5
Bad or very bad	4	0
Looking for information for		
Self	9	6
Other	10	0
Self and other	0	1

Thematic Analysis of Interview Data

Themes were identified under the following headings, framed by the questions used in the interview topic guide: the motivations for seeking help online; the benefits of seeking help in this way, and some of the challenges faced; the strategies employed in navigating online health information provision and determining what information to use and to trust; and finally, specific comments regarding the NHS Direct website service. These will be discussed in turn.

Motivations

Within the category of motivations, four concepts emerged through the thematic analysis: the desire for reassurance; the desire for a second opinion to challenge other information; the desire for greater understanding to supplement other information; and perceived external barriers to accessing information through traditional sources (including the desire to avoid “bothering” their health care provider).

One prominent reported motivation for seeking online health information was reassurance, often at the time symptoms appeared and prior to consultation with a health professional. As one participant stated *“sometimes you just want your fears eased”* [Interviewee 25, a 41-year-old woman]. In general, this online search for reassurance and relief from anxiety was not said to replace other forms of seeking help; rather, it was seen as an adjunct to other sources of help and information, not a substitute for them, thereby providing an extra layer of information but not necessarily altering consulting behaviors. As Interviewee 19 put it:

> *I think I probably followed a course of action I would have taken anyway.* [Interviewee 19, a 48-year-old man]

For the most part, the interviewees in this study reported seeking health information from official health websites that gave authoritative health information, and not from other users. This was not surprising given the route of recruitment through their use of the NHS Direct website. Even so, among the participants in this sample a few participants did report seeking nonprofessional “peer-to-peer” information. In these cases the motivation was again reassurance – wanting to know that the person was not alone in what they were experiencing. This was illustrated by Interviewee 17:

> *I’ve gone to a menopause site that specializes in that [peer-to-peer interaction]. There are lots and lots of contributors over several years and I search for that, have a read and see what other people think and then I’ve posted on that and said“Look, I don’t have what people classically call flushes”... I just have it at night. What do other people think? And then lots of people come on and say“Yes, that’s perfectly normal. That’s what I’ve experienced and this is not unusual. People do have...”...so quite often I get reassurance that I’m not an odd one out from this.* [Interviewee 17, a 49-year-old woman]

A few examples of the Internet providing “demand management” for primary care or emergency services were identified. Sometimes participants described the motivation of not wanting to “*bother*” their doctor with a problem that might be trivial. Interviewee 13 described how reassurance over a bloodshot eye eliminated the need for a general practice appointment.

> *It looks as if you should do something about it. I looked it up again on the website and it said "there's nothing to worry about," you know...it normally goes off on its own and it doesn't need a trip to the doctor's so again, it saved the trip to the doctor and it saved a lot of worrying.* [Interviewee 13, a 66-year-old woman]

However, while 13 interviewees talked about accessing the NHS Direct website as one of their first actions to find out information about symptoms, in most cases they did report going on to seek help from traditional health service sources, albeit sometimes with less urgency or less anxiety. This was the case whether they reported seeking help for themselves or for someone else. Furthermore, half the interviewees also stated that they would tend to see a professional as a first point of call if they had a health problem

> *As I say, it didn't make me do anything that I wasn't already contemplating, but I guess it gave me the answer to the question that I was looking for and then the peace of mind that it wasn't becoming an emergency I guess and that we should stick with it.* [Interviewee 9, a 32-year-old woman]

Where demand management appeared to be occurring in practice, this was usually explained by the avoidance of barriers to accessing traditional health services, such as difficulties in getting an appointment or in travelling to one.

> *It used to take two hours and two bus journeys to get to the doctors...It's easier to use than to get down to the doctor's...It's the time and the money...you know – those kinds of factors and then all the problems with getting appointments as well.* [Interviewee 10, a 25-year-old woman]

The desire for a second opinion following initial advice received from a heath professional was another reported motivation. Participants described the Internet as a way of accessing specialist knowledge, which they could use to challenge the advice given during their consultation. As in the example below from Interviewee 21, this challenge was an explicit response to not believing the health professional. At other times, illustrated by a quote from Interviewee 5, this was more about becoming fully informed on the range of divergent professional opinion.

> *They were telling me that treatment would be such and such and I thought"well I don't believe that and I'll use NHS Direct to see whether they can give me some information."* [Interviewee 21, a 59-year-old man]

> *Well, when you go to the doctor you've only got his opinion haven't you? I mean I'm sure he's basing it on knowledge and research and things like that, but I just wanted to see other opinions about it.* [Interviewee 5, a 55-year-old woman]

The next motivation described by participants was also related to researching information prior to or following a consultation, but was not motivated by a desire to challenge. Instead the reported motivation was to seek clarity and confirmatory information in greater depth. This could be characterized as "homework" to support informed decision making, which could be done at the individual's own pace. As Interviewee 20 explained:

> *It [the Internet] is excellent for a slower time study of information that my doctor hasn't fully explained.* [Interviewee 20, a 62-year-old man]

> *I was really looking to substantiate a little bit more about the treatment options that I was given by the GP.* [Interviewee18, a 46-year-old woman]

Benefits and Challenges: Convenience, Coverage, and Confidentiality

Interviewees volunteered a range of benefits of online health information seeking. These reported benefits clustered around three theme areas: convenience, coverage, and anonymity. The convenience of online health encompassed the ease and speed of access, at any time, and from any location, especially from home. Access could be *"in your own time...at your own pace"* [Interviewee 19, a 48-year-old man]. This was contrasted with issues in accessing traditional health services.

> *You can go on it any time of the day quite honestly, whereas you can't get your doctor any time of the day, or they have to ring you back and then you're sitting either waiting or...you know.* [Interviewee 24, a 58-year-old woman]

> *It's quick and it's direct. It's there in front of me every day and every evening.* [Interviewee 25, a 41-year-old woman]

In their responses, interviewees recognized that the Internet played a role in allowing them to become informed consumers, better able to share decisions with their health care provider. For example, Interviewee 18 (a 46-year-old woman) reported being able to *"make an informed decision"* in conjunction with her specialist, about treatment for fibroids, having sought information online. The benefit of coverage related to the wide range and depth of health information available on the Internet, and access to specialist medical knowledge. This access to esoteric medical knowledge was highlighted by Interviewee 4 (a 59-year-old woman):

> *It's [the Internet] the perfect tool for finding out something that you need to know about and you probably don't have the information unless you're a medic.* [Interviewee 4, a 59-year-old woman]

Confidentiality was the third area that emerged from the interviews as a key valued benefit for Internet health users. This encapsulated both the anonymous nature of online identity and the ability to use the Internet privately from any location. This could be of particular value for conditions that were more personal or stigmatizing.

> *Confidentiality...you're not speaking to someone about health issues. I mean for someone that has a lot more of a personal problem and they didn't really want to discuss it with someone it's ideal.* [Interviewee 22, a 20-year-old woman]

Interviewees also discussed some of the challenges of health-related Internet use but no prominent theme emerged. The issues raised included (1) inaccurate information leading to harmful health decisions, which was reported as more of a theoretical problem, rather than by anyone with direct experience; (2) misuse of accurate information, leading to inappropriate self-diagnosis: *"there's always the worry of misdiagnosing something, or reading something into it"* [Interviewee 19, a 48-year-old man]; (3) confusion caused by the sheer volume of information, which was sometimes perceived as being *"confusing"* and *"daunting"*; and (4) sometimes criticism of health-related Internet use for its *"impersonal"* nature, which lacked the quality of face-to-face contact, and which could not replace a real consultation.

Strategy: Navigating the Health Internet

Throughout the interviews, participants explained the strategies employed in navigating online health provision and determining what information to use and to trust. They reported finding NHS Direct Online either by using a search engine (almost always this was Google), or by going directly to the uniform resource locator (URL) once they were familiar with it. Choosing a site was regarded as a common sense activity by interviewees. They were well aware that the Internet could be a source of misleading information – *"there's a lot of crap on the Internet,"* as Interviewee 21 (a 59-year-old man) put it – but they used common sense to avoid this. For Interviewee 1, the Internet provided her with:

> *A vast range of information from the idiotic to the academic, so I've got a vast range of information and it's on tap so to speak. It's up to the individual to adjudicate whether the information is relevant, or whether it's valid...I do have enough common sense to evaluate what I see...I keep repeating that you need to use your discretion when you read...I would say that it could be a dangerous thing, on the other hand but I think the majority of people do have common sense.* [Interviewee 1, a 59-year-old woman]

Several participants expressed negative views regarding peer-to-peer sources of health information, related to concerns about its trustworthiness. For example, Interviewee 4 (a 59-year-old woman) was concerned that the information may be written by *"wild women from Minnesota,"* and Interviewee 5 explained:

> *How do you know if they're trustworthy? No, I wouldn't do that at all. I don't particularly like these chat rooms anyway...Because I don't know them. No, I don't want to talk to people I don't know about things really. I think it could be quite dangerous...Perhaps I'm being cautious but that's how I think.* [Interviewee 5, a 55-year-old woman]

"Brand recognition" was reported as very important to the interviewees in navigating the health Internet. Interviewees reported choosing sites that had "real-world" branding, that is, an identity that they recognized from their offline experiences. The importance of the brand in establishing that a site was trustworthy was a very strong theme across the interviews. The NHS brand in particular was seen by respondents as giving the website the valued qualities of being impartial, reliable, and up-to-date. As one interviewee put it *"You tend to trust the NHS don't you?"* [Interviewee 11, a 38-year-old woman]. Interviewees often contrasted this inherent trustworthiness of the NHS brand with their views on commercial health websites, particularly those produced by pharmaceutical companies:

> *I thought the NHS one probably has no axe to grind...Whereas if it's related to a drug company or somebody with herbal medicine and all of this sort of thing, I think they tend to be more biased, whereas the NHS is not trying to sell you something.* [Interviewee 3, a 44-year-old woman]

A further interesting finding regarding which sites were valued and used was the low esteem in which North American sites were sometimes held as reported by our British participants. This was partly due to a perception that US sites had commercial aims and were therefore seen as *"trying to sell something*" and partly the lack of local or cultural relevance for some of the information.

> *The thing about the NHS online is that you know you're looking at genuine stuff. The answers that you're going to get are absolutely spot on and you can rely and trust them, whereas if I just Google something I may end up on an American site or something. I wouldn't feel confident that the information I was looking at was absolutely right.* [Interviewee 25, a 41-year-old woman]

The NHS Direct Service

As would be expected given the route for recruitment, respondents made many comments about specific aspects of the NHS Direct website; for example, wanting further information on specific topics. Over and above these individual remarks, two broad issues concerning the NHS Internet service were present across the interviews and had generic relevance to health-related Internet provision. The first of these was the perception that the NHS Direct website was integrated with the real-world NHS service. As Interviewee 4 (a 59-year-old woman) put it *"I would hope that it ties in with the NHS generally, so it seemed to be the sensible place to go."* Interviewees had an expectation that there would be some connection between their use of a virtual health service and the care they received from the physical counterpart. Furthermore, they felt that, because they were NHS patients, using the NHS website was the "right thing to do," because of this perceived integration across online and traditional services.

> *Since we are under the NHS system, it would be logical for me to go first of all to the NHS Direct to see what the NHS's take was...As far as I'm concerned, if the NHS Direct website is offering this information then it should make it uniform all through the NHS...I specifically used the NHS website because we live in an NHS world and where better than to get it straight from the horse's mouth?* [Interviewee 1, a 59-year-old woman]

The second broad issue of generic relevance related to feedback about the clarity and simplicity of design of the NHS Direct website, in terms of the language used and the architecture of the site.

> *It's got clear information and there's enough there, but not like reels and reels that you get that you struggle to understand it and it's very well broken down into sections as well I think, so like very specific for children and adults.* [Interviewee 22, a 20-year-old woman]

Together with the issue of the NHS brand, which was described above under navigation strategy, the clarity of the site and the perceived link with the real-world service were the principal reasons reported for valuing the NHS Direct site in particular as a source of online health information.

Discussion

The survey findings with respect to the age, gender, and educational status of online health seekers add to the accumulated evidence of several studies over the last decade that have shown that being female, being younger, and having a higher level of educational attainment are all associated with more frequent health-related Internet use [11,19-23]. The reported health status profile of our survey participants appeared to be very close to that of the general population. Work in other countries has sometimes shown a tendency to overrepresent people with chronic illness among health Internet users [7,8,24,25], while others have not found this association [11,22]. The NHS Direct website is used for both acute and chronic problems, mild or serious, and is used by individuals for themselves and on behalf of family members, especially by women. It is therefore perhaps not surprising that the health status of the users in our study was similar to that of the general population. The majority of those surveyed were seeking information for themselves, which is consistent with the findings of others [11]. Furthermore, a large proportion of users (over 40%) had already sought help from a health professional for the same health issue prior to accessing the website.

Having established the characteristics of the users of the site, we undertook in-depth qualitative work to explore in detail their motivations and attitudes. In 2003, the lead author (JP) wrote a review paper that summarized the benefits and challenges of health-related Internet use [12]. In Table 1 we integrated these with the thoughts of other authors in this field [16,17]. The analysis of our interviews supports most of the theoretical benefits discussed in the literature, and indicates that the health Internet is delivering on its potential benefits, while at the same time presenting some challenges to health professionals. Participants' responses indicated that the Internet was being used as a tool to educate and reassure, and to sometimes challenge information received by health professionals. Previous work on the sociology of health-related Internet use has invoked theories of empowerment, democratization, and the challenge to health professional power [13,15,26] Most empirical work has indicated that, while these processes are taking place, the change is more subtle than many theorists have predicted, with the ongoing predominance of a biomedical model in the context of more-informed health consumers [27-29]. By sampling users of the NHS website it is perhaps not surprising that our findings support this model of evolutionary rather than revolutionary change, with health e-consumers seeking to become more informed through authoritative advice from official websites. Health-related Internet use was seen by most of our participants as a supplement to existing health service provision rather than a replacement for it [4,30]. The motivations of reassurance and of seeking greater understanding can be seen in this context. Even the motivation to find a second opinion to challenge other information was within the context of a model of biomedical authority. Our findings support the idea that online health resources are enmeshed with other (offline) approaches to seeking help [26], and that health-related Internet use is now embedded in everyday health practices [31].

The majority of online events were related to real-world consultations, whether as preparation for them or as a search for further information afterward [23,32,33]. There were few examples of demand management occurring in practice, in terms of reducing the need for consultations, but our findings do support the idea that a health website can lead to more appropriate use of other services. Peer-to-peer interaction was not a focus of this study, as this is not provided on the NHS Direct website, and the number of participants in our qualitative sample reporting use of online support groups for health conditions was not high. Nevertheless, some participants did discuss the value of online interaction with others with similar problems, in particular the reassurance of knowing they were not alone, as found in previous work [34], while others expressed concerns about the trustworthiness of peer-to-peer sources. Consumer access to poor-quality information on the Internet has been a long-standing concern in the eHealth literature [15]. We found that, in avoiding misinformation and identifying which information to trust, participants put great emphasis on recognition of brands such as the NHS, which were trusted in the non-Internet world, together with using common sense approaches to navigate the health Internet. The reported value of official branding of health websites in determining trustworthiness is supported by previous work [35]. The online benefits of convenience and anonymity are well established [36] and were widely reported, as was the expectation that online health services would be fully integrated with their real-world counterparts, something that remains an aspiration for the NHS in the United Kingdom but is not yet a reality.

Some theoretical benefits and challenges were not prominent in these interviews. The "green" potential of the Internet to reduce travel, but at the same time possibly reduce physical activity and lead to social isolation or depression [37], was not discussed by our participants. Nor were any ergonomic effects of computer use, or the problem of Internet addiction. The issue of the digital divide, although mentioned by three participants, did not emerge as a consistent theme. However, given that this sample were all Internet users, this was perhaps not surprising.

Limitations

Because this was an opt-in survey accessed via a weblink, it was not possible to calculate a response rate for the questionnaire. There were also design issues with the website during the survey period, which meant that the link to the survey was not always clearly visible to users. This affected the overall response and the number of individuals consenting to be interviewed in the second stage. To minimize social desirability bias, the researchers made it clear to interviewees that the researchers were independent of the NHS Direct organization, but those volunteering for interviews may still have been a particular population who wanted to relate their experiences with NHS Direct, good or bad. More women than men were interviewed due to having very few male volunteers. Interview methodology of this type, asking people to report how and why they used a particular source, may reflect attitudes rather than actual behavior, for which direct observation may be preferred. Nevertheless, questions were designed to focus on the most recent actual use of the Internet for health, rather than rely on hypothetical questioning. The participants were users of the NHS Direct website and were therefore not necessarily representative of the overall population of online health information seekers in the United Kingdom. However, the NHS site is the most popular health information site in the United Kingdom, and the demographic profile of respondents was similar to that of non-UK-based studies.

Conclusions

Given increasing resource constraints, the health care community needs to seek ways of promoting efficient and appropriate health care use, which should include consideration of how Internet health information is provided and used, and how traditional NHS services and online services can be best integrated. The study findings support a model of evolutionary rather than revolutionary change in health information use, with real-world trusted brands being used online, in conjunction with traditional consultations. It will be interesting to see whether in time, particularly as the younger “Internet generation” ages and eHealth literacy increases in all age groups [38], Internet health information will be trusted enough to be used as an alternative, as opposed to an adjunct, to other types of health-seeking activities, and by individuals of broader demographic profiles. Our findings fit with a “shared decision-making” model [39], where individuals seek information to help the decision-making process and confirm what they are being told, rather than seeking to become independent experts. One of the primary motivations was the seeking of reassurance, and the value of this in terms of health or social benefit or more appropriate service use needs to be further explored. The relationship between Internet use and health outcomes is an area for research development, including examination of the role of user empowerment. Health service providers should aim to harness the potential benefits of health-related Internet use, rather than see it as a burden or challenge.

Acknowledgments

This work is produced Professor John Powell under the terms of a postdoctoral research training fellowship issued by the National Institute for Health Research. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health.

Conflicts of Interest

Dr Shirley Large is Head of Research and Clinical Audit at NHS Direct.

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Abbreviations

NHS: National Health Service
URL: uniform resource locator

Edited by G Eysenbach; submitted 02.07.10; peer-reviewed by S Wyke; comments to author 06.08.10; accepted 21.10.10; published 23.02.11.

Please cite as:
Powell J, Inglis N, Ronnie J, Large S
The Characteristics and Motivations of Online Health Information Seekers: Cross-Sectional Survey and Qualitative Interview Study
J Med Internet Res 2011;13(1):e20
URL: http://www.jmir.org/2011/1/e20/
doi:10.2196/jmir.1600
PMID:

Original Paper

Subdividing the Digital Divide: Differences in Internet Access and Use among Rural Residents with Medical Limitations

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Abstract

Background: Access to health care is often contingent upon an individual's ability to travel for services. Certain groups, such as those with physical limitations and rural residents, have more travel barriers than other groups, reducing their access to services. The use of the Internet may be a way for these groups to seek care or information to support their health care needs.

Objective: The purpose of this study was to examine Internet use among those whose are, for medical reasons, limited in their ability to travel. We also examined disparities in Internet use by race/ethnicity and rural residence, particularly among persons with medical conditions.

Methods: We used data from the 2001 National Household Travel Survey (NHTS), a nationally representative sample of US households, to examine Internet use among individuals with medical conditions, rural residents, and minority populations. Internet use was defined as any use within the past 6 months; among users, frequency of use and location of use were explored. Control variables included sociodemographics, family life cycle, employment status, region, and job density in the community. All analyses were weighted to reflect the complex NHTS sampling frame.

Results: Individuals with medical conditions were far less likely to report Internet use than those without medical conditions (32.6% vs 70.3%, $P < .001$). Similarly, rural residents were less likely to report Internet access and use than urban residents (59.7% vs 69.4%, $P < .001$). Nationally, 72.8% of white respondents, versus 65.7% of persons of "other" race, 51.5% of African Americans, and 38.0% of Hispanics reported accessing the Internet ($P < .001$). In adjusted analyses, persons with medical conditions and minority populations were less likely to report Internet use. Rural-urban differences were no longer significant with demographic and ecological characteristics held constant.

Conclusions: This analysis confirmed previous findings of a digital divide between urban and rural residents. Internet use and frequency was also lower among those reporting a medical condition than among those without a condition. After we controlled for many factors, however, African Americans and Hispanics were still less likely to use the Internet, and to use it less often, than whites. Policy makers should look for ways to improve the access to, and use of, the Internet among these populations.

(J Med Internet Res 2011;13(1):e25) doi:10.2196/jmir.1534

KEYWORDS

Disabled Persons; Medical Condition Limiting Travel; Internet, Rural Communities; Minority Health

Introduction

A substantial number of Americans have physical or other conditions that reduce their ability to travel. Such conditions hamper their ability to see, operate a vehicle, gain access to public transportation, or walk to a desired destination. Many of these individuals, therefore, rely upon family members, friends, or other modes of transportation for their travel needs [1].

Rural residents have a slightly higher rate of disabling conditions than urban residents, particularly in the South [2]. These rural residents are especially vulnerable in regard to travel restrictions. The reduced availability of services, and relatively greater distance between services and housing centers, and the reduced availability of public transportation exacerbate these resident's travel difficulties [3]. These barriers in available transportation can lead to reduced utilization of services [1].

The evolution of the Internet as a resource, especially for health care information and services, may be an ameliorant for those with travel difficulties. Many patients rely on the Internet for gathering information about their conditions and treatment options, and for communication with their providers. Patients also use the Internet to garner social support, using the interface as a coping mechanism [4-6]. The Internet also can play an important role in the education and recruitment of patients for specific services or programs [7,8].

Internet access is influenced by available telecommunication infrastructure and the affordability of Internet services [9]. The high cost of providing services across the more widely dispersed rural population is one barrier to the development of infrastructure in rural areas [10]. As a result, rural areas lag behind in the infrastructure required for optimal Internet use (such as broadband or other high-speed service), and rural residents have lower reported use of the Internet than urban residents [11]. Since home availability of the Internet remains low in rural communities, and usage at work was also lower [12], rural residents were more likely than those in urban or suburban areas to use a source other than work or home for accessing the Internet [13].

Sociodemographic characteristics are also significantly associated with Internet use. African Americans and Hispanics were less likely than whites to report Internet access, and Hispanics were less likely than whites to report using the Internet for health-related issues [14]. Other socioeconomic characteristics, such as higher educational levels, younger age, and greater household income, were found to be associated with any prior use of the Internet among surgery patients [7,13]. A Pew Internet surveys found that Internet users who were female, were older, had a higher education and income, were white, were not employed full time, were married, and had a child under 18 living at home were more likely to report using the Internet to search for health information [15].

The digital divide between urban and rural populations has important implications for the health of rural residents, particularly those who are limited in their ability to travel. These individuals, as well as rural populations, generally have reduced access to primary care, coupled with greater travel distances to care [16,17]. They could benefit from Internet access, as Internet availability could facilitate research into health conditions, as well as providing additional links to services. The purpose of this study, therefore, was to examine Internet use among people with limited ability to travel. We also examined disparities in Internet use by race/ethnicity and rural residence, particularly among those with medical conditions.

Methods

Data Source

We analyzed a data set not generally used for health services research, the 2001 National Household Travel Survey (NHTS) of the US Department of Transportation. The 2001 NHTS, a multistage telephone interview, obtained information from a nationally representative sample of households from March 2001 through May 2002. Eligible participants were civilian, noninstitutionalized persons who considered themselves primary residents of the households sampled. In addition to examining travel and ability to travel, the 2001 NHTS asked respondents about their Internet use.

The overall response rate for the NHTS was 41% [18]. Survey responses were weighted to account for underresponse among specific populations. After merging the person and household data sets in the 2001 NHTS, we identified 44,507 respondents living in 25,616 households, which represent a weighted population of 200,257,143.

Definition of Variables

Dependent Variables

We defined three dependent variables: whether a respondent had accessed the Internet in the past 6 months (yes/no), frequency of use in the last 6 months among persons who reported use, and location of use among persons who reported use. Frequency of Internet use was measured dichotomously: *frequent use* included “almost every day” or “several times a week,” while *infrequent use* included “once a week” or “once a month”. *Location of use* was characterized by the NHTS as “home only,” “work only,” “other only,” “home and work,” “home and other,” “work and other,” and “home, work, and other.” In multivariate analysis, we compared “home only” to all other categories.

Independent Variables

We sought to examine three aspects of a potential digital divide: presence or absence of a *medical condition limiting travel* (hereafter, “medical condition”), *residence*, and *race/ethnicity*. *Medical condition* was coded as “yes” if the respondent indicated that he or she had a medical condition with any of the following characteristics: limits driving to daytime, limits use of public transportation, results in asking for rides, requires giving up driving, requires special transport, and results in less travel. Otherwise, the medical condition variable was coded as “no.” No finer distinctions, such as categories of physical or mental disease, were made available by the survey instrument.

We used the definition of rural used by the 2001 NHTS, developed by Claritas Inc. [18]. This approach divides the United States into grids, with population density within each geographic grid expressed as centiles (0 through 99). The definition of rural included centiles 0 through 19, while centiles 20 and above were considered urban.

Race and ethnicity were coded as white, African American, Hispanic, and other. Persons in multiple race/ethnicity groups were included in the “other” race and ethnicity category.

Control Variables

Other factors, in addition to residence and race/ethnicity, are known to influence Internet access and usage. These control variables, held constant in multivariate analysis, were conceptualized into two categories: demographic factors and ecological factors. Demographic factors were the respondent’s age group (<26, 26-50, 51-75, and >75 years), sex, education (high school or lower, college, and graduate school), household income (<\$20,000, \$20,000-\$44,999, \$45,000-\$70,000, and >\$70,000), family life cycle stage (young adult, young family, older family, or retired), and occupation type (sales, clerical, blue collar, white collar, or technical). Ecological factors were region (Northeast, Midwest, South, and West) and job density within the respondent’s area of residence. Job density was defined in the NHTS as “Jobs per square mile - Tract level”. Based on the distribution of job density, we categorized it into three groups: low (fewer than 96.1 jobs per square mile), medium (between 96.1 and 692.3), and high (greater than 692.3).

Statistical Approach

We first used univariate analysis to describe the study population. We next used bivariate analysis, with Wald chi-square tests of differences, to examine Internet use by the variables of interest (medical conditions, residence, and race/ethnicity). Finally, we conducted multivariate logistic regression to determine whether medical conditions, residence, and race/ethnicity were significantly associated with Internet use when holding demographic and ecological factors equal. All analyses were conducted in SAS-callable SUDAAN version 10 (RTI International, Research Triangle Park, NC, USA) to account for the complex NHTS sampling design. All analyses employed sampling weights, reflecting the underrepresented or oversampled groups in specific states. All testing was two sided and conducted at alpha = .05.

Results

In 2001, about two-thirds of Americans reported having accessed the Internet within the past 6 months (Table 1). Rural residents were less likely than their urban peers to report accessing the Internet (59.7 versus 69.4%, $P < .001$). Only about a third of persons who reported a medical condition that impaired their driving (32.6%) reported accessing the Internet, compared to 70.3% among those without a medically limiting condition ($P < .001$). A marked difference was also present across race/ethnicity. Nationally, 72.8% of white respondents, versus 65.7% of persons of “other” race, 51.5% of African Americans, and 38.0% of Hispanics, reported accessing the Internet ($P < .001$). Less than a third of rural African American or Hispanic respondents reported accessing the Internet compared to 64.5% of rural whites ($P < .001$, data not in table).

As might be expected, the likelihood of accessing the Internet increased linearly with education and income, and decreased with age ($P < .001$). Occupational differences may reflect job requirements; individuals in manufacturing and related industries were markedly less likely to report accessing the Internet than were those in other occupations ($P < .001$).

Table 1. Reported Internet use within the past 6 months, NHTS 2001[a], by respondent characteristics (n = 44,507 observations; estimated population 200,257,143)

Percentage reporting Internet use	Unweighted observations	Estimated population	Weighted proportions (%)
Total	30,128	135,011,405	67.4
Travel limitation due to a medical condition [b]			
Yes	1248	5,038,139	32.6
No	28,880	129,973,266	70.3
Residence [b]			
Rural	6139	23,975,873	59.7
Urban	23,989	111,035,532	69.4
Race [b]			
White	25,630	103,924,340	72.8
African American	1336	11,907,786	51.5
Hispanic	583	4,686,522	38.0
Other	2579	14,492,757	65.7
Age group (years) [b]			
<26	4734	27,894,654	80.6
26-50	16,503	77,161,873	77.6
51-75	8372	28,200,505	52.1
>75	519	1,754,372	14.6
Sex [b]			
Male	14,325	66,648,850	69.4
Female	15,803	68,362,555	65.6
Education [b]			
High school or lower	8123	37,041,567	47.0
College	16,227	72,802,951	79.8
Graduate school	5223	22,272,126	88.2
Not ascertained	555	2,894,760	58.9
Household income [b]			
<$20,000	2059	11,229,371	33.5
$20,000-$44,999	7109	33,725,334	59.0
$45,000-$70,000	8158	36,117,045	79.3
>$70,000	11,254	47,388,158	93.0
Not ascertained	1548	6,551,497	50.3
Family life cycle [b]			
≥1 adults, no children	10,162	44,707,004	73.3
≥1 adults, youngest child 0-15	12,381	59,678,984	76.4
≥1 adults, youngest child 16-21	3382	16,027,166	79.5
≥1 adults, retired, no children	4203	14,598,251	35.5
Occupation [b]			
Sales or service	5635	26,652,524	73.2
Clerical or administrative support	2942	13,083,350	85.0

Percentage reporting Internet use	Unweighted observations	Estimated population	Weighted proportions (%)
Manufacturing, construction, maintenance, farming	3051	14,462,202	55.8
Professional, managerial, or technical	10,419	46,326,247	90.6
Other	8081	34,487,082	48.3
Region [b]			
Northeast	5799	26,046,879	68.2
Midwest	7815	31,351,034	68.7
South	9535	46,769,938	65.0
West	6979	30,843,554	69.4
Job density [b]			
Low	6763	26,250,968	60.4
Medium	7766	32,642,536	71.4
High	15,599	76,117,901	68.5

[a] NHTS: National Household Travel Survey.

[b] Between-group differences significant, *P* < .001.

Among persons who did report accessing the Internet, the majority used it daily (54.2%; Table 2). Among persons with medical conditions, more than two-thirds (68.3%) reported accessing the Internet only from home, versus 38.7% of other individuals ($P < .001$). Rural residents were less likely to report daily use (47.0% vs 55.7%), and more likely to report use only once per month (13.3% vs 9.4%), than their urban peers ($P < .001$). Frequency of Internet use differed by race/ethnicity as well ($P < .001$): African Americans and Hispanics were less likely to report almost daily Internet use, and were more likely to report use only once per month. African Americans were less likely to have access at home (34.1%) than either Whites (40.8%) or Hispanics (40.3%), but were more likely to report use at work (9.9%, $P < .001$).

Table 2. Frequency and location of use among persons with Internet access, by residence and presence of a medical condition limiting travel

		Medical limitations			Residence			Race/ethnicity				
	All	Limited travel	No limitations	*P*-value	Rural	Urban	*P*-value	White	Afr. Am.[a]	Hispanic	Other	*P*-value
Frequency of access				.02			<.001					<.001
Almost every day	54.2	51.0	54.3		47.0	55.7		55.9	42.5	39.7	56.3	
Several times a week	23.4	24.3	23.3		25.1	23.0		22.9	28.1	26.2	22.1	
Once a week	12.3	11.5	12.4		14.6	11.9		11.8	15.4	17.2	11.8	
Once a month	10.1	13.2	10.0		13.3	9.4		9.4	13.9	16.9	9.8	
Location of access				<.001			<.001					<.001
Home only	39.8	68.3	38.7		44.7	38.8		40.8	34.1	40.3	37.3	
Work only	7.6	4.1	7.8		8.5	7.4		7.6	9.9	7.5	6.2	
Home and work	30.7	11.3	31.4		25.1	31.9		31.6	24.2	25.0	31.1	
Other	21.9	16.3	22.1		21.7	21.9		20.0	31.8	27.2	25.4	

[a] Afr. Am.: African American.

Adjusted odds for accessing the Internet and factors associated with intensity and location of use among persons who reported Internet access are presented in Table 3. With all personal and ecological characteristics held equal, rural residents were no less likely than urban residents to report accessing the Internet (odds ratio [OR] 0.89, 95% CI 0.76-1.04), and did not differ with regard to frequency or location of use. Among persons with a medical condition that limited travel, the odds of accessing the Internet were lower, even controlling for age and life cycle stage (OR 0.66, 95% CI 0.59-0.74). Medically impaired persons who did access the Internet were most likely to use it at home (OR 1.70, 95% CI 1.43-2.03).

The digital divide between the races in 2001 was extensive (Table 3). All minorities were less likely than whites to report any Internet access (OR 0.38, 95% CI 0.33-0.43 for African American; OR 0.20, 95% CI 0.17-0.24 for Hispanic; OR 0.51, 95% CI 0.45-0.58 for other). For African Americans, the odds of any use, of frequent versus infrequent use, and of use at home versus at other locations were all lower than for whites. Hispanics were similarly less likely to report any use and to report frequent use, although they did not differ in location of use from white respondents.

Other characteristics influenced accessing the Internet and type of use in a manner paralleling the findings shown in Table 1. In adjusted analysis, the odds of reporting any Internet access increased as education or income increased, and decreased as age increased. Women were less likely to report any Internet use and frequent use, with women who did use the Internet being more likely to access it at home than in other locations. Among persons using the Internet, lower income and education were associated with use at home versus other locations.

Table 3. Adjusted odds ratios (OR) that an individual will report selected types of Internet use, NHTS 2001[a]

	Internet access		Among respondents using the Internet			
	Within past 6 months		Frequent versus infrequent use		Home versus other location	
	OR	95% CI	OR	95% CI	OR	95% CI
Travel-limiting medical condition (referent: no condition)						
Yes	0.66	0.59-0.74	1.05	0.90-1.22	1.70	1.43-2.03
Residence (referent: urban)						
Rural	0.89	0.76-1.04	0.92	0.81-1.05	1.08	0.93-1.25
Race/ethnicity (referent: white)						
African American	0.38	0.33-0.43	0.67	0.59-0.77	0.76	0.64-0.89
Hispanic	0.20	0.17-0.24	0.61	0.51-0.74	0.92	0.74-1.14
Other	0.51	0.45-0.58	0.96	0.84-1.10	0.90	0.81-1.00
Demographic characteristics						
Age group (referent: <26 years)						
26-50	0.47	0.41-0.53	0.94	0.86-1.04	1.88	1.73-2.05
51-75	0.19	0.16-0.21	0.79	0.71-0.88	2.60	2.32-2.92
>75	0.05	0.04-0.06	0.76	0.56-1.03	4.39	3.25-5.91
Sex (referent: male)						
Female	0.87	0.82-0.93	0.69	0.64-0.74	1.50	1.42-1.60
Education (referent: graduate school)						
High school or lower	0.24	0.20-0.28	0.53	0.48-0.60	1.95	1.73-2.20
College	0.65	0.56-0.76	0.76	0.68-0.85	1.47	1.33-1.62
Not ascertained (not interpretable; used to prevent loss of observations)	0.29	0.23-0.38	0.65	0.50-0.85	1.47	1.17-1.86
Household income (referent: >$70,000)						
<$20,000	0.11	0.10-0.13	0.65	0.56-0.75	0.99	0.87-1.13
$20,000-$44,999	0.24	0.21-0.27	0.68	0.62-0.75	1.44	1.32-1.58
$45,000-$70,000	0.44	0.38-0.50	0.73	0.67-0.79	1.41	1.30-1.52
Not ascertained (not interpretable; used to prevent loss of observations)	0.20	0.17-0.23	0.74	0.63-0.89	1.29	1.09-1.53
Family life cycle (referent: ≥ 1 adults, youngest child 16-21)						
≥1 adults, no children	0.81	0.70-0.93	1.22	1.07-1.38	0.68	0.61-0.77
≥1 adults, youngest child 0-15	0.97	0.83-1.14	0.84	0.75-0.94	1.03	0.92-1.15
≥1 adults, retired, no children	0.50	0.42-0.59	1.16	0.99-1.36	1.57	1.33-1.85
Occupation (referent: professional, managerial, or technical)						
Sales or service	0.45	0.39-0.51	0.66	0.60-0.73	2.88	2.61-3.16
Clerical or administrative support	1.09	0.93-1.28	1.00	0.87-1.15	0.89	0.79-1.01
Manufacturing, construction, maintenance, or farming	0.26	0.23-0.29	0.39	0.35-0.44	5.46	4.92-6.06
Other	0.36	0.33-0.40	0.77	0.70-0.84	5.49	5.03-5.99
Ecological factors						
Region (referent: West)						
Northeast	0.86	0.76-0.98	1.07	0.96-1.18	1.23	1.11-1.36
Midwest	0.93	0.82-1.05	0.91	0.82-1.00	1.04	0.95-1.15

	Internet access		Among respondents using the Internet			
	Within past 6 months		Frequent versus infrequent use		Home versus other location	
	OR	95% CI	OR	95% CI	OR	95% CI
South	0.95	0.86-1.06	1.05	0.96-1.15	0.99	0.91-1.07
Job density (referent: high)						
Low	0.89	0.76-1.04	0.88	0.77-1.01	0.88	0.76-1.02
Medium	1.12	1.02-1.23	0.89	0.82-0.96	1.01	0.93-1.09

[a] NHTS: National Household Travel Survey.

Discussion

The present analysis sought to investigate differences in Internet access and use among persons affected by medical conditions, among rural residents, and across racial/ethnic groups. Persons with a medical condition that limits their availability to travel were deemed to have a particular need for Internet access, to allow them to obtain information and social support [4-8]. We found, however, that Internet use and frequency were lower among persons with a medical condition than those without; persons with a medical condition were more likely to access the Internet only from home. Lower odds for any Internet use within the past 6 months and Internet use exclusively from home persisted in adjusted analysis. Other factors not captured by the present analysis, including personal preferences and/or the inability to use computers due to the person’s limitations, may account for this particular type of digital divide.

Further research is needed to explore barriers to Internet use among persons whose travel is limited by medical conditions. Such research must take into consideration that Internet access alone does not always translate into its use for health information and support. Previous research suggests that the proportion of patients with Internet access who use the Internet for health information ranges from 89% among bariatric surgery patients to less than 50% among primary or tertiary care settings [4,19-22]. Thus, efforts should continue not only to improve Internet access among persons with medical conditions, but also to encourage their use of health-related information resources.

The unadjusted findings of the present study supported previous evidence of a geographic digital divide, as rural residents were less likely to use the Internet than their urban counterparts. Adjusted analysis, however, suggested that the characteristics of rural populations, rather than lower technology penetration in rural areas [11], accounts for the differences. With demographic and ecological conditions held constant, rural residents did not differ from their urban peers. In particular, the job-related factors included in the model (job density and occupational type) may explain the rural-urban differences found in the unadjusted analysis. Rural residents were more likely to be in low job density areas and to work in nonwhite-collar occupations, both of which were associated with a reduced likelihood of Internet use [12,13]. This is further supported by rural residents’ report of higher Internet use at home only (44.7%) than urban residents (38.8%).

Our study also confirmed previous work suggesting lower Internet use among African American and Hispanic populations [14]. In both unadjusted and adjusted analyses, all minority groups were less likely than whites to report Internet access within the past 6 months. Disparities in frequent use and use at home persisted among African American and Hispanic respondents even after statistical adjustment for income, education, occupation, and other demographic characteristics. Further research is needed to determine whether these disparities, measured in 2001-2002, persist 8 years later. Should this be the case, additional research will need to explore whether minority populations perceive Internet access to be of lesser utility than do white populations, or experience other cultural barriers to use.

Our study has several limitations. First, the NHTS was not designed for health research; thus, using it to define medically limited individuals may lead to overestimation of those who may be clinically disabled. In addition, all data are based on respondent self-report, which may bias findings in an unknown direction. On the other hand, the NHTS was the only source for information on both travel limitations and Internet use from a random sample of the US population. A second limitation is that the NHTS defines rural differently from many traditional geographic analyses; however, the use of deciles closely mirrors alternative measures, providing a suitable proxy for rurality. The age of the data (2001-2002) may reduce the generalizability of the findings given the rate of technological advancement; future analyses will use newer data as it comes available. Finally, this survey did not inquire about what types of information the user was seeking while accessing the Internet. It would be helpful to know, for example, whether those who have a medical condition that limits travel are seeking health information on the Internet at a rate that differs from those who are not limited.

Despite the limitations, the findings of the present analysis remain important and relevant: the digital divide persists for several vulnerable populations. While it is posited that Internet access can make health expertise broadly available, persons with medical conditions that limit travel, who might benefit from such access, were less likely to use the Internet than their peers. African American and Hispanics also were affected by the digital divide. For rural residents, multivariate analysis suggests that personal characteristics, rather than geography, limit Internet access and use.

Acknowledgments

This research was supported in part by Grant No. 6 U1C RH 00045-01 from the Federal Office of Rural Health Policy, Health Resources and Services Administration, and a grant from China Medical University, Taiwan (Grant No. CMU98-N2-18). We thank Dr. Andrew Johnson at the Department of Health Services Management, University of Kentucky, for his contributions to this study.

Conflicts of Interest

None declared

Authors' Contributions

Dr. Wang performed the analysis, wrote the results, and materially contributed to the literature review and the discussion. Dr. Bennett contributed to the literature review and discussion sections, aided in editing of the manuscript, and prepared the manuscript for submission. Dr. Probst aided in the analysis and wrote the discussion.

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Abbreviations

NHTS: National Household Travel Survey
OR: odds ratio

Edited by G Eysenbach; submitted 24.03.10; peer-reviewed by N Menachemi, N Zhang; comments to author 27.05.10; revised version received 15.11.10; accepted 15.11.10; published 03.03.11.

Please cite as:
Wang JY, Bennett K, Probst J
Subdividing the Digital Divide: Differences in Internet Access and Use among Rural Residents with Medical Limitations
J Med Internet Res 2011;13(1):e25
URL: http://www.jmir.org/2011/1/e25/
doi:10.2196/jmir.1534
PMID:21371989

Original Paper

Trust in the Internet as a Health Resource Among Older Adults: Analysis of Data from a Nationally Representative Survey

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Abstract

Background: Distrust in the Internet as a source of health information remains common among older adults. The influence of this distrust on Internet use for health-related purposes, however, is unclear.

Objective: The objective of our study was to explore how older adults' trust in the Internet influences their online health-related activities, and to identify potential targets for improving health-related Internet resources for older adults.

Methods: Data were obtained from a nationally representative, random digit-dial telephone survey of 1450 adults 50 years of age and older in the United States. A model was developed to conceptualize the hypothesized relationships among individual characteristics, distrust, and avoidance of the Internet as a health resource. Multivariate logistic regression analyses were conducted to examine the association between trust in online health information and use of the Internet for health-related purposes. Additional multivariate logistic regression analyses were conducted to identify the key characteristics associated with trust in online health information, adding sequentially the variables hypothesized to account for distrust among older adults: sociodemographic and health characteristics, inexperience and technical difficulties with the Internet, negative feelings toward the Internet, and lack of awareness about the sources providing the health information found online.

Results: The mean (SD) age of the study population was 63.7 (10.6) years. Of the 823 (56.8%) Internet users, 628 (76.3%) reported using the Internet as a health resource. Trust in the Internet as a source of health information was associated with using the Internet for a number of health activities, including searching for information about a specific health condition (adjusted OR 4.43, $P < .001$), purchasing prescription drugs (adjusted OR 2.61, $P = .03$), and talking with a health care provider about information found online (adjusted OR 2.54, $P = .002$). Older adults (age ≥65 years) were less likely to trust the Internet as a source of health information (OR 0.63, $P = .04$), even after adjusting for other sociodemographic characteristics and health and function. This age effect was only slightly attenuated (adjusted OR 0.69, $P = .13$) after adjusting for inexperience and technical difficulties with the Internet, but it disappeared entirely (adjusted OR 0.96, $P = .91$) after adjusting for other hypothesized contributors to distrust (including finding the Internet confusing because it provides "too much information," and lacking awareness about the source providing health information found online).

Conclusions: Website design features that clearly identify the source and credibility of information and minimize confusion may build trust among older adults and offer an opportunity to increase the utility of the Internet as a health resource for this population.

(J Med Internet Res 2011;13(1):e19) doi:10.2196/jmir.1552

KEYWORDS

Older adults; Trust; Online health information

Introduction

The Internet is a potentially important source of health information, providing accessible resources on topics ranging from specific diseases and treatment options, to health care providers and insurance plans, to healthy lifestyle choices and health products. The number of adults in the United States who report using the Internet as a source of health information increased from 25% in 2000 to 61% (or 83% of Internet users) in 2008 [1]. In fact, the Internet has become the first source that many people turn to for information about certain health conditions [2].

Older adults, a population in which the vast majority have one or more chronic health conditions [3], could stand to benefit tremendously from the convenient and inexpensive health resources provided by the Internet. Nevertheless, this group remains a relative minority in their direct use of online health information [4-6], with a recent Pew Internet survey finding that only 27% of adults aged 65 years and older and 59% of adults aged 50 to 64 years look online for information about health and medical issues (compared to 71%-72% of adults aged 18-49 years) [1].

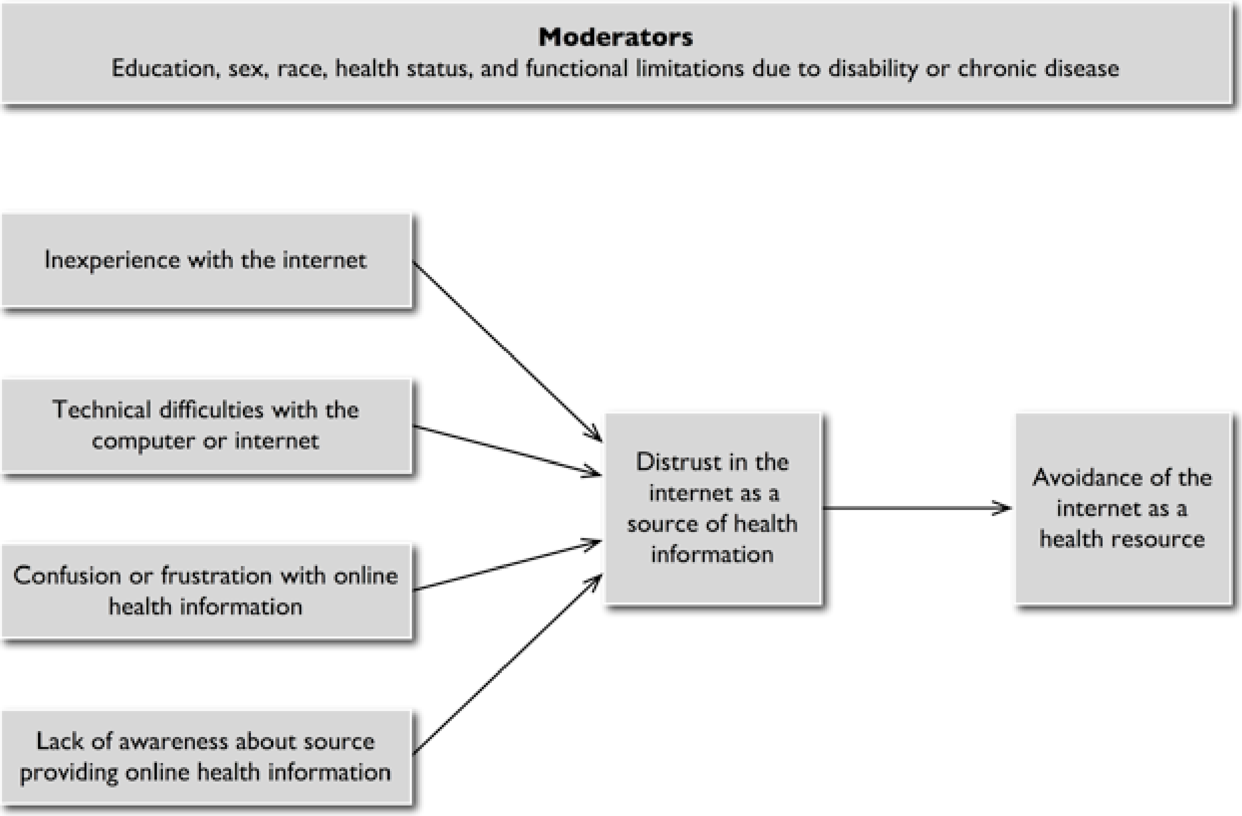
There are several possible explanations why use of Internet health resources remains low among older adults. First, barriers such as inexperience with technology or physical limitations may restrict computer usage by some individuals. For example, certain resources may be inaccessible due to website design factors such as small font size, overwhelming amounts of information, cluttered webpages, and lack of instructions [7,8]. Second, older individuals might prefer traditional sources of health information, such as physicians and pharmacists, over less familiar sources such as the Internet. These traditional sources of health information are sometimes referred to as “intermediaries,” experts who act as middlemen, providing consumers with the information that they seek. Online health resources, on the other hand, can be considered “apomediaries,” because they steer consumers to desired health information without standing between them [8]. While such resources have a number of benefits, they demand a certain level of knowledge, interest, and self-efficacy from users. Older adults, especially those with limited experience using technology, may have higher rates of computer-related anxiety and low computer self-efficacy, both of which correlate with slow technology adoption [9]. Further, these characteristics may lead to low levels of autonomy, resulting in a preference for more traditional sources of health information [8].

Finally, trust is likely to be another key factor in determining whether the Internet is a preferred source of health information [10]. While a universal definition of trust remains elusive among social scientists [11,12], it is generally accepted that the need for trust arises in the setting of risk, and that trust involves confidence in the reliability of an entity. Studies have shown that older adults are less likely than their younger counterparts to trust the Internet for health information [6,13,14]. One reason for this distrust may be due to difficulties assessing the credibility of online information sources. Credibility, or the believability, of a source is made up of two dimensions: trustworthiness (as subjectively perceived by the Internet user) and expertise (also subjectively perceived by the user, but sometimes influenced by objective characteristics such as comprehensiveness of information or sponsor’s credentials [15,16]). Older adults, who may be accustomed to trusting a health care provider for information, might find the process of assessing credibility of online material overwhelming, leading to general distrust in the Internet for any health-related purpose.

Distrust in online health information may be protective in certain circumstances [17], creating a motivating force for caution in a setting where not all sources are reliable. In 1997, an editorial in the *Journal of the American Medical Association* warned, “Let the reader and viewer beware,” because when it came to medical information on the Internet, “Those seeking to promote informed, intelligent discussion often sit byte by byte with those whose sole purpose is to advance a political point of view or make a fast buck” [18; page 1244]. While this warning still holds true today, the growing availability of patient portals and patient-driven online health communities [1] is gradually moving us toward a world in which the majority of our health care transactions and most available health information will be online. In this scenario, distrust and other existing obstacles to the use of Internet health resources could become substantial barriers to health care access and quality [10].

We sought to explore the role of trust in older adults’ use of the Internet as a health resource, using a nationally representative telephone survey that examined the utilization of and attitudes toward the Internet as a source of health information among adults 50 years of age and older. We developed a model that conceptualized potential relationships among individual characteristics, distrust in the Internet, and avoidance of the Internet as a health resource (Figure 1). We then performed a series of analyses in order to (1) explore the association between trust in the Internet and use of the Internet for health information and other health-related activities, and (2) identify potential targets for improving health-related Internet resources for older adults.

Figure 1. Characteristics hypothesized to influence distrust and avoidance of the Internet as a health resource among older adults



Methods

Data for this study were obtained from a Kaiser Family Foundation survey of health-related Internet use among adults 50 years of age and older. Details of the survey have been published previously [19]. Briefly, the survey was designed in consultation with Princeton Survey Research Associates (PSRA). PSRA conducted the telephone interviews in English between March 5 and April 18, 2004. The sample was drawn using standard list-assisted random digit-dialing methodology. As many as 10 attempts were made to contact every sampled telephone number.

A nationally representative sample of 1450 adults aged 50 years and older were interviewed, including 583 respondents aged 65 years and older. The overall response rate was 38% (the contact rate was 82%, 51% of those contacted consented to an interview, and 90% of those who consented completed the interview). The interviewed sample was weighted to match national parameters established by the US Census Bureau’s 2003 Annual Social and Economic Supplement for sex, age, education, race, Hispanic origin, US region, and number of adults in the household age 50 years or older. The margin of sampling error for the complete set of weighted data was ±3%, and for those aged 65 years and older it was ±4%.

Dependent Variables

Use of the Internet as a Health Resource

Survey respondents were asked a series of yes/no questions about whether they had ever used the Internet for a range of health activities, including obtaining information about a specific health condition or topic (including cancer, heart disease, arthritis, diabetes, Alzheimer’s disease, osteoporosis, high cholesterol, nutrition/exercise/weight loss, or mental health issues like depression or anxiety); obtaining information about a doctor, hospital, nursing home, home health agency, or other health care provider; looking for news about health policy issues; comparing prices for prescription drugs; and purchasing prescription drugs, vitamins, and supplements. Responses to these questions were analyzed first by constructing a single dichotomous dependent variable that captured any indication of having used the Internet as a health resource, and then in separate analyses in which each specific health-related activity was assessed as a dichotomous dependent variable. All respondents who indicated that they used the Internet for any health-related purpose were also asked whether online information had ever prompted them to change their behavior, to make a decision about a medical condition, to visit or talk to a health care provider, to change their health insurance plan, or to have a conversation with a friend or family member about the online health information.

Usefulness of the Internet as a Health Resource

Usefulness of the Internet as a health resource was assessed using the question, “How much has the information you have found on the Internet helped you take care of your health?” Responses were dichotomized as “somewhat” or “a lot” versus “only a little” or “not at all.”

Trust in the Internet as a Source of Health Information

All survey respondents were asked how much they trust the Internet “to provide accurate information about health problems or issues that are important to you." Responses were dichotomized as "somewhat" or "a lot" versus "not too much" or "not at all." The same question was also asked for other information sources, including health care providers, pharmacists, newspapers, magazines, books, television, radio, and friends or family. A mean trust score for non-Internet sources was calculated, and this score was used to adjust analyses for general trust in health information resources.

Independent Variables

Sociodemographics

Sociodemographic characteristics included age (analyzed as a continuous variable, and dichotomized using the prespecified cutoff of 65 years), sex, race (dichotomized as white and nonwhite), and education (categorized as high school or less, some post-high school education, and college graduate).

Health and Functional Status

Respondents were questioned about their overall health using a 5-point scale (collapsed as fair or poor, versus excellent, very good, or good). Their overall functional status was assessed with a single question: "Does any disability, handicap, or chronic disease keep you from participating fully in work, school, housework, or other activities?"

Internet Experience and Technical Difficulties

Respondents who reported using the Internet were asked how many years have passed since they first started going online (dichotomized as >5 years and ≤5 years). They were also asked how often they have technical problems with their computer or Internet access (categorized as often, sometimes, not too often, or never).

Reasons for Distrust Among Older Adults

Three additional survey questions were selected as measuring potential reasons for distrust among older adults. Respondents who used the Internet to look for health information were asked whether they would describe their experience as "frustrating because it's hard to find what I'm looking for," or "confusing because there's too much information." They were also asked how often they "look to see who provides the health and medical information" they find on the Internet (dichotomized as always, most of the time, or sometimes, versus hardly ever or never). This last question was used to test our hypothesis that individuals who were aware of the source providing online health information would be more likely to trust the information they obtained.

Statistical Analysis

Descriptive statistics of survey respondents' Internet use have been published previously [19]. We conducted a multivariate logistic regression of Internet users (n = 823) in order to identify how trust is associated with a person using the Internet as a health resource, and with that person finding the Internet useful as a health resource. We adjusted our models for individuals' health status and functional limitations, for inexperience and technical difficulties with the Internet, and for sociodemographics including age, sex, race, and education. Because of the large number of missing values for income (411/1450, 28.3%) and the strong correlation between income and education ($r = 0.49$), income was not included in any of our multivariate models.

We conducted additional analyses to identify the relationship between trust and a number of specific health-related Internet activities, including use of the Internet to obtain information about a specific health condition or health provider, to look for health policy news, and to purchase prescription drugs or make a treatment decision. These analyses were adjusted for sociodemographic and health characteristics.

Finally, we conducted sequential analyses examining potential underlying factors responsible for older adults' distrust in online health information. We first looked at the bivariate relationships between all independent variables and trust. We then conducted three multivariate logistic regressions, adding sequentially groups of variables that we hypothesized might influence the relationship between age and trust. In Model 1, we included sociodemographic characteristics (sex, race, and education), as well as the respondent's self-reported health status and functional limitations. In Model 2, we added years of Internet experience and frequency of technical difficulties with the computer or Internet. In Model 3, we added other hypothesized reasons for distrust: feelings of frustration or confusion toward online health information, and lack of awareness about the source providing the online health information. We also examined our full model after adjusting for individuals' trust in all non-Internet sources of health information.

Regression diagnostic procedures yielded no evidence of multicolinearity in any of the regression models (mean variance inflation factor = 1.21). Rates of item-level missing data were less than 5% for all independent variables used in analyses. Survey weights were used to adjust for the sampling design of the study. We performed all analyses using Stata version 11.0 (StataCorp, College Station, TX). All data were deidentified prior to acquisition of the dataset from the Kaiser Family Foundation.

Results

The mean (SD) age of the overall study population was 63.7 (10.6) years. There were 823 (56.8%) respondents who reported using the Internet, and the mean (SD) age of this subgroup was significantly younger than the subgroup of individuals who had never used the Internet, at 59.3 (8.1) versus 69.4 (10.7), $P < .001$. Among the Internet users, 745/823 (90.6%) reported having a computer at home, 700 (85.2%) reported having Internet access at home, and 404 (49.6%) reported having 5 or more years of Internet experience. There were 411/811 respondents (50.2% of Internet users) who reported using the Internet daily. Additional characteristics of the study population are described in Table 1.

Table 1. Characteristics of the study population

	Total population (N = 1450)			Online population (n = 823)		
	N	n	%	N	n	%
Sociodemographics and health status						
Age, mean (SD)	63.7 (10.6)			59.3 (8.1)		
≥65 years	1382	583	42.2	782	190	24.3
Sex, female	1450	915	63.1	823	489	59.4
Race, white	1409	1213	86.1	803	717	89.3
Education	1426			818		
Less than high school		171	12.0		27	3.3
High school graduate		520	36.5		216	26.4
Some college		337	23.6		244	29.8
College graduate		398	27.9		331	40.5
Employed	1431	620	43.3	815	480	58.9
Household income	1039			633		
<$30,000		398	38.3		124	19.6
$30,000-100,000		506	48.7		381	60.2
>$100,000		135	13.0		128	20.2
Fair or poor health status	1443	303	21.0	819	108	13.2
Functional limitations due to disability or chronic disease	1441	306	21.2	822	138	16.8
Primary caregiver for household member	1437	231	16.1	822	121	14.7
Computer and Internet Use						
Computer at home	1449	901	62.1	822	745	90.6
Internet access at home	1449	785	54.2	822	700	85.2
High-speed Internet access at home	1449	314	21.7	822	293	35.6
Internet experience >5 years	1449	404	27.9	814	404	49.6
Frequency of Internet use	1445			818		
Never		627	43.2		—	—
Less than weekly		111	7.7		111	13.6
Weekly		296	20.5		296	36.2
Daily		411	28.4		411	50.2
Frequency of Internet use for health information	1445			823		
Never		822	56.9		195	23.7
Less than monthly		389	26.9		389	47.3
Once or twice per month		158	10.9		158	19.2
At least weekly		76	5.3		76	9.2
Trust in Internet as a source of health information	1291			802		
Not at all		480	37.2		124	15.5
Not too much		125	9.7		89	11.1
Somewhat		478	37.0		404	50.4
A lot		208	16.1		185	23.1

There were 628 respondents who reported having used the Internet as a health resource (76.3% of Internet users), and more than a third of them did so at least once a month (Table 1).

Among Internet users, age was not a predictor of a person having used the Internet as a health resource (Table 2), and this remained true when we examined age as a continuous variable (adjusted OR 0.99, *P* = .64). Older adults were less likely than those under age 65 years to report that the Internet had helped them care for their health (OR 0.54, *P* = .02), but this effect was diminished after adjusting for trust, years of Internet experience, and other covariates (adjusted OR 0.65, *P* = .11). Trust, however, was significantly associated with using the Internet as a health resource (adjusted OR 4.84, *P* < .001) and with finding the Internet useful as a health resource (adjusted OR 3.74, *P* < .001).

Table 2. Characteristics associated with a person using the Internet for health information and finding the Internet useful as a health resource

	Ever used the Internet for health information, N = 823 (Internet users)				Finds the Internet useful as a health resource, N = 628 (online health information users)			
	Unadj OR	*P*-value	Adj OR	*P*-value	Unadj OR	*P*-value	Adj OR	*P*-value
Main variables of interest								
Age ≥65 years[a]	0.78	.27	1.19	.48	0.54	.02	0.65	.11
Trust (somewhat/a lot) in Internet as source of health information[b]	5.87	<.001	4.84	<.001	3.75	<.001	3.74	<.001
Other covariates								
Female	1.27	.22	1.48	.10	1.41	.08	1.19	.44
Nonwhite	1.29	.45	1.31	.50	1.53	.18	2.02	.07
Education[b]								
Some post-high school education	1.48	.12	1.34	.33	1.15	.59	1.15	.64
College graduate	1.84	.01	1.43	.23	1.04	.87	0.83	.54
Fair/poor health status[b]	0.92	.78	0.95	.90	1.18	.60	1.03	.93
Functional limitations due to disability or chronic disease	1.28	.39	1.86	.17	0.89	.66	0.94	.85
Internet experience >5 years	1.91	.002	1.77	.035	1.30	.19	1.36	.21
Technical difficulties with computer/Internet	0.91	.52	0.98	.91	0.95	.68	0.97	.85

[a] Age is presented as a dichotomous variable for clarity. When age is analyzed as a continuous variable, the relationship with ever using the Internet for health information remains nonsignificant, but the relationship with finding the Internet useful as a health resource is significant (adjusted OR 0.97, *P* = .03).

[b] Comparison group is “not at all/not too much” for trust in online health information, “high school or less” for education, and “excellent/very good/good” for health status.

Trust was significantly associated with the performance of a number of online health-related activities, even after adjusting for sociodemographic and health characteristics. Individuals who reported trusting the Internet “somewhat” or “a lot” for health information were significantly more likely to report that they had searched for information about a specific health condition (adjusted OR 4.43, *P* < .001), and that they had used the Internet to obtain information about topics ranging from their health care provider (adjusted OR 2.24, *P* = .007), to health policy news (adjusted OR 3.37, *P* = .007), to prescription drug prices (adjusted OR 4.93, *P* < .001). They were also significantly more likely to purchase prescription drugs and nutritional supplements online (adjusted OR 2.61, *P* = .03 and adjusted OR 3.43, *P* = .002, respectively). In addition, among the 628 respondents who had any history of using the Internet for health information, those with higher levels of trust were more likely to change their behavior because of the online information (adjusted OR 2.15, *P* = .03), and they were more likely to talk with a health care provider about the online information (adjusted OR 2.54, *P* = .002).

Finally, in a series of multivariate logistic regression models in which we sequentially added variables of interest, we examined the relationship between age and trust in the Internet as a source of health information (Table 3). In bivariate analyses, Internet users 65 years of age and older were significantly less likely than those younger than 65 to report trusting the Internet for health information (OR 0.63, *P* = .04). This relationship persisted after adjusting for other sociodemographic and health characteristics (Model 1), and was only slightly attenuated (adjusted OR 0.69, *P* = .13) after adjusting for Internet experience and technical difficulties with computers and the Internet (Model 2). The age effect disappeared entirely (adjusted OR 0.96, *P* = .91), however, after adjusting for other hypothesized contributors to distrust (Model 3), such as finding the Internet confusing because it provides “too much information” (adjusted OR 0.47, *P* = .03), and not routinely identifying the provider of online health information (adjusted OR 0.53, *P* = .04). These relationships were virtually unchanged when we adjusted for overall trust levels in non-Internet sources of health information.

Table 3. Characteristics associated with trust in the Internet as a source of health information among adults ≥50 years of age who use the Internet (n = 823)

	Bivariate relationships		Model 1: age, sex, race, education, and health and function		Model 2: Model 1 + Internet experience and technical difficulties		Model 3: Model 2 + other hypothesized reasons for distrust	
	Unadj OR	*P*-value	Adj OR	*P*-value	Adj OR	*P*-value	Adj OR	*P*-value
Age ≥65 years [a]	0.63	.04	0.63	.04	0.69	.13	0.96	.91
Female	1.48	.04	1.67	.01	1.79	.01	1.46	.21
Education[b]								
Some post-high school education	1.45	.13	1.31	.29	0.91	.73	0.68	.30
College graduate	2.47	<.001	2.53	<.001	1.81	.04	0.98	.96
Nonwhite	1.21	.55	1.13	.73	1.13	.75	0.90	.84
Fair/poor health status[b]	0.80	.43	0.90	.74	1.42	.37	1.79	.32
Functional limitations due to disability or chronic disease	0.70	.17	0.89	.71	1.03	.93	1.09	.85
Internet experience >5 years	1.62	.02	—		1.78	.02	1.25	.50
Technical difficulties with computer/Internet	0.89	.41	—		1.03	.84	0.92	.69
Negative feelings toward online health information								
Frustrating: hard to find what is needed	0.49	.009					0.99	.99
Confusing: too much information	0.53	.02	—		—		0.47	.03
Lack of awareness (never/hardly ever) of source providing health information found online[b]	0.42	.002	—		—		0.53	.04

[a] Age is presented as a dichotomous variable for clarity. When age is analyzed as a continuous variable, the adjusted ORs and *P*-values for Models 1, 2, and 3 are as follows: Model 1 = 0.96 (*P* = .002), Model 2 = 0.96 (*P* = .006), Model 3 = 0.99 (*P* = .77). Adjusted ORs and *P*-values for other covariates in the models are essentially unchanged when age is analyzed as a continuous variable.

[b] Comparison group is "high school or less" for education, "excellent/very good/good" for health status, and "sometimes/mostly/always" for awareness of online health information source.

Discussion

In this nationally representative survey of adults aged 50 years and older, we found that individuals who reported trusting the Internet as an information source were significantly more likely to report that the Internet had helped them care for their health, and were also more likely to use the Internet for a number of important health-related activities, including searching for information about a specific health condition, comparing prescription drug prices and purchasing medications, obtaining information about a health care provider, and talking with their provider about information found online.

While the relationship between trust and Internet use appears intuitive, there are many circumstances in which distrust in online health information is appropriate [17]. The Internet lacks an effective quality control mechanism, and this, combined with the ease of replicating online material, leads to the spread of false information [20]. Older adults, many of whom use the Internet for a relatively limited number of functions and are unfamiliar with a metric for trustworthiness, are likely to have low levels of autonomy and may not have the tools that are required to assess the credibility of online health information. Our findings suggest that older adults' distrust may be a significant barrier to their optimal usage of the Internet for their health. This is of concern, given that the Internet offers an efficient means to obtain information and conduct important health-related activities, and many websites today provide reliable, up-to-date, and sometimes tailored health information. Such a resource could be especially valuable for someone who is homebound due to multiple health problems or because of their caregiving obligations.

As the Internet's capabilities as a health resource expand, it is important that older individuals be provided with tools and knowledge to assess the credibility of online health information [15]. This is especially critical given that dubious information regarding medical issues can result in physical or mental harm [8]. The results of our study highlight several potential targets for improving older adults' trust in the Internet as a health resource. While adults aged 65 years and older were significantly less likely to trust the Internet for health information, this association disappeared after accounting for two significant factors: one was confusion due to overwhelming amounts of information, and the other was lack of awareness about the source providing health information found online (a key step to assessing the credibility of a website). These issues could be addressed through websites that incorporate senior-friendly design elements (eg, an uncluttered layout with a large font size and comfortably sized buttons and links) [7,21] and through the promotion of websites that are clearly associated with trustworthy institutions (ie, via credibility cues like images and logos) [22]. Clarifying the source and credibility of information may be especially important for individuals with lower levels of autonomy who tend to gravitate toward traditional intermediaries for health information [8].

An example of a site that embraces these concepts is the NIH Senior Health website, which presents information from government agencies such as the National Cancer Institute and the National Institute on Aging about a multitude of health conditions. The website is tailored to meet the needs of an older, less-experienced Internet user, with a simple design, and options to increase the text size, enhance contrast, and hear the text read aloud [23]. The growth of health portals may provide other trustworthy sources of information. Portals such as those developed for patients of Kaiser Permanente [24], Group Health Cooperative [25], and the Veterans Affairs Healthcare System [26] direct users to reliable information and expertise that is often personally tailored to an individual's specific health needs [10]. A survey of Kaiser Permanente patients found that 87% of respondents over the age of 65 years were satisfied with Kaiser's My Health Manager [27]. The role of such portals for older individuals who distrust or avoid using the Internet for their health, however, remains to be seen.

While the data for our study were derived from a nationally representative sample of adults aged 50 years and older, the structure of the survey introduced some limitations. Our reliance on an existing dataset necessitated the use of available measures, including measures that were created de novo for the survey and have not been externally validated. There may be unmeasured characteristics that influence a person's trust in online health information but were not assessed in this survey, such as general trustfulness and specific health issues and information needs. In addition, the data in this study were cross-sectional, and as such we cannot make any conclusions about causality or mediation in our analyses. Biases may have resulted from nonresponse and from self-reported data, with common method variance potentially explaining some degree of the high level of internal consistency we saw in certain constructs. Finally, our use of 2004 data is also a limitation, given demographic changes in Internet usage and the rise of new website features, such as the option of communicating with health care providers online, and the growth of well-informed online patient communities. Nevertheless, this survey covered unique territory, and there is reason to believe that the association between trust and information-seeking behavior could transcend the developments since the survey was conducted.

In conclusion, in this nationally representative sample of older adults, we found that trust in online health information is significantly linked to use of the Internet for a wide range of health-related purposes. While the association between distrust and diminished use of the Internet is not surprising, the strength and consistency of this relationship suggests that building trust, in part through the development and promotion of simple and credible websites and health portals, is likely to be a crucial step in improving the accessibility and utility of online health resources for older adults. Future research should focus on identifying the specific design features, content, and functions that will optimize the value of such resources.

Acknowledgments

The authors thank the Kaiser Family Foundation for providing the survey data, and especially thank Vicky Rideout, Vice President for Media and Education, for her role in developing the survey. The authors also thank Michele Heisler for her feedback regarding data analysis, and Shirley Chen for her assistance with manuscript preparation. This article was made available as Open Access with the support of the University of Michigan COPE Fund, http://lib.umich.edu/cope.

Conflicts of Interest

None declared

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Abbreviations

PSRA: Princeton Survey Research Associates

Edited by G Eysenbach; submitted 19.04.10; peer-reviewed by E Montague; comments to author 28.07.10; revised version received 14.09.10; accepted 05.10.10; published 16.02.11.

Please cite as:
Zulman DM, Kirch M, Zheng K, An LC
Trust in the Internet as a Health Resource Among Older Adults: Analysis of Data from a Nationally Representative Survey
J Med Internet Res 2011;13(1):e19
URL: http://www.jmir.org/2011/1/e19/
doi:10.2196/jmir.1552
PMID:21324832

Original Paper

Presenting Evidence to Patients Online: What Do Web Users Think of Consumer Summaries of Cochrane Musculoskeletal Reviews?

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Abstract

Background: The Internet has the potential to be an effective medium for delivering health care knowledge to consumers. While computer usability research makes recommendations about how to present Web-based information generally, there remains no clear guidance on how to present specific forms of health care research evidence online in a way that facilitates understanding and good health care decision making.

Objective: The two goals of this study were to describe the Cochrane Musculoskeletal Group’s (CMSG’s) process for developing online patient-focused summaries of systematic reviews and to evaluate the impressions of these summaries formed by users.

Methods: A process for summarizing the results of systematic reviews via consumer summaries has evolved over 15 years. An evaluation of this approach took the form of Internet surveys on the Arthritis Society of Canada website and surveys of members of the Canadian Arthritis Patient Alliance (CAPA). Respondents provided information on background, relationship to the decision, their satisfaction with and preparation for decision making, and suggestions for improvements to the summaries. Survey data were collected between August 1, 2005, and February 28, 2006.

Results: A total of 261 respondents completed the survey. The majority (226/261 or 87%) of respondents reported having an arthritis-related condition. The consumer summary approach was generally reviewed favorably by respondents, with most agreeing that the summary provided appropriate information (177/261 or 68%), would be useful to others (160/261 or 61%), was well laid out (159/261 or 61%), was easy to learn from (157/261 or 60%), and was useful to the reader (153/261 or 59%). Areas of potential improvement were indicated by relatively fewer respondents agreeing that they could easily find all the information they wanted (118/261 or 45%), by a substantial proportion being unable to judge whether the providers of the information are reliable (80/261 or 31%), and by a similar proportion being unable to determine whether the information presented was the best available (68/261 or 26%).

Conclusions: The CMSG has developed an approach to summarizing the results of often-technical systematic reviews into public-friendly consumer summaries. Our online survey showed that this approach was generally well liked but identified specific areas for improvement. Feedback from this survey will help to reshape and improve the current template for consumer summaries used by the CMSG.

(J Med Internet Res 2011;13(1):e5) doi:10.2196/jmir.1532

KEYWORDS

Decision support techniques; health care surveys; Internet; patient education; patient satisfaction; patient-centered care; musculoskeletal diseases

Introduction

Background

A key aspect of the rapidly changing face of health care is the explosion of knowledge targeted at health care consumers. In part, because of advancing information technology allowing access to them, knowledge producers are increasingly seeing consumers as an important target group. In a recent review of 56 Canadian organizations producing practice guidelines between 2000 and 2005, it was found that 630 unique guidelines had been developed; of these, 42.7% included consumer versions or were intended for consumers [1]. Furthermore, many major governmental and nonprofit organizations such as the UK National Institute for Health and Clinical Excellence (NICE) [2], the US Agency for Healthcare Research and Quality (AHRQ) [3], the Journal of the American Medical Association [4], the Cochrane Collaboration [5], along with many patient condition-specific organizations (eg, Arthritis Society of Canada [6]) now disseminate research evidence directly to health care consumers, primarily via the Internet. Indeed, targeting patients can be an effective strategy to reduce the gap between research knowledge and clinical practice [7,8].

Development of consumer-targeted health knowledge is not only on the rise because of “push” from knowledge producers but also because of “pull” by consumers [9]. Consumers are often highly motivated to maximize the quality of their own care and are demanding greater involvement in decisions surrounding their own health care [10]. This is manifested as a demand for health care knowledge, with the Internet serving as an important mode of delivery. For example, about 80% of Canadians over the age of 16 now report using the Internet, with health information being the most commonly reported search topic [11,12].

The Internet has many advantages as a medium for delivering health care knowledge to consumers. For knowledge producers, the Web can provide wide distribution at relatively little cost. Its potential for interactivity can allow both an improved learning environment and data gathering alongside dissemination activities. Furthermore, knowledge can be updated with relative ease and low cost when compared to print or other media. For consumers, the Web is accessible, free, convenient, and allows for learning at a pace the individual finds most comfortable.

Despite these advantages, effective dissemination of online health care knowledge can be limited by variable quality and indeterminate reliability [13]. Relevant literatures exist, but have not been exploited. Computer usability research makes general recommendations about presenting Web-based information [14,15], but these lessons have often not been followed in presenting health information online. Similarly, considerable research from the patient decision-support and human decision-making literatures [16,17] has not been translated into specific recommendations for facilitating good decision making based on online health information. We propose that specific approaches to presenting health care research knowledge online to consumers need to be developed and evaluated.

The Cochrane Musculoskeletal Group (CMSG) has produced consumer summaries of over 100 of its systematic reviews of health care interventions for arthritis and other related conditions. These consumer summaries are targeted at patients but have only recently become widely available on the Internet and are now accessible by over half of the world’s population through country-level subscriptions to the Cochrane Library and consumer-targeted websites (eg, Arthritis Society of Canada [6] and Arthritis Victoria in Australia [18]).

While these summaries were developed with extensive consumer input, they were primarily developed in a paper format, which may not have translated well into effective online information tools. Guidance for producing effective online tools comes from at least two sources. First, the human-computer interaction literature identifies components of effective online information, as well as means to measure them [15]. For example, the extent to which a computer website is favorably rated by users has been categorized into 5 domains of satisfaction including aesthetics, likeability, usability, emotion, and expectation [14,19]. Second, a substantial literature has grown up around the Ottawa Decision Support Framework [16,20,21] focused on measuring constructs related to good-quality decision making. Based on this literature, we sought to examine the extent to which the CMSG summaries were seen to be relevant to such constructs.

Objectives

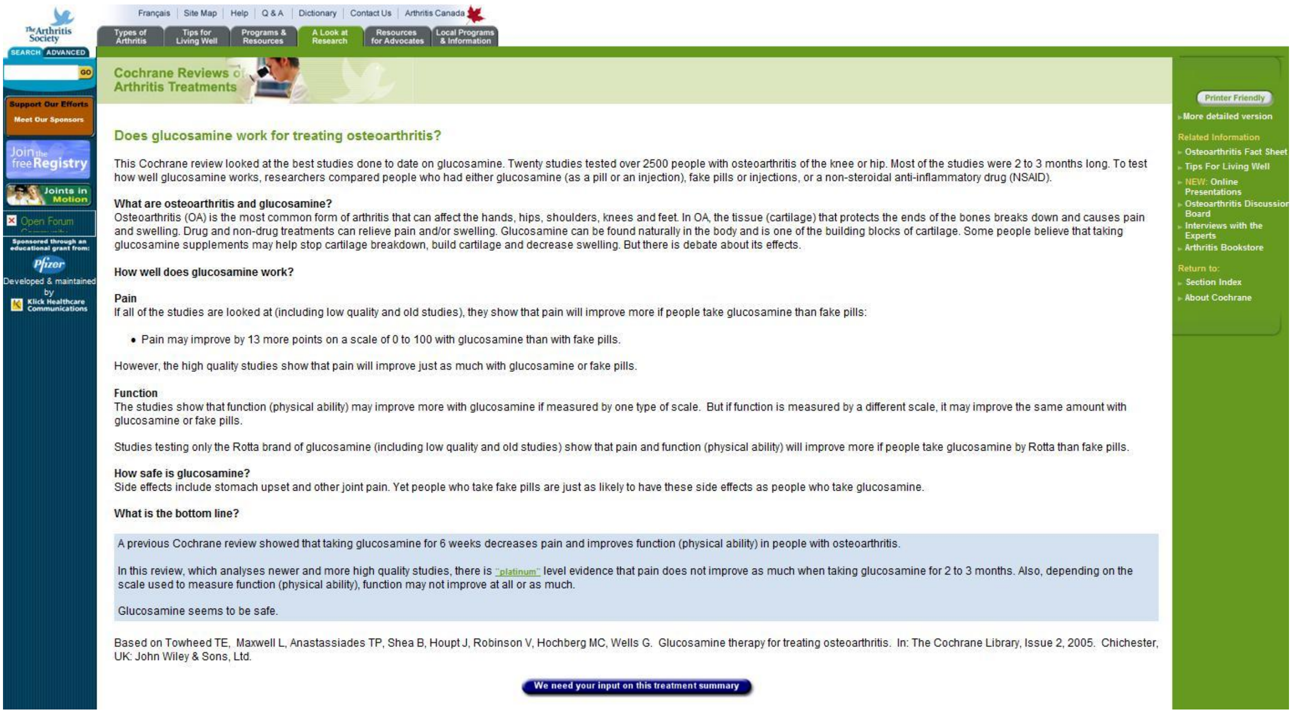
This paper had two primary objectives: (1) to provide a narrative describing the work of the CMSG in creating online consumer summaries of the evidence from systematic reviews and (2) to evaluate the impressions of these summaries formed by users of the Arthritis Society of Canada website via an Internet survey. This knowledge will contribute toward establishing guidelines about how to summarize and present research evidence to consumers on the Internet.

The Cochrane Musculoskeletal Group Consumer Summaries

The CMSG consumer summaries have evolved over the last 15 years. Initially developed on an ad hoc basis, they have been revised and standardized based on the recommendations of a variety of guidelines for creating patient information [22-24], evidence from research [25], and user feedback. Summaries are regularly distributed and feedback sought from consumer members of the CMSG at annual CMSG meetings and from consumers and research professionals at workshops at Cochrane Colloquium meetings [26,27].

What has resulted is the standard 1-page summary now used by the CMSG (see example, Figure 1). Each summary usually consists of no more than 400 words and typically takes consumers approximately 5 minutes to read. Each summary is divided into short sections with illustrative, standardized questions as headers. An introductory section (section 1) provides background on what and who was studied and mentions the Cochrane Collaboration as the source of the information. Section 2 answers questions about the intervention and the condition, for example, “What are osteoarthritis and glucosamine?” Section 3 answers questions about the effectiveness of the intervention, for example, “How well does glucosamine work?” Section 4 answers questions about safety, explicitly addressing both benefits and harms, for example, “How safe is glucosamine?” The final section provides a single-statement summary of the overall meaning of the results and provides a Web link to the description of the level of evidence underlying these statements (ie, platinum, gold, silver, and bronze levels of evidence). This method for grading scientific evidence was derived by Tugwell et al and incorporates the types of studies and quality of evidence into the ranking [28]. This section answers the question, “What is the bottom line?”

Figure 1. Example of a consumer summary



Does glucosamine work for treating osteoarthritis?

This Cochrane review looked at the best studies done to date on glucosamine. Twenty studies tested over 2500 people with osteoarthritis of the knee or hip. Most of the studies were 2 to 3 months long. To test how well glucosamine works, researchers compared people who had either glucosamine (as a pill or an injection), fake pills or injections, or a non-steroidal anti-inflammatory drug (NSAID).

What are osteoarthritis and glucosamine?
Osteoarthritis (OA) is the most common form of arthritis that can affect the hands, hips, shoulders, knees and feet. In OA, the tissue (cartilage) that protects the ends of the bones breaks down and causes pain and swelling. Drug and non-drug treatments can relieve pain and/or swelling. Glucosamine can be found naturally in the body and is one of the building blocks of cartilage. Some people believe that taking glucosamine supplements may help stop cartilage breakdown, build cartilage and decrease swelling. But there is debate about its effects.

How well does glucosamine work?

Pain
If all of the studies are looked at (including low quality and old studies), they show that pain will improve more if people take glucosamine than fake pills:

- Pain may improve by 13 more points on a scale of 0 to 100 with glucosamine than with fake pills.

However, the high quality studies show that pain will improve just as much with glucosamine or fake pills.

Function
The studies show that function (physical ability) may improve more with glucosamine if measured by one type of scale. But if function is measured by a different scale, it may improve the same amount with glucosamine or fake pills.

Studies testing only the Rotta brand of glucosamine (including low quality and old studies) show that pain and function (physical ability) will improve more if people take glucosamine by Rotta than fake pills.

How safe is glucosamine?
Side effects include stomach upset and other joint pain. Yet people who take fake pills are just as likely to have these side effects as people who take glucosamine.

What is the bottom line?

A previous Cochrane review showed that taking glucosamine for 6 weeks decreases pain and improves function (physical ability) in people with osteoarthritis.

In this review, which analyses newer and more high quality studies, there is "platinum" level evidence that pain does not improve as much when taking glucosamine for 2 to 3 months. Also, depending on the scale used to measure function (physical ability), function may not improve at all or as much.

Glucosamine seems to be safe.

Based on Towheed TE, Maxwell L, Anastassiades TP, Shea B, Houpt J, Robinson V, Hochberg MC, Wells G. Glucosamine therapy for treating osteoarthritis. In: The Cochrane Library, Issue 2, 2005. Chichester, UK: John Wiley & Sons, Ltd.

Sections are kept short, and information is provided in a logical flow to facilitate interpretation by a wide range of audiences. While formal readability evaluations have been carried out at various points during the development process of these summaries, questions about the validity of formal readability evaluations have been noted [29]. We found that for these summaries the technical terminology describing the diseases and treatments in CMSG reviews often inflated readability scores, while eliminating this terminology to reduce readability scores often caused more problems than it solved for users. Rather than relying on formal readability scores, we opted to ensure that all technical terms were clearly defined, and that all language was clear and readable. We saw readability analysis, therefore, as a means to end (a readable document dealing with technical issues) rather than an end itself (a document with a particular readability score).

We also strove to maintain the active voice throughout, based on the recommendations of a number of guidelines [30-32]. When available, outcome probabilities are presented in natural frequencies with consistent denominators (eg, “72 out of 100”), explicitly describe the time frame to which the results apply (eg, “after 6 months of treatment, 10 patients out of 100 will improve will improve”), and present the numbers in multiple ways (eg, “this means that 12 more people will improve”) to facilitate understanding [16]. Table 1 describes what we see as key components of successful summaries as informed by the experience of the CMSG development process. While these individual recommendations have not been empirically tested in the current context, their combination gave rise to the summaries evaluated here.

Table 1. Preliminary recommendations for presenting consumer summaries online

Recommendations	
1	Consider existing standards for clear presentation of risk information (eg, [16])
2	Pilot test individual summaries on the target audience
3	Provide links to definitions for technical terms
4	Maintain consistent formatting between summaries
5	Consider providing information-rich displays (eg, charts and graphs) in addition to clear language
6	Consider the readability, or in cases where technical terms are unavoidable, the lexical density of the language
7	Indicate level of evidence supporting risk estimates (eg, gold and silver)
8	Provide links to more detailed information
9	Prominently display information on the provider and timeliness of the information
10	Keep summaries short (at approximately 400 words) and provide short bottom-line statements of key messages

In total, over 100 consumer summaries of systematic reviews for treatments of arthritis-related conditions have been produced and made available by the CMSG between 1993 and 2005. All are available online through the Arthritis Society of Canada website [6] and were the focus of our online survey. This site contains a wide variety of information about the many conditions related to arthritis, tips for living well, drug information, discussion forums, self-management programs, and research information. The consumer summaries are located in the latter section of the website and can be reached in 2 clicks from the home page. The summaries are organized by type of arthritis, and links are provided to related information on the website. To evaluate and improve the summaries, we conducted a Web-based survey of a subset of visitors to the Arthritis Society Website who read 1 or more CMSG summaries.

Methods

Survey: Overall Approach

Over the years, CMSG summaries have been subjected to many rounds of focus groups, interviews, and other forms of qualitative testing and evaluation. We chose to conduct an evaluation using a Web-based survey for 2 main reasons. First, the majority of this work was carried out on paper-based summaries, and we wanted to know how well the summaries translated to an online environment. Second, most of this qualitative testing was carried out on a select sample of people who were closely aligned with the CMSG, and we wanted to elicit the impressions of a wider range of types of respondents. In addition, while our survey should not be considered theory-derived, the choice of constructs was primarily informed by principles of computer usability [15,19] and the Ottawa Decision Support Framework [20,21], around which constructs relevant to good quality decision making have been developed.

Survey Development

This study was approved by the Ottawa Hospital Research Ethics Board. We designed an exploratory Web-based survey to evaluate user impressions of the CMSG consumer summaries. After the author group identified all the key constructs to be included in the survey, reviews of the literature were carried out for validated measures of the relevant constructs, and, where appropriate, such measures were included in the original survey or versions modified for Web-based administration. An iterative process of design, evaluation by the author team, and redesign resulted in a draft version of the survey that was programmed for the Web. The survey was then pilot tested at the Carleton University Human Oriented Technology Laboratory by 5 senior students trained in issues of computer usability. These students completed the survey and provided feedback on how to improve the aesthetic qualities, layout, content, and navigational ease of the survey.

The final version of the survey consisted of a cover letter and 5 sections and included both open-ended questions and closed-ended questions with pull-down menu or check box-type response options.

The cover letter of the survey included the names of principal investigators on the project, the purpose of the study, and the length of time the survey was expected to take. It also stated that completion and submission of the survey would serve as tacit consent that the subject’s responses could be used in the study. Details of duration and location of data storage were not provided unless specifically requested by the participant.

The survey consisted of 5 sections. The first addressed summary-specific issues such as how long participants had spent reading the summary. Subsequent sections included items on user experience, satisfaction with the way the information prepared them for decision making, experience with computers, background/demographic information, and suggestions for improvement. The complete survey consisted of 1 screen displaying a total of 53 items.

Survey Questions

Summary-specific items measured the time spent reading the summary as an indirect measure of the care with which reviewers read the items (categorized in 5-minute increments). Also measured was confidence in participants’ understanding of the key points of the summary (on a 5-point scale from “not at all” to “very” confident) as a key prerequisite of good decision making as described by the Ottawa Decision Support Framework [20,21]. Finally, items targeting the extent to which the respondent was closely related to the issue included how participants had discovered the treatment summaries (ie, by exploring arthritis.ca, through a search engine, a recommendation of a physician, friends/family, or a support group, or other); participants' main reasons for reading the summary (ie, for personal relevance, general interest, or other), and interest in arthritis (ie, "I have arthritis," "I know someone with arthritis," or other). The summary the respondent had read was logged automatically.

Computer user experience was measured using 14 items (Table 4) related to 5 domains of user satisfaction [19] including (1) aesthetics, (2) likeability, (3) usability, (4) emotion, and (5) expectation. Each item was rated on a 6-point scale from "strongly disagree" to "strongly agree" with an option of "no opinion/don't know." Also, 4 items (the summary is boring, the summary is frustrating, learning from the summary seems hard, I had to read too much) were phrased in the opposite direction from the rest of the items, and reported item means were reversed for ease of comparison.

Satisfaction in how the information materials prepared them for decision making was measured using 11 items adapted from Graham and O'Connor [33]. Items elicited respondents' feelings of support and preparation to make decisions (Table 5). Items were rated on a 5-point scale from "not at all" to "a great deal." Finally, an open-ended question asked for advice on how the consumer summaries could be improved. Note that items from both the user experience and satisfaction with preparation for decision-making instruments were analyzed separately, as neither scale had been validated in the form administered in this survey. Our goal for these items was to describe people's impressions of the consumer summaries rather than target potential underlying constructs. Analysis and validation of underlying constructs for these items will be the subject of separate investigation.

We included 6 computer expertise items selected from a scale reported by Liaw et al [34], which asked respondents to self-report on their experience with (1) computers in general, (2) the Internet/World Wide Web, (3) Internet search engines, (4) word processing software, (5) database software, and (6) computer programming languages. Participants were asked to rate each of these 6 items on a 5-point scale ranging from 0, "none at all" to 4, "a great deal." The 6 items were summed to produce a scale score ranging from 0 to 24. We then categorized this scale into thirds to indicate respondents with low, middle, and high levels of self-reported computer experience.

Background questions included demographic questions about sex, age, education, location of residence, and employment status.

Sampling and Recruitment

Sample size for this descriptive survey was based on estimates of the amount of traffic to the website and the response rate to the online questionnaire. We chose to aim for 300 respondents to yield a wide range of opinions on each of the 10 summaries attached to the survey. In prior years, approximately 17,000 users visited the relevant section of the Arthritis Society of Canada website. From this pool, previous (1-question) surveys administered on this website had typically yielded 200 to 500 responses per month. Based on an estimated completion rate of 30% of that number, we planned to collect 60 to 150 responses per month and take between 2 and 5 months to collect the data.

Recruitment to the survey proved a bigger challenge than expected. As a result, we engaged in 3 relatively separate recruitment strategies. First, we used a convenience sampling strategy in which the administrator of the Arthritis Society of Canada website posted a link on the home page of the site encouraging any visitors to the site to consider completing a voluntary, Web-based, open version of the survey. Respondents were assured of the confidentiality of their data, but this version did not specifically state that ethics board approval had been granted. Second, the society distributed a letter on behalf of the study authors to the provincial Arthritis Society educational team leaders asking them to encourage their local members and contacts to complete the Web-based survey. Finally, an electronic invitation to participate in a closed version of the survey was sent to all 463 members of the Canadian Arthritis Patient Alliance (CAPA), an advocacy group closely related to the Arthritis Society of Canada. Members of CAPA typically have arthritis or have a strong interest in arthritis advocacy.

Administration

The Web survey was linked to 10 of the most popular CMSG summaries on the Arthritis Society of Canada website. All 10 summaries were standardized with regard to format and content as of July 2005 (see Figure 1).

Respondents chose the summary that was most relevant to them either by clicking on it during their Internet session or by being directed by an email recruitment letter to a list of the 10 target summaries. A link to the survey itself was appended to the bottom of each selected summary, and instructions on the survey indicated that participants should complete the survey about the summary they had just read. Summary topics addressed issues around various treatments for osteoarthritis, rheumatoid arthritis, and shoulder and elbow pain. Each summary generally described the effects of a single intervention, such as drug interventions (eg, methotrexate or glucosamine) or nonpharmacologic treatments (eg, exercise or ultrasound).

To the extent possible, administration of the closed version of the survey to CAPA members was governed by Dillman's Tailored Design Method [35]. A prenotification to complete the survey, an invitation to visit the summaries and complete the survey, and 2 reminder emails were sent via email. This version of the survey consisted of 1 screen displaying a total of 71 items including most questions from the earlier version (with the exception of 2 arthritis.ca website feedback items) plus 1 additional scale, the Medical Data Interpretation Test [36], which was excluded from analysis due to technical problems. An appendix with the CAPA prenotification, CAPA cover letter, CAPA survey, Web link on the Arthritis Society of Canada website, Web survey, and the 10 consumer summaries can be obtained from the authors. Correspondence assured respondents of the confidentiality of their data and stated that the survey had been approved by the Ottawa Hospital Research Ethics Board.

All survey items were provided in a consistent order for all participants; no randomization of questions was carried out. All participants saw the same questions; no adaptive questioning or question branching was required. Completion of items was not enforced and the options "not applicable," "no opinion," and "rather not say" were included for all items comprising preexisting scales. Respondents were not asked to review responses before submitting the survey. No incentives were provided for respondents to complete the survey.

Data Collection and Statistical Analysis

The online survey compiled respondent data automatically into a Microsoft Excel file maintained by the Arthritis Society Web master and provided to the study researchers. Data collected were anonymous, organized by identification numbers created by the Arthritis Society. Access to data was limited to the principal investigators and one research assistant. No technical methods were used to prevent multiple entries from the same individual. The reviewing agency flagged the use of "cookies" (ie, small pieces of software code placed on the user's machine from the survey server intended to track usage) as a potential ethical concern. The authors determined that the inclusion of cookies as a method of determining who had previously completed the survey adds little information over and above the use of the other acceptable methods (Web traffic logs or a specific question on the survey) and the use of cookies was not implemented for this study. As a result, the CAPA email survey provided a website link for respondents who previously completed the survey elsewhere, which advised against duplicate entries. Incomplete surveys were assessed manually by viewing Excel data files to determine whether any respondents had stopped short of completing the survey and simply submitted what had been completed. No statistical correction for nonrepresentative sampling was computed. Surveys were presented as a single webpage requiring 1 submission of data upon completion; therefore, it was not possible to determine rates of how many people had agreed to submit but had not submitted their final data. Nonresponder information was not available, making it impossible to compute view rates or participation rates for the Web administered survey. Time to complete the survey was not computed, as a time stamp was given at time of submission of the survey only.

Survey data were collected between August 1, 2005, and February 28, 2006. Closed-ended items were analyzed using frequencies and descriptive statistics using SPSS, version 16 (SPSS Inc, Chicago, IL, USA) and SAS, version 9.1 (SAS Institute Inc, Cary, NC, USA). Missing data were assessed on a question-by-question basis. Open-ended comments about how to improve the summaries were assembled into Microsoft Excel and examined for themes. In the next step, 3 coders (authors JB, AL, NS) reviewed all comments provided by respondents and coded them into 1 or more of 12 themes determined by an initial scan of the responses. Disagreements over how comments should be categorized into themes were resolved by consensus. We employed the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) reporting guideline to inform our report of this study [37].

Results

Over the 7-month period from August 2005 through February 2006 that the survey was available on the Arthritis Society website, 162 site visitors responded to the survey; the number of hits to the survey-relevant summaries during this time period was not collected. Of the invitations we sent to the CAPA members, we obtained 99 responses out of 395 successfully delivered emails (25%). After comparisons of demographic characteristics showed no important differences between the website and CAPA respondents, responses from the 2 groups were combined for a total of 261 responses.

Table 2 describes the background and summary-specific characteristics of the respondents. The majority (176/261 or 67%) of respondents were female, and 56% (147/261) were between the ages of 45 and 64 years of age. Most were well educated, with 77% (202/261) of respondents reporting at least some postsecondary education, and 35% (92/261) were employed full-time. Respondents were distributed across western (British Columbia, Alberta, Saskatchewan, Manitoba; 49/261 or 19%), central (Ontario, Quebec; 61/261 or 23%), and eastern Canada (New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland; 115/261 or 44%) and included respondents from all 10 provinces, but none from the 3 northern territories. Approximately 7% (17/261) of respondents were not from Canada.

Respondents showed variable computer experience, but 48% (125/261) reported a moderate level of experience. A substantial majority (226/261 or 87%) reported that they themselves had some form of arthritis. Of the 10 different target summaries, 48% (124/261) of respondents chose a summary focused on rheumatoid arthritis, while another 41% (107/261) chose osteoarthritis. Nearly half (111/261 or 48%) reported spending less than 5 minutes reading the summaries. The most common ways in which the summaries were discovered were by simple exploration of the Arthritis Society of Canada website (60/261 or 23%), upon physician recommendation (55/261 or 21%), or through support groups like CAPA (44/261 or 17%), while the most common reasons for reading the summaries were for personal relevance (169/261 or 65%) or general interest (51/261 or 20%).

Table 2. Characteristics of respondents

Characteristic	% of Respondents n = 261
Sex	
Female	67.4
Male	17.6
Missing	14.9
Age (years)	
< 45	21.5
45 to 54	26.4
55 to 64	29.9
65 and over	9.2
Missing	13.0
Education	
High school or less	9.6
Some postsecondary	36.0
Bachelor’s degree or higher	41.4
Missing	13.0
Employment	
Full-time	35.3
Part-time	9.6
Retired	18.4
Disability leave	14.2
Unemployed	4.2
Other	2.7
Missing	15.7
Geographic location in Canada	
Western	18.8
Central	23.4
Eastern	44.1
Outside Canada	6.5
Missing	7.3
General computer experience	
Low	15.7
Moderate	47.9
High	25.3
Missing	11.1
Arthritis experienced by	
Respondent	86.6
Other	5.4
Missing	8.1
Information sought for	
Rheumatoid arthritis	47.5
Osteoarthritis	41.0

Characteristic	% of Respondents n = 261
Other	11.5
Time spent reading the summary (minutes)	
< 5	42.5
5 to 10	34.1
> 10	11.9
Missing	11.5
Summary discovered by	
Exploring arthritis.ca website	23.0
Physician recommendation	21.1
Support group recommendation	16.9
Search engine	5.4
Friend/family recommendation	3.8
Other	16.1
Missing	13.8
Reason for reading the summary	
Personal relevance	64.8
General interest	19.5
Other	4.2
Missing	11.5

Table 3 describes the number and percentage of the 261 respondents reviewing each consumer summary and self-reported time spent reviewing each summary. Of the 10 consumer summaries, 3 accounted for 54% (141/261) of respondents. A significant proportion of respondents spent less than 5 minutes reviewing each summary (summary-specific range of the percent of respondents who spent less than 5 minutes reviewing the summary, 25% to 70%).

Table 3. Number and percentage of respondents reviewing each consumer summary and self-reported time spent reviewing that summary page

Summary Title	Reviewed the Summary n (% of 261)	Reported Spending ≤ 5 Minutes Reviewing the Summary n (% of 261)	Reported Spending > 5 Minutes Reviewing the Summary n (% of 261)	Did Not Report Time Viewing the Summary n (% of 261)
Does exercise help osteoarthritis of the hip or knee?	52 (19.9%)	29 (55.8%)	20 (38.5%)	3 (5.8%)
Does glucosamine work for treating osteoarthritis?	45 (17.2%)	19 (42.2%)	24 (53.3%)	2 (4.4%)
Does methotrexate work to treat rheumatoid arthritis?	44 (16.9%)	11 (25.0%)	19 (43.2%)	14 (31.8%)
Does etanercept work to treat rheumatoid arthritis?	30 (11.5%)	11 (36.7%)	18 (60.0%)	1 (3.3%)
Does physical therapy work to treat ankylosing spondylitis?	20 (7.7%)	6 (30.0%)	10 (50.0%)	4 (20.0%)
Does folic acid decrease side effects in patients taking methotrexate for rheumatoid arthritis?	19 (7.3%)	8 (42.1%)	9 (47.4%)	2 (10.5%)
Does occupational therapy help people with rheumatoid arthritis?	17 (6.5%)	9 (52.9%)	6 (35.3%)	2 (11.8%)
Do antimalarials work to treat rheumatoid arthritis?	14 (5.4%)	7 (50.0%)	7 (50.0%)	0 (0.0%)
Do steroid injections work to treat tennis elbow?	10 (3.8%)	7 (70.0%)	2 (20.0%)	1 (10.0%)
Does ultrasound therapy work to treat osteoarthritis of the knee?	10 (3.8%)	4 (40.0%)	5 (50.0%)	1 (10.0%)
Total number (%) of respondents	261 (100%)	111 (42.5%)	120 (46.0%)	30 (11.5%)

Table 4 describes responses to the 14 user experience items. A number of items indicated favorable impressions by respondents, with a majority either strongly or moderately agreeing with statements that the summary used language that was appropriate (196/261 or 75%), provided expected information (178/261 or 68%), (didn’t) involve too much reading (172/261 or 66%), would be of use to many others (160/261 or 61%), was well laid out (159/261 or 61%), (wasn’t) hard to learn from (157/261 or 60%), (wasn’t) frustrating (154/261 or 59%), was useful to me (153/261 or 59%) and (wasn’t) boring (149/261 or 57%). Somewhat fewer respondents agreed that they could find all the information they wanted (118/261 or 45% strongly or moderately agreed). Finally, several items suggested that many respondents felt unable to judge the credibility or reliability of the summaries. Relatively few agreed that the summary clearly provided information on the providers of the information (112/261 or 43%). Furthermore, large proportions of respondents selected “no opinion/don’t know” to whether the information is up-to-date (54/261 or 21%), the providers of the information are reliable (80/261 or 31%), and the information presented was the best available (68/261 or 26%).

Table 4. Percentage of respondents for items of user satisfaction (higher percentages indicate greater satisfaction)

Item of User Satisfaction	"Strongly Agree" to "Moderately Agree" % of 261	Less Than "Moderately Agree" % of 261	"No Opinion/ Don't Know" % of 261	No Response % of 261
The summary uses appropriate language.	75.1	11.1	1.2	12.6
The summary provided the info I expected.	67.8	18.8	0.8	12.6
I had to read too much.[a]	65.9	20.3	0.8	13.0
This summary would be useful to many others.	61.3	24.1	1.5	13.0
The summary is well laid out.	60.9	23.8	1.9	13.4
Learning from this summary is hard.[a]	60.2	26.4	0.0	13.4
This summary is frustrating. [a]	59.0	26.1	1.9	13.0
The information was useful to me.	58.6	28.4	0.4	12.6
This summary is boring. [a]	57.1	28.7	0.8	13.4
The information is up-to-date.	51.7	14.9	20.7	12.6
I can easily find all the information I want.	45.2	39.9	1.9	13.0
The summary clearly presents who provides the information.	42.9	35.3	8.4	13.4
The providers of the information are reliable.	42.9	14.2	30.7	12.3
The information presented was the best available.	31.8	29.9	26.1	12.3

[a] These items are reversed, that is, to the respondent, the questions appeared as written, but the scores reported in this table are reversed to ensure agreement percentages reflect a positive opinion of the summary for all items.

Table 5 describes responses to the items related to preparation for decision making. In general, the responses indicated that the summary would improve preparation for decision making, particularly to help to identify questions to ask the physician (157/261 or 60%). Relatively few agreed with the statement that the summary helps you know that your values affect your decisions (103/261 or 40%).

To probe in more detail issues around people's impressions of the summaries, we asked respondents to provide us with feedback about how we might improve the summaries. Of the 261 respondents, 131 provided 1 or more comments. Table 6 presents the themes identified, the relative frequencies with which those themes were mentioned, and shows examples of comments relevant to each theme. The most commonly cited themes were to provide more detail about the treatment and options, risks and the research; to provide additional interactivity or functionality to the summaries; to make the language clearer or simpler; and to increase the use of pictures, graphs or colors. Several people specifically requested the summaries use point form and provide more bottom lines about the treatments, and several suggested that more detailed information about the credibility of the information should be provided.

Table 5. Percentage of respondents by satisfaction with preparation for decision making

The Summary Would:	"Quite a Bit" or "A Great Deal" % of 261	Less Than "Quite a Bit" % of 261	No Response % of 261
Help identify questions you want to ask	60.2	26.8	13.0
Help you think about how involved you want to be	55.2	32.2	12.6
Prepare you to communicate your opinion	54.4	32.6	13.0
Prepare you to make a better decision	51.3	36.0	12.6
Help you prepare for a follow-up visit	50.6	36.0	13.4
Help recognize that a decision needs to be made	47.1	40.2	12.6
Help make a follow-up visit run more smoothly	46.0	41.4	12.6
Help you think about pros and cons of the decision	45.2	39.9	14.9
Help you organize your own thoughts	44.8	42.5	12.6
Help you think about what is most important	43.3	44.1	12.6
Help you know that your values affect decisions	39.5	48.3	12.3

Table 6. Frequency of themes and examples of theme-relevant quotes of respondents' impressions of the summaries (n = 131)

Theme	Frequency	Examples of Quotes
Need more information about treatment	40	*…length of time before effects are felt, how the meds can be taken...dosage of the meds (how often)...* [Respondent 175]
Need more information about risks, side effects, or contraindications	15	*The risk of treatment to patients should always be included. When I make a decision, I always want to know the risks involved.* [Respondent 140]
Need more information about research details	15	*Refer to other studies done or ones planned. More details on number of cases studied...* [Respondent 198]
Need more information about other treatment options	13	*It would be interesting to know how well treatments other than [X] perform for comparison.* [Respondent 85]
Need more information about the disease	8	*Try to explore the psychological issue with patients suffering [ankylosing spondylitis], such as depression, suicide, etc.* [Respondent 251]
Need additional interactivity, website functionality	20	*Maybe you could have a basic summary and have sections that expand if more detail is needed...* [Respondent 212]
Use pictures, graphs, or colors	12	*... though the statistics are interesting and indeed useful, perhaps presenting the information in a more visual manner...* [Respondent 182]
Make language clearer or simpler	12	*In an effort to use simple language, this summary was often vague and imprecise.* [Respondent 203]
Improve the format of the material	10	*A solid recommendation to do or not to do would help take away the uncertainty of decision making...* [Respondent 257]
Need more information about credibility	9	*Wasn't real clear on the source of the information.* [Respondent 241]
Compliments	8	*I found [it] to be straightforward, easy to comprehend.* [Respondent 223]

Discussion

The 15-year evolution of the CMSG consumer summaries has resulted in a successful standardized presentation format that enables brief but clear presentation of research evidence for a wide range of treatments and interventions for musculoskeletal disorders. Because these consumer summaries were carefully tested as paper-based tools but hadn't been tested as Web-based tools, we decided to evaluate how they performed on the Web and what specific areas needed work in order to improve them as Web-based tools. Our survey showed that the tools were generally rated favorably and identified specific areas for improvement, which we discuss below.

Amount of Detail

One key finding was that many respondents reported wanting additional information to be available from the summaries. Less than half of respondents (118/261 or 45%) agreed that they could easily find all the information they wanted. Open-ended comments also revealed that many respondents wanted more details about specific risks, about the types of studies comprising the research, and about the type of participants in the studies (presumably so that they could compare themselves to the study participants). Many respondents also wanted more information about the condition and its various treatment options.

We note that our sample of respondents was likely quite sophisticated in terms of its existing knowledge on arthritis-related issues. Over 77% (202/261) of respondents had some postsecondary education, and many came through recruitment from the Canadian Arthritis Patient Alliance group, members of which are likely to be actively engaged in issues of musculoskeletal disorders. This sample may, therefore, have been quite well informed already about issues around their illness (226/261 or 87% had personally experienced some arthritis condition) and, therefore, preferred relatively detailed information.

A key challenge when presenting any health information online is dealing with the variability in user needs. Nearly half (111/261 or 48%) spent less than 5 minutes reading the consumer summaries, and the clear majority (200/261 or 77%) reported spending 10 minutes or less reading them. The standardized format used here was designed primarily to yield clear, concise summaries of systematic reviews. Yet many users will wish to use these summaries as springboards for more detailed information searches. This need for more flexible, interactive information presentation was evident in our survey findings: 2 commonly cited themes were to increase use of interactivity and to include more in the way of graphs, charts, and other information-rich display formats. To facilitate such uses, it seems likely that rather than trying to create a one-size-fits-all solution that would be too detailed for some and not detailed enough for others, the challenge for developers is to provide a flexible, interactive approach that can allow users to tailor for themselves the amount and type of information they review [38]. This approach is becoming increasingly feasible on the Web, and suggests a clear avenue for future research.

We have begun this work in at least 3 ways. First, we are exploring the utility of providing links within these summaries to other, more detailed descriptions of the systematic reviews. Second, the consumer summaries are housed within the larger Arthritis Society website that includes a wealth of information on all aspects of musculoskeletal disorders; efforts to link from the summaries to this additional information may well improve areas identified in this survey. Third, we are currently conducting research on how to adapt more detailed decision support tools such as patient decision aids for use online, discussed in more detail below.

Layout and Language

While the majority of respondents felt our consumer summaries incorporated clear language and were well laid out, some respondents did feel that the language or formatting could be improved. Within the CMSG, we have avoided evaluating the summaries using readability algorithms due to the number of technical, often complex terms at the heart of the reviews. Instead, our goal has been to use relatively few content words per sentence (ie, use lower lexical density) and a clear, logical progression from background information to the effects of treatment [29]. While this approach appears to be a qualified success, there may be opportunity for linking terms; such an approach can allow optional, more detailed information and definitions to be provided without adding length or clutter. We are currently exploring the use of such techniques in another study.

Credibility of the Source

Many people were unable to judge the credibility or reliability of the summaries or did not know who the providers of the information were. This is a concern since assessment of the credibility of online information is a key component of evaluating health information [24]. Our summaries included a statement that the research is based on a Cochrane review, a reference to the review at the bottom of the summary, and a link to a website, About Cochrane, that describes the processes involved in writing a review. Clearly some respondents did not see or make use of this information; more investigation of how to make this information more salient to users will be important.

Preparation for Decision Making

While user experience was generally positive, fewer than half of the respondents felt that the summary helped them recognize that a decision needs to be made, think about pros and cons, know how their values affect their decision, organize their own thoughts, or prepare to make a better decision. It is unsurprising that these summaries should not have all information necessary to prepare people for a decision since they are limited chiefly to providing information about the treatment options and the pros and cons of the treatments [39]. We are currently assessing whether patient decision aids, that is, decision support tools designed to help people make specific and deliberative choices among options, may be useful when presented online. While their effectiveness has been demonstrated in a variety of other presentation formats [20], it remains an open question how such tools can most effectively be employed via the medium of the Web and for what situations such tools may be most useful. These tools not only present information on the options and outcomes relevant to the person's health status but often also include exercises to help patients explicate factors such as how they value the different options, preference for role in decision making, or choice predisposition. Patient decision aids can be much more detailed and, therefore, longer than consumer summaries. Use of these more detailed tools may be warranted in situations where a decision cannot be made on the basis of a consumer summary.

Limitations

The response rate and makeup of our sample of respondents is one clear limitation of the present study. The Web subsample was collected over a period of 7 months from summaries that see hundreds of visitors per month. While we have no information on nonresponders, we have to assume that our relatively slow accrual rate suggests that we were only obtaining data from a small, select group of visitors to the site. The CAPA survey subgroup likely exhibits similar biases. Despite our best efforts, logistical limitations prevented us from obtaining a high response rate from the CAPA survey sample. The response rate (99/395 or 25%) suggests that we may have a very select sample of the CAPA group, which itself is likely quite different from the target population of all arthritis patients using online information. In total, we must assume that our sample is biased with respect to our overall target population. We have chosen to interpret our results not as a sample representative of all arthritis sufferers, but as one of a relatively sophisticated sample of well-educated patients. Future work will be needed to assess whether these findings generalize to the wider population of arthritis patients who use online information.

A second clear limitation of the current work is the lack of a control group against which to compare the survey findings. We chose the single-group design in order to evaluate the CMSG model for presenting consumer information online as it is currently being implemented on the Canadian Arthritis Society website, and we chose to use the information derived from it to inform future controlled studies. Our use of previously validated measures (eg, computer experience and satisfaction with preparation for decision making) gives us confidence in the constructs we have measured, but ongoing work using controlled designs will assess the extent to which the levels of these constructs can be improved upon using other approaches.

Conclusions

The relationship between the Cochrane Musculoskeletal Group and the Arthritis Society has created an excellent opportunity for research producers to target those people who would benefit most from this research information. The current work focuses specifically on engaging in this knowledge translation process in an online environment and makes clear that while we are on the right track, there is more work to do in order to understand how best to communicate systematic review information online. We have begun this work and provided some initial recommendations about how consumer summaries should look. Feedback from this survey will help to reshape and improve on the current presentation format for consumer summaries used by the CMSG. Our results should also provide initial guidelines to other developers of patient information who wish to reach consumers via the Internet.

Acknowledgments

We would like to thank the Arthritis Society of Canada and the Canadian Arthritis Patient Alliance for their support of this survey and, in particular, Rob Watts, manager of Internet resources, Arthritis Society of Canada; Anne Dooley, cochair of research, Canadian Arthritis Patient Alliance; and Colleen Maloney, vice president, Canadian Arthritis Patient Alliance. Also thanks to Anton Saarimaki who programmed the survey for the Web and to Dr Ann Cranney for clinical input. This work was funded by an operating grant from the Canadian Institutes of Health Research (CIHR; MOP-68973). Dr Brehaut is a CIHR New Investigator in Knowledge Translation.

Conflicts of Interest

None declared

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Abbreviations

AHRQ: (US) Agency for Healthcare Research and Quality
CAPA: Canadian Arthritis Patient Alliance
CHERRIES: Checklist for Reporting Results of Internet E-Surveys
CSMG: Cochrane Musculoskeletal Group
NICE: (UK) National Institute for Health and Clinical Excellence

Edited by G Eysenbach; submitted 17.03.10; peer-reviewed by A Gagliardi, M Sampson, R Bannuru; comments to author 21.04.10; revised version received 14.06.10; accepted 10.07.10; published 18.01.11.

Please cite as:
Brehaut JC, Santesso N, O'Connor AM, Lott A, Lindgaard G, Syrowatka A, Graham ID, Tugwell PS
Presenting Evidence to Patients Online: What Do Web Users Think of Consumer Summaries of Cochrane Musculoskeletal Reviews?
J Med Internet Res 2011;13(1):e5
URL: http://www.jmir.org/2011/1/e5/
doi:10.2196/jmir.1532
PMID:21247863

Original Paper

Health Literacy and Task Environment Influence Parents' Burden for Data Entry on Child-Specific Health Information: Randomized Controlled Trial

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Abstract

Background: Health care systems increasingly rely on patients' data entry efforts to organize and assist in care delivery through health information exchange.

Objectives: We sought to determine (1) the variation in burden imposed on parents by data entry efforts across paper-based and computer-based environments, and (2) the impact, if any, of parents' health literacy on the task burden.

Methods: We completed a randomized controlled trial of parent-completed data entry tasks. Parents of children with attention deficit hyperactivity disorder (ADHD) were randomized based on the Test of Functional Health Literacy in Adults (TOFHLA) to either a paper-based or computer-based environment for entry of health information on their children. The primary outcome was the National Aeronautics and Space Administration Task Load Index (TLX) total weighted score.

Results: We screened 271 parents: 194 (71.6%) were eligible, and 180 of these (92.8%) constituted the study cohort. We analyzed 90 participants from each arm. Parents who completed information tasks on paper reported a higher task burden than those who worked in the computer environment: mean (SD) TLX scores were 22.8 (20.6) for paper and 16.3 (16.1) for computer. Assignment to the paper environment conferred a significant risk of higher task burden ($F_{1,178} = 4.05$, $P = .046$). Adequate literacy was associated with lower task burden (decrease in burden score of 1.15 SD, $P = .003$). After adjusting for relevant child and parent factors, parents' TOFHLA score (beta = -.02, $P = .02$) and task environment (beta = .31, $P = .03$) remained significantly associated with task burden.

Conclusions: A tailored computer-based environment provided an improved task experience for data entry compared to the same tasks completed on paper. Health literacy was inversely related to task burden.

Trial registration: Clinicaltrials.gov NCT00543257; http://www.clinicaltrials.gov/ct2/show/NCT00543257 (Archived by WebCite at http://www.webcitation.org/5vUVH2DYR)

(J Med Internet Res 2011;13(1):e13) doi:10.2196/jmir.1612

KEYWORDS

Medical history-taking; pediatrics; health literacy; computer literacy; task performance and analysis; information dissemination; health records, personal

Introduction

To improve children's health, effective disease management in attention deficit hyperactivity disorder (ADHD) requires iterative data exchange between pediatric health providers and parents of affected children [1,2]. The classic model of office-based and paper-driven information exchange with the physician as the locus of control often fails to gather data needed for ADHD care [3,4]. Health care systems increasingly rely on technology to organize and deliver care while, at the same time, expecting patients to take on more responsibility for chronic disease management [5,6].

Pediatric providers rely on parents of children with ADHD to report on changes in the child's health status in order to make treatment decisions [1,2,7]. Parent-provided data on child behaviors and medication use is the first and most elemental information task in a series of data exchanges between a parent and a pediatric health provider that result in health-promoting actions in ADHD. Design of novel, patient-driven systems that support iterative reporting of health information requires better understanding of how parents experience the process of data entry in a single episode [8-10]. To date, no published research has reported on patients' experience of data entry or identified parent-specific traits or skills that affect task burden related to electronically mediated health communication.

To inform the development of personal health records (PHRs) that invite longitudinal engagement [11,12], and to better understand factors relevant to parents' successful data entry of information key to ADHD management, we designed a clinical trial to explore the burden experienced by parents during data entry efforts in paper-based and computer-based environments. In addition, we explored health literacy as a parent-specific variable and its impact across task environments [13-15].

The specific aims of this project were to determine (1) the variation in burden imposed on parents by data entry efforts across paper-based and computer-based environments, and (2) the impact, if any, of parents' health literacy on the task burden experienced across those environments.

Methods

Overview

We completed an unblinded, randomized controlled trial of patient-completed data entry tasks using paper-based and computer-based environments to investigate the task burden experienced by parents. Parents of children with ADHD were randomized on the basis of their score on the Test of Functional Health Literacy in Adults (TOFHLA) to provide information on their children's behaviors, prescribed medications, and potential side effects to medications using either commonly used structured paper forms or a computer-based data entry interface designed to capture the same scope of content. The Committee on Clinical Investigation (Children's Hospital Boston, Boston, MA, USA) approved the study protocol and the trial was registered.

Participants

We recruited English-speaking and Spanish-speaking parents of school-aged children with ADHD. To be eligible for the study, the parent confirmed the following: the child's age between 5 years and 12 years, that a physician had diagnosed the child with ADHD, that the child resided primarily with the parent, that the parent was the person who managed the child's health, and that the child was taking or had recently (within the last 4 months) been taking a prescription medication to treat ADHD. Exclusion criteria were the parent's report of any of the following diagnoses in their child: autism, pervasive developmental disorder, Asperger's disorder, bipolar disorder, or mental retardation. These criteria were intended to create a study cohort that best resembled a community-based sample of parents caring for a child with ADHD whose disease could be reasonably managed by a primary care provider, and for whom standard forms used in ADHD care for the tracking of symptoms and side effects for medications would be appropriate.

We recruited parents from the greater Boston metropolitan area to participate during a 20-month study period from 2007 to 2009. Outreach efforts for recruitment included newspaper advertisements, letters sent from pediatric practices to inform parents of children receiving care at those practices of our study, emails and listserv postings via parent-support groups specific to ADHD, flyers and brochures displayed and/or handed out at community health centers, adult education centers, child care centers, and other community-based organizations where parents of children with ADHD might visit for services or support. To facilitate recruitment of parents with lower literacy, all materials were developed according to plain-language standards, and personal contact with parents was emphasized among those facilitating our outreach. To facilitate recruitment of Spanish-speaking parents, Spanish-language advertisements were placed in community papers, and Spanish-language materials were used at clinical and community sites where Spanish-speaking parents were known to receive services.

Consent and Randomization

Parents who indicated interest in the study were screened and completed a stepwise process of consent that included viewing a video explaining the study, discussing the study with research staff, reviewing a one-page plain-language document describing major features of the study and privacy laws, and verbally acknowledging that any questions they had were answered and they wished to proceed with enrollment.

Prior to randomization, each parent completed the full TOFHLA, a literacy instrument that has been validated in English-speaking and Spanish-speaking populations [16]. The TOFHLA produces a scaled score ranging from 0 to 100 that categorizes functional literacy into three groups: inadequate, marginal, and adequate. Parents were assigned to a "lower literate" group (who scored inadequate/marginal on the TOFHLA) and a "literate" group (who scored adequate on the TOFHLA). Based on this group assignment, each parent was randomized through a mixture of permuted blocks with the goal of equal distribution of literacy levels across the two treatment arms (paper-based tasks vs computer-based tasks). A serially numbered sequence of study IDs with assignments to the two trial arms grouped in randomly permuted blocks of 2, 4, and 6 was generated. This procedure ensured approximate balance between the study arms at any point in time and prevented inadvertent or deliberate bias on the part of those conducting enrollment.

Study procedures

Study procedures were completed at a location of the parent's choosing, with the intention that a majority of parents would prefer to complete tasks in a familiar environment of their own home or a nearby location. In theory, the site where health data tasks related to chronic disease management are completed would mimic where the majority of observations and decisions are made – namely, everyday familiar environments such as the home or nearby community sites.

Primary study procedures

Parents randomized to paper first were handed an envelope containing three forms with written instructions for completion. Forms were either in English or Spanish according to the language the parent stated they used in health communication. The parent was told that "these forms are ones similar to what a doctor's office might send you and ask that you fill out before your next appointment. Please open the envelope and fill out the forms to the best of your ability." Forms in the envelope were the National Initiative for Children's Healthcare Quality (NICHQ) Vanderbilt parent assessment form, a medication side-effects inventory, and an open-ended request for information on current medications (Figure 1) [17]. All forms were printed in black and white on 8.5 × 11 inch paper. The research assistant observed parents' effort with the paper forms and timed the process of data entry but did not provide interpretation of content.

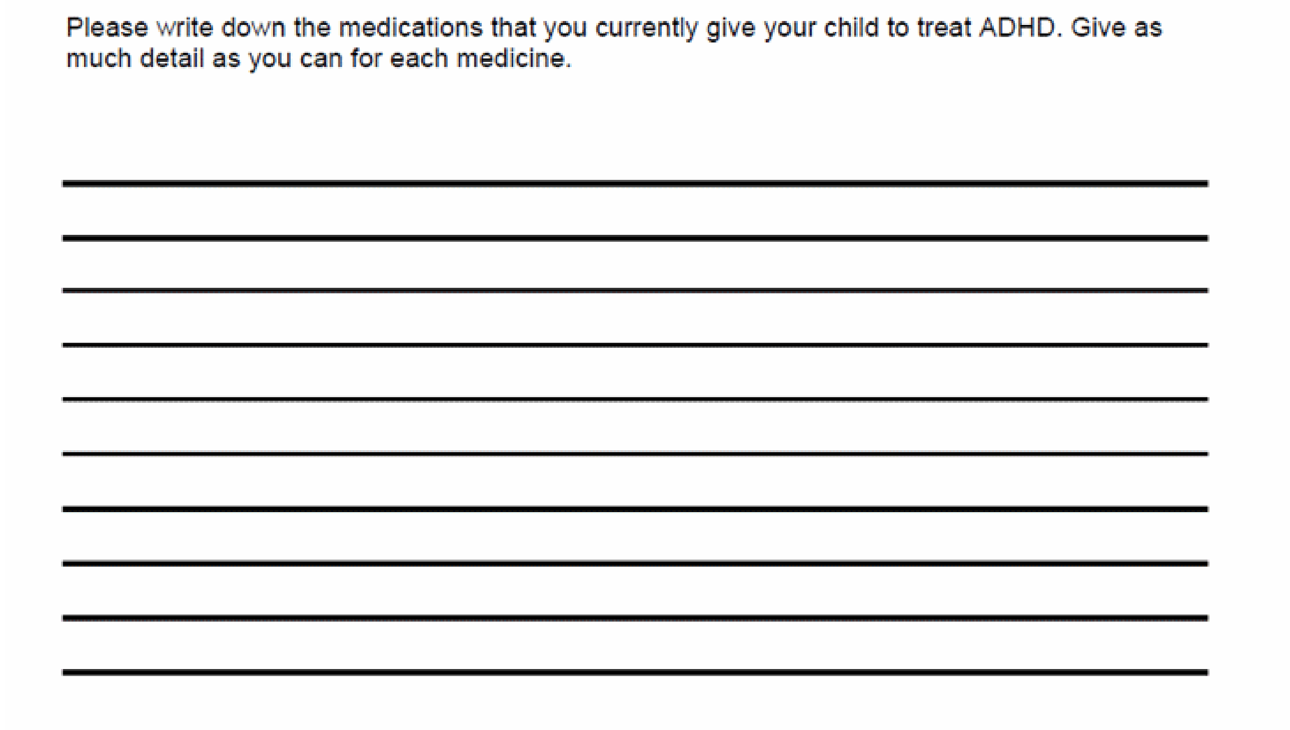
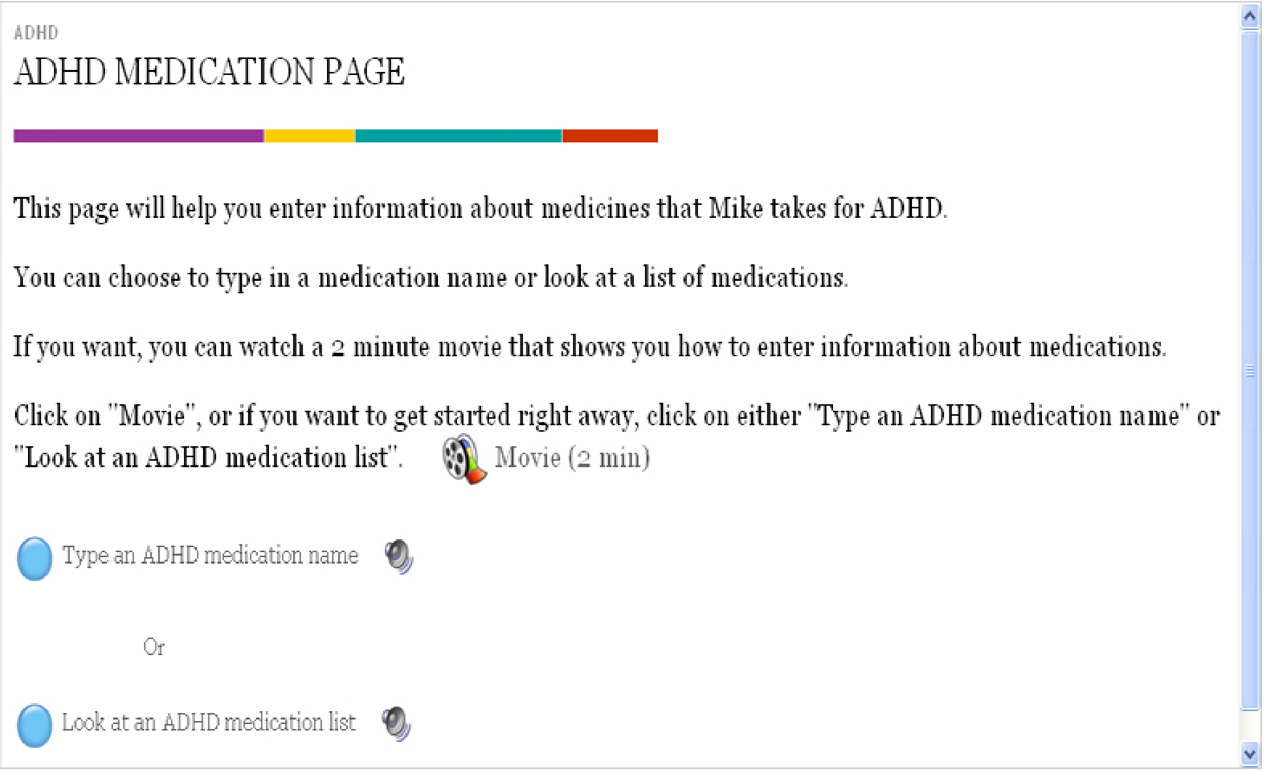


Figure 1. Single-page, paper-based request for information on current medications

Please write down the medications that you currently give your child to treat ADHD. Give as much detail as you can for each medicine.

Parents randomized to computer first were introduced to a laptop computer running the ADHD data entry application [18]. The research assistant supervised the parent in completing a log-in procedure that brought up the introductory screen for the ADHD application. At this point, the parent was instructed to follow the directions on-screen and complete the work on their own. The content of computer-based tasks mirrored the content of the paper-based forms, but the structure and workflow on the computer were designed to provide the parent with a guided experience that facilitated comprehension and successful completion of each task (see Figure 2 and Multimedia Appendix 1). The computer application was the end result of a user-centered design process whose goal was the creation of an electronic environment usable by parents with varied technology-specific skills and educational experience [18]. Prerecorded videos were available to help parents who had questions on navigation or content-specific tasks. On-screen navigation required the use of the mouse and familiarity with the scrollbar for vertical movement through displayed content. The research assistant observed the parents' effort with the computer but did not provide interpretation of content or act as a "help desk" in giving technical assistance.

Figure 2. Screen shot of the computer application that guides parents' entry of medication-specific data



ADHD

ADHD MEDICATION PAGE

This page will help you enter information about medicines that Mike takes for ADHD.

You can choose to type in a medication name or look at a list of medications.

If you want, you can watch a 2 minute movie that shows you how to enter information about medications.

Click on "Movie", or if you want to get started right away, click on either "Type an ADHD medication name" or "Look at an ADHD medication list".

After completion of either paper-based tasks or computer-based tasks, each parent was then administered the National Aeronautics and Space Administration Task Load Index (NASA TLX) [19]. The NASA TLX is a multidimensional rating procedure that provides an overall workload score based on a weighted average of ratings on six subscales: Mental Demands, Physical Demands, Temporal Demands, Own Performance, Effort, and Frustration. The degree to which each of the six factors contributes to the workload score is determined by the subject's responses to pairwise comparisons between the six factors. Magnitude ratings on each subscale are obtained after completion of task performance. Visual analog scales are used to capture subjects' ratings of task difficulty. The NASA TLX demonstrates content and construct validity and is widely used in human performance studies [20]. A Spanish-language version of the NASA TLX was developed for this study via a process of translation-back translation to ensure that the Spanish text retained the intent of the original English.

After the first data entry task, each parent completed a series of surveys that included questions on how they perceived the task, demographics, technology-specific experience, prior use of health-related forms, and information about their child's ADHD care. After all surveys were finished, the parent was asked to complete the data entry task using the alternative task environment to which they were not randomized first.

Outcomes and Definitions

The primary outcome was the NASA TLX total weighted score.

Calculation of the total weighted score for the NASA TLX combines the tally of the number of times a given domain was judged more important to the task experience in pairwise comparisons with the quantification of each domain's actual burden using a visual analog scale [19]. Each total score is the product of the tally and raw rating ($c_i = a_i$ x $b_i i = 1,2,...,6$). The weighted rating is the sum of adjusted ratings divided by 15, as the equation in Figure 3 shows.

Secondary outcomes were domain-specific task load, the rank order of task domains, and parental preference for task environment.

Figure 3. Equation used to calculate the total Task Load Index weighted score

$$\frac{\sum_{i=1}^{6} c_i}{15} = \frac{\sum_{i=1}^{6} (a_i \times b_i)}{15}$$

Statistical Methods

The primary unit of analysis was the parental participant. Analyses were completed using an intention-to-treat approach. Sample size for the trial was based on a priori assumptions regarding parents’ accuracy and completeness in report of clinical data, and did not rely on assumptions for NASA TLX scores. The trial met its predetermined sample size of 180 subjects. The primary outcome of the weighted NASA TLX was examined in the normalized format for the primary analysis and the raw score for the secondary analysis.

Since the NASA TLX total weighted score was skewed and the generalized linear model requires the outcome variables to be normally distributed, the weighted score was normalized using the SAS procedure PROC RANK, which computes normal scores, and the resulting weighted scores appeared to be normally distributed with mean equal to 0 and standard deviation equal to 1.

Both crude and adjusted association between the normalized score and task environment were calculated. In the multivariable regression model, covariates included health literacy, years since child’s diagnosis, and the parents’ gender, educational level, race, acculturation, comfort with computers, frequency of computer use, experience in Internet purchasing, experience with paper health forms, and comfort with ADHD terms.

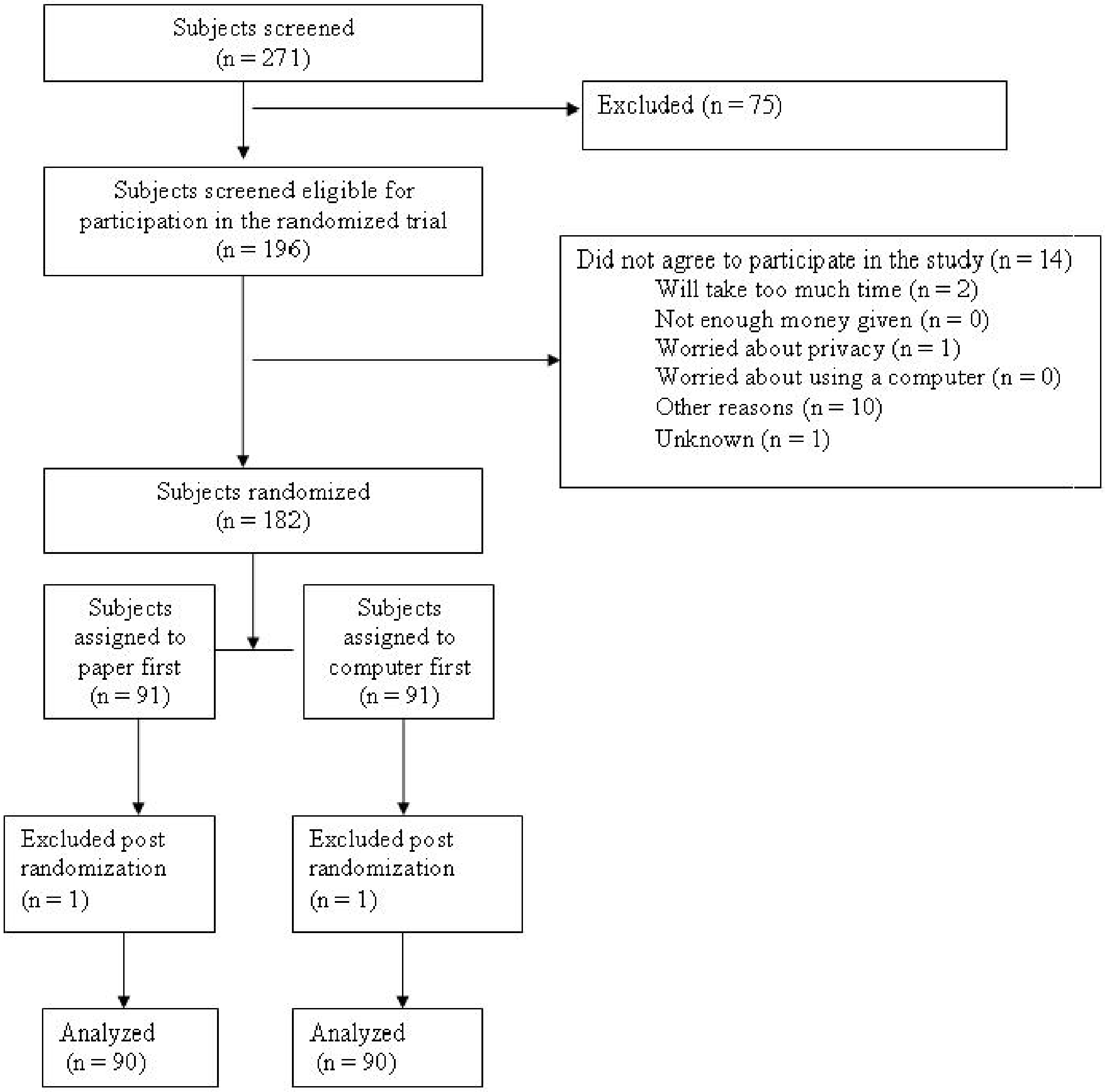
For secondary analysis, nonparametric methods were implemented. The Wilcoxon rank sum test was used to determine whether domain-specific score was associated with task environment, since we only focused on the crude association. The chi-square test was used to determine whether the rank order of task domains or parental preference for task environment was associated with task environment.

All analyses were completed using SAS version 9.1 (SAS Institute Inc, Cary, NC, USA). Tests with the significance level of 5% were considered.

Results

We recruited and enrolled parents of school-aged children with ADHD in our randomized controlled trial of data entry tasks. A total of 271 parents were screened, 194 of 271 (71.6%) were eligible, and 180 of 194 eligible subjects (93%) constituted the trial cohort for analysis. See Figure 4 for a full account of the screening and enrollment process.

Figure 4. Flowchart of the screening and enrollment process



Description of Parental Cohort

Parents in the enrolled cohort were a diverse group of individuals on the basis of education, race, ethnicity, and experience with the topic of ADHD. Overall, the majority of parents reported exposure to and comfort with the use of computers, including how to navigate the Internet. Table 1 shows the distribution of parents' characteristics across the randomized groups.

Table 1. Baseline characteristics according to randomization

Characteristic	Randomization	
	Paper	Computer
Number of subjects	90	90
TOFHLA[a] score, mean (SD)	90.90 (9.12)	92.09 (8.92)
TOFHLA category, n (%)		
Inadequate	1 (1)	2 (22)
Marginal	4 (4)	3 (3)
Adequate	85 (94)	85 (94)
Gender, n (%)		
Male	4 (4)	7 (8)
Female	86 (96)	83 (92)
Ethnicity, n (%)		
Hispanic or Latino	10 (11)	10 (11)
Not Hispanic or Latino	65 (72)	70 (78)
Other	15 (17)	10 (11)
Race, n (%)		
White	42 (47)	48 (53)
Black	25 (28)	25 (28)
More than one race	9 (10)	2 (2)
Other	14 (16)	15 (17)
Education level, n (%)		
Some grade school/some high school	8 (9)	9 (10)
Graduated from high school/GED[b]	18 (20)	12 (13)
Some college or vocational school beyond high school	29 (32)	26 (29)
Graduated from 2-year or 4-year college	20 (22)	25 (28)
Post-college graduate courses or degree	15 (17)	18 (20)
Comfort with ADHD[c] words, n (%)		
Very uncomfortable	8 (9)	12 (13)
Uncomfortable	6 (7)	8 (9)
No opinion	6 (7)	10 (11)
Comfortable /very comfortable	70 (78)	60 (67)
Experience with paper ADHD form, n (%)		
Yes	80 (89)	80 (89)
No	10 (11)	10 (11)
Comfort with technology, n (%)		
Very uncomfortable	12 (13)	12 (13)
Uncomfortable	3 (3)	6 (7)
No opinion	13 (14)	5 (6)
Comfortable	14 (16)	24 (27)
Very comfortable	48 (53)	43 (48)
Years since child’s diagnosis (n, %)		
<1	21 (21)	23 (26)

Characteristic	Randomization	
	Paper	Computer
1-5	54 (60)	48 (53)
>5	15 (17)	19 (21)

[a] TOFHLA: Test of Functional Health Literacy in Adults.

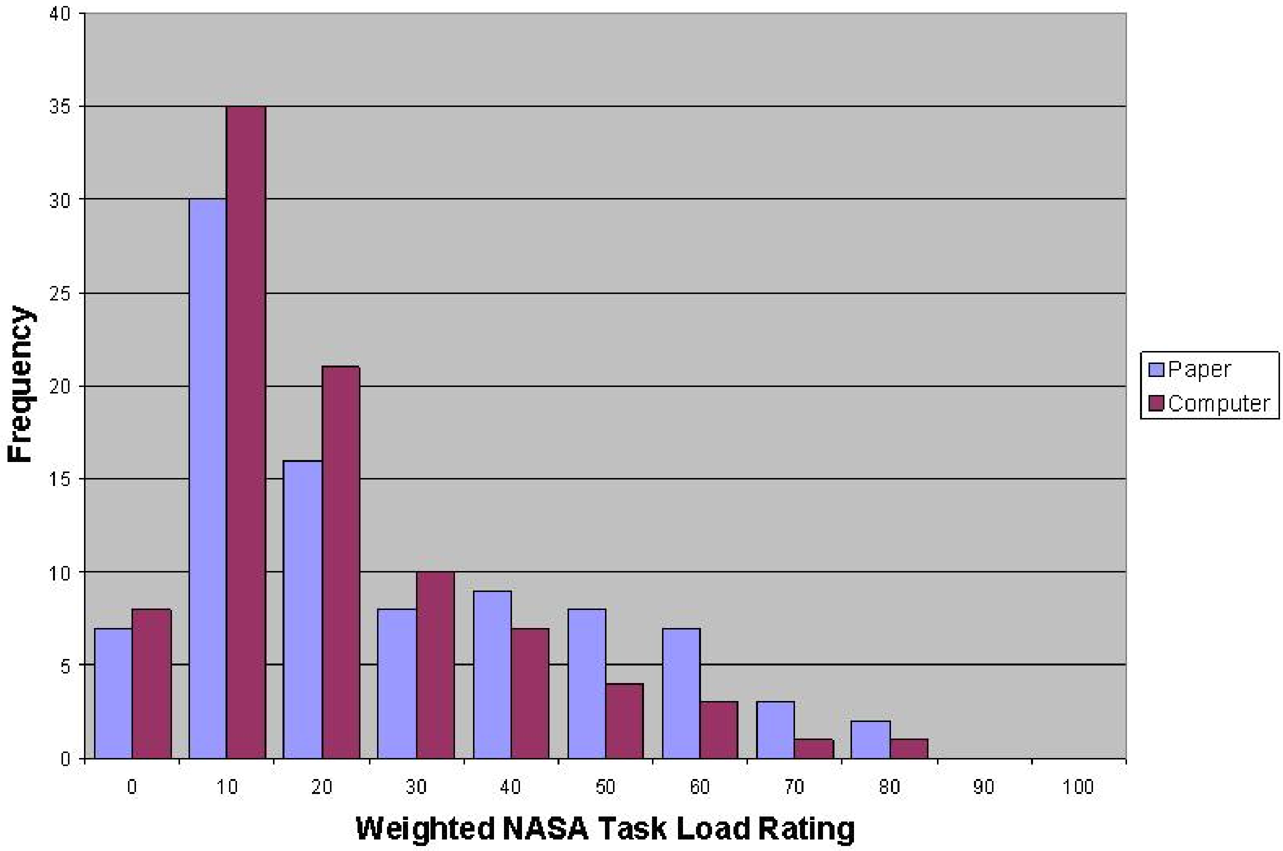
[b] GED: general educational development.

[c] ADHD: attention deficit hyperactivity disorder.

Impact of Task Environment on Task Experience

Parents who completed the information tasks in the paper environment reported higher task burden than those who worked in the computer environment: mean (SD) of TLX score for paper was 22.8 (20.6) and for computer was 16.3 (16.1). In a generalized linear model with TLX score as the dependent variable, assignment to the paper environment conferred a significant risk of higher task burden ($F_{1,178} = 4.05$, $P = .046$). Figure 5 graphically displays the distribution of TLX scores across the two task environments.

Figure 5. Distribution of National Aeronautics and Space Administration Task Load Index (NASA TLX) score by task environment



Impact of Health Literacy

Health literacy as measured by the TOFHLA showed an inverse relationship to task experience. Across all subjects, adequate literacy was associated with lower task burden (decrease in burden score of 1.15 SD, *P* = .003). Subjects who scored adequate on the TOFHLA were significantly more likely to experience lower task burden in the paper environment (decrease in score of 1.63 SD, *P* < .001). This differential effect for paper-based tasks was not as prominent for parents using the computer. In the computer environment, subjects who scored adequate had a lower but nonsignificant difference in burden score than those who scored marginal/inadequate for literacy (decrease in score of 0.68 SD, *P* = .11).

In a generalized linear model that controlled for task environment, subjects who scored adequate for literacy were significantly more likely to experience lower task burden (decrease in score of 1.15 SD, *P* < .001).

Analysis of Health Literacy’s Adjusted Association With Task Burden

A multivariable model was constructed to further explore the strength of health literacy’s association with task burden as the dependent variable, and health literacy modeled as a continuous covariate (see Table 2). After adjusting for years since their child's diagnosis and the parents' gender, educational level, race, ethnicity, acculturation, comfort with computers, frequency of computer use, use of the Internet to make purchases, experience with paper health forms, and comfort with ADHD terms, parents' TOFHLA score remained significantly associated with task burden ($F_{1,178}$ = 5.4, *P* = .02). Of note, task assignment also remained significant in this model ($F_{1,178}$ = 4.6, *P* = .03). Data entry in the computer environment and a higher TOFHLA score both favored an improved task experience by parents.

Table 2. Crude and adjusted linear regression models with task burden as outcome

Variable name	Beta	Standard error	*P*-value
Crude model			
Task environment (paper vs computer)	.294	0.146	.04
Health literacy score	-.0293	0.008	.0003
Multivariable model			
Task environment (paper vs computer)	.310	0.145	.03
Health literacy score	-.024	0.010	.02
Internet purchase experience (yes vs no)	.354	0.188	.06
Generic computer experience (yes vs no)	-.424	0.229	.06
Comfort with ADHD[a] words (yes vs no)	-.202	0.176	.25
Time since diagnosis	-.072	0.069	.30
Education (high school yes vs no)	.188	0.197	.34
ADHD paper form experience (yes vs no)	-.213	0.239	.37
Race (white vs others)	-.081	0.165	.62
Born in the United States (yes vs no)	-.108	0.239	.65
Parent gender (male vs female)	.086	0.304	.78
Comfort with computer use (yes vs no)	-.039	0.175	.82

[a] ADHD: attention deficit hyperactivity disorder.

Secondary Analysis of Individual TLX Domains

The six domains that constitute the NASA TLX (mental demand, physical demand, temporal demand, effort, frustration, performance) were explored for their individual relationships to task environment and to the health literacy of subjects. In all domains except physical demand, the paper environment was associated with higher task burden, although no significant differences between medians were found. Table 3 highlights the details of this comparison.

Table 3. Comparison of task burden for individual domains in paper versus computer environments

Domain	Paper		Computer		*P*-value
	TLX[a] score	IQR[b]	TLX score	IQR	
Mental demand	67.5	(20-195)	50	(15-120)	.11
Physical demand	0	(0-0)	0	(0-10)	.12
Temporal demand	2.5	(0-40)	0	(0-25)	.37
Effort	50	(5-180)	40	(0-120)	.19
Frustration	0	(0-20)	0	(0-10)	.45
Performance	2.5	(0-75)	0	(0-30)	.06

[a] TLX: National Aeronautics and Space Administration Task Load Index.

[b] IQR: interquartile range.

We also explored which domains were ranked by subjects as the most and least important contributors to burden across the two environments. Subjects ranked mental demand as the most influential contributor to burden across both task environments, with 47 subjects in the paper environment and 43 subjects in the computer environment ranking it first. Subjects also reported that both task environments required significant effort, with 35 subjects in the paper environment and 37 subjects in the computer environment ranking it first. Least influential domains across both environments were physical demand (9 paper, 12 computer) and frustration (10 paper, 14 computer). We found no statistically significant differences when comparing the summative rank for each domain between those assigned to paper and those assigned to computer (data not shown).

We further investigated the relationship between health literacy and the rank order of domains judged to be most and least important to subjects when data from both task environments was combined. For mental demand and effort, subjects who scored adequate on the TOFHLA were no more likely than those who scored marginal/inadequate to rank either domain as most important (mental demand, 88/170 vs 2/10, *P* = .10; effort 68/170 vs 4/10, *P* = 1.0). Notably, subjects who scored adequate on the TOFHLA were more likely than those who scored inadequate/ marginal to rank the domain of frustration as least important (115/170 vs 3/10, *P* = .03). There was no significant difference in ranks for the domain of physical demand by TOFHLA category (data not shown).

Parents’ Preferences Regarding Task Environments

After completion of data entry tasks within both paper-based and computer-based environments, parents were surveyed with regard to their preference for which environment they would use if they had to repeat the task in the future. Most (141/180, 78.3%) stated their preference for the computer-based task environment. Table 4 summarizes the reasons given by parents for their preference of task environment for data entry (note that parents were able to choose multiple reasons that explained their preference).

Parents’ preference did not vary based on which task environment they were assigned to first (c^2_1 = 180) = 0.10, *P* = .74). Literacy scores varied between parents who preferred the computer environment to paper, but this variation was not statistically significant (mean TOFHLA score for computer (paper) was 94 (77), c^2_1 = 180) = 3.5, *P* = .06).

Table 4. Number of participants in each group selecting reasons for preference on task environment

Reason	Preference	
	Computer	Paper
It is easier to complete this version	89	10
It is quicker to complete this version	61	10
I feel more comfortable completing this version	29	19
It is easier to read the instructions and questions in this version	25	2
I like writing more than typing, or vice versa	16	3
Other	27[a]	9
Total	141	39

[a] 4 responses indicate benefit for storage and organization; 4 responses indicate convenience as a benefit; 3 responses indicate benefit for improved quality of record; 3 responses indicate benefit for capacity to edit.

Discussion

Principal Results

In this randomized trial, parents completing data entry tasks specific to their child’s ADHD reported superior task experience using a tailored computerized environment compared to using standard paper forms for tracking symptoms, medications, and side effects. The majority of parents preferred the computer environment for the task of entering health information. Notably, working in the computer environment attenuated a disparity with regard to parents’ literacy level and its association with reported task experience. Our results support the contention that a tailored, patient-centered electronic interface provides benefits that lead to patients’ being more willing to re-engage in a subsequent information-giving task – a key construct in optimizing disease control.

Our study was notable for its examination of health literacy as a predictor and the identification of the independent effect of literacy as a predictor for parents’ report of task experience. Lower health literacy was associated with higher task burden independent of the task environment. Although assignment to the computer environment attenuated this disparity, it was not eliminated completely. Specific attributes of the tailored electronic interface may explain the improvement in disparity compared to paper. These include the interface’s multimedia format with colors and pictures that reinforce the parent-child relationship, the navigational path of a home page with 3 defined steps, and feedback about progress through the application. [14,15,21].

Health literacy remained a significant factor in explaining variation in task experience even after adjustment for variables that account for parents’ technology experience, experience with paper forms, sociodemographic descriptors, and years since child’s diagnosis. This finding reinforces the importance of considering literacy during the design of patient-centered information solutions that include data entry tasks [14]. The work of documenting information is not just an expressive act of communication. It also demands skills in reading, problem solving, and organization as an individual attempts to understand and implement the instructions [22].

Comparison to Prior Work

Models of technology acceptance have identified important constructs that underlie individuals’ willingness to engage with an electronic interface: these include self-efficacy with regard to technology, as well as perceived ease of use and usefulness [23,24]. The primary outcome of our study, the NASA TLX, summarizes and quantifies each subject's perceptions of what it took to complete the task and the amount of burden imposed. Importantly, the domains of the TLX include attributes that address both self-efficacy (performance) and ease of use (demand on body, mind, and time). Parents' endorsement of the computer as the preferred environment if the task is repeated in the future can be viewed as a summative, parent-level view of which environment best fits the repeated work of communicating health data specific to ADHD.

Our work addresses a debate in the literature as to whether the digital divide negatively affects traditionally underserved patients on the basis of education, income, or literacy. Our findings highlight a benefit of the computer-based environment for lower-literate parents that are in concert with two prior studies; namely, that a tailored computer-based user interface can meet the needs of patients presumed to be challenged by a computer environment due to lack of knowledge, skills, or self-efficacy. Chen and Zhang in their work comparing graphic and text-based user interfaces noted that "novice users" obtained benefit from a more graphic-based approach compared to expert users, who performed equally well in both environments [25]. In addition, research in cancer communication noted that lower-income patients demonstrated higher access rates than more educated subjects to a comprehensive computer-based support system designed for ease of use [26].

Our results reinforce findings from an earlier study that reported how data entry tasks on health topics impose some effort and mental demand on the reporter [27]. We did not find any differences across the task environments with regard to how individual domains contributed to the overall task experience. The parents with adequate literacy were not different from parents scoring marginal/inadequate with regard to how they ranked the domain with the greatest impact on overall burden.

This investigation of task experience purposefully recruited a community-based sample of parents and studied their data entry efforts in the context of their usual daily environment [28]. Efforts to understand and optimize patient-centered information management strategies require a diverse group of subjects who are completing health tasks at home or a location they frequent in their community – that is, in the physical environment where the task would actually be completed. Although this type of field research introduces variability, as different homes and community locations may introduce different distractions from noise and interruptions, the randomized nature of the trial provides some protection for unmeasured confounders.

Our results inform development of pediatric-specific electronic solutions that call for parents' report of data on behalf of their children. Health literacy, independent of other factors, affects the user experience specific to data entry. Structured electronic interfaces that attend to plain-language goals, provide sufficient "help" functionality, and include multimedia strategies for communication of health data have the potential to mitigate disparity on the basis of health literacy.

Limitations

Several important factors limit our results. We cannot directly address the task burden of longitudinal engagement with a PHR, as we studied only one episode of data entry. Further, the data entry step is only the first of a series of likely interactions that a given patient would have with a PHR, and our findings with regard to task burden for patient-PHR interactions must be viewed conservatively. Our investigation of literacy is limited by the small number of individuals with lower literacy in our recruited cohort. The possibility of a selection bias in our parent sample may persist despite efforts during recruitment to reach eligible parents through social-support networks and community-based service agencies that are not traditional sites of health care delivery. Despite these issues, the results provide a novel perspective on parents' perception of task burden across two common channels used for health communication: paper and computer. Furthermore, the community-based nature of our study of data entry tasks provides important generalizability.

Conclusions

This study suggests that a tailored computer-based environment provided an improved task experience for data entry compared to the same tasks completed on paper. Health literacy was inversely related to task burden. Disparities in burden experienced by parents with lower literacy in the paper environment were attenuated by assignment to completion of tasks using the computer. Health literacy is the most significant predictor of task burden across measured parental characteristics. These findings are relevant to the design and implementation of PHR solutions for pediatric chronic disease where parents' data entry is a key step in information exchange about their child's health.

Acknowledgments

Important contributions to this project were made by Rosanna Batista and Ana Fernandes and the authors thank them for their work in managing the study and recruiting parents. This work was wholly funded by a grant from the National Institutes of Health, National Library of Medicine (R01 LM009256) to Dr. Porter. An abstract that reported results included in this manuscript was presented in October 2009 at the Health Literacy Annual Research Conference, Washington, DC, USA and in May 2010 at the Pediatrics Academic Societies Meeting, Vancouver, BC, Canada. At the time of the study, Dr. Porter was affiliated with Children's Hospital Boston and Harvard University, Boston, MA, USA.

Conflicts of Interest

None declared

Multimedia Appendix 1

Slide 1 displays the one-page unstructured paper form used by parents to document medications. Slides 2-8 display screen shots from the attention deficit hyperactivity disorder (ADHD) application specific to reporting on medications.

[PPT file (Microsoft Powerpoint File), 817 KB - jmir_v13i1e13_app1.ppt]

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Abbreviations

ADHD: attention deficit hyperactivity disorder
NASA: National Aeronautics and Space Administration
NICHQ: National Initiative for Children’s Healthcare Quality
PHR: personal health record
TLX: Task Load Index
TOFHLA: Test of Functional Health Literacy in Adults

Edited by G Eysenbach; submitted 12.07.10; peer-reviewed by C Bermúdez-Tamayo; comments to author 05.08.10; revised version received 03.10.10; accepted 20.12.10; published 26.01.11.

Please cite as:
Porter SC, Guo CY, Bacic J, Chan E
Health Literacy and Task Environment Influence Parents' Burden for Data Entry on Child-Specific Health Information: Randomized Controlled Trial
J Med Internet Res 2011;13(1):e13
URL: http://www.jmir.org/2011/1/e13/
doi:10.2196/jmir.1612
PMID:21269990

Original Paper

Enhancement of Medical Interns' Levels of Clinical Skills Competence and Self-Confidence Levels via Video iPods: Pilot Randomized Controlled Trial

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Abstract

Background: Designing and delivering evidence-based medical practice for students requires careful consideration from medical science educators. Social Web (Web 2.0) applications are a part of today’s educational technology milieu; however, empirical research is lacking to support the impact of interactive Web 2.0 mobile applications on medical educational outcomes.

Objectives: The aim of our study was to determine whether instructional videos provided by iPod regarding female and male urinary catheter insertion would increase students’ confidence levels and enhance skill competencies.

Methods: We conducted a prospective study with medical trainee intern (TI) participants: 10 control participants (no technological intervention) and 11 intervention participants (video iPods). Before taking part in a skills course, they completed a questionnaire regarding previous exposure to male and female urinary catheterization and their level of confidence in performing the skills. Directly following the questionnaire, medical faculty provided a 40-minute skills demonstration in the Advanced Clinical Skills Centre (ACSC) laboratory at the University of Auckland, New Zealand. All participants practiced the skills following the demonstrations and were immediately evaluated by the same faculty using an assessment rubric. Following the clinical skill evaluation, participants completed a postcourse questionnaire regarding skill confidence levels. At the end of the skills course, the intervention group were provided video iPods and viewed a male and a female urinary catheterization video during the next 3 consecutive months. The control group did not receive educational technology interventions during the 3-month period. At the end of 3 months, participants completed a follow-up questionnaire and a clinical assessment of urinary catheterization skills at the ACSC lab.

Results: The results indicate a decline in skill competency over time among the control group for both male and female catheterizations, whereas the competency level was stable among the experimental group for both procedures. Interaction results for competency scores indicate a significant level by group and time (P = .03) and procedure and group (P = .02). The experimental group's confidence level for performing the female catheterization procedure differed significantly over time ($P < .001$). Furthermore, confidence scores in performing female catheterizations increased for both groups over time. However, the confidence levels for both groups in performing the male catheterization decreased over time.

Conclusions: Video iPods offer a novel pedagogical approach to enhance medical students' medical skill competencies and self-confidence levels. The outcomes illustrate a need for further investigation in order to generalize to the medical school population.

(J Med Internet Res 2011;13(1):e29) doi:10.2196/jmir.1596

KEYWORDS

Medical education; healthcare; mobile technology; urinary catheterisation

Introduction

Medical students obtain a rich learning experience in the Advanced Clinical Skills Centre (ACSC) at The University of Auckland, New Zealand. They take courses such as crisis management in anesthesia, open and laparoscopic surgical skills, advanced cardiac life support, general surgical skills, gynecologic principles, orthopedics, and general physician assessment skills. Faculty members at the ACSC provide students with modern human-patient simulations as a part of the medical education curriculum and are willing to try new medical pedagogy to enhance learning outcomes.

The traditional apprenticeship model for teaching clinical skills is no longer feasible due to the shortage of faculty [1]; however, this educational model may be augmented with simulation training, centralized skills training centers, and Web/Medicine 2.0 applications [2,3] that support a constructivist approach to learning [4]. Enhanced medical trainee education, by using new and emerging technologies for teaching and learning, may increase team communication and collaboration, skill engagement and performance, and competency with consequent adverse events, or preventing medical errors. Furthermore, there is an ethical imperative to ensure optimal treatment without doing harm to patients and, therefore, technological advancements may provide a safe environment for medical students to practice [5]. The aim of this experimental study was to determine whether female and male urinary catheter insertion videos provided via video iPods would increase medical students' confidence levels and enhance skill competencies.

Background

Medical video technology delivered via a mobile device has great potential for cultivating a positive learning landscape in medical schools. Educators know that millennial students, born between 1980 and 1994, are technologically adept, stressed, high-achieving, confident, and self-assured [6]. These students demand convenience and require specific educational direction and guidance while attending college. Therefore, the introduction of mobile audiovisual technologies for this type of student is ideal because of the convenience they provide and the specific educational content they deliver. These students are accustomed to waking up and automatically having the current medical news, viewpoints, research, and education to listen to and perhaps view while commuting to the university, work, or the gym. This is made possible by podcasts and video mobile technologies.

Conceptual Framework

From an educational theoretical perspective, Mayer's cognitive theory of multimedia learning posits that people learn best when images are combined with words in an electronic learning environment [7]. Mayer's definition of multimedia includes animation and narration, not just corresponding text and static illustrations. Mayer's studies involve the use of short multimedia tutorials and result in significant learning outcomes. Therefore, Mayer's theory of multimedia learning served as the conceptual framework for this study.

Purpose

The aim of this investigation was to determine whether female and male urinary catheter insertion videos provided via video iPods would increase medical students' confidence levels and enhance skill competencies and retention. It is important to measure both confidence and competence because self-confidence is not always a reliable indicator of skill competence. This study was designed around a central hypothesis that medical students who receive medical skill videos delivered via a mobile technology would have increased self-confidence and skill competency.

Literature Review

Students in the health care professions have benefited from repeatedly listening to learning material at their convenience via mobile technology and have reported high satisfaction using audio and video formats in learning [8,9]. Social Web (Web 2.0) applications, such as podcasts/vodcasts, are becoming common technology applications in health care professional education, and novel research is being conducted and published regarding learning outcomes [10-12]. While no one has clearly defined and agreed on what Medicine or Health 2.0 is, researchers have determined the term originated from the concepts of medicine and Web 2.0 [13]. A podcast/vodcast may consist of an audio and/or video file distributed to a selected media player over the Internet, some smart phones, and iPad-style notebooks, or downloaded to an iPod-like device. Video podcasts may then be referred to as Medicine/Health 2.0 tools to affect health care and education, and perhaps even in underserved countries where mobile health technology is expanding [14].

In regard to use of video iPods in higher education, audio and video formats prove effective in enhancing learning outcomes [14-17]. Health care professional students report satisfaction in listening to lecture material and viewing clinical skills [16]. This innovative pocket-sized mobile device is becoming part of physicians' repertoire of diagnostics, educational tools, and research interventions. However, there is a paucity of evidence around how mobile technology, and using it as a platform for medical education, affects practitioner competence in clinical skills and procedures.

Research Questions

Urinary catheterization of male and female patients is an important technical skill requiring practice. Therefore, we formulated research questions and invited a cohort of medical trainee interns (TIs) attending a clinical skills rotation at ACSC to participate in the study. We set out to answer the following questions. What are TIs' levels of confidence in performing male and female urinary catheterizations prior to a clinical skills course? What are TIs' levels of competence and confidence in performing female and male urinary catheterization after a clinical skills course? What are TIs' levels of competence and confidence in performing male and female urinary catheterization (comparing the control and intervention groups) at 3 months after a clinical skills course? These questions are critical given that urinary catheterization may be a contributing factor to nosocomial infections and other medical conditions [18,19].

Methods

Sample

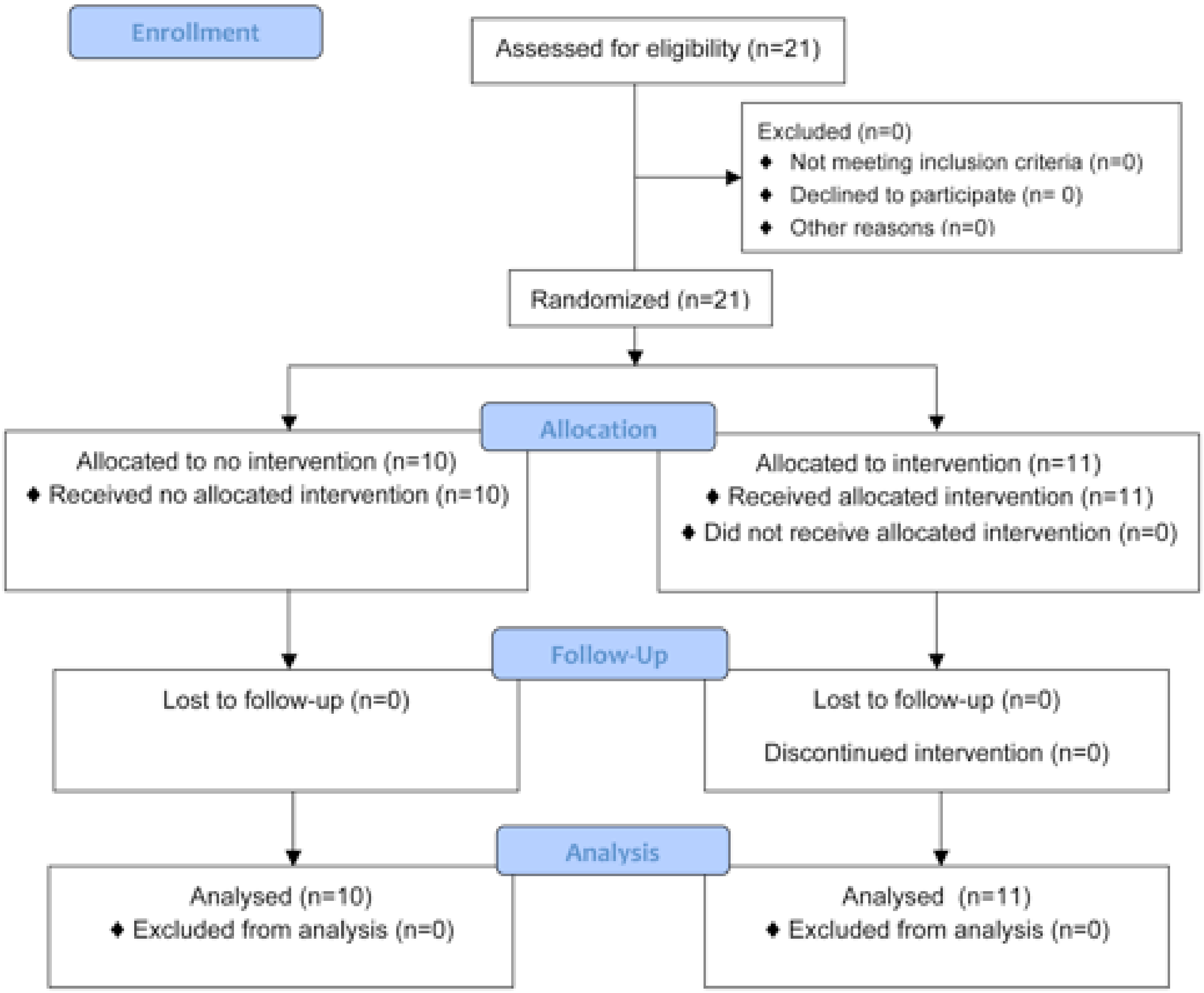
This was a prospective study using a random sample. Carrying out a prospective study with randomized participants in medical education is challenging for three reasons: (1) a randomized trial, particularly if a control group is involved, is perceived to put some students at a disadvantage, (2) variables are difficult to control, and (3) appropriate outcome measures are difficult to identify [20]. We designed and carried out the study with these reasons in mind in order to control for confounding variables.

The study sample consisted of 21 final-year medical TIs attending the University of Auckland's School of Medicine (see Figure 1). Medical TI participants who completed 6 years of medical training were randomized into two groups. The control group (n = 10) and the intervention group (n = 11) were enrolled in a clinical skills course lasting 2 consecutive days. All TIs are required to complete the clinical skills course during the final year of medical school. Six clinical-skill course cycles are held throughout the year, and we randomly selected this study sample from the six cycles of TIs rotating through the scheduled courses in 2006.

Since the participants were enrolled in an established teaching course, Institutional Review Board of Protection of Human Subjects approval was not required. Furthermore, trials including health care providers as participants are exempt, and therefore this randomized control trial was not registered [21]. We obtained consent to participate in the study from the medical TI participants.

A power analysis was not conducted for this experimental study. TIs were assured that participation in the study was voluntary and would not have an effect on any course grades or employment at the University of Auckland.

Figure 1. CONSORT flow diagram



Precourse Evaluation: Skill Experience

The skills taught during the clinical skills course were advanced cardiac life support, lumbar puncture procedure, nasogastric tube insertion, urinary catheterization of a male and a female patient, and the care of an open contaminated wound. Participants were asked at the onset to state expected learning outcomes from the clinical skills course and at the end of the study to evaluate the course. Precourse questionnaires were newly developed and distributed by the medical school faculty to both groups of TIs before instruction on male and female urinary catheterization. The precourse evaluation questionnaire contained five questions concerning (1) prior exposure to the male and female urinary catheterization skill, (2) self-reported level of confidence in performing the skills, (3) importance of mastering the procedures for male and female urinary catheterizations, (4) to what extent TIs would make use of the clinical procedure in future medical practice, and (5) TIs' level of fatigue before receiving training for the medical skills.

Another purpose of the precourse questionnaire was to determine levels of TIs' preexisting knowledge that might confound the results of the study [20]. Validity and reliability of the newly developed questionnaire were not assessed. All questionnaires were collected from the TIs by the clinical skills course director and kept in the director's locked office cabinet. Participants were assured that their precourse questionnaire responses would be kept confidential and that the data would be kept for 5 years before being securely disposed of.

Competency and Confidence Levels

Directly after completing the precourse questionnaire, the TIs viewed a professionally filmed 15-minute male urinary catheter insertion video and a 15-minute female urinary catheter insertion video in the ACSC on a television monitor. Immediately following the videos, the TIs viewed a live 10-minute demonstration of the male and female urinary catheterization skill (5 minutes for each skill) performed on a mannequin by a physician in the ACSC. The total training time was approximately 40 minutes. The TIs were directly given the opportunity to practice each skill on the male and female mannequins in the ACSC under the supervision of clinical tutors. All TIs participated in the practice session. Each practice procedure lasted on average 10 minutes.

The TIs then completed both procedures while being formally assessed by a physician faculty member who used a 16- and 15-item paper-based competency skill evaluation tool for the male and female catheterization procedures, respectively. An ACSC faculty physician wrote the competency skill evaluation tools. The assessment tool consisted of a written skill checklist, comprising direct observation with criteria, for steps in the demonstrated/learned procedures. Kneebone [22] recognizes that there "is as yet no uniform approach to measuring performance"; however, we chose this method because we did not consider the clinical skills to be sufficiently complex to warrant a more arduous form of assessment. The reliability and validity for this form of assessment are high for surgical skills procedures, since subjectivity is removed from the evaluation process [23]. Each participant had to satisfactorily demonstrate insertion of a urinary catheter into the male and female simulation mannequins while being assessed against a set of standardized procedure metrics.

The students' competency scores were calculated by averaging the 16 clinical procedural steps for the male catheterization skill and the 15 clinical procedural steps for the female catheterization. The procedural steps were setting up a sterile field; maintaining sterility during urinary catheter tray setup; choosing the correct size and type of catheter; explaining the procedure to the patient; questioning the patient about allergies to iodine, latex, and adhesives; washing hands before donning sterile gloves; demonstrating correct technique for donning sterile gloves; cleansing the patient's skin while maintaining aseptic technique; properly draping the patient with a sterile towel; inserting the catheter while adhering to sterile technique; ascertaining correct depth of catheter insertion before inflating the Foley catheter balloon; gently pulling back on the catheter to confirm balloon inflation and position; correctly connecting and anchoring the catheter; indicating that patient's foreskin would be replaced at the end of the procedure; and properly documenting the patient's chart (date of insertion, volume of balloon inflation, and any complications). The student either "correctly" or "incorrectly" performed each step of the procedure.

Following this evaluation process, TIs were randomly assigned to two groups: control and intervention. The randomization process involved consecutively numbering 21 envelopes, provided by a third party not involved in conducting the study, with allocation to either the intervention (video iPod) or control group (no technology) in each envelope. After consenting to participate in the study, TIs were irreversibly randomized by being provided the sealed envelope. The intervention group was given unlimited access to two ACSC faculty-prepared videos (see Figure 2) presented via a video iPod: female (Multimedia Appendix 1) and male urinary catheterization procedures (Multimedia Appendix 2). Use of the video iPod was explained to the intervention group, and members of the intervention group were contacted by email 2 weeks after receiving the video iPods to inquire about technical difficulties using the hardware or software. To avoid a confounding variable, the control group was not given any technological intervention for 3 months. The intervention group was asked not to share the videos delivered via the video iPods with their peers or discuss the learning process.

Figure 2. Advanced Clinical Skills Centre faculty-prepared video of a female catheterization (University of Auckland, New Zealand)

After 3 consecutive months, all participants were reevaluated against the same set of standardized metrics used before the intervention and by the same evaluators who conducted the training course to ascertain students' competency in the urinary catheterization skills. Evaluators were blinded to which group was being assessed. TIs filled out a 3-month follow-up course questionnaire that measured exposure to the male and female urinary catheter procedures since attending the initial clinical skills course at the ACSC and their confidence levels (secondary end point) for each catheterization procedure. The ACSC staff member researcher responsible for arranging the follow-up meeting used text messaging to remind participants of the upcoming 3-month follow-up evaluation at the ACSC.

Results

Sample

Data were entered into SPSS version 18 (IBM Corporation, Somers, NY, USA) for statistical analyses. Demographic data (see Table 1) were entered and a male/female catheterization experience variable was calculated.

Table 1. Demographic characteristics of trainee interns (N = 21)

Characteristic	Intervention group (n = 11)	Control group (n = 10)
Males	5	2
Females	6	8
Age range (years)		
16-26	8	9
27-36	3	0
37-46	0	1

Precourse Evaluations: Skill Experience

Before learning the clinical skill procedure, students' experience was measured as the number of times they had performed a urinary catheterization. For the 3-month follow-up experience measurement, the number of times students had "performed" or "assisted" with the clinical procedure was included in the data collection. Table 2 shows results for skill experience with male and female catheterization procedures. For the control group, we did not obtain data for one participant at the 3-month follow-up on both procedures. For the intervention group, we obtained data for 10 participants at the precourse and 3-month follow-up times. For one question at the 3-month follow-up time, we obtained only eight responses.

Table 2. Trainee interns' urinary catheterization skill experience in terms of the number of times they had seen, assisted in, or performed the procedure

Time point of study	Catheterization procedure	Control group					Intervention group				
		0	1-2	3-4	>4	Total n	0	1-2	3-4	>4	Total n
Before course											
Preintervention	Male	0	7	3	0	10	2	5	2	1	10
Preintervention	Female	0	8	2	0	10	2	6	0	2	10
Seen since course											
3-month follow-up	Male	1	4	4	0	9	2	5	2	1	10
3-month follow-up	Female	3	3	1	2	9	5	4	0	1	10
Assisted since course											
3-month follow-up	Male	3	6	0	0	9	5	2	1	0	8
3-month follow-up	Female	6	3	0	0	9	9	0	0	1	10
Performed since course											
3-month follow-up	Male	1	4	1	3	9	7	0	1	2	10
3-month follow-up	Female	6	2	1	0	9	7	2	0	1	10

Competency and Confidence Levels

A high procedural score suggests higher TI competency. The results indicate a decline in competency over time in the control group for both female and male catheterizations. However, the competency level was stable in the intervention (video iPod) group for both procedures. The postcourse male urinary catheter insertion competency scores were nearly equal for the control and intervention groups and close in value to the postcourse female urinary catheterization competency scores for the control group. The greatest difference was in the intervention group competency score for the female catheterization procedure at the 3-month follow-up course, which was higher than the other competency scores (see Table 3).

The TIs' confidence levels were measured at the pre-, post-, and 3-month follow-up course for female and male catheterizations separately. The mean values for the participants are reported in Table 3. The change scores indicate a practical significance and perhaps, with a larger sample size, the results would have been different and deemed clinically significant.

Table 3. Trainee interns' skill competency and confidence scores by procedure (N = 21)

	Time point of study	Control group mean (SE)[a]	Intervention group mean (SE)
Skill competency by procedure			
Female catheterization	Postcourse	1.79 (0.07)	1.88 (0.07)
	3-month follow-up course	1.61 (0.07)	1.88 (0.08)
	Change score	0.18	0.00
Male catheterization	Postcourse	1.83 (0.07)	1.79 (0.07)
	3-month follow-up course	1.69 (0.70)	1.80 (0.07)
	Change score	0.14	0.01
Skill confidence by procedure			
Female catheterization	Precourse	2.51 (0.32)	3.36 (0.35)
	Postcourse	2.64 (0.32)	3.59 (0.35)
	3-month follow-up course	3.61 (0.32)	4.50 (0.35)
	Change score	1.10	1.14
Male catheterization	Precourse	3.94 (0.32)	4.60 (0.35)
	Postcourse	3.84 (0.34)	4.31 (0.37)
	3-month follow-up course	2.89 (0.34)	3.93 (0.35)
	Change score	1.05	0.67

[a] SE: standard error.

As noted in the group-by-time interaction (control vs intervention by post- vs 3-month follow-up course), the intervention competency scores were stable for male and female catheterization procedures, while the control group competency scores for female and male catheterizations became smaller. Possible interactions between variables were investigated by using the Kenward-Roger autoregressive correlation matrix. The calculated interaction effect for the interaction between group (control vs intervention), procedure (female vs male catheterization), and time (pre-, post-, 3-month follow-up course) was not significant at the .05 level. However, the group-by-time interaction and the procedure-by-group interaction were significant at the .05 level. The results are highlighted in Table 4.

Table 4. Interaction results for trainee interns' competency scores (N = 21)

Interaction variables	Analysis of variance	*P* value
Group by procedure by time	$F_{1,27.4} = 0.05$	.83
Group by time	$F_{1,27.6} = 5.55$	.03
Procedure by group	$F_{1,21.1} = 7.39$	.02

In regard to TI confidence levels, there was no statistically significant interaction between group (control vs intervention), procedure (female vs male catheterization), and time (post- vs 3-month follow-up course). Neither was there a statistically significant interaction between group (control vs intervention) and time (pre- vs 3-month follow-up course). However, there was a statistically significant interaction between procedure (female vs male catheterization) and time (pre- vs 3-month follow-up course). Over time the confidence scores in performing the female catheterization procedure increased for both groups, while the confidence scores in performing the male catheterization procedure decreased. The results are presented in Table 5.

Table 5. Interaction effects for trainee interns' catheterization skill confidence levels (N = 21)

Interaction variables	Analysis of variance	*P* value
Group by procedure by time	$F_{2,53.7} = 0.49$	.62
Group by time	$F_{2,55.4} = 0.33$	.72
Procedure by time	$F_{2,56.5} = 19.13$	<.001

Discussion

Principal Findings

Urinary catheterization skill competency declined over time in the control group for both male and female catheterizations, whereas the competency level was stable in the intervention group for both procedures. This finding is consistent with findings from other studies where a particular skill or procedure is not practiced: competency is likely to diminish over time. The study cohort of final-year medical TIs also would not have the opportunity to perform urinary catheterization on a regular basis for various clinical reasons [24,25]. Interaction results for competency scores indicate a significant level by group and time, and by procedure and group. The intervention group's confidence level for performing the female catheterization procedure differed significantly over time. Furthermore, TIs' confidence scores in performing female catheterizations increased in both groups over time. However, the confidence scores for both groups in performing the male catheterization decreased over time.

From a clinical education point of view (patient anatomy and comfort level of the TI participant), the male procedure may have been more challenging for the female medical students, who constituted the majority of the study's sample. If gender is a factor and has potential effects on performance and safety, then more research needs to be conducted. In regard to evaluating the student's gender with respect to male and female patients in the clinical setting, anecdotal evidence from researchers' experiences highlights this as a potential educational issue. Also, data suggest a trend for the intervention group to access the two videos via the video iPods just before the 3-month follow-up assessment period and not throughout the 12 weeks following the instruction and immediate postcourse assessment. In the future, researchers may want to measure time-on-viewing (also called time-on-learning) the videos and assess where the students viewed the videos. Time-on-viewing is a significant factor in learning a skill and may be logged in a personal journal by the learner [26]. Learning space is also a factor affecting learning, and it may be beneficial to analyze the effects of time-on-viewing and location-of-learning on medical students' competency, confidence, and knowledge-retention levels.

The significance of implementing mobile devices as learning tools needs to be further evaluated for future educational purposes. Developers of computer-based instruction and other learning technologies benefit from gathering information from formative evaluation strategies when developing instructional media in order to assess clinical judgment and practice [27]. Hence, it may be helpful to conduct a pilot study with the goal of determining which media format is most beneficial for medical students' learning and demonstrating clinical skills before making a final decision about adopting these and other popular mobile social learning technologies. Furthermore, it is recommended that the educator provide the listener/viewer with some sort of interactivity option with the podcast/vodcast producer(s) to answer questions or provide user feedback regarding the podcast/vodcast [28].

Limitations

Even though the statistically significant improvement in student confidence levels for performing the female urinary catheterization clinical skill over time was positive, the primary limitation of this study is the small sample size. Other concerns that need to be taken into consideration in medical education research include: technical requirements and potential problems that students might encounter with video iPods; pressure to perform the skills in a specific way because medical faculty are conducting a study of clinical skill proficiency; and the effect of time-on-viewing and location-of-learning these clinical skills via the video iPod on medical students' competency and confidence levels.

Conclusion

The use of mobile devices, such as a video iPod, smart phone, or iPad-like notebook, for health care professional education is interesting and promising. A convenient and ubiquitous mobile technical device providing scenario-based video presentations enhances a constructivist approach to medical education. There are many potential educational uses of the video iPod for patients, families, and their health care providers all over the world. Furthermore, it is beneficial to offer the audience viewing the videos on mobile devices some interaction with the devices and/or to provide feedback from the podcast/vodcast presenter [28]. The results of this small experimental study suggest that video iPods enhance medical students' confidence in performing the female urinary catheterization procedure over time in a learning resource center, and medical students' skill competency levels remained the same over time when they accessed the video demonstrations, via a video iPod, of the medical procedure. Social learning technologies, such as the video iPod, engage learners and provide an environment where students may connect, cultivate ideas, and collaborate while learning important clinical skills, in keeping with the concept of Medicine 2.0 [29]. Learning outcomes are influenced by mobile technology and offer a convenient adjunct to traditionally designed medical school courses.

Acknowledgments

We wish to thank Elizabeth Robinson PhD and Shannon Halkyard EdD(c) for their assistance with the statistical analyses.

Conflicts of Interest

None declared

Multimedia Appendix 1

Female catheterization

[MP4 file (MP4 Video File), 55,767 KB - jmir_v13i1e29_app1.mp4]

Multimedia Appendix 2

Male catheterization

[MP3 file (MP4 Video File), 71,948 KB - jmir_v13i1e29_app2.mp4]

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Abbreviations

ACSC: Advanced Clinical Skills Centre
TI: trainee intern

Edited by G Eysenbach; submitted 28.06.10; peer-reviewed by M Kamel Boulos, J Brixey; comments to author 01.09.10; revised version received 25.10.10; accepted 24.01.11; published 01.03.11.

Please cite as:
Hansen M, Oosthuizen G, Windsor J, Doherty I, Greig S, McHardy K, McCann L
Enhancement of Medical Interns' Levels of Clinical Skills Competence and Self-Confidence Levels via Video iPods: Pilot Randomized Controlled Trial
J Med Internet Res 2011;13(1):e29
URL: http://www.jmir.org/2011/1/e29/
doi:10.2196/jmir.1596
PMID:21447471

Original Paper

Assessing the Acceptability and Usability of an Interactive Serious Game in Aiding Treatment Decisions for Patients with Localized Prostate Cancer

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Abstract

Background: Men diagnosed with localized prostate cancer face a potentially life-altering treatment decision that can be overwhelming. Enhancing patient knowledge through education can significantly reduce feelings of uncertainty while simultaneously increasing confidence in decision making. Serious games have been shown in other populations to increase health knowledge and assist with the health decision-making process. We developed an interactive serious game, Time After Time, which translates evidence-based treatment outcome data into an accessible and understandable format that men can utilize in their prostate cancer treatment decision-making process. The game specifically aims to raise men's awareness and understanding of the impact of health-related quality of life issues associated with the major treatment options and to enrich their conversations with their health care providers.

Objective: This study determined the acceptability and usability of the alpha version of Time After Time, an interactive decision aid for men diagnosed with localized prostate cancer, in order to inform future iterations of the serious game.

Methods: The study employed a mixed methods approach to assess the acceptability and usability of the Time After Time serious game using qualitative focus groups and a quantitative Likert scale survey.

Results: A total of 13 men who had already completed treatment for localized prostate cancer completed the survey and participated in focus group meetings. The majority of the study participants rated Time After Time as an appropriate decision tool for localized prostate cancer and verified that it meets its goals of increasing focus on side effects and generating questions for the patient's health care team. However, participants also expressed concerns about game usability and the diversity of information covered regarding treatment options and potential treatment outcomes.

Conclusions: Serious games are a promising approach to health education and decision support for older men. Participants were receptive to the idea of a serious game as a decision aid in localized prostate cancer. However, usability issues are a major concern for this demographic, as is clarity and transparency of data sources.

(J Med Internet Res 2011;13(1):e4) doi:10.2196/jmir.1519

KEYWORDS

serious games; prostate cancer; shared decision-making; usability

Introduction

The American Cancer Society predicts that 1 out of every 6 men will receive a diagnosis of prostate cancer in his lifetime, and for 1 in 35, this diagnosis will result in fatality [1]. Prostate cancer accounts for 25% of all cancer cases in American men [2]. The mortality rate from prostate cancer has decreased throughout the past decade, and diagnoses of early or local stage cancer have a 100% 5-year survival rate [2]. However, prostate cancer treatments often come with serious side effects, which can significantly affect patient quality of life in the short- and long-term.

The Severe Uncertainty of Prostate Cancer Treatment

Men diagnosed with localized prostate cancer face a potentially life-altering decision with few facts to guide them. Clinical trials show no single best treatment [3]. While each of the widely accepted and mutually exclusive treatment options has a similar chance of extending life [3], risks of serious side effects such as incontinence and impotence differ according to procedure. Seeking a second opinion can add confusion to the decision-making process, as the majority of physicians recommend their own specialty's treatment [4].

Additional factors influencing patients' localized prostate cancer treatment decisions include fear and uncertainty, misconceptions about treatment efficacy and risks, and applying others' experiences to their own cases [5]. Many men frequently choose an option simply to "get the decision off their minds" [6]. Research has shown that enhancing patient knowledge through education can significantly reduce feelings of uncertainty while simultaneously increasing confidence in decision making [7,8].

The uncertain task of choosing a treatment for localized prostate cancer is made more complicated due to comparable cancer-specific survival outcomes for all active treatments. In response to this added complication, the basis on which patients select a treatment has started to shift [9-14]. Focusing on health-related quality of life (HRQOL) can demonstrate measurable differences between treatment options in the short- and long-term. [15] As more published research reveals the HRQOL issues associated with prostate cancer treatment options [15,16], it is imperative that this research be made available to patients.

To date, a variety of decision aids have been developed to address the challenges of localized prostate cancer treatment decisions, and these decision aids have successfully demonstrated the ability to increase knowledge, enhance active involvement in decision making by patients, and decrease patients' decisional anxiety [9,17]. Lin et al performed a meta-analysis of 13 studies examining the impact of decision aids on the experience of men diagnosed with prostate cancer, 7 of which included an assessment of decision aids' effect on treatment choice [9]. Of these 13 studies, 4 in particular showed that decision aids can impact prostate cancer treatment choice (patients choosing a treatment other than surgery, a treatment that differed from their doctors' recommendation, or changing their treatment choice from their initial preference) [10,17-19]. These studies have demonstrated the potential for decision aids to facilitate patient empowerment in the decision-making process, and have suggested an effective link to potentially more conservative treatment choices. However, more research is still needed on the real-world role of localized prostate cancer decision aids [9] and on whether decision aids actually help patients choose the treatment that best aligns with their lifestyle preferences [3,10].

The Evolving Role of Serious Games

As the link between patients' knowledge and positive health outcomes evolves, researchers increasingly look to interactive gaming technology as a vehicle for delivering health information. Serious games employ interactive game elements for purposes other than entertainment, such as education or training [20-22]. Lieberman defined an interactive game as an experience that involves rules, an assigned challenge that is serious in intent, movement toward a goal, and a defined ending [23]. Garris et al stated that games create a system that the user chooses to enter in order to accomplish a goal or overcome a problem contained within the game [24]. They also emphasized the iterative nature of games, that is, the built-in potential of the interactive game to support repeated "rounds" or game cycles.

Serious gaming represents a potential tool to effectively address health issues. Previous studies have shown success using games to impact factors such as disease management, behavior change, and health education [25,26]. While current literature focuses largely on the effect of serious health games on youth, evidence exists to support the use of serious health games to impact the health of older adults [27,28]. Approximately 40% of Americans aged 50 to 65 play video games [29]. Additionally, studies have shown that using interactive computer games can have a positive impact on elderly adults, specifically by improving levels of psychological health and cognitive functioning [28,30-32].

Designing an Interactive Decision Aid

In response to the difficulties facing men diagnosed with localized prostate cancer, we decided to capitalize on the potential of serious games to assist with the treatment decision-making process. We sought to develop a serious game that would guide users through a simulated experience of the common impacts on HRQOL over the short- and long-term to help them determine which treatment strategy would be most acceptable to them, based on their personal preferences. As such, we based our serious interactive game, Time After Time, on the premise that eliciting users' HRQOL preferences would offer unique and valuable insight to aid the decision-making process for localized prostate cancer treatment.

The game attempts to elicit user preferences regarding the impact of treatment side effects on a user's preferred quality of life. Side effect scenarios are presented to users of Time After Time based on statistical probabilities derived from a large, prospective, multiregional study [15]. This study collected data from 1208 patients using the expanded prostate cancer index composite (EPIC), the landmark tool to measure HRQOL after prostate cancer treatment [33]. The EPIC survey tool evaluates patient function and bother in 5 major domains (vitality, urinary bother, urinary control, bowel control, and sexual function) at baseline and at 2, 12, and 24 months following treatment in order to characterize treatment-specific impacts on HRQOL. We used the published data set from this study [15] and the EPIC tool to functionally elicit user HRQOL preferences regarding side effects associated with the 3 active prostate cancer treatments (prostatectomy, brachytherapy, and external radiotherapy) and watchful waiting, accepted as standard care by the US National Institutes of Health National Cancer Institute [34]. Users of Time After Time rate side effects that they would potentially experience immediately after treatment, after 2 months, and after 12 months according to their personal lifestyle preferences.

Although EPIC was originally developed as a retrospective tool, it has been successfully employed in prospective HRQOL research. The developers of EPIC tested a prospective version of the survey instrument and found that the modified version accurately predicted urinary and bowel symptoms and was slightly less accurate at predicting sexual symptoms at 12 months posttreatment [35]. Pinkawa et al used the original, retrospective EPIC in a 2009 prospective study of the impact of age and comorbidities on HRQOL in localized prostate cancer and concluded that prospective use of EPIC was accurate across all domains from the patient's perspective [36].

While EPIC has been validated as a prospective tool for predicting symptoms, our game attempts to elicit feelings about future events—a notoriously difficult task [37]. One recent study that prospectively examined how men ranked the importance of 11 factors in localized prostate cancer treatment found that men's pretreatment feelings about what is important in prostate cancer treatment generally aligned with their posttreatment ratings [38]. While most men altered rankings of importance in at least 1 of the 11 factors 6 months after they chose their management course, the authors found that "the majority of pre-post evaluations were very consistent" [38].

The design of the game's graphical interface used to present side effect combinations came from themes identified in an unpublished qualitative study of interviews with prostate cancer survivors in which men described the processes they went through to make their treatment decisions. A recurring theme that emerged throughout the interviews included a visual in which men laid out information regarding treatment options on a table as a key part of their decision-making process. We incorporated this visual into Time After Time by using playing cards to display potential side effects. These cards were laid out on the user's screen, or virtual "table," and organized by time period into the 5 main side effect domains used by EPIC survey.

The Time After Time Experience

Users begin playing Time After Time by securely logging in to the game using their personal username and password. Once they have logged in, they go through a guided orientation round before starting the official rounds of game play. White boxes appear with instructional explanations of imagery and symbols to help the user become familiar with the game's interface and instruct their movements for each round to come. Time After Time allows the user to explore potential side effects of 4 treatment options: radical prostatectomy, brachytherapy, external radiotherapy, and watchful waiting. Side effects appear throughout the game using playing card imagery. For each treatment and each time period (immediately after treatment, 2 months after, and 12 months after), side effect card combinations are shown to the user (Figure 1). Each time a user reads a side effect card, he must rate it on a 5-point scale from 1, "no problem" to 5, "big problem." Throughout this process, users may save any card that is unclear or that raises new questions to a list of questions for his doctor that can be accessed at the end of at least one round of game play (Figure 2).

Figure 1. A side effect card in which side effects appear to the user using playing card imagery

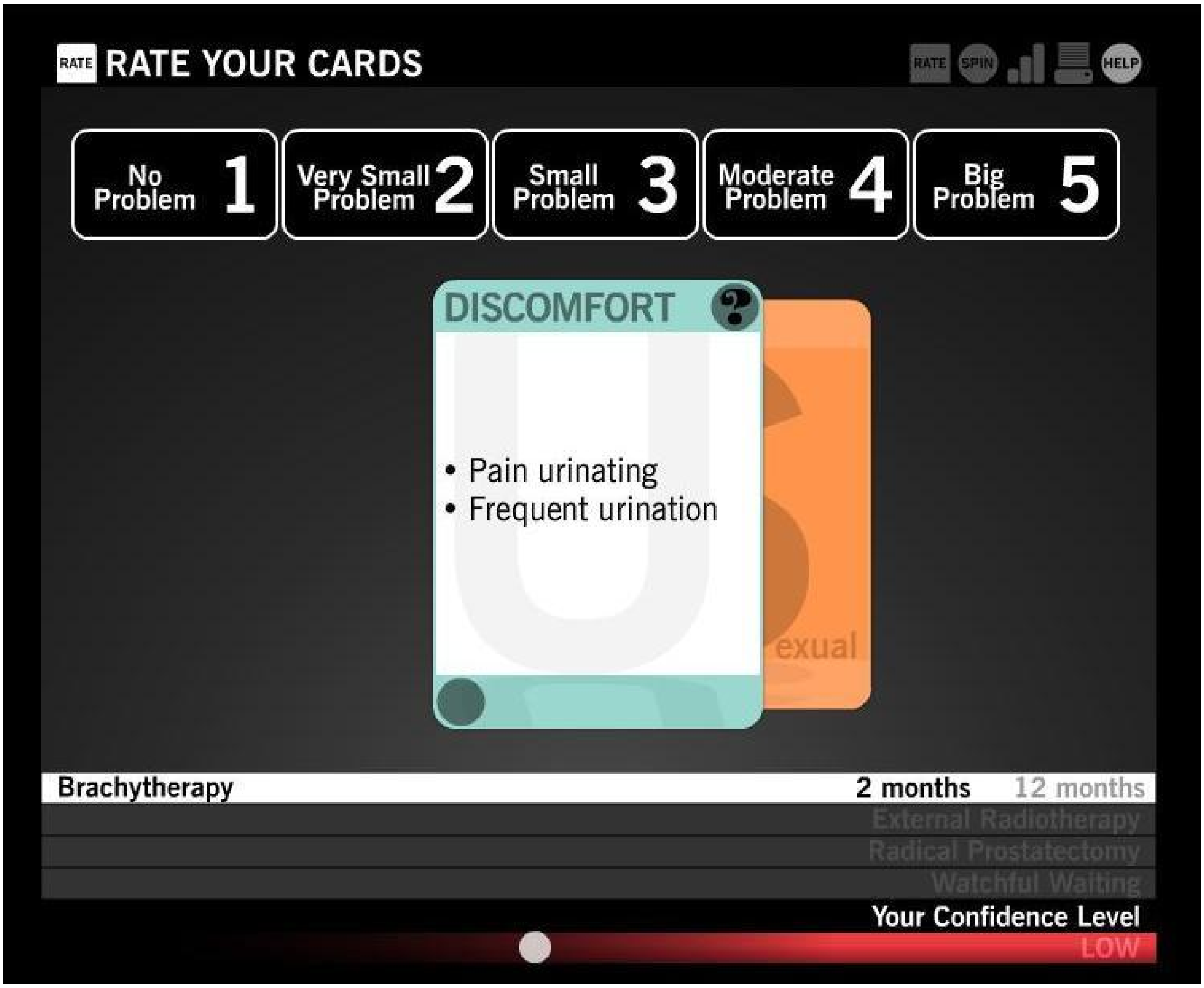
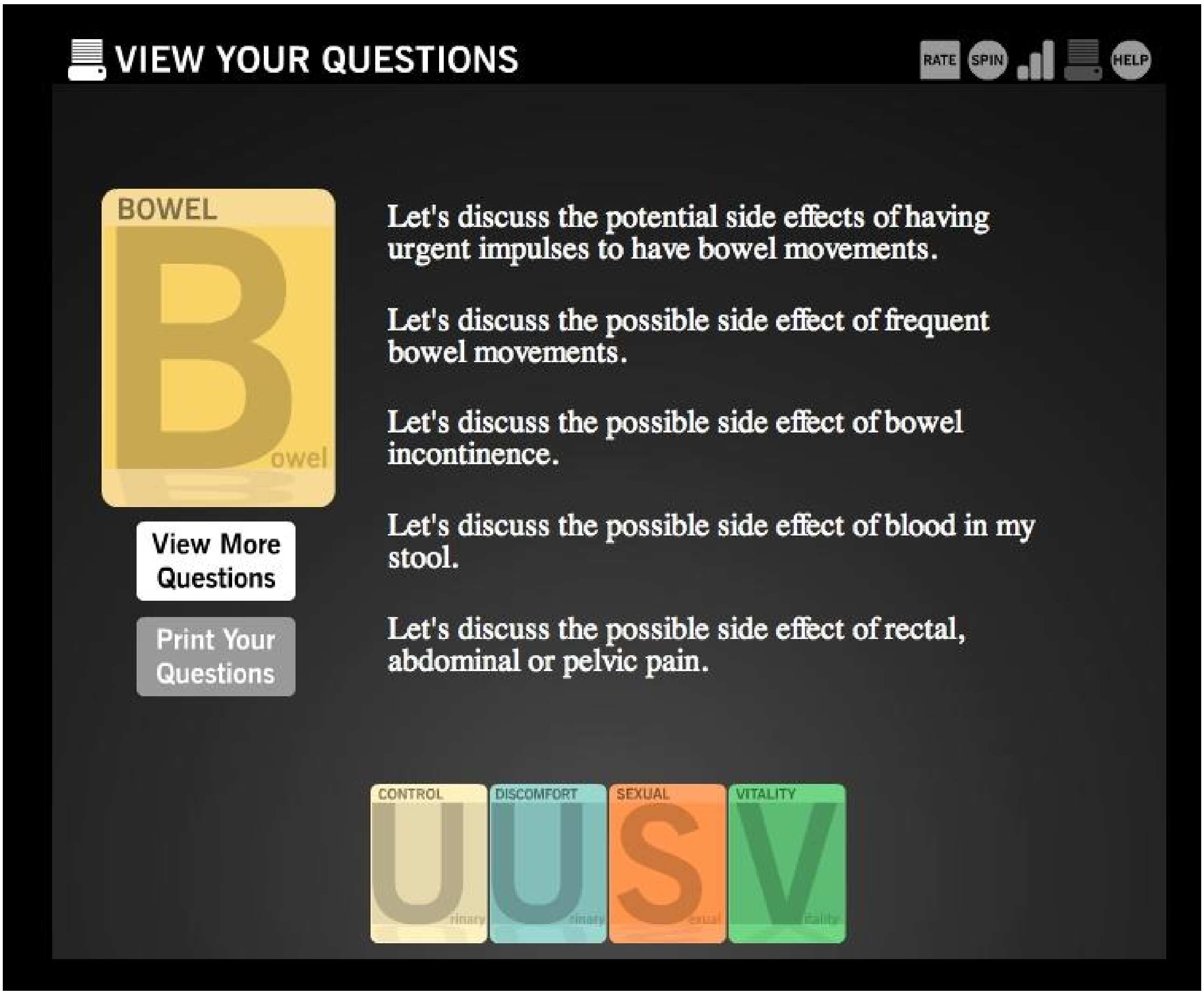


Figure 2. The section of the game that allows users to save questions that arise through interacting with the game for discussion with their care providers



Let's discuss the potential side effects of having urgent impulses to have bowel movements.

Let's discuss the possible side effect of frequent bowel movements.

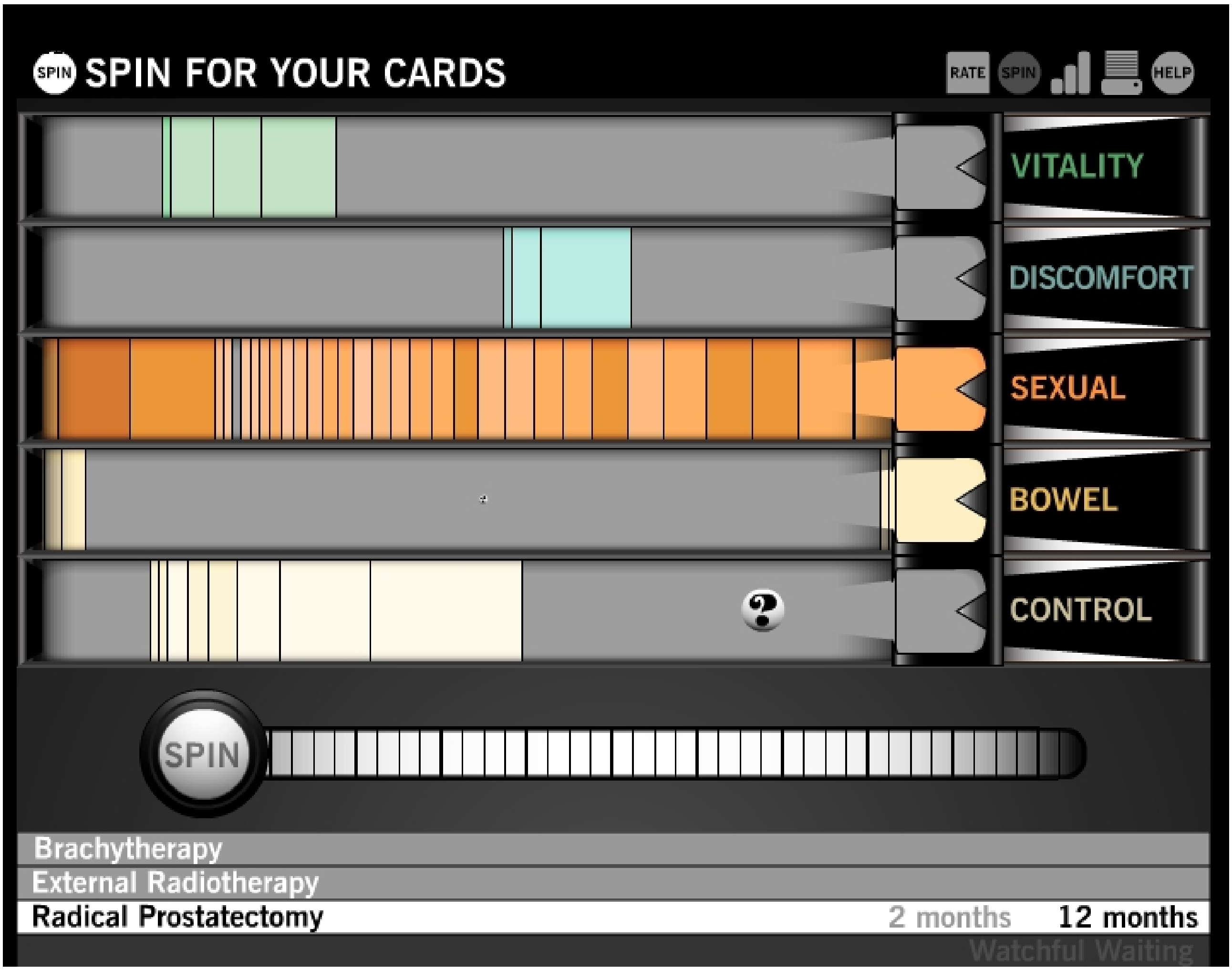
Let's discuss the possible side effect of bowel incontinence.

Let's discuss the possible side effect of blood in my stool.

Let's discuss the possible side effect of rectal, abdominal or pelvic pain.

Game play begins after the guided round by presenting the user with the immediate side effects of watchful waiting for him to rate according to his preferences. After watchful waiting, the user is similarly guided through the immediate effects of radical prostatectomy, brachytherapy, and external radiotherapy. After the user has rated the side effect cards in all 4 treatments in the time period immediately following treatment, he is introduced to the spinner screen using another guided orientation round. Using slot machine-like imagery, the spinner screen graphically displays probabilities of different side effects in 5 domains: vitality, urinary discomfort, sexual, bowel, and urinary control (Figure 3). Each time the user spins, the user is dealt side effect cards corresponding to the treatment and time period he is exploring. He then rates these cards using the same 5-point scale as during the immediately after treatment time period. The spinner and card imagery reinforce the role of chance in the sense that the cards the user is dealt are based on actual probabilities (derived from the EPIC studies) [15].

Figure 3. The spinner screen, which uses slot machine-like imagery to display probabilities of different side effects



After the user has rated side effect cards at the time periods of 2 months posttreatment and 12 months posttreatment, he sees a categorized summary of how he rated cards by time period and side effect domain (Figure 4). This summary provides a visual cue of which domains he considers most and least problematic. Round 1 concludes when the user has completed rating the side effect cards in all of the treatments and time periods. After round 1, the user can view his results, which include the treatment for which the possible side effects best match the user's preference ratings, a ranked comparison on all treatments (Figure 5), a ranked list of which domains concern the user most, and the list of questions generated for the doctor (Figure 2). The user can also play additional rounds of Time After Time to experience alternate side effect possibilities, thereby helping the user refine the game's results to more accurately reflect their preferences.

Figure 4. The summary screen, which displays the user’s rating of side effects by period and domain

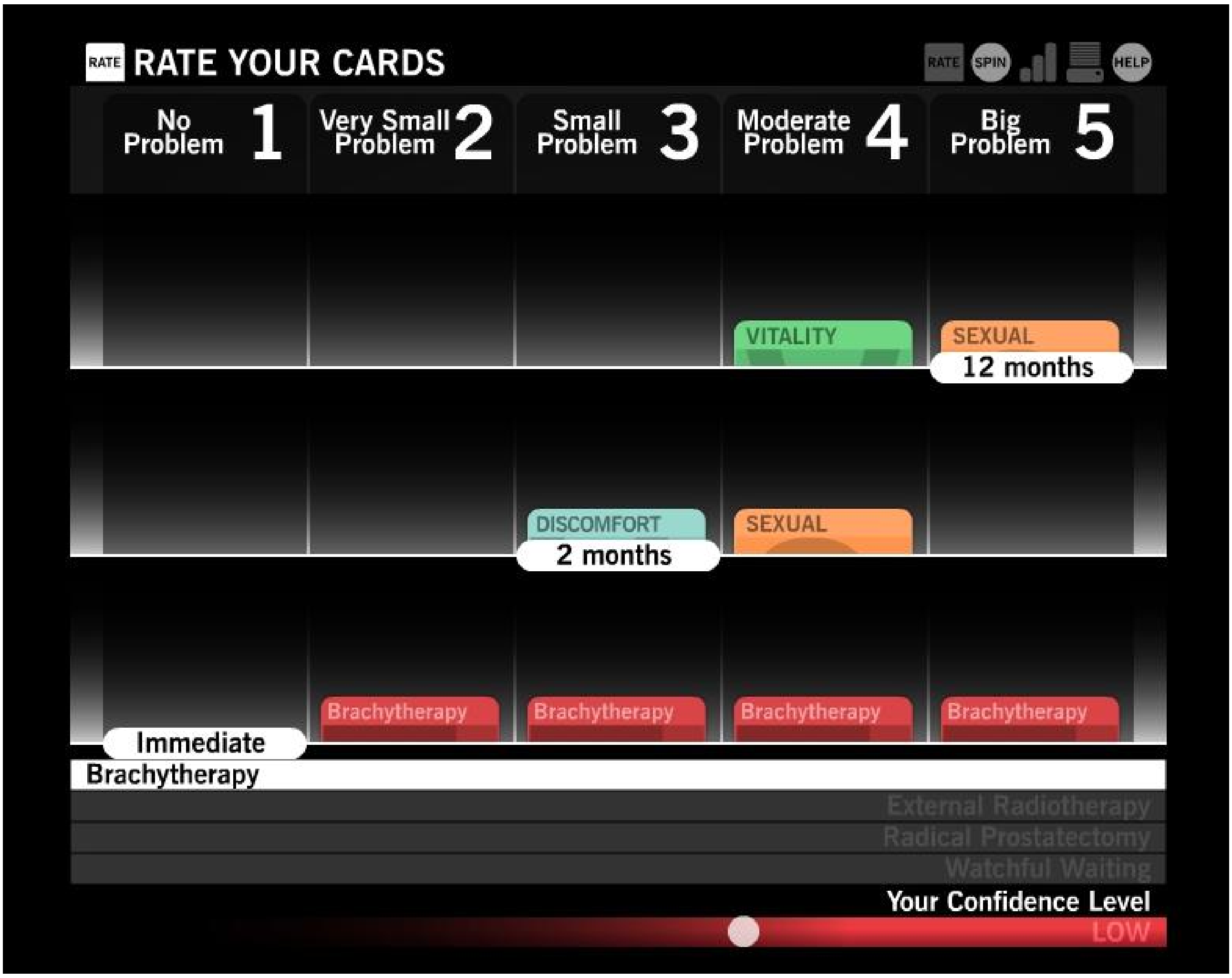
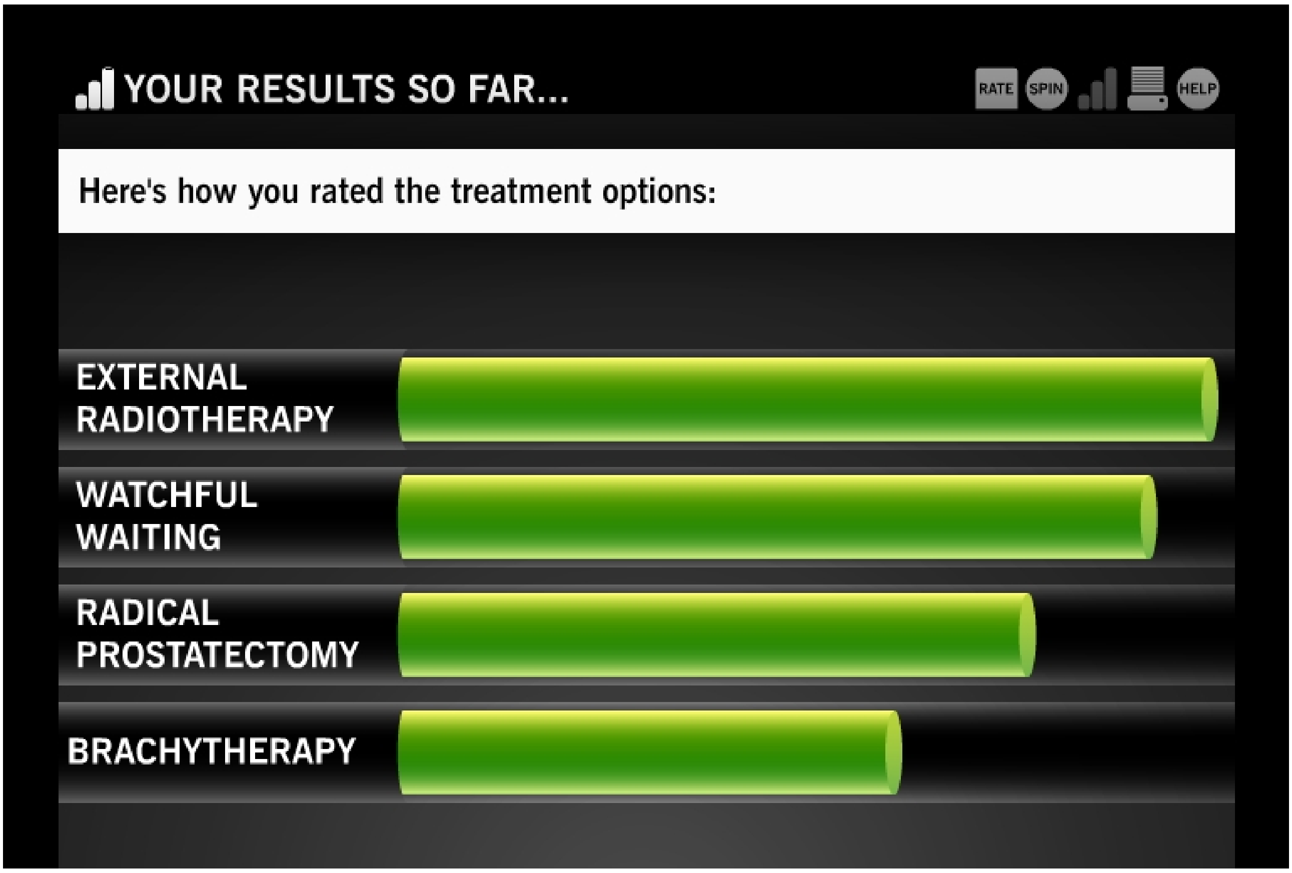


Figure 5. The first-round results screen, which includes a ranked comparison of all treatments (users are encouraged to complete more rounds to refine their results)


YOUR RESULTS SO FAR...

Here's how you rated the treatment options:

Time After Time was designed to help patients understand how side effects could impact their HRQOL following different treatment options, with the goal of increasing patient confidence and empowering their participation in the decision-making process. This paper presents the results of a preliminary user-feedback study of Time After Time. A common practice in game design involves employing user input to inform various stages of game development [39,40]. Additionally, typical software development procedures require stages of testing, beginning with the earliest usable version of the technology, or the alpha version [41]. Following these practices, we recruited prostate cancer survivors to evaluate the alpha version of Time After Time. The study attempted to determine the acceptability and usability of the interactive decision aid for men diagnosed with localized prostate cancer and collect user feedback to inform future iterations of the serious game.

Methods

Study Design

The research team used a mixed methods approach to assess usability of Time After Time by combining a survey and focus group study. We focused on users early on and continuously in our development of the serious game, a practice commonly followed in game design [39-42]. The iterative development process we employed involved using quantitative and qualitative testing with small samples of potential users throughout the game development process to diagnose and address problems [41,43].

Prior to recruiting participants, the institutional review board at The Methodist Hospital Research Institute in Houston, Texas, approved the study protocol. A primary facilitator and 1 or 2 additional team members ran each focus group session. Facilitators consulted 2 experienced researchers with substantial experience in focus group mediation prior to the initiation of the study. Consultations included one-on-one instructional demonstrations with researchers and a review of literature on focus group facilitation [44]. A practice focus group session was held prior to recruiting study participants.

Focus group sessions consisted of a short introduction, game play, questionnaire completion, and group discussion. After 45 minutes of independent game play, participants completed a written survey based on their experiences. The unvalidated survey instrument was developed for this study with the goal of providing a quantitative assessment of the game’s usability and acceptability. The session ended with a 45-minute, semistructured focus group discussion based on a predetermined set of questions that guided topics covered by the groups.

Participants

Inclusion criteria for focus group participants included men between the ages of 45 and 85 who were diagnosed with localized/early-stage (sometimes called stage I or stage II) [45] prostate cancer after 1998 and before November 2007. The age range was chosen to reflect the population of men typically screened for localized prostate cancer [46] and for whom the game is designed, as well as to maximize our ability to recruit participants for the study. Additionally, the range in dates specified for diagnosis ensured the exclusion of newly diagnosed patients in order to minimize any psychological risks that could arise by allowing an unvalidated version of the game to influence treatment decisions. We did not stratify by age, race, or socioeconomic class but did make efforts to include a diverse sample.

Recruiting for focus groups took place during monthly meetings of a local Houston prostate cancer support group, as well as through emails to the groups' online listserv. During the 6-month study period, a total of 13 participants attended 1 of 4 focus group sessions (3 groups of 3 participants and 1 group of 4 participants). Recruiting was concluded following the completion of these 4 focus group sessions, as focus group transcript analyses revealed a repetition of themes and responses indicating we had achieved a level of saturation appropriate for the preliminary testing of Time After Time [43,47].

Data Collection and Analysis

We collected quantitative measures of acceptance and usability from an 18-item instrument based on a 7-point Likert scale (Multimedia Appendix 1). This instrument was developed in line with user-centered game design principles, which use surveys or questionnaires to collect attitudinal data regarding participant views [41]. In keeping with this methodology, Likert items were designed for participants to rate their overall impressions of the game, how easily they were able to use the game, and usability of specific game features.

Focus group discussions were recorded and transcribed verbatim. Using grounded theory as the basis for analysis of focus group data [48], an audit committee of 5 researchers conducted a thorough review of the focus group session transcripts. Of the 5 researchers, 2 were experienced in coding and had training in qualitative analysis methods. Researchers induced thematic patterns from their analysis of the transcripts and, as such, were able to define and report frequencies of key themes. Definitions were arrived upon through committee discussions and dialogue, and disagreements were resolved through reliance upon the verbatim transcripts to ensure the highest level of consistency and accuracy.

Specific attention was paid to the identification of themes regarding acceptability and usability of Time After Time. Acceptability was defined as participants' willingness to use Time After Time specifically, and an interactive computer game in general, in decision making for localized prostate cancer treatment. Researchers defined usability as the potential user's ability to navigate through a session of game play. The key measure of usability was the users' self-reported perceptions of the game's ease of use [43].

Results

The results of the focus groups address the study's 3 major questions: (1) Do users accept the interactive computer game as a decision aid for localized prostate cancer? (2) Can users easily navigate and use the interactive computer game? (3) Does the game effectively increase users' confidence and participation in the decision-making process?

Survey Instrument Results

Participants completed the survey instrument immediately following game use (Multimedia Appendix 2). Answers were rated on a scale of 1 to 7, 1 corresponding to "strongly agree" and 7 corresponding to "strongly disagree." The scale was designed so that means closer to 1 would indicate a more positive response and means closer to 7 would indicate a more negative response. Likert data were analyzed using mean values, which is in accordance with standard assumptions for interval data analysis [49].

Item 4 of the survey ("An interactive website is effective for providing information") had the mean closest to 1, indicating positive perception of an interactive computer game's ability to provide information on treatments and side effects (mean 2.77). Survey results for item 8 of the instrument ("While using the interactive website, it is clear which time period is being explored") indicated participants generally understood the game's simulated time period of immediately, 2 months, and 12 months after treatment, but the proximity to the middle point suggests that this area of simulation could be improved in the future (mean 3.08). Features that received negative user feedback included the "spinner" screen displaying side effect probabilities (mean 4.67), and the screen displaying the final treatment ranked highest by the user (mean 4.92).

Acceptability: The Game's Role in the Treatment Decision Process

Focus group discussions began with the participants describing their own treatment decision-making process. All participants stated that they conducted their own research when trying to decide on a treatment for localized prostate cancer. Speaking one-on-one with doctors, friends, or family members previously diagnosed and treated for prostate cancer was cited by 10 out of the 13 participants as crucial to their personal research on treatments. In addition, the men revealed that in conducting their own research on localized prostate cancer and its treatment options, they often used a diary or journal for personal note taking. Participants discussed using such notes during appointments with their doctors and stressed the importance of recording their own notes and questions throughout their decision-making process.

The utility of Time After Time's feature allowing users to highlight side effect cards they do not understand and print questions at the end of the game was validated by participants in all focus groups. Participants repeatedly expressed their appreciation for the game's option to print questions on treatments and side effects, given their tendency to use personal note taking to document their research and inform conversations with their doctors. One user stated,

> *I think [the print option is] good because to me…because so many times you go to the doctor and you're just so overwhelmed. And you don't know what to ask them, because you say…well, the doctor says, "Do you have any other questions?" and I say, "Well, I can't remember what they are."*

Acceptability: Users' Perceptions of a Serious Game for Localized Prostate Cancer

Participants were asked to discuss their feelings surrounding the use of an interactive computer-based decision aid in general, and Time After Time in particular, to make a treatment decision for localized prostate cancer. In all, 5 men stated they would not use the Time After Time computer game as a way to definitively choose a course of treatment. However, when asked whether they would use the game as a part of their decision-making process, 10 of the 13 participants reported that they would welcome it as a mechanism to enhance their education, in addition to their other preferred methods of research. As one man stated,

> *I look at [Time After Time] as being a tool, one of the tools, not the final tool. I don't think I would make a decision based on this, but I would use it and then use other things to [help me] make a decision.*

Participants found usefulness in the game's ability to raise more and better questions for their doctors, as well as its ability to reveal new information on the side effects of treatment they should consider during their decision making process. Commenting on the lack of understandable information when researching his own prostate cancer treatment options, one participant expressed a desire for "a tool that might help you make a better decision…because I was ravenous for information when I found out about [my diagnosis]."

Usability: Game Design and Content

The focus group participants revealed flaws in the game design that sometimes made it difficult for them to navigate and sometimes distracted them from the game's intended purpose. Participants often had trouble completing a full round of the game without help from study staff and were not always clear on what they needed to do next in the game. However, the majority of men verbally reported successfully grasping the concept of treatment simulation for 3 time periods.

Another aspect of treatment decision making that participants discussed was the descriptions of the side effects covered throughout the game. A third of the participants requested greater detail in the descriptions on the side effect cards. For them, phrases like "urinary incontinence" or "erectile dysfunction" did not communicate the actual experience or meaning of the side effect for someone who lacked personal experience. Additionally, about 30% of participants requested that the game include a wider variety of treatments that extended beyond the 4 options presently included. Rapidly developing technologies and the emergence of new treatment methods represented important considerations for men in the midst of the decision-making process.

Usability: Time After Time and Decision Making in Localized Prostate Cancer

Focus group discussions revealed that the game's design currently leaves out several aspects of treatment decision making that participants identified as crucial features of the experience. For example, many participants reported that when they made their own treatment decisions, long-term survival rate was the most important factor they considered. The possibility of cancer recurrence, as related to specific treatments, represented a vital aspect of their treatment decision. Thus, participants expressed a desire for the game to cover a time period of 5 to 10 years, as opposed to just 12 months, to reflect the possibility of recurrence posttreatment. Also, participants requested that the game more effectively communicate the possibility for side effects to dissipate over time. Many brought up the availability of surgery or medication, which may have the ability to diminish the severity or eliminate negative side effects in the long term. As such, participants requested that the game include a reference to the variety of options available posttreatment to prostate cancer survivors.

A dominant theme brought up in all focus groups was the request for the inclusion of a prologue introducing Time After Time that contains more in-depth explanations regarding the goal of the game, limitations of the analysis process, and the context in which men diagnosed with localized prostate cancer should use Time After Time. Additionally, 10 out of 13 participants expressed the desire for Time After Time to include user input. As one participant described,

> *For some people, it's about "man, I'm going to live as long as I can." I know people like that. I'm not one of those people. I want to live a really good life for whatever time I have left. And those sorts of qualifying questions about "where are you in life?" [are what is missing from Time After Time]…[What the game needs] is a little bit more qualification about who are you and what are you doing.*

A recurring theme in focus group sessions surrounded the availability of the medical data on which Time After Time was based. Over half of the participants requested a transparent description of the statistical foundation supporting the side effect scenarios generated while using the game. Of the 13 participants, 8 wanted the game to display the numerical probabilities corresponding to side effect scenarios and final treatment rankings produced by the game. All of the men expressed a desire for increased transparency in describing how the game used their feedback on the side effects to produce the results they received. However, 7 men did not recognize the connection between the side effect scenarios presented and the probability statistics on which the game was based.

In summary, the results of the focus groups revealed a role for an interactive computer game such as Time After Time in the decision-making process for localized prostate cancer, provided that future iterations address specific usability issues (navigation and introductory information), content issues (longer time frames, extended descriptions of treatment, and posttreatment options), and acceptability issues (personalization and direct explanations of statistical data).

Discussion

Patients diagnosed with localized prostate cancer must choose among a range of treatment options, most commonly watchful waiting, radical prostatectomy, external beam radiotherapy, and brachytherapy. However, selecting the best treatment presents patients with a significant challenge due to the lack of evidence identifying a single option as most effective for treating localized prostate cancer. Patients must consider not only the survival consequences and acute morbidity of each approach to treatment, but also the possible effects those approaches can have on quality of life. The difficulty involved in choosing a treatment plan for localized prostate cancer makes the availability of accurate, accessible, and understandable information crucial to the treatment decision process. Our findings support the use of serious video games as a potential way to enhance education on treatment side effects and prepare patients for more active participation in conversations with their medical team.

Bringing Side Effects Into Focus

The majority of participants named survival and chance of recurrence as primary factors impacting their treatment decision. The men exhibited the tendency for patients to neglect how side effects of treatments could affect their HRQOL in their decision-making process. The gap in adequate and accurate knowledge regarding side effects associated with localized prostate cancer treatments presents an opportunity and a need for enhanced patient education.

In the focus group sessions, participants validated the game's ability to focus their attention on the side effects of prostate cancer treatments. This new focus helped them differentiate between treatment choices and view the possible outcomes of each treatment in light of their lifestyle preferences. As one participant said,

> *[Time After Time brings] side effects right up front as part of decision making because you know even though we don't think that things like incontinence or impotency would affect you as much as cancer—if you are comparing cancer to everything else, cancer is going to win—but prostate cancer is not that way.*

As an interactive decision aid, Time After Time can fill this knowledge gap by providing men diagnosed with localized prostate cancer with evidence-based education on the HRQOL impacts of treatment side effects.

The Need for Personalization in Game Design

One of the most common remarks made by participants surrounded the absence of game personalization through the input of user-specific data. Personal life situations and lifestyle preferences represented crucial components of every focus group participant's self-described treatment decision process. In all focus groups, men highlighted the crucial need for the game to address factors such as age, marital status, and physical health before diagnosis. For them, the game must have a way of incorporating personalized information into its analysis.

The results of the survey instrument served to support the overarching themes and purpose of the Time After Time interactive game (Multimedia Appendix 2). Participants responded more positively (as indicated by means closer to 1) to items regarding the overall idea of the game and its ability to provide users with information on treatments and side effects. Negative results (indicated by means closer to 7) focused on specific implementation of game features. We believe that the participants' generally positive attitudes toward the idea of the game for the general public, combined with less positive responses about the applicability of the game to their own personal cases, reflect their expressed desire for more personalization. Participants could imagine the game being a valuable tool for a patient who fit the "norm" and/or who has yet to explore the nuances of the treatment decision, but they personally found aspects of their own situations that they would have liked the game to address in a transparent way.

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While participants validated the utility of the option to print out questions for their doctors regarding treatments and side effects in the current version of the game, future iterations of the game should incorporate a more interactive note-taking feature. Enhancing patients' ability to record relevant information, thoughts, or questions could significantly improve their experience of the game as a decision aid. Additionally, participants emphasized the immense value they found in conversations with other survivors, family members, and doctors during their decision-making process. Adding a social networking component to Time After Time could enhance its relevancy by integrating the benefits of person-to-person communication with the game's educational value.

Participants also wanted the game to include the actual probability data related to each side effect domain displayed as a number and in some kind of chart or graph in addition to the more interpretive format in which the data are currently presented. A total of 9 men expressed a desire for such numbers accompanied by background data to fully grasp the concept of probability demonstrated through the presentation of side effect scenarios. For them, Time After Time must include these data and an enhanced level of detail on the game's foundational concept to establish the overall purpose and validate the credibility of the game as a decision aid.

A review of the focus groups supports Time After Time's potential to provide useful and relevant education on treatment side effects and to augment patient conversations about treatment options with their doctors. However, a need for a more literal translation of game concepts became evident in participants' difficulties interpreting instructions, navigating different user modes and screens, and understanding the correlation between abstract themes of probability and side effect scenarios. Incorporating a more direct translation of the game's goals and functional steps could greatly enhance Time After Time's ability to act as a supplement to current methodologies used in localized prostate cancer decision making.

Limitations

Some limitations affecting this study may have had an impact on the range and quality of information gathered from the focus groups and survey instrument. The small sample size recruited solely from an active prostate cancer support group and its online community granted us valuable insight into how men diagnosed with localized prostate cancer experienced treatment decisions but leaves this study unable to make a wider generalization to all men diagnosed with the disease. Future evaluations of Time After Time should strive to recruit participants from sources other than support groups to reduce potential recruiting bias that may arise from men in support groups having different needs than the population of men with localized prostate cancer regarding the treatment decision-making process. Additionally, our use of participants who had already received treatment for localized prostate cancer may also represent a limitation. Although the questions were worded to minimize this factor, the participants' perspectives as men who have lived through the treatment decision are likely to differ from the perspectives of the game's intended audience, that is, men who have not yet chosen a treatment.

The presence of a female discussion facilitator in each of the focus group sessions presents a potential limitation to the type and extent of responses given during focus group discussions, as participants may have felt reluctant or anxious discussing sensitive side effect issues with a female. An introductory explanation of the game given by the facilitator to familiarize participants with the game may have resulted in a skewed participant experience.

Predicting how one will feel in the future, particularly about novel experiences such as surgery, represents an inherently difficult task [37,50]. While several studies have addressed decisional regret in localized prostate cancer treatment [51-53], we were able to find only one that prospectively examined whether expectations men had about how they would feel about specific aspects of management matched their lived experiences posttreatment [38]. Although this study's results were promising, people's ability to predict their feelings regarding future health states remains an important limitation of our study. Future projections of preferences regarding conditions not yet experienced are often subject to biases that can skew the accuracy of people's predictions [37]. In response to this issue, other researchers in our group have completed preliminary validation studies on a prospective tool for evaluating health-related quality of life based upon the well-accepted Medical Outcomes Study SF-36 Health Survey [54-56].

Finally, there are limitations to the use of Likert-type self-report scales. Self-report questionnaires may measure self-concepts that do not necessarily reflect actual behavior and may be subject to bias and error. Another limitation of Likert scales is the primacy effect [57,58], where respondents are more likely to choose the options on the left side of the page. (In this study, the negative options were on the right side of the page.) However, the mixed methods approach used combined observation of participants and open-ended discussion of questions with a scaled survey, which has been suggested as a tool for partially overcoming these limitations [59].

Conclusion

Our initial research has made clear that game-based interactive decision aids for localized prostate cancer like Time After Time have the potential to fill an important need for newly diagnosed patients. The majority of the study participants believed that Time After Time represents a valuable step in the development of an appropriate decision tool for localized prostate cancer. Participants verified that the game meets the goals of increasing focus on HRQOL issues, generating questions for the patient's health care team, and providing a new educational avenue to augment the patients' participation in choosing a treatment for localized prostate cancer.

However, opportunities to improve the game's usability exist. For the subsequent version of the game, researchers will attempt to take further steps in improving the standard of decision making for localized prostate cancer. We plan to modify and enhance the design and functionality of Time After Time to provide a construct through which patients can match their expectations and preferences with realistic goals, thereby better preparing them for the outcomes of their treatment choices and reducing the decisional conflict typically associated with localized prostate cancer.

Acknowledgments

This work was supported in part by a grant from the Abramson Center for the Future of Health, Houston, TX. Ms. Mani gratefully acknowledges support from the Finger Fellowship in Sustainable Health. The authors would also like to acknowledge the significant contribution of our partner ArchImage in the development of the serious game Time After Time, and of Dr. Judith McFarlane and Dr. Amalia Issa for their consultation on focus group methodology.

Conflicts of Interest

None declared

Multimedia Appendix 1

Likert survey instrument used to assess acceptance and usability of interactive computer games

[PDF file (Adobe PDF File), 16 KB - jmir_v13i1e4_app1.pdf]

Multimedia Appendix 2

Graph of survey instrument results

[PDF file (Adobe PDF File), 150 KB - jmir_v13i1e4_app2.pdf]

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Abbreviations

EPIC: expanded prostate cancer index composite
HRQOL: health-related quality of life

Edited by G Eysenbach; submitted 17.02.10; peer-reviewed by D Thompson, H Witteman; comments to author 17.03.10; revised version received 28.06.10; accepted 12.07.10; published 12.01.11.

Please cite as:
Reichlin L, Mani N, McArthur K, Harris AM, Rajan N, Dacso CC
Assessing the Acceptability and Usability of an Interactive Serious Game in Aiding Treatment Decisions for Patients with Localized Prostate Cancer
J Med Internet Res 2011;13(1):e4
URL: http://www.jmir.org/2011/1/e4/
doi:10.2196/jmir.1519
PMID:21239374

Original Paper

Type of Evidence Behind Point-of-Care Clinical Information Products: A Bibliometric Analysis

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Abstract

Background: Point-of-care (POC) products are widely used as information reference tools in the clinical setting. Although usability, scope of coverage, ability to answer clinical questions, and impact on health outcomes have been studied, no comparative analysis of the characteristics of the references, the evidence for the content, in POC products is available.

Objective: The objective of this study was to compare the type of evidence behind five POC clinical information products.

Methods: This study is a comparative bibliometric analysis of references cited in monographs in POC products. Five commonly used products served as subjects for the study: ACP PIER, Clinical Evidence, DynaMed, FirstCONSULT, and UpToDate. The four clinical topics examined to identify content in the products were asthma, hypertension, hyperlipidemia, and carbon monoxide poisoning. Four indicators were measured: distribution of citations, type of evidence, product currency, and citation overlap. The type of evidence was determined based primarily on the publication type found in the MEDLINE bibliographic record, as well as the Medical Subject Headings (MeSH), both assigned by the US National Library of Medicine. MeSH is the controlled vocabulary used for indexing articles in MEDLINE/PubMed.

Results: FirstCONSULT had the greatest proportion of references with higher levels of evidence publication types such as systematic review and randomized controlled trial (137/153, 89.5%), although it contained the lowest total number of references (153/2330, 6.6%). DynaMed had the largest total number of references (1131/2330, 48.5%) and the largest proportion of current (2007-2009) references (170/1131, 15%). The distribution of references cited for each topic varied between products. For example, asthma had the most references listed in DynaMed, Clinical Evidence, and FirstCONSULT, while hypertension had the most references in UpToDate and ACP PIER. An unexpected finding was that the rate of citation overlap was less than 1% for each topic across all five products.

Conclusions: Differences between POC products are revealed by examining the references cited in the monographs themselves. Citation analysis extended to include key content indicators can be used to compare the evidence levels of the literature supporting the content found in POC products.

(J Med Internet Res 2011;13(1):e21) doi:10.2196/jmir.1539

KEYWORDS

Databases, Factual; Bibliometrics; Medical Informatics; Evidence-based Medicine

Introduction

Studies of the information-seeking practices of physicians suggest that the use of electronic resources for clinical care has increasingly become a standard method of information access alongside traditional methods of textbook and colleague contact [1-4]. Ease of access plays an important role in the popularity of electronic resources for answering clinical questions at the bedside, but lack of time is one of the main factors found to contribute to limited use of evidence-based medicine (EBM) by residents and consulting physicians [2,4-7]. Electronic information resources improve timely access in the form of desktop or mobile product applications by presenting information to clinicians in a summarized format.

Point-of-care (POC) products, the subject of this study, are resources we define as electronic bedside information tools that provide summarized medical information for use by health care professionals. A few examples of these products are UpToDate, eMedicine, DynaMed, and Clinical Evidence. Other arbitrary designations used to refer to these products are e-textbooks, evidence-based resources, and decision support tools. Haynes' 6S pyramid model of preappraised resources, a modification of the 5S model, describes these products as summaries [8,9]. Many of these resources do claim to be evidence based in their descriptions or policy statements. However, the foundation for the evidence basis is not always transparent.

To date, this class of information products has been studied in terms of features, usability, impact on health outcomes, scope of coverage, and ability to answer clinical questions. POC products have been ranked by user "perception of content" [10], "perceived usefulness" [11], and satisfaction with interface and overall search experience.

The ability of electronic information resources to help clinicians find correct answers at the point of care at the time of need is critical. Research has expanded beyond documenting variation in user experience and satisfaction to examining the impact POC products have on clinical practice and patient outcomes.

Seeking to measure the impact of electronic information products on patient outcomes, Bonis and colleagues compared acute care hospitals with and without access to UpToDate and found that hospitals with access to UpToDate were associated with better patient care quality and outcomes performance, and shorter lengths of stay [12].

In an observational study of residents and specialists comparing UpToDate versus PubMed, Hoogendam and colleagues concluded that UpToDate was the preferred source and answered more patient-related questions, but included the many complexities of the findings in the discussion [13]. Other observational studies have shown that third-year family medicine residents at a 5-hospital residency program directed only 3% (15/532) of their clinical questions to electronic resources [14], while emergency department physicians received 29%(36/126) of their answers from electronic resources [15].

Alper et al showed that the percentage of questions answered by 14 individual electronic information resources may range widely but, in combination, much higher rates could be achieved [16]. Following up on that work, Fenton and Badgett examined the scope of coverage and overlap between two information resources, UpToDate and US National Guideline Clearinghouse [17].

In a 2004 comparison study, three EBM resources were used to answer sets of complex and general clinical questions. A combined total of 35% (28/80) of the test questions were left unanswered [18]. In another study published in 2005, clinicians using six electronic information sources increased the number of correctly answered questions by 21%, and were also more likely to correct their wrong answers [19]. Alper et al found that primary care physicians using DynaMed answered more clinical questions (263/347, 75.8%) and found more answers that changed clinical decisions (224/347, 64.6%) than did the comparison group's 15 typical information resources (209/351, 59.5%), without increasing search time [20].

McKibbon and Fridsma examined the effectiveness of electronic information resources chosen by 23 primary care physicians in the United States and Canada [21]. This study found that, when physicians used their own information resources, they correctly answered only 42% of their questions versus 39% before searching. In some cases, participants changed correct answers to incorrect. McKibbon and Fridsma [21] concluded that

> *...the evidence base of the resources must be strong and current...We need to evaluate them well to determine how best to harness the resources to support good clinical decision making.*

To our knowledge, very few studies focus on evaluation of the content that supports disease POC products. For example, Trumble and colleague's 2006 product evaluation measured features and usability, but also added weighted factors for specific evidence features for the purpose of ranking the products: graded evidence, summary of evidence, updating, authorship, references, and within-text bibliography at the end [22]. The weighted evidence feature resulted in a ranked list of POC products. Farrell evaluated the five most-used resources as identified by a survey of 52 Canadian health librarians [23]. Usability and comprehensiveness of each product were tested, with level of evidence noted if included in the answers retrieved. Banzi et al recently reviewed 18 products in depth using a scoring instrument and found differences in the volume of coverage, EBM content, and editorial methodology [24]. A 2009 evaluation by Abernethy et al, which examined the reliability of compendia methods for off-label oncology indications, found discordance and lack of currency in cited references [25].

Our objective was to use a bibliometric approach using citation and content indicators as another method to evaluate a set of POC resources.

"Bibliometrics is the quantitative study of physical published units, or of bibliographic units, or of the surrogates for either," as defined by Broadus in a 1987 paper outlining the history of attempts to describe the new term [26]. Citation analysis falls within that broader term, and "...involves the construction and application of a series of indicators of the 'impact', 'influence' or 'quality' of scholarly work, derived from citation data, i.e. data on references cited in footnotes or bibliographies of scholarly research publications" [27].

Citation analysis for evaluation of groups and individuals and to describe broad scientific developments has been scrutinized since the introduction of *Science Citation Index* in 1961 [28,29]. Implications of the citation behavior of authors have been studied and defined, with much concern regarding its administrative application to individual scientists [30-32].

The indicator associated with citation analysis is the impact factor, which Garfield [33] describes as a measure of utility:

> *They provide an objective measure of the utility of impact of the scientific work. They say nothing about the nature of the work, nothing about the reason for its utility or impact. Those factors can be dealt with only by content analysis of the cited material and the exercise of knowledgeable peer judgment.*

This study expands citation analysis beyond count indicators, such as simply counting the reference to certain articles or authors in the monographs and/or the overlap analysis, to include pertinent content indicators from the bibliographic or citation record, specifically the MEDLINE publication type and publication year. Our intention is that the addition of the publication type indicator, in Garfield's words, suggests "something about the reason for its utility or impact" [33]. The aggregate of the indicators and the impact on the quality of the POC product are also of interest in this investigation, rather than the individual authors or articles.

Methods

We measured four indicators in this study: distribution of citations, type of evidence, product currency, and citation overlap.

Distribution of citations is the number of citations within each POC product and as distributed across the disease topics. It was measured to give a sense of the depth of coverage within each product, as well as across all products. This measure was also used to compare topic coverage within products and across the five different products.

When an evidence-based recommendation for treatment or other aspect of care is made, an original source should be cited to support the recommendation. Our proxy for evidence was publication type. We chose this surrogate as it can be readily compared and evaluated in terms of the types of evidence typically found in evidence hierarchies through pyramid representations or grading schemes. This approach was also more realistic and feasible given the time restrictions of the study.

Citation publication date is important because we want to know that these products are providing the most current information to users. Years were grouped in an every-3-years format with the exception of pre-2001 citations. When clinicians are searching for evidence relevant to current practice, they are less likely request retrieval of articles more than 10 years old. We therefore grouped pre-2001 into one category.

We also looked at citation overlap, as we expected to find significant overlap among products for the same topics. Citation overlap across products would give us an indication of consistency of content across products.

Topic Selection

(See Multimedia Appendix 1.)

Four final disease topics were selected for the study from the National Library of Medicine's (NLM) Clinical Question Collection [34] through a three-step selection process. The topics were to be restricted to a small number in order to effectively manage the data display in this initial study. The first step in identifying questions from the collection was to randomly select numbers. A random integer generator produced 35 random numbers between 1 and 4654 [35]. The main topics from the corresponding 35 clinical questions from the NLM's Clinical Question Collection were then examined for inclusion/exclusion criteria. Topics were required to be a main entry in each POC product, and drug/substance topics were excluded, as it is not uncommon for drug information content to originate from third-party licensed resources. We did not follow a rigid protocol to identify a topic as a main entry; reviewers simply checked to see that there was an article for each condition in the product. This resulted in 15 topics from the original 35.

To further limit the number, we then compared the resultant 15 topics against the US Centers for Disease Control and Prevention's top 10 leading causes of death for all people as listed in the 2007 Chartbook [36].The topic must be listed to be included in the study. There were 8 topics remaining after the second-phase screening. In the third phase of selecting topics, we excluded four additional topics (tuberculosis, influenza, pneumonia, and follicular thyroid carcinoma) because they did not consistently cover the same scope across all five POC products. For example, the topic tuberculosis was represented by a single monograph in some products, while in others, diagnosis and other aspects were written as separate monographs.

Product Selection

Two authors (AK, AS) selected the products.

The products were selected from the top 10 rankings for evidence products in the Texas Consortiums Study in conjunction with the 5 selected resources in Farrel's evaluation of POC resources [22, 23]. The POC resources common to both rankings were selected. These were ACP PIER, BMJ's Clinical Evidence, UpToDate, and FirstCONSULT. An additional two resources from the Texas Consortium Study were selected that are similar to the other products in terms of function and presentation of materials: DynaMed and Essentials Evidence Plus (formerly known as InfoPOEMS), for a total of 6 POC products.

Due to anticipation of space limitation in reporting of the results data, we wanted to limit the test to a maximum of 5 products and therefore eliminated Essential Evidence Plus. Access was available through institutional subscriptions to all products except DynaMed, for which we obtained trial access.

Data Collection

Data were collected during a 6-week period from mid-December 2008 to the end of January 2009. All four topic monographs were located in each of the POC resources. References accompanying a monograph entry were retrieved and saved in a Word document. Any additional reference lists such as "Further Reading" were not included.

All references were subsequently transferred into a reference management product. Along with typical elements of a citation, Medical Subject Heading (MeSH) indexing, the MEDLINE publication type assignment, and the PMID (a unique citation ID assigned to citations in PubMed) were collected. Citations with no PMID were assigned a unique identifier using a structured guide that we created. We attempted to verify Web citations and other nonjournal citations to obtain complete details as to the source and type of publication. For the purpose of consistency in this analysis, from this point forward all references and citations will be referred to as "citations."

Data Analysis

Topics were divided between two authors (AK, AS) for individual review of the citations. We discussed any uncertainty in review of the citations to come to consensus. No interrater reliability was calculated. To identify publication types for the citations we used the NLM's MEDLINE indexing as a reference point in the citation classification process. (Note that when citations are input into MEDLINE, they are assigned index terminology including publication type from a standardized list of index terms.) We developed a protocol for assigning publication type based on this premise in conjunction with the Publication Type Classification System, which we devised to account for the limitations of simply using the MEDLINE publication type indexing (see Table 1). Further details on the protocol for assigning publication type may also be found in Multimedia Appendix 2. The development of the classification system scheme was guided by the hierarchy of evidence. While there is no standardized EBM pyramid hierarchy, we used the Dartmouth College Library's EBM pyramid scheme [37] as a reference point to develop our Publication Type Classification System, as it is the pyramid used by many health sciences libraries when presenting evidence-based resources (see Table 1). Guideline developers may conduct systematic reviews as part of the synthesis of the guideline; however, they are not one and the same. Furthermore, not all guidelines are based on evidence (some are consensus opinion) and therefore we classified guidelines as a distinct publication type from systematic reviews.

Table 1. Publication type classification system

Publication type category	Details
Guideline	Includes both evidence-based and consensus guidelines
Systematic review	Included both systematic reviews and meta-analyses
Review	Narrative reviews, synopses, and other review types not considered systematic reviews
Primary research, other	Includes case-control, cross-sectional, cohort, case-series, unclear study type, or a combination study design
Randomized controlled trial	
Report	Used for government publications, statistical data reports, technology assessments, *Morbidity and Mortality Weekly Report* (MMWR), and working group/task force stand-alone reports
Animal study	Animal-only study
Other	Includes items such as letters, comments, editorials, abstracts, and books. Letters, comments, and editorials were examined in full text as needed to identify any reports of study data
Unknown	Unable to verify citation

Because systematic review is not a publication type in MEDLINE indexing, we further examined citations designated with the NLM publication type review to identify and classify into the systematic review category as appropriate. A set of criteria was devised for assigning citations to the systematic review category. The criteria were based on definitions of systematic reviews in JAMAevidence *Users'Guide to the Medical Literature* [38] and Cook's 1997 article, "Systematic reviews: synthesis of best evidence for clinical decisions" [39]. The following is Cook's definition [39]:

> *Systematic reviews are scientific investigations in themselves, with preplanned methods and an assembly of original studies as their "subjects." They synthesize the results of multiple primary investigations by using strategies that limit bias and random error. These strategies include a comprehensive search of all potentially relevant articles and the use of explicit, reproducible criteria in the selection of articles for review. Primary research designs and study characteristics are appraised, data are synthesized, and results are interpreted.*

Additional details regarding classification of systematic reviews are available in Multimedia Appendix 3.

Furthermore, we reviewed the abstracts and full text as needed for citations that were indexed with the publication types comments, letters, and/or editorial to determine whether any study data were reported. This decision was made since we encountered several instances where study data was reported in these publication types. These general MEDLINE publication types (comments, letters, and editorials) were then more descriptively reassigned to one of the publication type categories in Table 1. We re-examined all citations originally categorized as such and determined whether study data were reported based on meeting the following criteria that the authors created: sample/or subjects being studied were described characteristically/or in quantity (must have this); and traditional outlining of an abstract was present in the MEDLINE abstract or full text (for example, Objectives/Introduction/Problem; Methods/Subjects; Results; Discussion/Conclusion).

Data were analyzed using STATA version 10 (StataCorp LP, College Station, TX, USA).

Results

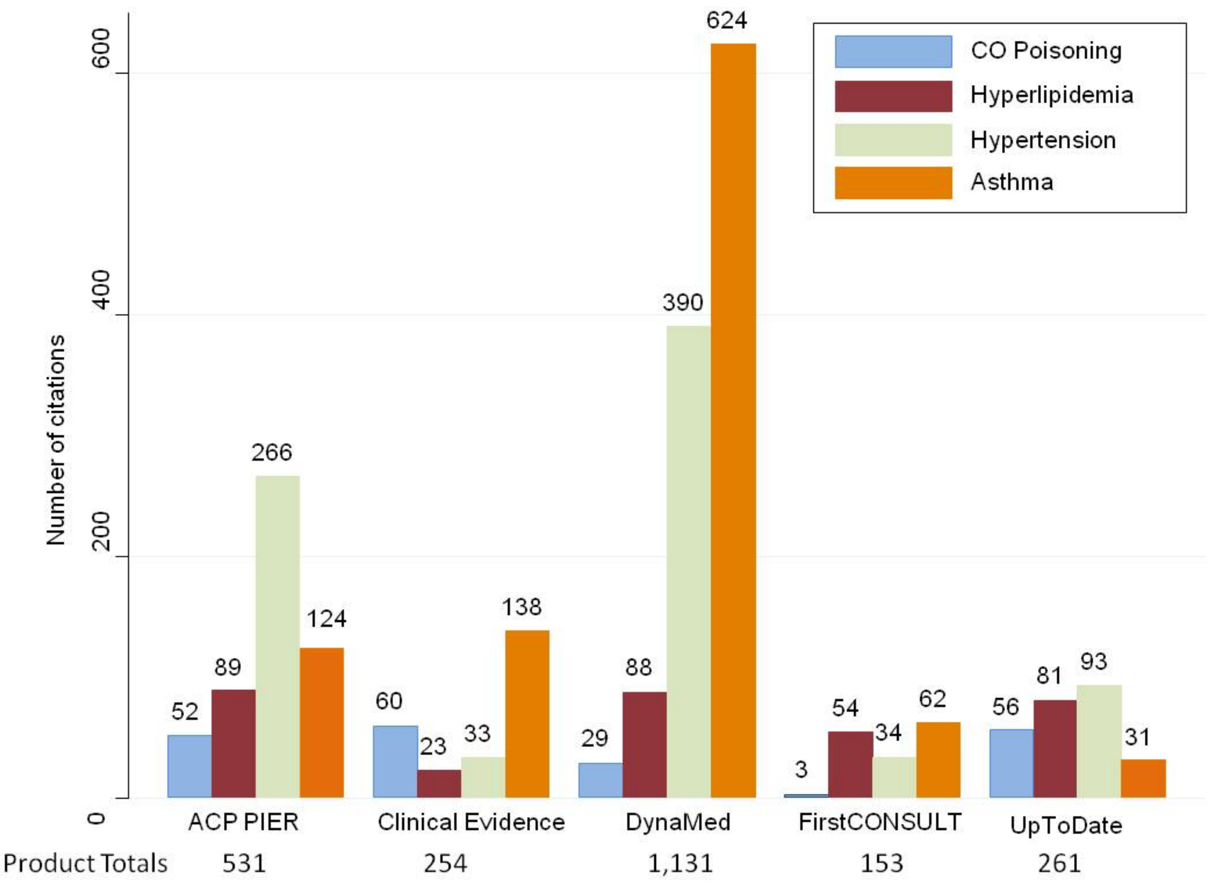
Five POC products met inclusion criteria: UpToDate, FirstCONSULT, ACP PIER, Clinical Evidence, and DynaMed. The four final topics were hypertension, asthma, Carbon monoxide poisoning (CO poisoning), and hyperlipidemia. The last updated date for topics and products is noted in Table 2.

Table 2. Last updated date (day/month/year) for topics within point-of-care products

	ACP PIER	DynaMed	FirstCONSULT	UpToDate	Clinical Evidence
Carbon monoxide poisoning	1/30/2006	11/21/2008	9/28/2007	1/10/2008	1/23/08
Hypertension	11/26/2008	1/26/2009	8/24/2007	10/8/2008	2/1/2007
Asthma	11/25/2008	1/15/2009	8/23/2007	9/26/2008	Not available from authors
Hyperlipidemia	11/26/2008	1/13/2009	8/24/2007	5/27/2008	2/6/2008

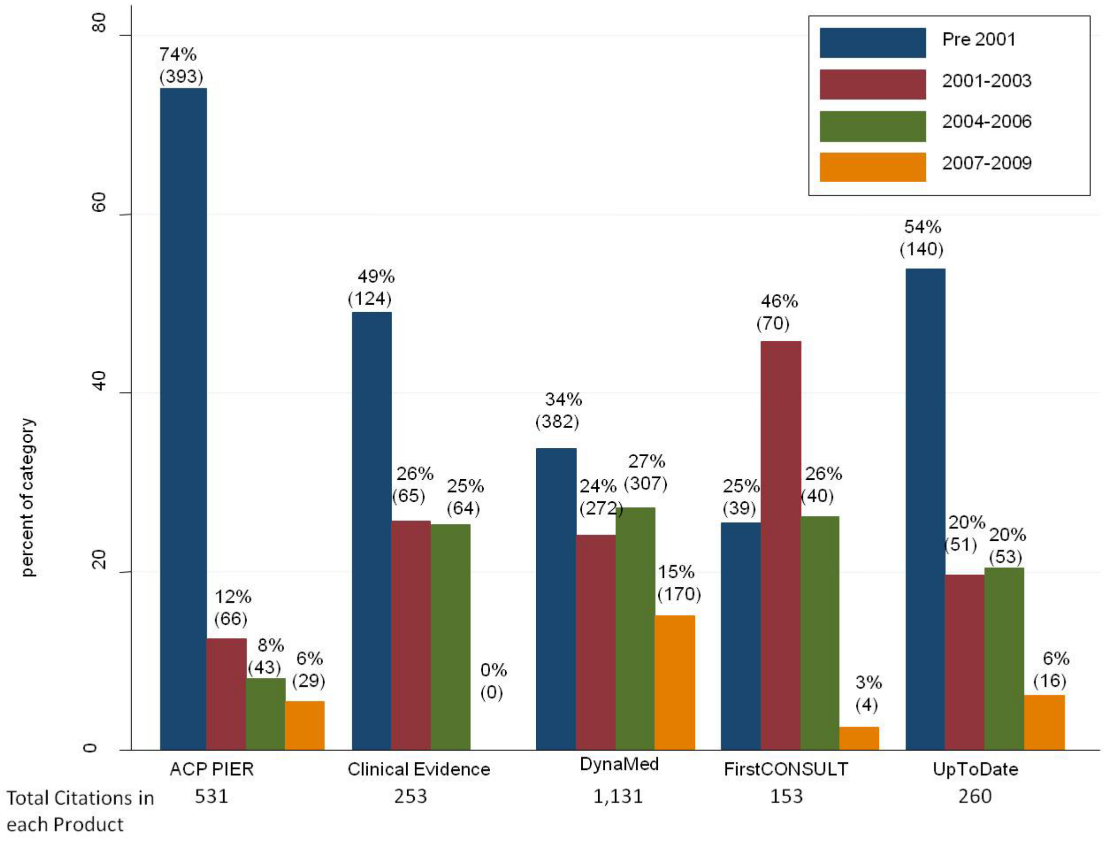
We retrieved a total of 2330 citations from the five POC products combined. As seen in Figure 1, almost half (1131/2330, 48.5%) of these citations originated from DynaMed, while only 6.6% (153/2330) of the citations from the total were obtained from FirstCONSULT. Figure 1 also illustrates the variation in the number of citations within each POC product across the four topics. For example, Clinical Evidence and DynaMed show greater proportions of citations for the topic asthma within each product, while ACP PIER and UpToDate have greater proportions of citations for hypertension. It is also interesting to note the fluctuation in citation count for the topics hyperlipidemia and CO poisoning.

Figure 1. Number of citations for all topics within each point-of-care product



The distribution of citations by date for all four products is represented in Figure 2, revealing a general pattern of the pre-2001 group containing the greatest number of citations for each of the products, and the 2007-2009 group containing the fewest. Only FirstCONSULT did not follow this pattern: the 2001-2003 grouping had the greatest number of citations in FirstCONSULT.

Figure 2. Currency of citations in point-of-care products



Note that two observations are missing from analysis, both Web addresses that are either broken or no longer available, one from Clinical Evidence and one from UpToDate: (1) Clinical Evidence – Office of National Statistics, http://www.statistics.gov.uk, no date, no indication of document to retrieve, from CO Poisoning monograph, (2) UpToDate – www.cdc.gov/nceh/airpollution/carbonmonoxide/cofaq.htm, accessed for UpToDate August 9, 2005, from CO Poisoning monograph.

Figure 3 and Table 3 show the distribution of publication types found in all topics combined for each POC product. FirstCONSULT used the largest proportions of citations with the publication types systematic review and randomized controlled trial. It should be noted that the review publication type category included a small number of evidence reviews, and synopses as defined by Haynes [9], such as Family Physicians Inquiries Network (FPIN) and ACP Journal Club articles. These totaled 7% (20/286) of the total reviews. We found 18 in DynaMed, 1 in FirstCONSULT, and 1 in Clinical Evidence. This was a result of the MEDLINE indexing of these types of articles under the MeSH publication type review.

Figure 3. Distribution of publication types found in all topics combined for each point-of-care product (see Table 1 for further details on category definitions)

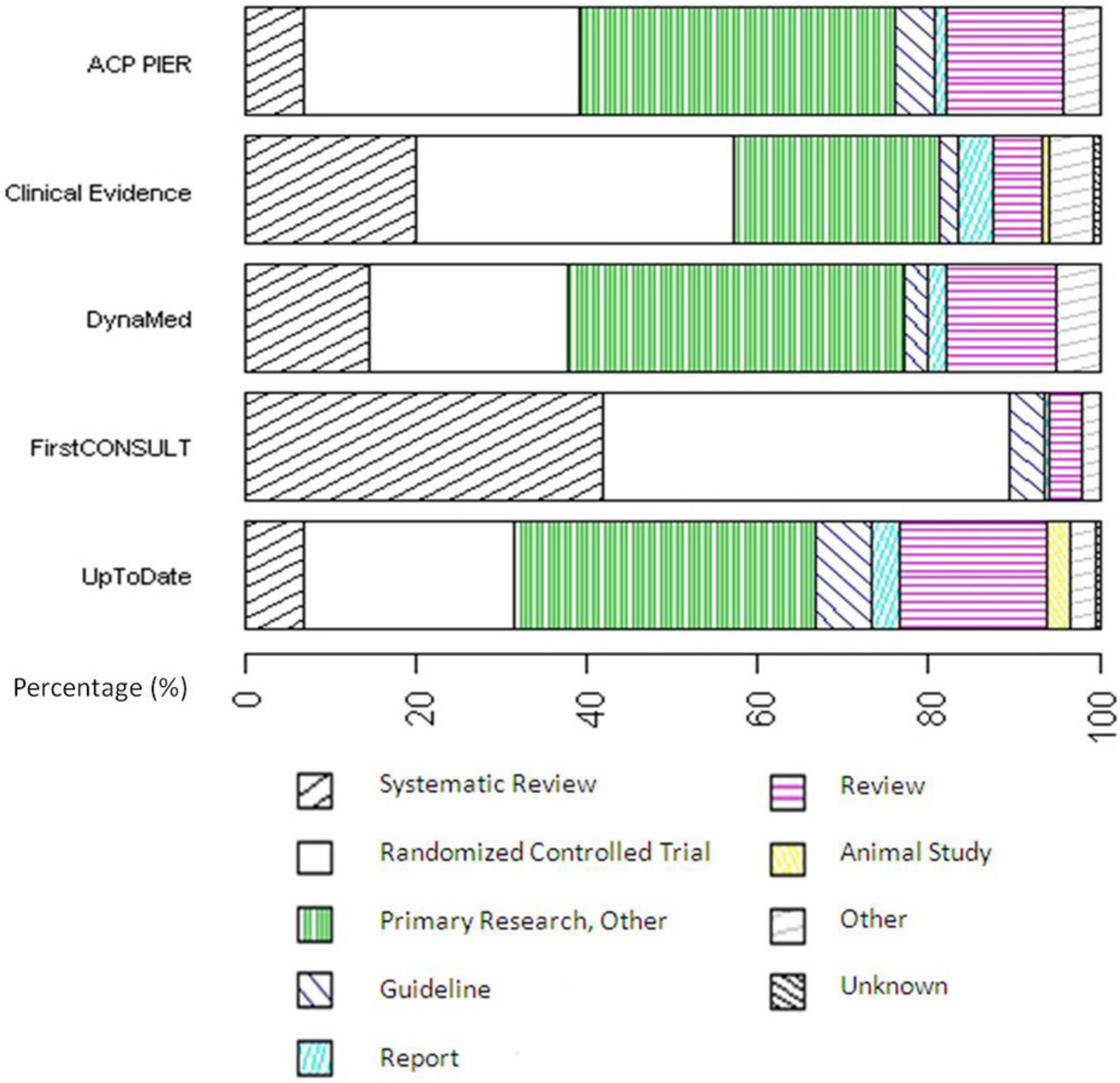


Table 3. Detailed analysis of publication types by point-of-care product (may not total 100% due to rounding)

Publication type	ACP PIER % (n)	Clinical Evidence % (n)	DynaMed % (n)	FirstCONSULT % (n)	UpToDate % (n)	Total % (n)
Systematic review	7.0 (37)	20.1 (51)	14.5 (164)	41.8 (64)	6.9 (18)	14.3 (334)
Randomized controlled trial	32.2 (171)	37.0 (94)	23.3 (263)	47.7 (73)	24.5 (64)	28.5 (665)
Primary research, other	36.9 (196)	24.0 (61)	39.3 (444)	0.0 (0)	35.2 (92)	34.0 (793)
Guideline	4.5 (24)	2.4 (6)	2.9 (33)	3.9 (6)	6.5(17)	3.7 (86)
Report	1.3 (7)	4.0 (10)	2.0 (23)	0.7 (1)	3.4 (9)	2.1 (50)
Review	13.8 (73)	5.9 (15)	13.0 (147)	4.0 (6)	17.2 (45)	12.3 (286)
Animal study	0.0 (0)	0.8 (2)	0.0 (0)	0.0 (0)	2.7 (7)	0.4 (9)
Other	4.3 (23)	5.1 (13)	5.0 (57)	2.0 (3)	3.1 (8)	4.5 (104)
Unknown	0.0 (0)	0.8 (2)	0.0 (0)	0.0 (0)	0.4 (1)	0.1 (3)
Total	100.0 (531)	100.1 (254)	100.0 (1131)	100.1 (153)	99.9 (261)	99.9 (2330)

An unexpected finding in this study was the very limited overlap between citations across all products, particularly considering the major topics and the summary nature of the information resources.

The monographs for the four topics in all POC products yielded 2330 references. Only two (0.09%) out of the total pool of references were found in all five products. A total of 90.9% (1907/2099) citations were unique, with the topics asthma and hypertension having the greatest number of unique citations across the five POC Products. CO poisoning had the fewest citations overall. The drop-off from the number of unique citations in a POC product to those appearing in additional products is striking: topics appearing in two products fall to the area of 3% and lower (see Table 4).

Table 4. Overlap of citations, all topics across all point-of-care products

# Observations[a]	Combined	CO Poisoning	Hyperlipidemia	Hypertension	Asthma
5 times	2 (0.1%)	2 (0.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
4 times	4 (0.2%)	1 (0.1%)	2 (0.1%)	0 (0.0%)	1 (0.0%
3 times	25 (1.2%)	3 (0.1%)	8 (0.4%)	8 (0.4%)	5 (0.2%)
2 times	161 (7.7%)	15 (0.7%)	17 (0.8%)	61 (2.9%)	65 (3.1%)
Unique	1907 (90.9%)	147 (7.0%)	269 (12.8%)	670 (31.9%)	830 (39.6%)
Total # citations	2099				

[a] This designation indicates in how many products a reference was found to be cited. For example, 2 times (from the # Observations column) indicates that 161 references of the total 2099 (= 2 + 4 + 25 + 161 + 1907) references (from the Combined column) were found to be cited in two products; 1907/2099 (90.9%) citations were found in only one product. Thus, if the number in the # Observations column is multiplied by the Combined column and added, the final sum is 2330 (= 5 × 2 + 4 × 4 + 3 × 25 + 2 × 161 + 1 × 1907). The overlap of citations was counted by using STATA and Excel.

Discussion

This study demonstrates that the characteristics of POC content can be evaluated and used to compare products at a level of detail beyond what is currently available. While time consuming, a bibliographic analysis reveals surprising and critical information about these POC products: they can vary greatly in content, from the raw number of citations, to the types of evidence, to the currency of those citations.

It was expected that the 2004-2006 grouping of literature would be larger than the 2007-2009 grouping in terms of number of current citations, because it does take some time for systematic reviews and other summarized information resources to be compiled. It was surprising to see that Clinical Evidence contained no citations for the 2007-2009 time period. We can only surmise that this may have been due to the time to update a monograph given the strict editorial policy, and that a separate tab provided access to the latest updated citations that had not yet been incorporated into the monographs.

It is also notable that three of the five POC products show close to 50% or more citations in the pre-2001 range. The number of citations in an entire product database can also have meaning in the interpretation of currency results and in general. Also, many other topics within these products may have greater numbers of current citations. Large sets incorporating older citations may signify access to historic perspectives, while small databases may be closely controlled for other reasons. This was a small test of only four topics and may not be representative of the products as a whole.

The minimal overlap of citations was not only a surprise to us, it was also contrary to expectations expressed by Moed [27]:

> *A reference list thus contains a certain fraction of unique references, but at the same time there is also a considerable amount of similarity among reference lists.A reference list normally contains a portion of references to documents that are cited in other reference lists as well.*

And yet, in a particularly narrow area of medical literature, we found very little overlap.

One important factor this study reveals, as was found in the Abernethy study on compendia [25], is that summary products, such as POC products, vary in content as determined by differences in literature cited for the same topics in different products, quality regarding types of evidence cited, and currency. There are no standards for guidance on developing content for these products. Users should be aware of this and judiciously appraise POC product information content when using resources to obtain information for applying evidence-based practice principles. According to the Haynes 6S pyramid of evidence-based resources, textbook-like summaries, which is how most of the products we evaluated were categorized, fall near the top of the pyramid of evidence-based information resources, which suggests they are among the superior tiers of evidence-based information**.**

However, as reiterated by Strauss and colleagues, authors of *Evidence-Based Medicine: How to Practice and Teach EBM* [40], in a 2009 article entitled “Managing evidence-based knowledge: the need for reliable, relevant and readable resources” [41], not all products that claim to be evidence based are created equal. Strauss and Haynes in this same paper provide guidelines on how to appraise these products and other resources. At the very least, they recommend that the “the minimum criteria for an evidence-based resource would be adherence to the following: Does the resource provide an explicit statement about the type of evidence on which any statements or recommendations are based? Did the authors adhere to these criteria?” [41]. These same questions apply when appraising POC products.

Readers should interpret our findings with some limitations in mind, the most significant being that we analyzed relatively few topics. We did not evaluate the methodological quality of cited studies. Additionally, we collected data within a 6-week time period without regard to the products' updating schedules. Some assigned publication type classifications may be subject to bias, as the citations were not all independently reviewed by two authors. It should be noted that the proportion of publication types found in each of the POC products may depend on the policies set by their editorial boards. For example, Clinical Evidence follows explicit methods that include evaluating studies from the literature against specific quality criteria prior to inclusion in the monograph.

Sackett et al define EBM as "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" [42]. He further emphasizes that "Evidence-based medicine is not restricted to randomized trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions" [42]. These critical points about the definition of "evidence-based" should be considered when interpreting our results.

It was our intention to test the potential usefulness of citation/content analysis in this initial study of POC products. Additional tests of more topics and POC products are necessary to confirm and further explore these preliminary results. Further evaluation to look at the quality of citations examined in our study would add strength to the current findings. Furthermore, in light of the minimal citation overlap for topics, it would be helpful to examine the recommendations made for topics with the least overlap, and whether there were differences in recommendations across products for those topics. Finally, it would be beneficial to users if there were standards in product content development for labeling a resource "evidence-based," as this would minimize variation and arbitrary designations.

Acknowledgments

Part of this study was funded by Grant Number UL1 RR024153 from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH), and NIH Roadmap for Medical Research. The authors would like to thank Nancy Hrinya Tannery, Health Sciences Library System, University of Pittsburgh, for reviewing the manuscript.

Conflicts of Interest

None declared

Multimedia Appendix 1

Topic selection flowchart

[PDF file (Adobe PDF File), 82 KB - jmir_v13i1e21_app1.pdf]

Multimedia Appendix 2

Publication type protocol

[PDF file (Adobe PDF File), 57 KB - jmir_v13i1e21_app2.pdf]

Multimedia Appendix 3

Systematic review classification criteria

[PDF file (Adobe PDF File), 57 KB - jmir_v13i1e21_app3.pdf]

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Abbreviations

CO: carbon monoxide
EBM: evidence-based medicine
MeSH: Medical Subject Heading
NLM: National Library of Medicine
POC: point of care

Edited by G Eysenbach; submitted 02.04.10; peer-reviewed by K McKibbon, F Magrabi, R Banzi; comments to author 20.07.10; accepted 06.11.10; published 18.02.11.

Please cite as:
Ketchum AM, Saleh AA, Jeong K
Type of Evidence Behind Point-of-Care Clinical Information Products: A Bibliometric Analysis
J Med Internet Res 2011;13(1):e21
URL: http://www.jmir.org/2011/1/e21/
doi:10.2196/jmir.1539
PMID:

Original Paper

Protected Health Information on Social Networking Sites: Ethical and Legal Considerations

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Abstract

Background: Social networking site use is increasingly common among emerging medical professionals, with medical schools even reporting disciplinary student expulsion. Medical professionals who use social networking sites have unique responsibilities since their postings could violate patient privacy. However, it is unknown whether students and residents portray protected health information and under what circumstances or contexts.

Objective: The objective of our study was to document and describe online portrayals of potential patient privacy violations in the Facebook profiles of medical students and residents.

Methods: A multidisciplinary team performed two cross-sectional analyses at the University of Florida in 2007 and 2009 of all medical students and residents to see who had Facebook profiles. For each identified profile, we manually scanned the entire profile for any textual or photographic representations of protected health information, such as portrayals of people, names, dates, or descriptions of procedures.

Results: Almost half of all eligible students and residents had Facebook profiles (49.8%, or n=1023 out of 2053). There were 12 instances of potential patient violations, in which students and residents posted photographs of care they provided to individuals. No resident or student posted any identifiable patient information or likeness in text form. Each instance occurred in developing countries on apparent medical mission trips. These portrayals increased over time (1 in the 2007 cohort; 11 in 2009; P = .03). Medical students were more likely to have these potential violations on their profiles than residents (11 vs 1, P = .04), and there was no difference by gender. Photographs included trainees interacting with identifiable patients, all children, or performing medical examinations or procedures such as vaccinations of children.

Conclusions: While students and residents in this study are posting photographs that are potentially violations of patient privacy, they only seem to make this lapse in the setting of medical mission trips. Trainees need to learn to equate standards of patient privacy in all medical contexts using both legal and ethical arguments to maintain the highest professional principles. We propose three practical guidelines. First, there should be a legal resource for physicians traveling on medical mission trips such as an online list of local laws, or a telephone legal contact. Second, institutions that organize medical mission trips should plan an ethics seminar prior the departure on any trip since the legal and ethical implications may not be intuitive. Finally, at minimum, traveling physicians should apply the strictest legal precedent to any situation.

(J Med Internet Res 2011;13(1):e8) doi:10.2196/jmir.1590

KEYWORDS

Protected health information, medical missions, Internet

Introduction

Online social networking applications (eg, Facebook, Flickr, Twitter, and YouTube) have become the fastest-growing mechanism to exchange personal and professional information. With 85%-95% of students on college campuses using these communication mediums, and all age groups, even senior citizens, rapidly adopting their use [1,2], online social networking applications have emerged as a significant means of interaction for sharing everything from casual greetings to displaying wedding photographs and lobbying for humanitarian fundraising.

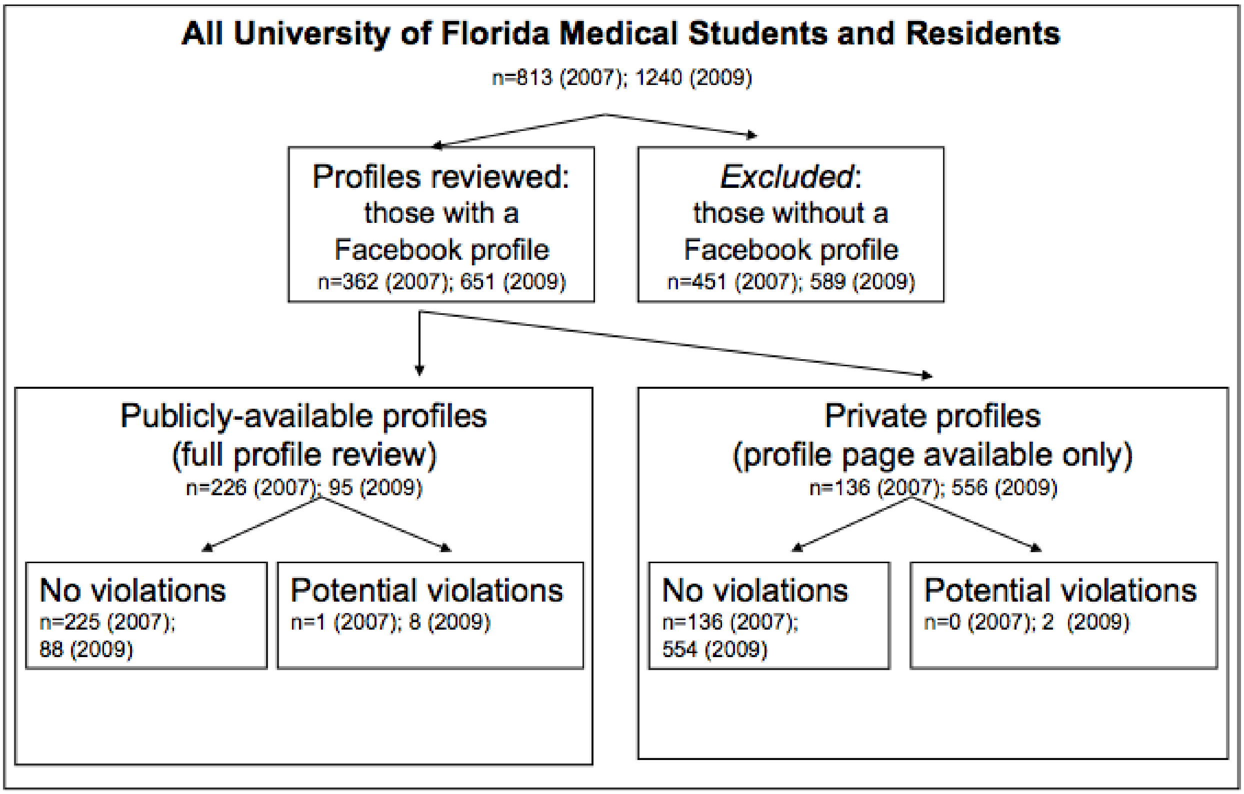
Medical professionals who use social networking sites have unique responsibilities, since their postings could portray themselves in unprofessional ways [3] or, most important, potentially violate patient privacy [3,4]. Publicized breaches of privacy might stem from careless oversights to malicious, illegal, and blatantly unprofessional behaviors. Most worrisome would be those that involve medical students and residents, since their unprofessional behaviors are known to be linked to lifelong licensure problems with state medical boards [5]. Poignantly, Chretien et al recently demonstrated that a significant number of academic medical institutions have experienced incidents of unprofessional student online postings in which some were severe enough to end in student dismissal, although the reasons for these dismissals were not disclosed [6]. Broadly stated, breaches of patient confidentiality involve the identification or potential identification of a patient in any way. Many laws, including the Health Information Portability and Accountability Act (1996, HIPAA), are in place to defend this principle [7,8]. In this context, this study aimed to document whether medical trainees ever share or discuss their patient interactions in their online profiles.

Methods

The University of Florida's Institutional Review Board approved as exempt a multidisciplinary team to perform two cross-sectional analyses of Facebook profiles of medical students and residents (2007, 2009). For the purposes of this study, we considered eligible all medical students (n = 501 in 2007, 528 in 2009) enrolled at the University of Florida, Gainesville, and the associated medical residents with available full names (n = 312 in 2007, 712 in 2009) employed by the Shands Hospital. Descriptive findings from each cohort have been published elsewhere [3,9]. In brief, Facebook proceedings allow any registered user of Facebook access to every Facebook profile according to each individual owner's chosen preferences for privacy. To be a Facebook user, an applicant only needs to supply an email address and choose a password. Once a user, one can scan Facebook profiles anonymously, without revealing to the profile owners that their site has been viewed. Drawing on these parameters, the first profile search associated with this study was done from June 7 to June 11, 2007, where three researchers used personally created Facebook accounts to manually search for the study subjects' online profiles using a university-generated list of names of students and residents. The second cohort was searched from September 2 to October 7, 2009, where only one study author (EB) used a personal account to manually search for the study subjects' online profiles using the 2009 university lists. Given that the study began in 2007, it did not use any face-recognition software, since it was not available at the time, and our study protocol did not include searching "friends' sites" for the study subjects. We likewise could not discern how often a profiler used Facebook, nor could we tell the duration that a profiler had the account. We could not discern the frequency with which a subject accessed Facebook. This study was part of a larger study on trends of social networking site use among medical students and residents [3,9]. We first determined whether each student or resident had a Facebook account and whether that account was "private" or "public," a designation that each user can activate to limit some, or all, of a site's content. Sites were deemed private if the following message appeared on the site of interest: "_____ only shares certain information with everyone. If you know ____, add him/her as a friend on Facebook." Three study authors (EB, LT, KD) compared their individual analyses of the content. We found a high degree of interrater reliability using intraclass correlation (type 1, *df* = 6) = 0.9, for the public profiles of medical students and residents in characterizing material with complete unanimity for the comparisons of potential patient privacy violations [9]. We searched a total of 1023 profiles (n = 372 profiles in 2007 and 651 in 2009; see Figure 1 for flowchart of subjects and profiles reviewed).

For the purposes of this study, we reviewed sites for possible privacy violations to explicitly examine how students are using sites according to legal and ethical professional norms. Once a profile related to a study subject was found, any potential violation within a site was counted as one, even if a profile had multiple representations. For private sites, where optional Facebook privacy settings can limit non-"friends" from viewing part or most of the site, study authors reviewed only the profile photograph(s) and available content on their front page, where Facebook users can choose to list information such as name, address, and favorite hobbies. For publicly available profiles (n = 233, 62.6% in 2007; n = 95, 14.6% in 2009), we manually scanned all information, including all scrolled wall posts in text form and extensive albums for photographs, for patient information, such as names, dates, and procedures, photographs of patients or procedures, or any mention of patients. We also recorded available demographic information of the subjects (gender, year in training, relative age of subject). At the end of the study, in September 2010, we reviewed the sites that had potential privacy violations; all sites were now private and could not be reviewed. We performed our analyses using SPSS PASW Statistics, version 17 (Chicago, IL), and we accepted a level of significance of $P < .05$ using a Student t test for comparison [10].

Figure 1. Enrollment of medical students and residents' Facebook profiles



Results

A significant proportion (49.8%) of medical students and residents had profiles (n = 1023 out of 2053 eligible students and residents). Students and residents increased their use of Facebook, with 44.5% using Facebook in 2007 (n = 362 of 813), compared to 52.5% in 2009 (n = 651 of 1240, *P* < .0001). By 2009, a majority (85.4%) of profiles were made private by their owners compared to 37.6% in 2007 (*P* < .001). However, we found significant and increasing evidence of potential privacy violations (n = 12; 1 of 372 in 2007, 10 of 651 in 2009; *P* = .03). Medical students were more likely than residents to have these violations (10 students, 1 resident; *P* = .04). In each instance, all of which were photographic patient information, the profile owners illustrated themselves providing health care to individuals (see deidentified examples, Figures 2-5; authors added the face blockouts). We did not find any textual evidence of patient information or likeness that could potentially violate patient privacy.

In each of these groups of photographs, the profile owner was apparently on a medical mission trip, performing health care in another county. These photographs were placed in photo albums that the profile owner explicitly labeled (eg, "mission trip" or "Dominican Republic"), giving the viewer a context for understanding where they are from. Among "private" profiles (n = 701), two displayed themselves on their profile picture with identifiable patients, which is the information first available on any profile when a user peruses Facebook profiles. For those with publicly available Facebook profiles (n = 328 total, 233 in 2007; 95 in 2009), 10 additional sites had potential privacy violations within their profile's photo albums. Photographs included trainees interacting with identifiable patients or performing medical examinations or procedures such as vaccinations. Of note, in each photograph, the recipient of the care was a child.

Figure 2. Example of a potential violation of patient privacy

Figure 3. Example of a potential violation of patient privacy

Figure 4. Example of a potential violation of patient privacy

Figure 5. Example of a potential violation of patient privacy

Discussion

This study reveals that students and residents place protected health information on their publicly available social networking sites. This exposes significant concerns with the ethical and legal aspects of patient portrayals, a problem well debated with cyberspace issues [11,12], but one that has been magnified by the recent phenomenon of online social networking [13]. As an unanticipated outcome, these violations seem only to be in the context of medical mission trips. Medical missions, defined as a "group of people traveling from a developed country to a developing country for a short period of time" [14] with the purpose of providing needed health care, are viewed as highly professional, benevolent acts [15]. Nonetheless, posting photographs or information from such events challenges US and international laws of patient privacy, regardless of whether content is posted to a publicly available or private profile. Imagery of humanitarian trips is common, even supported in medical settings [15]; perhaps the reason why this online imagery is not only common but increasing. It is likely, given the increasing frequency of these portrayals, that medical students and residents believe they are representing themselves in a prosocial manner on their online profile, forgetting or ignoring that this can conflict with their professional responsibilities. Nonetheless, any single incident of an online depiction represents the tension between personal pride in compassionate acts and unethical and potentially illegal representations and descriptions of individuals receiving medical care.

Medical mission trips offer an opportunity to trainees and doctors alike to learn to practice medicine outside of the highly technical US hospitals and to gain personal satisfaction in treating patients who may otherwise not have access to care. However, these acts of compassion or benevolence should not be available for public or private discussion or viewing outside the context of the doctor-patient relationship. Medical trainees and providers at all levels need to apply legal and ethical practices of patient privacy at all times of their working careers. We believe that photographs of patients from medical mission trips are unethical and unprofessional, yet, due to variances in established international and emerging Internet law, they are only a possible privacy violation.

HIPAA (1996) [7,8] and other laws such as the Health Information Technology for Economic and Clinical Health Act demonstrate that the legal aspects of protecting patient identities in the digital age are complex [16-18]. In this study, students and residents do not appear to violate patient privacy at their own US institutions through online postings, but they seem to not equate this standard to medical mission trips in other countries. The Hippocratic Oath, HIPAA, and individual state and international laws all articulate different regulatory standards of patient privacy to which health care providers, as "covered entities," must adhere. While extensive and at times confusing, they are nonetheless the law. Medical mission trips within the United States, for example, would characterize written patient health information on the Internet as HIPAA violations [7,8], but potentially not a photograph if it is not a "full-face photographic image" [19]. Other countries, such as Argentina, have stricter patient privacy laws that may include any photography [20]. Further, state laws in the United States may dictate higher standards than the federal HIPAA law for their licensed practitioners. In Florida, for example, all physicians are required to always maintain patient confidentiality regardless of where they are. To date, there is no legal precedent for the adjudication of these potential online violations, nor guidance from the medical literature on how to maintain high standards of patient privacy in the age of online social networking. To the contrary, in fact, one publication (predating online user-generated content) *advocated* the use of digital photography, ostensibly for its ease of transmission and reproduction [21]. It is yet unknown who, outside of the individual patient, could claim a violation when viewing online content. Nonetheless, awaiting legal action is ill advised.

Like the legal aspects, the ethics involved are multifaceted. In speaking to the responsibilities of health care providers who place patient information online, social networking sites challenge the difference between public and private information. In fact, one might argue that, while these sites are public, users are likely operating under the expectations of privacy [22]. However, users of social networking sites not only choose to have profiles with photos, text, and other self-created content, they also have control over whether such content is available to everyone (publicly available) or whether their profile and its content are private to some or all. Of note, since this study was performed, Facebook has changed its privacy features (December 2009), requiring users to actively select what it describes as "simplified privacy settings." However, its default settings allow for unrestricted public access, much to the consternation of Internet privacy and security experts [23]. It remains unknown how medical professionals will respond to this privacy option. Additionally, current academic discussions describe the exact nature of what is public versus private, or identified versus deidentified on the Internet as not dichotomous [24], and that privacy is ultimately a function of social context, meaning that displays and disclosure of information may be appropriate in some contexts but not in others [13]. Profiles and postings of any type—public or private—are ultimately the responsibility of the creators, who in this case are practicing medical trainees and/or professionals who have completed HIPAA and confidentiality training. Unique to the fields of health care, these roles and their attendant responsibilities continue beyond the end of a shift and into all spheres of their lives, including when traveling abroad.

Additional ethical considerations may question what duty that we, as authors, have in collecting and analyzing data obtained from public online social networking sites [12,13,16]. Foremost, as medical professionals, we are bound to report potential abuses of children [25]. We do not feel this has occurred. Additionally, it could be argued that research on social networking sites is voyeuristic, hence inappropriate. Leading researchers, however, have likened social network research to research on newspaper personal ads [26], removing much of the mystery surrounding its potential. We believe that medical educators need to be particularly sensitive to educating our students and residents about patient privacy with clear and salient guidance on the various aspects of professionalism as it pertains to online postings. Given the overwhelming popularity of social networking applications such as Facebook, and their convenient and compelling means by which to exchange personal information, educators must better inform students that posting patient information may lead to serious, unintended, and irreversible consequences.

Practical Recommendations

We make the following recommendations. First, there should be a legal resource for physicians traveling on medical mission trips such as an online list of local laws, or a telephone legal contact. To our knowledge, this does not exist. Second, we believe institutions that organize medical mission trips should plan this type of ethics seminar prior to the departure of any trip, since the legal and ethical implications may not be intuitive. Further, while an understanding of local privacy laws prior to departure on a medical mission trip would be ideal, it is nonetheless, at minimum, advisable to be cautious and apply the strictest legal precedent to any situation. For example, physicians should never write any patient information in text form or use a full-face photograph of a patient receiving any treatments. If photographs of individuals are desired, written consent should be obtained (although the wording of such documents may still not be legally defensible in that country). Additionally, subjects should only be shown in profile or in shadows, or physicians/medical professionals should use photo editing software to deidentify patients' faces (see Figures 2-5 for the authors' examples of ways to deidentify patients and trainees). While photographs can play a central role for both physicians (eg, in dermatology) and patients (eg, the birth of a child), they are one of the most difficult legal and ethical considerations in online portrayals and as such demand careful attention.

Study Limitations

This study has several limitations. First, this study was performed at a single institution, where it is possible that the students and residents with patient portrayals did in fact receive permission from the individuals that they photographed. However, no acknowledgement or supportive information regarding this consideration was available on the individual profiles. Second, while it appears that medical students are more likely than residents to post content that may violate patient privacy, this likely is a function of the structure of medical school in which students in their fourth year have the most time for trips overseas and their younger age [27]. Finally, we cannot comment on profiles that have been made private. It is likely, perhaps even more likely, that photographs or even text that may violate patient privacy exists on private sites, since profile owners may feel their audience is not public. However, given the large number of profile friends Facebook users have (sometimes thousands), the notion of privacy is again contextual [26]. Yet patient privacy is not contextual. It is concrete and unyielding to electronic and other innovations for social networking.

Conclusions

As a profession, we have made considerable strides to protect patient privacy. We have not, however, adequately impressed upon students and residents that online social networking sites and blogs are, in essence, broad communities with a public audience. They are arenas, such as medical mission trips, in which patient information must be guarded just as it would be in any health care situation. Future studies should explore the motivations behind such postings, but we believe the observations found in this study merit swift action, since the nature of social networking sites allows for immediate assumptions by the observer, whether or not these assumptions are formed within the context that the profiler intended. Medical mission trips require the same high professional standards of patient privacy that all medical situations require, whether in a highly technical US tertiary care center or in a rural medical clinic in another country.

Acknowledgments

We would like to thank the Office of Privacy at the University of Florida, specifically Susan Blair and B Dianne Farb, JD, for their careful review of this manuscript. Publication of this article was funded in part by the University of Florida Open-Access Publishing Fund.

Conflicts of Interest

None declared

Authors' Contributions

All of the authors are responsible and qualified for the reported research. They have all participated in the concept and design, analysis and interpretation of data, and drafting and revision of the manuscript and approve the manuscript as submitted. All of the authors have had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. None of the authors, to our knowledge, have any undisclosed affiliations, conflicts of interests, or financial arrangements with any organizations mentioned in the manuscript.

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Abbreviations

HIPAA: Health Information Portability and Accountability Act

Edited by G Eysenbach; submitted 27.06.10; peer-reviewed by T Lagu, F Grajales III; comments to author 05.08.10; revised version received 22.09.10; accepted 21.10.10; published 19.01.11.

Please cite as:
Thompson LA, Black E, Duff WP, Paradise Black N, Saliba H, Dawson K
Protected Health Information on Social Networking Sites: Ethical and Legal Considerations
J Med Internet Res 2011;13(1):e8
URL: http://www.jmir.org/2011/1/e8/
doi:10.2196/jmir.1590
PMID:21247862

Original Paper

How Strong are Passwords Used to Protect Personal Health Information in Clinical Trials?

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Abstract

Background: Findings and statements about how securely personal health information is managed in clinical research are mixed.

Objective: The objective of our study was to evaluate the security of practices used to transfer and share sensitive files in clinical trials.

Methods: Two studies were performed. First, 15 password-protected files that were transmitted by email during regulated Canadian clinical trials were obtained. Commercial password recovery tools were used on these files to try to crack their passwords. Second, interviews with 20 study coordinators were conducted to understand file-sharing practices in clinical trials for files containing personal health information.

Results: We were able to crack the passwords for 93% of the files (14/15). Among these, 13 files contained thousands of records with sensitive health information on trial participants. The passwords tended to be relatively weak, using common names of locations, animals, car brands, and obvious numeric sequences. Patient information is commonly shared by email in the context of query resolution. Files containing personal health information are shared by email and, by posting them on shared drives with common passwords, to facilitate collaboration.

Conclusion: If files containing sensitive patient information must be transferred by email, mechanisms to encrypt them and to ensure that password strength is high are necessary. More sophisticated collaboration tools are required to allow file sharing without password sharing. We provide recommendations to implement these practices.

(J Med Internet Res 2011;13(1):e18) doi:10.2196/jmir.1335

KEYWORDS

Privacy; security; passwords

Introduction

Information technology is being increasingly used in clinical trials. One recent study estimated that 41% of Canadian clinical trials are using an electronic data capture (EDC) system [1]. Researchers are also turning more to electronic medical records as a source of clinically relevant patient data, and this is fueled by their growing adoption in practice [2-6].

The data collected during clinical trials consist of sensitive personal health information (PHI). Most clinical trial data sets contain fields such as participant initials, date of birth, and gender; information about the location of the participant's residence; and the clinical trial site where the participant is receiving treatment. This kind of information can be used to reidentify individuals [7-10]. In some cases, clinical trial data contain detailed contact information (eg, email addresses, residence address, or telephone numbers) for participants to receive reminders of upcoming visits or reminders to complete specific data collection forms.

Despite strong assurances about the safety of PHI entrusted with researchers [11] and arguments about the paucity of publicly known privacy violations in medical research [12], there have been recent publicized cases of data breaches from clinical trials [13]. Risky behaviors that can result in data breaches when handling data in clinical trials have been reported [14]:

- Engineering and mathematics graduate students were participating in a study that involved the analysis of medical images. These students did not receive sufficient education on privacy issues and how to handle PHI. Consequently, they were exchanging the personal data of subjects among themselves by email without any encryption.
- There were reported cases of study coordinators taking data home to finish some work off by saving it on to a memory stick or emailing the information to public accounts that they can access from home (eg, Gmail, Sympatico, or Rogers accounts). The data that were taken home were not encrypted.
- In one study progress notes had to be completed in an EDC system during a patient visit. There were cases where the physician or nurse completing the clinical notes mentioned the patient's name, family physician name, sibling or parent name, or other identifying information in what they wrote. Therefore, even if the structured questionnaires used to collect data in a clinical research study exclude any identifying or potentially identifying information, patients can potentially be identified from the clinical notes that were submitted as part of the study.
- Another example involved the audit trails. If, for example, a nurse saved identifying information in the notes or comments section in an EDC form and then subsequently deletes that information, the information remains in the audit trail. In this scenario patients were reidentifiable through data that were available in the audit trails.
- In one study where an EDC was used, there were examples of password sharing (to avoid having to re-log in every time an individual was to work on a shared computer), and passwords written on notes posted on monitors were common.

Computer users are known to use email quite often to share files, and frequently as their primary file-sharing mechanism [15-18]. One survey of US enterprises found that approximately one-quarter reported that personal information (including PHI) was included in outbound emails in breach of regulations, and one-third had investigated a violation of data-protection regulations related to email within the previous year [19].

An earlier qualitative study indicated that email was often used to transfer information during Canadian clinical trials [14]. It has been noted that email is the most widely used communication mechanism in clinical trials [20]. One survey found that 50% of professionals working on clinical trials use email as their predominant method for sharing information [21], and two-thirds of clinical trials professionals responded that documents and files are exchanged with investigative sites via email [22]. Unfortunately, there are many ways for an adversary to access information sent by email, either during transmission or at its destination (see Multimedia Appendix 1).

In the United States the Health Insurance Portability and Accountability Act (HIPAA) permits the electronic transmission of PHI without encryption if the risk is deemed reasonable [23]. However, under many state breach notification laws the transmission of unprotected personal information by email may be considered a breach (see Multimedia Appendix 1). Many health care providers admit that they do not encrypt patient data when they are transmitted electronically [24]. On the other hand, some states, notably Nevada and Massachusetts, have mandated the encryption of electronic personal information in transit over public networks [25,26]. Noncompliance can subject data custodians to significant fines and penalties. It is likely that more states will follow with similar laws. Furthermore, recognizing the potential for a breach, various health systems have mandated the encryption of data transferred by email for delivering care and for research purposes [27-29].

Trials using an EDC system will have raw data available in electronic form throughout the study. Regulated trials need to comply with the US Food and Drug Administration's (FDA's) 21 Code of Federal Regulations (CFR) Part 11 regulations where electronic systems are used [30-35], and these include provisions for securing data to avoid tampering and ensure data integrity. Regulated trials have a higher likelihood (than unregulated trials) of being audited, and the FDA has publicized its intention of increased audits [36]. Failure to address FDA concerns expressed in warning letters could result in delays in drug and device submissions. The out-of-pocket clinical development costs for a self-originated new drug are estimated to be on average $282 million (US $467 million for capitalized costs) [37], making any delays in submissions to the FDA quite costly. Therefore, there are strong incentives by sponsors to implement reasonable security practices for such trials.

Trial participants have the expectation that their PHI will be protected by the sponsors and sites collecting data. There are also potential financial and social harms to participants if their PHI is inadvertently disclosed (see Multimedia Appendix 1).

To investigate the extent to which research staff actually protect PHI, in this paper we report on two studies: (1) a direct evaluation of one behavioral indicator of secure information management practices: the strength of passwords used to transfer encrypted electronic health information among the stakeholders in regulated Canadian clinical trials, and (2) a series of interviews of study coordinators to understand their file-sharing practices and how files are protected when shared.

Methods

We performed two studies to investigate password strength and file-sharing practices in the context of clinical trials. Each is described below. Both study protocols were reviewed and approved by the research ethics board of the Children's Hospital of Eastern Ontario Research Institute, Ottawa, Canada.

Study 1: Password Strength Analysis

Over a period of 6 months the first author contacted stakeholders in 15 clinical trials known to him to determine whether they were interested in participating in this study. All of these trials used a form of EDC system for data collection and management.

Stakeholders in four clinical trials were willing to participate in this study. Stakeholders were site coordinators, statisticians, monitors, and study project managers. Three studies had at least one commercial sponsor and were consequently expected to follow FDA regulations. The fourth trial did not have a commercial sponsor but was sufficiently high in profile that it received strong regulatory oversight by Health Canada.

The clinical trials that participated were not representative of all clinical trials in Canada. They were, however, likely examples of trials where the stakeholders were sufficiently comfortable with their security practices that they agreed to participate.

The stakeholders identified password-protected electronic files that were generated or created during these trials and that were sent or received by email. All files met the following criteria:

- Their format was either Microsoft Office (Microsoft Corporation, Redmond, WA, USA) or ZIP (eg, WinZip Computing, Mansfield, CT, USA) (compressed archive; the contents of the compressed files may be any other data file type, such as Word, Excel, SAS, or XML data files). All Microsoft Office files were version 2003 or earlier (for example, with the .doc or .xls file extension).
- They were encrypted or protected using a password.
- The files were sent by email between sites, data management groups, statistical analysis groups, external consultants, or central labs with at least one party in the communication within Canada.
- They were suspected or known to have PHI of the participants.

We chose these file formats because they are the most commonly used based on their market penetration. Focusing on these document types provided us with an indicator of password strengths used by PHI custodians when they are free to select whatever password they want.

Even if the EDC system used in the trial supported some form of secure file sharing, the email exchanges we obtained the files from were with individuals involved in the trial but who did not have an account on the EDC system (eg, external statisticians and information technology specialists).

In total we examined 15 files from the four clinical trials. Nine were ZIP files and the remainder were Microsoft Office documents.

We purchased two commercial password recovery tools (Visual Zip Password Recovery Master version 6.2, Rixler Software, and Accent Office Password Recovery version 2.6, AccentSoft Utilities, St Petersburg, Russian Federation) and attempted to recover the passwords. We selected those tools based on listings at the openwall.com site, usability, and recommendations from security administrators at our institutions. Using commercial tools allowed us to assess the risk from an unsophisticated adversary.

One tool would attempt to recover the password for the Word document, and the second tool would attempt to recover the password for the whole of the ZIP archive (ie, there is one password for the whole archive). The tools use a number of techniques, including a dictionary attack, common password patterns, heuristics, brute force to recover the password, and by taking advantage of known vulnerabilities.

For dictionary attacks, we enhanced the dictionaries used to include Canada-specific terms (such as city and province names and famous personality names) and other commonly used terms and passwords (see Multimedia Appendices 2 and 3).

There are known vulnerabilities in some of the encryption methods that are used for these file types. Up to and including Word 2003, the default encryption was “97/2000 compatible.” This was an RC4 stream cipher with a 40-bit key. Because of the small key size, it would be possible to try all binary keys until one that works is found. This would not recover the password itself but would allow an adversary to access the contents of the password-protected file. Similarly, older versions of WinZip used the ZIP 2.0 encryption standard, which was considered weak. Only versions 9 and above of WinZip provide stronger encryption algorithms, such as Advanced Encryption Standard.

We used a computer running a 2 GHz dual processor with 2 GB of memory to execute the tool. The password recovery tools were allowed to run for 24 hours on each file before they were stopped.

The password recovery process was performed under the auspices of or by the stakeholder(s) themselves. Therefore, no files were transferred to any entity outside the data custodian to perform this study. The password recovery software was installed on a virtual machine and the software was run within the virtual machine on the data custodian’s equipment. The first author participated in running and monitoring the execution of the software. Each virtual machine instance, including all of the data files within it, was deleted after the analysis. We determined how many files had their password recovered during the 24-hour period.

Study 2: Study Coordinator Interviews

We identified 121 study coordinators who responded to a previous survey [1] and were located within the Toronto-Ottawa-Montreal corridor. We randomly selected a subset of 80 coordinators and sent each an email request to participate in a 1-hour interview. Assuming that we would not be able to reach 25% of the group due to a change in contact information following the previous study (eg, change of employment, relocation), we expected our email invitation to be received by approximately 60 coordinators in total. We expected a response rate of 33% from those 60 [38]. We therefore planned for a group of 20 interviewees. The purpose of the interviews was to understand the file-sharing practices used within a recent clinical trial in which each coordinator had been involved.

The 80 selected individuals were invited by email to participate (Multimedia Appendix 4 contains the text of the invitation email). As an incentive to participate, we organized a raffle for an iPod shuffle (Apple, Cupertino, CA, USA) that took place after the interviews had been completed. All interviewees were entered in the raffle.

Depending on the location and timing, some interviews were conducted face-to-face and some were conducted by telephone. The interviews were recorded and then transcribed verbatim. The open-ended interview questions are presented in Multimedia Appendix 4. The interview guide included a series of questions on the electronic file-sharing practices used during the conduct of clinical trials. Specifically, the questions elicited information related to how research coordinators addressed security and privacy issues and why they made certain file-sharing choices during clinical trials.

We used a general qualitative thematic approach to analyze the interview transcripts [39]. NVivo software version 8 (QRS International, Cambridge, MA, USA) facilitated the management and analysis of the data. We analyzed the data by developing a “start list” of codes based on the interview guide for the study, as well as the issues and themes that we expected to see in the data. However, recognizing that some codes would emerge or disappear during the analysis, we only used these predefined codes as starting points and embraced any new or revised issues or themes that emerged from the data.

Results

Password Strength Analysis

The ZIP files contained more than 2000 data files in their archive. In all cases the tools were able to recover the password, except for one file where the password could not be cracked within the 24-hour period. One of the recovered files contained coding information and dictionaries, and therefore did not have any PHI.

In all cases the recovered passwords were poorly constructed [40], with names of local locations (eg, “ottawa”), names of animals (eg, “cobra”), car brands (eg, “nissan”), and common number sequences (eg, “123”). This makes it easier for password recovery tools to guess them.

The files with recovered passwords that had PHI included Microsoft Word, Microsoft Excel, SAS, and XML (Clinical Data Interchange Standards Consortium Operational Data Model format files). They contained raw data from the clinical trials. In total, more than 10,000 patient records were in these files, and many with PHI on the subjects. For example, fields included name of study site, dates of screening and randomization, date of birth, initials, gender, and medical history.

For Microsoft Office document files, password-protecting a document is not the same as encrypting its contents [41]. Password protection controls the actions that can be performed on the document, such as who can modify a document, but the contents themselves are not encrypted. It may not always be obvious to an end user that such document protection does not protect the document contents themselves. A different program that ignores the document protections can be used to read the unencrypted contents, or they can be examined through a binary file viewer. All of the files in our sample were encrypted, but all used the default “97/2000 compatible” encryption.

Passwords on older versions of Word and Excel files are relatively straightforward to recover under certain conditions [42]. Word and Excel 2003 also have an option to use an RC4 stream cipher with a key length of up to 128 bits. A weakness in the implementation of the encryption module makes it possible for an adversary to compare two versions of a password-protected file to recover its plaintext contents [42,43]. In such a case password strength would not have affected the ability to extract the PHI. However, in our study we had only one version of each document and therefore our files were not vulnerable to this attack.

All of the ZIP files in our data set used the ZIP 2.0 encryption standard. All of the recovered passwords from the ZIP files were poor choices, and most of them were in our dictionaries or derived from words in the dictionaries (eg, ottawa followed by a digit).

Study Coordinator Interviews

We interviewed 20 study coordinators in the Toronto-Ottawa-Montreal corridor.

There was a marked difference between industry-sponsored trials and investigator-initiated trials. Specifically, industry-sponsored trials tended to have more formal processes in place to protect PHI and defined mechanisms for sharing data among those directly involved in the trial.

The three primary modes for sharing electronic information in the context of trials were as follows.

By Email

Data sent by email included mostly queries and responses to queries (eg, questions to sites about inconsistent or incomplete data for a particular patient). According to our informants, patient information was rarely encrypted when sent this way.

If PHI data files were sent by email then they were encrypted. This was used to justify the transmission of such files using an inherently insecure medium. If there was no EDC system in use in the trial or it did not support file sharing, then files were exchanged between any of the individuals and organizations working on the trial. If an EDC system that supported file sharing was deployed, then email was used to send data files to individuals who do not have accounts on the system.

Shared Drives

These drives were used within sites to store all trial information, including keys linking pseudonyms to patient names and Case Report Form (CRF) data. All site staff working on the trial would normally have access to the files on the shared drive. If the files were protected, the same password was often used for all of the files, and all staff who needed to access the documents would know that password. Formal processes for changing individual and shared credentials after the departure of staff were often not defined. Generally, individuals would not be taken off the access list once the trial was complete.

The file formats that we considered encourage the sharing of passwords. For example, it is not possible to assign different passwords to each individual who needs to access each of these documents. A single password is used for a document, and all individuals who need to read the document know that same password. If many documents need to be exchanged, it is not practical to have a different password for each one; therefore, often a single password is used for all documents and this password is shared among all users.

EDC Systems

In trials using EDC systems that support file sharing (through either an internal email system or document management features), individual patient-level data would be shared through the EDC system. The amount of access control would depend on the specific EDC system in question. If the EDC system did not support file sharing then most often email would be used.

It should be noted that, given the sensitivity of the topic, the interviewees may have held back some information. Specifically, they may not have been willing to share information about poor security practices in the trials they were participating in. Consequently, our results should be seen as an optimistic view of current practices.

Discussion

Summary

Previous work had indicated that password-protected files containing the PHI of clinical trial participants were being sent by email. Our initial study objective was to examine the strength of the passwords used to protect those files. Strong passwords were seen as an indicator of following good security practices in the context of clinical research.

We obtained a sample of 15 encrypted files that were sent by insecure email and were able to recover the passwords for 93% (14/15) of the files using commercial password recovery tools. Thirteen of those 14 files (93%) had sensitive health information in them. Therefore, in total 13/15 files were recovered *and* had PHI (87%). Since we were able to recover passwords using off-the-shelf tools, then it would be quite easy for an unsophisticated adversary to also do so. This result is consistent with previous research showing that health care professionals choose weak passwords to access patient data when there are no restrictions on password strength [44].

Perhaps more alarming, all of the Office and ZIP files in our sample used the default weak encryption methods. Therefore, an adversary had two different ways to extract the PHI: by attacking the weak algorithm itself or by attacking the weak password. In the current version of the WinZip tool (version 14.5), the default encryption is *still* based on the weak ZIP 2.0 standard.

At the time of this study the default applications for these file formats (ie, Microsoft Office and WinZip) did not enforce any password strengths, which means users could create any password they wished. For example, in earlier versions of WinZip that did provide password protection it was not possible to enforce a particular password strength (older versions of WinZip are still available [45]). Similarly, only recent versions of Microsoft Word have provided password strength enforcement [46]. Therefore, the passwords chosen were those that the stakeholders believed were sufficiently strong.

A follow-up interview study to examine the file-sharing practices of clinical trial study coordinators indicated that some PHI was exchanged by email that was not encrypted (eg, queries about specific patient data). Shared drives were another commonly used mechanism for exchanging files containing participant PHI. Shared drives create additional risks because, in practice, all files posted on the drive share a common password, and this common password is also shared among all stakeholders who need to access any one of the files. Sharing passwords is a violation of best-security practices. Furthermore, this goes against another best practice of limiting access to PHI to only the information that an individual needs (ie, a person who needs to access a single file should not get the password to access all files). From a regulatory perspective, it is also not possible to maintain audit trails of modifications made to files on shared drives.

Recommendations

Encrypt PHI Sent by Email

Protocols can be employed to securely exchange information that was sent by email using PGP (Pretty Good Privacy) or S/MIME (Secure/Multipurpose Internet Mail Extensions) [47]. However, these tools remain quite difficult for people to use [48-50]. Furthermore, in an enterprise setting where the key management complexities are handled by a central information technology department, they are still complicated to use when communicating beyond institutional boundaries and therefore may not be suitable for distributed collaborations that cross such boundaries.

Some products bypass the key management complexities by sending a plaintext notification email to the receiver that they have received a message with a link to a secure website where they can pick up their email [51]. The receiver, however, then needs to create an account on the secure website to pick up the message. In the context of clinical trials with staff joining and leaving throughout, such an option may be workable if creating an account is simple.

Another common approach is to use the built-in password protection capabilities available in tools for common file formats (such as WinZip and Microsoft Office) and then transmit the encrypted files. Instructions for encrypting Microsoft Office and ZIP files are available [41,42,52-54]. However, caution should be exercised when using some of these tools. The default encryption standard may be a weak one. A strong encryption algorithm must be selected or set as the default.

If file encryption tools will be the main mechanism used to protect PHI, then all PHI needs to be in files, including queries and their responses.

Users may get confused between encrypting a file and protecting parts of it with a password (which does not encrypt it). Therefore, an alternative that avoids the potential for confusion is to use an external file encryption tool [55], whereby it would be clear that the whole file is being encrypted.

Enforce Strong Passwords

Where file encryption with passwords will be used, policies need to be put in place to ensure that strong passwords are also used. Ensuring password strength would mitigate the type of attack we describe in this paper. Standards for passwords are available [56], as well as general guidelines on email security [47] and information management security in the health care context [57].

The default applications for creating Office and ZIP files can enforce passwords, but only if the most recent versions are used, as only these have such capabilities, and they need to be set up to enforce password strength.

This needs to be augmented with privacy training for study coordinators so that they have an appreciation of privacy risks when using information technology in the conduct of trials. Training should cover procedures for the handling of electronic data, as well as providing background on the security risks of the specific technologies used in the study.

Minimize Password Sharing

In collaborative workflows that are common in clinical trials, current methods for file sharing are risky because they require password sharing, for example, by sharing files through email or on shared drives. It does not matter how strong a password is; if many individuals know that password then it is not a secure password.

Shared passwords make it difficult to maintain clear audit trails of individuals responsible for particular changes, which is a critical requirement in 21 CFR Part 11. For example, if multiple individuals at a site are able to view and edit an encrypted document on a shared drive because they all have the password, this would likely run afoul of the regulations because audit trails of modifications made to individual files are not maintained with shared drives.

Encryption of documents today assigns the password to the document rather than to the individual. To eliminate password sharing means creating multiple copies of each document with a unique password for every user. Commonly used contemporary tools cannot handle such additional password management complexity.

A more practical solution is to use collaboration environments, such as Microsoft SharePoint or equivalent ones. These allow the creation of repositories with different access controls for different users without the need to encrypt the documents themselves or store them on hosted email servers. Collaboration environments can also maintain detailed audit trails and version control.

Make File-Sharing Systems Inclusive

Modern EDC systems support secure email communications between stakeholders in the trial within the walls of the system, and some provide secure file sharing and document management mechanisms. Despite this capability, some of the stakeholders in clinical trials do not have access to the EDC system. For example, an external statistician would not normally have an EDC account and therefore may be sent a data file by email. The user base for such systems can be quite large, including individuals across multiple organizations, and these individuals change during a trial [58]. In addition, if there are multiple staff working on a trial within a single site, then they ought to all have EDC system accounts, otherwise mechanisms such as shared drives are used. Therefore, the use of an EDC system with good security practices around file sharing is insufficient insurance against inappropriate security practices unless *everyone* who needs to access files has an account on it.

File-sharing capabilities may not be embedded within an EDC system, but may also be complementing an EDC system (eg, a document management system). In such cases the same conditions noted above would need to apply.

In the future, the use of federated authentication systems could allow file sharing that is more appropriate to the workflows in clinical trials.

Strengthen Data Breach Notification Exemptions

It should not be taken for granted that the default file encryption algorithms used to protect PHI are strong. In fact, we found that emailing the ZIP files in our sample would be considered a data breach under the US Health Information Technology for Economic and Clinical Health (HITECH) Act because they all used the weak ZIP 2.0 standard. Furthermore, the emailing of files encrypted using the default encryption in Word 2003 and earlier would also be a breach under the US HITECH Act. Therefore, the simple technical act of encryption does not ensure that this was done effectively [59,60]. A good example illustrating this is the case of TJX Companies, the parent company of some of the largest retailers in the United States, whereby adversaries were able to crack a weak encryption algorithm and access more than 90 million credit card numbers [61,62]. Encryption exemptions should always require that the algorithms used must meet a minimal standard.

Encryption exemptions in breach notification laws should explicitly consider the strength of the passwords that are used. If, for example, a sensitive document on someone’s hacked Gmail account is encrypted and the password is “password,” then the encryption is somewhat meaningless, however strong the algorithm itself is. Based on the results of our study, it seems prudent to consider password strength in determining whether an exemption applies: it should not be assumed that encryption, even with a strong algorithm, means that it was done adequately and that the adversary would not be able to figure out the password. Some states, such as North Carolina and Oregon, recognize the risk of an adversary acquiring the decryption key or password [59], and therefore would not allow an encryption exemption from notification under those conditions.

Limitations

Given the small number of trials from which we obtained files, broad generalization of the results is difficult. But we did expect that only trials that had good security and privacy practices would be willing to participate. We also expected that only study coordinators who were comfortable with the quality of their security practices would be willing to participate in the interviews. Therefore, the findings are expected to be biased toward those who were security-aware and were investing in protecting the data. Should this be case, then the more general state of affairs would be worse than depicted by our conservative results.

All of our data were collected from Canadian trials and Canadian coordinators. While the regulated trials from which we collected data had international sponsors and our interviewees participated in and discussed practices in international trials, our findings are specific to practices within a Canadian geography.

Our results indicate a potential privacy risk rather than an actual risk, since we do not know whether anyone has actually inappropriately accessed these files and cracked their passwords. However, this should not dilute the seriousness of the risk, since one purpose of having good password management practices is to act as a deterrent against an attack.

Conclusions

When sharing files containing PHI in the context of clinical trials, it is critical to encrypt all PHI. However, such a practice does not provide much protection if the passwords are weak or if the passwords are widely shared. Our study indicated that the passwords used are not strong and could be compromised using a commercial password recovery tool, and that some file-sharing practices used in clinical trials promote the wide sharing of passwords among study staff.

These results suggest that stronger oversight is needed on the transfer of health information in the context of clinical trials, and better training and enforcement (technical and procedural) of good security practices.

Acknowledgments

We wish to thank Liam Peyton for reviewing an earlier version of this paper.

Conflicts of Interest

None declared

Multimedia Appendix 1

Background on email file sharing in clinical trials

[PDF file (Adobe PDF File), 48 KB - jmir_v13i1e18_app1.pdf]

Multimedia Appendix 2

A manually constructed password list file

[ZIP file (ZIP Archive), 3168 KB - jmir_v13i1e18_app2.zip]

Multimedia Appendix 3

The “npasswd” password quality-checking tool dictionary.

[GZ file (GZIP Archive), 5518 KB - jmir_v13i1e18_app3.gz]

Multimedia Appendix 4

Invitation and questions

[PDF file (Adobe PDF File), 20 KB - jmir_v13i1e18_app4.pdf]

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Abbreviations

CFR: Code of Federal Regulations
CRF: Case Report Form
EDC: electronic data capture
FDA: Food and Drug Administration
HIPAA: Health Insurance Portability and Accountability Act
HITECH Act: Health Information Technology for Economic and Clinical Health Act
PHI: personal health information

Edited by G Eysenbach; submitted 13.08.09; peer-reviewed by K Shuaib, D Chen, F Manion; comments to author 03.09.09; revised version received 23.12.10; accepted 12.01.11; published 11.02.11.

Please cite as:
El Emam K, Moreau K, Jonker E
How Strong are Passwords Used to Protect Personal Health Information in Clinical Trials?
J Med Internet Res 2011;13(1):e18
URL: http://www.jmir.org/2011/1/e18/
doi:10.2196/jmir.1335
PMID:

Original Paper

The Use of Physician-Patient Email: A Follow-up Examination of Adoption and Best-Practice Adherence 2005-2008

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Abstract

Background: Improved communication from physician- patient emailing is an important element of patient centeredness. Physician-patient email use has been low; and previous data from Florida suggest that physicians who email with patients rarely implement best-practice guidelines designed to protect physicians and patients.

Objective: Our objective was to examine whether email use with patients has changed over time (2005-2008) by using two surveys of Florida physicians, and to determine whether physicians have more readily embraced the best-practice guidelines in 2008 versus 2005. Lastly, we explored the 2008 factors associated with email use with patients and determined whether these factors changed relative to 2005.

Methods: Our pooled time-series design used results from a 2005 survey (targeting 14,921 physicians) and a separate 2008 survey (targeting 7003 different physicians). In both years, physicians practicing in the outpatient setting were targeted with proportionally identical sampling strategies. Combined data from questions focusing on email use were analyzed using chi-square analysis, Fisher exact test, and logistic regression.

Results: A combined 6260 responses were available for analyses, representing a participation rate of 28.2% (4203/14,921) in 2005 and 29.4% (2057/7003) in 2008. Relative to 2005, respondents in 2008 were more likely to indicate that they personally used email with patients (690/4148, 16.6% vs 408/2001, 20.4%, $c^2_1 = 13.0$, $P < .001$). However, physicians who reported frequently using email with patients did not change from 2005 to 2008 (2.9% vs 59/2001, 2.9%). Interest among physicians in future email use with patients was lower in 2008 (58.4% vs 52.8%, $c^2_2 = 16.6$, $P < .001$). Adherence to email best practices remained low in 2008. When comparing 2005 and 2008 adherences with each of the individual guidelines, rates decreased over time in each category and were significantly lower for 4 of the 13 guidelines. Physician characteristics in 2008 that predicted email use with patients were different from 2005. Specifically, in multivariate analysis female physicians (OR 1.48, 95% CI 1.12-1.95), specialist physicians (OR 1.43, 95% CI 1.12-1.84), and those in a multispecialty practice (OR 1.76, 95% CI 1.30-2.37) were more likely than their counterparts to email with patients. Additionally, self-reported computer competency levels (on a 5-point Likert scale) among physicians predicted email use at every level of response.

Conclusions: Email use between physicians and patients has changed little between 2005 and 2008. However, future physician interest in using email with patients has decreased. More troubling is the decrease in adherence to best practices designed to protect physicians and patients when using email. Policy makers wanting to harness the potential benefits of physician-patient email should devise plans to encourage adherence to best practices. These plans should also educate physicians on the existence of best practices and methods to incorporate these guidelines into routine workflows.

(J Med Internet Res 2011;13(1):e23) doi:10.2196/jmir.1578

KEYWORDS

email; physician-patient relationship

Introduction

The use of email is poised to revolutionize the delivery of health care with improved efficiency, convenience, satisfaction, or access to care [1-4]. In the clinical setting, email has the potential to be a tool of efficiency for physicians and convenience for patients. It offers yet another means of communication for physician and patient, and has even been used by some as a substitute for clinic visits when appropriate [5,6]. Despite the opportunities offered by this communication technology, physicians' adoption of email with patients remains low [6-10].

Among the current literature, relatively little attention has been given to how physician-patient interaction through email has changed over time. We do know that email usage with health care providers among patients in the general US population continues to increase, albeit slowly [11]. Although early research reported a reluctance by patients to use email as a communication medium with their physicians [10,12], more recent studies have shown patients to be mostly willing to embrace the idea [13-17]. In examining the barriers and facilitators to physician-patient email communication, recent studies have suggested patient age [18,19], patient race [18,19], patient health status [18], physicians' satisfaction with their work [20], physician specialty [21], and physician workload [22] to be correlated with email usage. Despite the presence of a few scholarly explorations within this niche, more studies are necessary to determine specific aspects of physician adoption of email as a communication medium.

A 2005 study from our group [9] identified correlates of physicians' adoption of email use with patients and evaluated physician compliance with best-practice recommendations established by the American Medical Association (AMA) and American Medical Informatics Association (AMIA) [23]. We found that certain physician characteristics were associated with increased likelihood of email use with patients. Moreover, we found that the best-practice guidelines designed to protect physicians from liability issues, as well as protecting the privacy of the patient, were being used very infrequently. In the current study, we made ready use of updated physician data that we collected in 2008 from Florida using similar survey techniques. We examined whether email use with patients has changed over time (ie, 2005-2008). Moreover, given that adherence to best practices was low in 2005, we were interested in determining whether physicians more readily embraced the AMA/AMIA guidelines in 2008. Lastly, we explored the current physician and practice characteristics associated with email use with patients; and determined whether these factors changed relative to 2005.

Methods

We used a pooled time-series design that took advantage of two large-scale surveys of physician use of health information technologies in Florida. The two surveys used similar sampling strategies but did not necessarily target the same physicians in both 2005 and 2008. Data and methods from the first survey, conducted in 2005 (N = 14,921), have been previously reported [24-27]. The second survey, conducted in 2008 (N = 7003), had many identical questions. In the current analysis, we focused upon the questions pertaining to email use that were identical in both surveys and analyzed the combined data. The 2008 survey is attached (see Multimedia Appendix 1).

Survey

Similar to the 2005 survey, for the 2008 survey we identified physicians by using Florida Department of Health lists of individuals licensed to practice allopathic or osteopathic medicine and who had a practice address in the state. The focus of the study was on physicians practicing in outpatient settings, so physicians who are typically hospital based (eg, radiologists, pathologists, anesthesiologists, and emergency physicians) were excluded. In 2008, we targeted 50% of all primary care physicians (general internists, family physicians, general pediatricians, general practitioners, and obstetricians/gynecologists) and a 12.5% random stratified sample of other medical and surgical specialists throughout the state. This sampling methodology was proportionately equal to 2005 but sampled half as many physicians.

As in 2005, the 2008 survey was administered with the assistance of an on-campus survey research laboratory that tracked respondents using a 6-digit identifying code. Physicians were initially sent a survey and cover letter describing the study and urging their participation. After 4 weeks, nonrespondents were sent another copy of the survey and an updated cover letter further encouraging their participation. Participants returned their completed surveys in an enclosed prepaid business reply envelope. Staff at the survey research lab kept track of outgoing and incoming surveys and updated addresses retuned as undeliverable as needed. Staff at the survey research lab entered the data and randomly checked for accuracy. The response rate for the 2008 survey was 29.4% (2057/7003), which was very similar to the 2005 response rate of 28.2% (4203/14,921). The institutional review board at Florida State University approved the study protocol.

Statistical Analyses

Data from 2008 and 2005 were stacked into a single dataset and prepared for analyses. Descriptive statistics were computed for the 2008 sample and various analyses were conducted as follows. First, we compared the frequency of email use among physicians in 2005 with 2008 using chi-square analysis. Next, we compared 2005 and 2008 adherence rates with best-practice email guidelines developed the AMA and AMIA using the Fisher exact test for binary categorical variables. Lastly, based on the 2008 data, we investigated the physician and practice characteristics associated with email use by specifying a logistic regression model that computed odds ratios and 95% confidence intervals. Our predictive model, with email use as the dependent variable, included independent variables for physician gender, age, practice size (measured as the number of physician employed by the practice), physician specialty (primary care or other), practice setting (single or multispecialty), and physician competency as a computer user (measured on a self-reported 5-point Likert scale). This analysis was similar to the one previously conducted with 2005 data [9] to allow for an examination of how current predictors of email use compared with previous findings. All analyses were conducted in SPSS version 16.0 (IBM Corporation, Somers, NY, USA) and significance was considered at the *P* < .05 level.

Results

A total of 2057/7003 responses were returned in the 2008 survey, representing a 29.4% participation rate. Demographic and practice characteristics of respondents from both 2005 and 2008 are shown in Table 1. Overall, the 2008 sample included a greater proportion of female physicians and a higher proportion of family physicians and general internists. The 2008 sample also included a smaller proportion of surgical and medical specialists. Lastly, respondents in 2008 indicated having greater access to the Internet via high-speed connections, and fewer respondents indicated having dial-up access only.

Table 1. Demographic and practice characteristics of responding physicians

	2008 Results (n = 2057)	2005 Results (n = 4203)	*P*-value
Gender: male, n (%)	1434 (70.4%)	2479 (75.9%)	<.001
Mean (range) years in current community	15.0 (<1-53)	14.7 (<1-52)	.14
Mean (range) years since medical school graduation	21.9 (<1-60)	21.3 (<1-65)	.08
Specialty, n (%)			
Family medicine	575 (28.1%)	756 (18.3%)	<.001
Internal medicine	453 (22.2%)	783 (18.9%)	
Pediatrics	306 (15.0%)	602 (14.6%)	
Obstetrics/gynecology	205 (10.0%)	454 (11.0%)	
General surgery	24 (1.2%)	42 (1.0%)	
Surgical specialty	154 (7.5%)	393 (9.5%)	
Medical specialty	184 (9.0%)	709 (17.1%)	
Other	142 (6.9%)	397 (9.6%)	
Presence of Internet access	1941 (95.5%)	3824 (96.4%)	.07
High-speed access/wireless access	1641 (90.2%)	2857 (85.3%)	<.001
Dial-up connection only	48 (2.6%)	406 (12.1%)	<.001

Changes in Email Use Over Time

In 2008, 408/2001 physicians (20.4%) indicated that they personally used email from their office to communicate with patients, which was significantly higher than the 16.6% (690/4148) of respondents in 2005 (*P* < .001) (see Table 2). Of those who emailed with patients in 2008, few reported using email frequently (59/408, 14.6%) compared with those who reported using email occasionally (161/408, 40.0%) or rarely (183/408, 45.4%). For those physicians who did use email with their patients, the *frequency* of email use did not differ between 2005 and 2008. Specifically, the 59 doctors in 2008 who indicated that they frequently used email with patients represented 2.9% of a total of 2001 physicians who responded to the email question in the survey. This rate was identical to the 2005 rate reported previously by our group [9].

Table 2. Physician's self-reported email use with patients and other entities

	n (%) of Physicians		c^2	DF[a]	P-value
	2005 (n = 4148)	2008 (n = 2001)			
Personally uses email with patients from office practice	690 (16.6%)	408 (20.4%)	13.0	1	<.001
Frequency of email communication with patients					.41
Often	120 (17.4%)	59 (14.6%)	1.8	2	
Occasionally	255 (37.0%)	161 (40.0%)			
Rarely	314 (45.6%)	183 (45.4%)			
Would you like to email with patients in the future					
Yes	463 (13.4%)	151 (10.1%)	16.6	2	<.001
No	1823 (52.8%)	869 (58.4%)			
Do not know yet	1166 (33.8%)	468 (31.5%)			
Uses email from office practice with entities other than patients	2593 (63.0%)	1272 (63.8%)	0.30	1	.59
If so, with which groups (check all that apply)?					
Family member or caregiver of patients	435 (16.8%)	217 (17.2%)	0.75	1	.75
Other doctors	1652 (63.8%)	761 (60.2%)	4.6	1	.033
Business-related communications	1298 (50.1%)	664 (52.5%)	1.9	1	.17
Hospitals	757 (29.2%)	445 (35.3%)	14.5	1	<.001
Pharmaceutical companies	531 (20.5%)	304 (24.1%)	6.4	1	.012
Personal friends or family members	1923 (74.2%)	916 (72.5%)	1.4	1	.24
Other	333 (12.9%)	130 (10.4%)	5.0	1	.026

[a] DF: degrees of freedom.

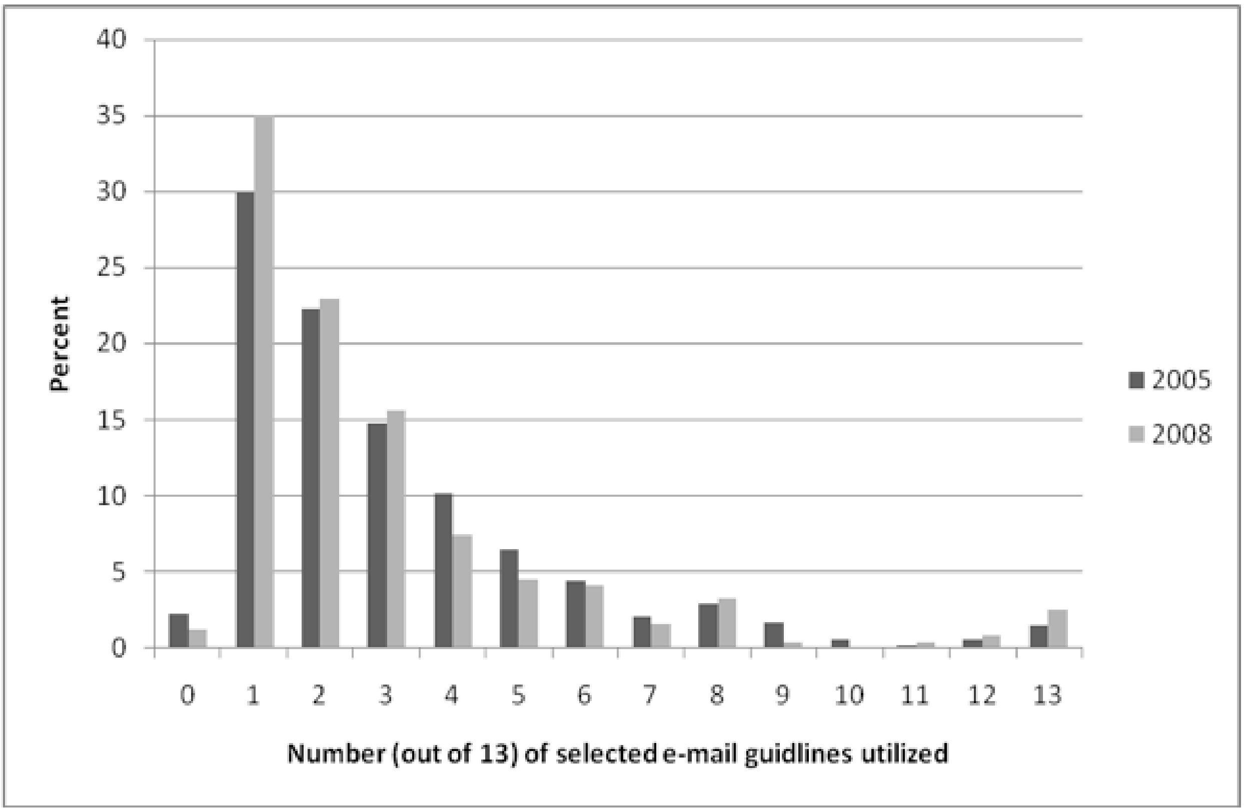
Those who did not currently use email with their patients were asked about their future interest in doing so. Compared with 2005, a greater proportion of physicians in 2008 indicated not being interested in future email use with patients (869/1488, 58.4% in 2008 vs 1823/3452, 52.8% in 2005 in 2008, $c^2_2 = 16.6$, $P < .001$); likewise, the proportion of physician indicating wanting to email with patients in the future decreased over time (463/3452, 13.4% in 2005 vs 151/1488, 10.1% in 2008, $c^2_2 = 16.6$, $P < .001$) (see Table 2).

The rate of email use by respondents with entities other than patients did not change over time (2593/4148, 63.0% vs 1272/2001, 63.8%, $P = .59$) (Table 2). However, the frequency of email use with specific (nonpatient) groups differed between 2005 and 2008. Specifically, respondents were less likely to email with other doctors in 2008 (1652/2593, 63.8% vs 761/1272, 60.2%, $c^2_1 = 4.6$, $P = .03$), and more likely to email with hospitals (757/2593, 29.2% vs 445/1272, 35.3%; $c^2_1 = 14.5$, $P < .001$) and pharmaceutical companies (531/2593, 20.5% vs 304/1272, 24.1%, $c^2_1 = 6.4$, $P = .01$).

Of the 408 respondents who indicated using email with patients in 2008, only 6 doctors (1.5%) reported that they abided by all the AMA/AMIA guidelines. Figure 1 presents the number and percentage of guidelines that physicians reported adherence to in 2005 and 2008. While more physicians in 2008 indicating abiding by at least one of the guidelines, the differences overall did not differ.

When comparing the individual best-practice categories between 2005 and 2008, rates decreased over time in each category and were significantly lower in 2008 for 4 of the 13 guidelines (Table 3).

Figure 1. Number and percentage of selected email guideline items being adhered to by physicians in Florida in 2005 and 2008



Specifically, from 2005 to 2008, the percentage of physicians who printed email communication and placed it in patients' charts decreased from 48% (331/689) to 39% (159/408) (c^2_1 = 8.4, *P* = .004); the percentage of physicians who informed patients about privacy issues with respect to email decreased from 36.3% (250/689) to 29.2% (119/408) (c^2_1 = 5.7, *P* = .02); the percentage of physicians who notified patients to discuss emails when they become too lengthy decreased from 21.5% (148/689) to 15.7% (64/408) (c^2_1 = 5.5, *P* = .02); and the percentage of physicians who sent patients a message to inform them of completing a request decreased from 16.1% (111/689) to 11% (45/408) (c^2_1 = 5.4, *P* = .02).

Table 3. Physician's self-reported adherence to recommended guideline items when emailing patients

Nationally recommended policies	n (%) of Physicians 2005 (n = 689)	 2008 (n = 408)	c^2	DF[a]	*P*-value
Print email communication and place inpatients' charts	331 (48.0)	159 (39.0)	8.4	1	.004
Inform patients about privacy issues with respect to email	250 (36.3)	119 (29.2)	5.7	1	.02
When email messages become too lengthy, notify patients to come in to discuss or call them	148 (21.5)	64 (15.7)	5.5	1	.02
Establish a turnaround time for messages	111 (16.1)	53 (13.0)	1.9	1	.16
Request patients put their names or identification numbers in the body of the message	111 (16.1)	59 (14.5)	0.5	1	.75
Send a new message to inform patient of completion of request	11 (16.1)	45 (11.0)	5.4	1	.02
Establish types of transactions	11 (16.0)	64 (15.7)	0.0	1	.91
Explain to patients that their message should be concise	70 (10.2)	31 (7.6)	2.0	1	.16
Remind patients when they do not adhere to guidelines	55 (8.0)	30 (7.4)	0.1	1	.71
Develop archival and retrieval mechanisms	57 (8.3)	32 (7.9)	0.2	1	.74
Instruct patients to put category of transactions in subject line of message	48 (7.0)	21 (5.1)	1.4	1	.23
Configure automatic reply to acknowledge receipt of patients' messages	42 (6.1)	20 (4.9)	0.7	1	.41
Request patients to use autoreply features to acknowledge clinician's message	28 (4.1)	15 (3.7)	0.1	1	.47

[a] DF: degrees of freedom.

Predictors of Email Use in 2008

We investigated whether physician and practice characteristics among 2008 respondents were associated with email use with patients. Specifically, we present unadjusted and multivariate relationships between email use and gender, age, practice size, specialty, and practice setting in Table 4.

Table 4. Predictors of email use with patients among physicians in Florida (n = 1766)

	Physicians who used email with patients	Unadjusted odds ratio (95% CI)	Adjusted odds ratio[a] (95% CI)
Gender			
Male	274 (19.7%)	1.00	1.00
Female	130 (21.9%)	1.14 (0.90-1.44)	1.48 (1.12-1.95)
Age			
Less than 40 years old	78 (22.3%)	1.00	1.00
41-50 years	133 (22.1%)	0.99 (0.72-1.36)	1.21 (0.85-1.71)
51-60 years	131 (21.1%)	0.93 (0.68-1.28)	1.35 (0.94-1.94)
61 years or older	62 (15.2%)	0.63 (0.43-0.90)	1.16 (0.76-1.79)
Practice size			
Solo practice	122 (18.0%)	1.00	1.00
2-9 physicians	199 (19.9%)	1.13 (0.88-1.46)	0.93 (0.71-1.23)
10-49 physicians	51 (29.7%)	1.66 (1.14-2.41)	0.98 (0.61-1.56)
50 or more physicians	29 (35.8%)	2.54 (1.55-4.16)	1.29 (0.68-2.43)
Physician s pecialty			
Primary care	243(18.6%)	1.00	1.00
Other	162 (23.7%)	1.36 (1.08-1.70)	1.43 (1.12-1.84)
Practice s etting			
Single specialty	240 (17.5%)	1.00	1.00
Multispecialty	133 (28.7%)	1.89 (1.48-2.41)	1.76 (1.30-2.37)
Competency as a computer user			
Very sophisticated	74 (35.4%)	1.00	1.00
Sophisticated	172 (25.0%)	0.61 (0.44-0.85)	0.55 (0.38-0.79)
Neutral	137 (17.9%)	0.40 (0.28-0.56)	0.38 (0.26-0.55)
Unsophisticated	23 (8.4%)	0.17 (0.10-0.28)	0.14 (0.08-0.26)
Very unsophisticated	2 (4.9%)	0.94 (0.22-0.40)	0.10 (0.02-0.43)

[a] Adjusted odds ratios control for all variables in the table.

In an unadjusted analysis of 2008 data, physician in the oldest age category (61 years or older) were significantly less likely to email with patients than those in the youngest category (OR 0.63, 95% CI 0.43-0.90). Moreover, as practice size increased, so did the tendency among respondents to indicate they used email with patients. For example, those in practices with 50 or greater physicians were significantly more likely than those in solo practices to email with patients (OR 2.54, 95% CI 1.55-4.16). Lastly, specialist physicians were more likely than primary care physicians (OR 1.36, 95% CI 1.08-1.70) and those in a multispecialty practice were more likely than those in a single specialty practice (OR 1.89, 95% CI 1.48-2.41), to email with patients.

In multivariate analyses of 2008 data that controlled for confounders, female physicians were more likely to indicate they email with their patients (OR 1.48, 95% CI 1.12-1.95). Additionally, specialist physicians were more likely than primary care physicians (OR 1.43, 95% CI 1.12-1.84) and those in a multispecialty practice were more likely than those in a single specialty practice to use email with their patients (OR 1.76, 95% CI 1.30-2.37). Self-reported computer competency levels among physicians predicted email use at every level of response. When compared with “very sophisticated” computer users, “sophisticated” users (OR 0.55, 95% CI 0.38-0.79), neutral users (adjusted OR 0.38, 95% CI 0.26-0.55), “unsophisticated” users (OR 0.14, 95% CI 0.08-0.26), and “very unsophisticated” users (OR 0.10, 95% CI 0.02-0.43) were all less likely to use email with patients. Lastly, in the multivariate analysis, physician age and practice size were no longer associated with email use with patients.

Discussion

The benefits of email communication between physician and patient have been espoused by many researchers [1,5,6]. It has been reported that email between physician and patient can improve efficiency and workflow within a medical practice, and improve access to care and convenience to patients [1,5,6,28]. Despite the improvements this communication medium can provide, Florida physicians in 2005 were infrequently using emailing with patients [9]. In the current study, we made use of newly collected data from Florida to examine trends in email use by physicians over time.

The main finding of our analysis suggests that, while a higher percentage of physicians reported having tried emailing with patients in 2008 than in 2005, the proportion of physicians who are actively doing so on a regular basis did not change significantly during this time frame. Furthermore, physicians who had not yet tried emailing with patients had a waning future interest in doing so. On the contrary, relative to 2005, physician use of email from their practices with entities other than patients remained high. In fact, in 2008, physicians reported an increase in email use with individuals at hospitals and pharmaceutical companies, suggesting that physicians did see value in this communication medium with selected stakeholders.

A troubling trend involves the lack of adherence to professionally developed best practices designed to protect physicians who choose to email with patients. In 2005, we found that very few doctors abided by most of the recommended best practices developed by the AMA and AMIA. Our updated data from 2008 suggest that even fewer physicians who email with patients were adhering to these best practices. Specifically, even though a greater number of physicians reported abiding by at least one of the 13 guidelines, overall, fewer physicians reported adherence to all 13 guidelines with significant reductions in 4 guidelines. It is possible that physicians were not aware that these guidelines exist. Furthermore, it is possible that, despite their knowledge of these guidelines, physicians found it difficult to incorporate these best practices into their routine workflows. It is also possible that these guidelines may be perceived as outdated given that they were published in 1998 when email usage was much more infrequent between doctors and patients. Our belief is that the guidelines are still relevant and thus, given our findings, physicians are still exposing themselves to potentially unnecessary liability when they fail to heed the recommendations of the AMA and AMIA with respect to email use. Efforts should be made to draw attention to these guidelines, as well as simultaneously demonstrating how these guidelines can be adopted by physicians and integrated into their practice's workflow.

In 2008, several physician or practice characteristics were associated with email use with patients. In multivariate analyses, female physicians, specialty physicians (as opposed to primary care physicians), and those in a multispecialty practice were all more likely than their counterparts to use email with their patients. Given the increasing time demands on primary care physicians in terms of providing recommended services and preventative care [29], and the increasing length and volume of primary care visits [30], these physicians may have less time available to devote to emailing patients. This is particularly important in light of the national trend toward improving patient-centered medical homes in which primary care physicians are empowered to increase services, including through electronic means, to their patients.

On the other hand, physicians in multispecialty practices can gain economies of scale that help with certain administrative processes [31], which may provide more free time to use email with patients. Lastly, it is not clear why female physicians were more likely than their male counterparts to use email with patients. However, previous researchers have found that female doctors were more likely to earn continuing medical education (CME) credits online [32] and be responsive to email invitations to CME programs [33], both activities that may increase their proclivity to use information technology within their practice. More research is needed to more fully understand this trend.

While, in 2005, physicians in the largest practices emailed with patients most frequently, practice size was no longer a significant predictor of email use in 2008. Furthermore, while age was negatively associated in univariate analysis with patient email use in both 2005 and 2008, multivariate analysis of 2008 data that included the newly available measure of self-reported computer sophistication made differences by age disappear. Our data show that computer sophistication may be a better predictor than age of technology adoption among physicians. Those who were very sophisticated computer users were significantly more likely to report emailing with patients than those who were sophisticated, neutral, unsophisticated, or very unsophisticated in increasingly higher proportions.

There are several limitations of this study worth mentioning. First, given that our data relied on self-reported information, we realize that our data are limited by participants' ability to recall information accurately and their willingness to do so. Second, we recognize that response rates to both surveys were suboptimal. However, several researchers, including our group using the current data, have found that response bias in studies of health information technology are not likely, given the noncontroversial nature of questions on such surveys [34,35]. Third, given the pooled time-series nature of our analyses, we cannot be certain that the same physicians responded to our survey in 2005 and 2008. Even though we used very similar sampling methodologies, the characteristics of the 2005 and 2008 samples were different in some ways, including gender and specialty. Although these differences may be true changes in demographic characteristics among Florida physicians over time, we recognize that these differences may be a weakness of the study. Lastly, our study was conducted in a single US state where demographic, socioeconomic, and medicolegal characteristics affecting physicians may not generalize well to the rest of the country. Thus, we recommend caution when interpreting our results as reflective of physicians outside of Florida.

If physician-patient email communication is indeed valued as a patient-centered approach to improving health care quality, more effort will be needed to alleviate physician reluctance to engage in this activity. In Florida, the proportion of physicians who regularly email with patients rose only slightly between 2005 and 2008. This was a period when other health information technology applications such as electronic medical records and e-prescribing increased significantly in adoption nationally and in Florida [36,37]. Policy makers will need to seriously consider ways in which to encourage this activity if the potential benefits from physician-patient emailing are to be realized. Physicians who are using or are considering using email with patients are urged to become knowledgeable of best practices, which they can employ in their organizations.

Acknowledgments

Data collection for this project was funded by a grant from the Physicians' Foundation for Health System Excellence. The funder played no role in the analysis, presentation of data, or writing of this manuscript.

Conflicts of Interest

None declared

Multimedia Appendix 1

Survey of physician information technology use in Florida 2008, developed by Nir Menachemi, PhD and Robert G Brooks, MD

[PDF file (Adobe PDF File), 47 KB - jmir_v13i1e23_app1.pdf]

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Abbreviations

AMA: American Medical Association
AMIA: American Medical Informatics Association
CME: continuing medical education

Edited by G Eysenbach; submitted 24.05.10; peer-reviewed by H Atherton; comments to author 08.08.10; revised version received 22.08.10; accepted 10.11.10; published 25.02.11.

Please cite as:
Menachemi N, Prickett CT, Brooks RG
The Use of Physician-Patient Email: A Follow-up Examination of Adoption and Best-Practice Adherence 2005-2008
J Med Internet Res 2011;13(1):e23
URL: http://www.jmir.org/2011/1/e23/
doi:10.2196/jmir.1578
PMID:21447468

Original Paper

Packaging and Labeling of Pharmaceutical Products Obtained from the Internet

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Abstract

Background: For patients, the prescription container label may be the only source of instructions on how to take their medicines. In the United States, the legal requirements for a prescription label are set by federal law and state statutes. The container should be comparable to that which manufacturers use to package drug products and should preserve a product's identity, strength, quality, and purity and prevent contamination. Safety features such as a child-resistant closure should be provided. Pharmaceutical products purchased from international online pharmacies are not approved by the Food and Drug Administration (FDA) and may not meet US guidelines for labeling and packaging.

Objective: The study objective was to determine whether commonly purchased pharmaceutical products obtained from international online pharmacies are comparable to products dispensed in the United States with regard to labeling and packaging.

Methods: During March 2006 through January 2007, 41 pharmaceutical oral dosage form samples were obtained from international Internet pharmacy websites for evaluation: 18 generic simvastatin samples, 18 generic amlodipine samples, and 5 generic sildenafil samples. Contents for each package were observed and recorded and comparison of the prescription labeling and packaging of these products was made with prescription labeling and packaging requirements in the United States.

Results: Of the 41 drug products obtained from online pharmacies from 12 different countries, only 1 product (from Canada) would meet both labeling and packaging guidelines for products dispensed in the United States. Of those not meeting the requirements, 7 were dispensed in paper envelopes with label affixed that was either handwritten or typed and contained missing information such as name and address of dispenser, name of prescriber, name of patient, and directions for use. Another 3 products did not have a label affixed to the drug product, but information was printed on a paper document enclosed in the shipping package, while 28 products did not have labels affixed to the drug product. In all, 39 of the 41 drug products' packaging would not meet the US guidelines. Aside from the Canadian product, only 1 product from Mexico was dispensed in a container that would meet guidelines established in the United States. In total, 35 products were not dispensed in plastic vials but were dispensed in unit dose packages, paper envelopes with loose dosage forms, blister packs of drugs held together with rubber bands, or a combination of these packaging forms.

Conclusions: Results suggest that labeling and packaging standards for international generic drug products are not equivalent to labeling and packaging standards in the United States. This suggests dissimilar and substandard distribution processes compared with those in the United States, which in turn presents a challenge to patient comprehension and health literacy and may affect patient adherence to drug treatment regimens. These findings have strong implications for drug product quality, patient outcomes, therapeutic effectiveness, and safety.

(J Med Internet Res 2011;13(1):e22) doi:10.2196/jmir.1441

KEYWORDS

Internet pharmacy; online pharmacy; drug importation; drug label; pharmaceutical packaging

Introduction

For patients, the prescription container label may be the only source of instructions on how to take their medicines [1]. According to the United States Pharmacopeia (USP),

> *the term "labeling" designates all labels and other written, printed, or graphic matter upon an immediate container of an article or upon, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling upon the immediate container [2].*

In other words, "labeling" can refer to drug products from a manufacturer, and "label" can apply to drug products dispensed by a pharmacist on a prescription order.

In the United States, the legal requirements for a prescription label are set by federal law and state statutes [2,3]. At the federal level, the required items of information for the prescription product label can be found in Section 503 (b) (2) of the Federal Food, Drug, and Cosmetic Act (Table 1) [3]. States may have additional labeling requirements required by law [2].

Table 1. Guidelines for prescription labeling and packaging

Prescription Labels[a]	Prescription Packaging[b]
1. Serial number of prescription 2. Date of prescription or date of its filling 3. Name of prescriber 4. Name of patient if stated on prescription 5. Directions for use, including precautions, if contained in prescription	1. Light-resistant; Protects light-sensitive product and/or contents against photochemical deterioration 2. Moisture-proof closure 3. Child-resistant container with safety closure 4. Container preserves product's identity, strength, quality, purity as Type as specified by manufacturer

[a] Federal requirements only; individual state requirements may differ

[b] Includes requirements set by drug manufacturers dispensed to patients by licensed practitioners; exceptions include drugs requiring direct and immediate access (eg, oral contraceptives and certain cardiac drugs)

The National Association of Boards of Pharmacy (NABP) provides recommendations for state statutes on required items of information for outpatient prescription labels [4]. These recommendations augment federal requirements and include such items as name (proprietary or generic) and strength of drug product dispensed, special requirements with regard to the name of the product if an equivalent drug product is dispensed, name of the manufacturer or distributor of the product dispensed, beyond-use date of the product, quantity dispensed, number of refills, and name or initial of the dispensing pharmacist.

In the United States, it is the professional responsibility of pharmacists to label the dispensed drug product with the items stated in the federal law in addition to any state requirements for the state in which he or she is practicing.

In addition to proper labeling, pharmacists should select packaging that maintains the integrity of the drug product. The pharmacist's choice of container should be based primarily on the type and quantity of medication to be dispensed and manner of use [5]. The container should be comparable to that which manufacturers use to package drug products and should preserve a product's identity, strength, quality, and purity and prevent contamination. The type of container to be used by a pharmacist when dispensing a prescription drug is found in the manufacturer's prescription product's labeling and is regulated by the US Food and Drug Administration (FDA). The FDA regulation does not apply to products intended to be dispensed in the manufacturer's original container. Manufacturer's packaging and storage information is generally found on the original container or in the package insert.

In addition to packaging requirements for dispensing drug products, special consideration should be made for the closure on the prescription container. The closure must inhibit penetration of moisture and contaminants that can have a deleterious effect on oral dosage forms. A well-known example in pharmaceutics is the breakdown of aspirin into acetic acid and salicylic acid in the presence of moisture.

If the original package is intended to go directly from the pharmacist to the patient, manufacturers must place prescription drugs in child-resistant packages. Similarly, pharmacists must dispense prescription drugs for oral use to the patient in containers with child-resistant safety closures unless the patient or prescriber specifically requests otherwise.

A request for a safety container that is not child resistant must be obtained by the patient as a signed waiver and may apply to all of a patient's dispensed medications. The pharmacist must maintain a record of the signed waiver request. Exceptions exist to these requirements, such as packaging of oral contraceptives because of their functional design, and certain types of cardiac drugs, such as nitroglycerin. In these instances, patients may need immediate access to the medication.

In addition, the closure must comply with guidelines specified in the Poison Prevention Packaging Act 1970 [6]. This federal law was enacted as a result of reports of a significant number of accidental poisonings of children after ingestion of household chemicals, including medications. Closures that must comply with these safety guidelines include both legend and over-the-counter (OTC) drug products.

Often, prescription drugs are sold in bottles with a seal that must be removed the first time the bottle is opened. This is an example of “tamper-evident” packaging that was introduced in the 1980s. The design of tamper-evident packaging makes it apparent if the packaging has been previously opened. The Tylenol crisis of 1982 highlighted the need for manufacturers to provide safeguards to altering drug product packaging [7].

In general, pharmaceutical products purchased from international online pharmacies are unapproved by the FDA, and in addition to possibly not meeting standards of formulation, may not meet quality standards for labeling and packaging [8]. International online pharmacies may offer convenience and potential cost savings to consumers, but potential health risks exist to patients from these types of drug purchases [9,10].

Currently, there is a paucity of information on packaging and labeling of pharmaceutical products imported via the Internet. The Office of Compliance in FDA’s Center for Drug Evaluation and Research initiated a study to determine the quality of a select group of pharmaceutical products purchased via the Internet from foreign sources. Packaging was a significant problem with virtually all of the Internet purchase samples. Many had either no or minimal labeling information for proper use. Some drug samples were shipped loosely in unlabeled plastic bags [11].

This paper reports on the variability of labeling and packaging for drug products obtained via the Internet. The objective of this study was to determine whether commonly purchased pharmaceutical products obtained from international online pharmacies are comparable to products dispensed in the United States with regard to labeling and packaging. This information is valuable for identifying trends in drug quality that may exist with consumer drug importation via the Internet.

Methods

Website Identification and Sample Acquisition

Drug product acquisition and website attributes were described previously in a report on drug quality, and a similar process was followed for this study [12]. For all other drug product samples, searches of the World Wide Web were conducted with the browser Internet Explorer 6.0. The websites for the Internet pharmacies were located by using the advanced search options of Google (http://www.google.com). The keywords selected for entry into the query box of the browser included the search terms “generic simvastatin,” “generic amlodipine,” generic sildenafil,” “online pharmacies,” and “Internet pharmacy.” All proprietary forms of oral drug products were identified on the websites for prospective procurement. Our perspective was that of a consumer seeking to purchase these prescription medications online or comparison price shopping. For Internet drug purchases, a consumer credit card was used for financial transactions as specified on the websites. Prescription requirements were noted, and for drug products requiring a prescription (ie, products obtained from Canada), a prescription was issued by a physician from the Texas Tech University Health Sciences Center School of Medicine and faxed to the Internet pharmacy as specified on the website.

Physical Characterization

Upon receipt of drug product samples, the contents for each package were observed and recorded, and data were organized in tabular format. Comparison was made between the shipped items and prescription labeling and packaging requirements in the United States. Any additional distinguishing qualities were noted.

Results

Website Identification and Sample Acquisition

During March 2006 through January 2007, simvastatin, amlodipine, and sildenafil drug product samples were purchased from international markets from 41 websites. A checklist of attributes was created for each specific drug product (Table 2).

Table 2. Characteristics of pharmaceutical tablet samples from international markets obtained from the Internet

Product Name [a]	Manufacturer	Lot Number	Product Expiration Date	Product Source (Laboratory)	Shipping Source	Product Source (website URL)
Simvastatin						
Apo-Simvastatin	Apotex	GP5249	2006 AL	Toronto, Ontario, Canada	Canada	http://www.canadamednet.com[b]
Co-Simvastatin	Cobalt	AC641	02-2006	Mississauga, Ontario, Canada	Canada	http://www.minitdrugs.com[b]
Novo-Simvastatin	Novopharm	20392C	05-2006	Toronto, Ontario, Canada	Canada	http://www.Canadacure.com[b]
Pms-Simvastatin	Pharmascience	20329A	01-2006	Montreal, Quebec, Canada	Canada	www.universaldrugstore.com[b]
Simvastatin	Generics (United Kingdom) Limited	5C07SH	03-07	Hertfordshire, England, United Kingdom	United Kingdom	www.CanadaPharmacy.com[b]
Simlo-20	Ipca Laboratories	VO4010R	11-07	Mumbai, Maharashtra, India	India	www.safemeds.com
SIMLIP-20	Okasa Pharma	NS6002	12-07	Mumbai, Maharashtra, India	India	www.qualitygenerics.com
Starstat 20	Mepro Pharm	03065M	05-07	Mumbai, Maharashtra, India	India	overseasrxdrugs.com
Simi-20	Preet Pharm	PMI-2001	07-07	Delhi, India	India	www.fairrx.com
Zorced	Productos Farmaceuticos Collins SA de CV	2734F4K	11-06	Guadalajara, Jalisco, Mexico	Mexico	www.pharmacymex.com
Simvastatina ratiopharm	Ratiopharm Espana	Z-03	11-08	Madrid, Spain	Spain	www.tristatemeds.com
Simlo-20	Ipca Laboratories	V05007R	05-07	Mumbai, Maharashtra India	India	www.xlpharmacy.com
Simvastatin	Unicure Remedies	24205	05-07	Vadodara, Gujarat, India	India	www.worldremedium.com
Simastin 20	Zaneka Healthcare Pvt	SAA602	12-07	Haridwar, India	India	www.generic-pharmacy-online.net
Bestatin 20	Berlin Pharmaceutical Industry	06000065	01-09	Bangkok, Thailand	Thailand	www.healthworldconnect.com
Simlup-20	Mepro Pharm	08124M	11-06	Mumbai, Maharashtra, India	India	www.rx2world.com
Simlup-20	Mepro Pharm	02044M	03-06[c]	Mumbai, Maharashtra, India	Fiji Islands	www.inhousepharmacy.com
Simvastatin	Not provided	None	03-08	Not provided	India	www.supersavermeds.com
Amlodipine						
Amlodac-5	Cadila	ZF1141	03-08	Dholka, Ahmedabad, India	India	www.qualitygenerics.com
Amlip-5	Okasa Pharma	NN6004	01-09	Mumbai, Maharashtra, India	India	www.freedoms-pharmacy.com
Amlip-5	Okasa Pharma	NN5007	06-08	Mumbai, Maharashtra, India	India	www.rx-list.net
Aginal-5	Alembic Ltd	6931003A	02-08	Vadodara Gujarat India	India	www.valuepharmaceuticals.com

Product Name [a]	Manufacturer	Lot Number	Product Expiration Date	Product Source (Laboratory)	Shipping Source	Product Source (website URL)
Norvasc	Pfizer New Zealand	55805036	10-10	Auckland, New Zealand (Made in China)	Fiji Islands	www.inhousepharmacy.com
Amlopres-5	Cipla Ltd	Not provided	12-08	Mumbai Central, Mumbai, India	India	www.npmeds.com
Amlopine	Berlin Pharmaceutical	0600652	04-09	Bangkok, Thailand	Thailand	www.1anabolic-steroids.com
Amlodac-5	Cadila	ZF1143	03-08	Dholka, Ahmedabad, India	India	www.sharpmeds.com
Amlibon	Ind-Swift, Ltd	AC5J02J	09-07	Samba, Jammu, India	India	www.xlpharmacy.com
Amdepin-5	IRM Pharma	6001	02-08	Dholka, Ahmedabad, India	India	www.aclepsa.com
Delfidin	Akums Drugs & Pharmaceuticals	06085AAV	07-07	Ranipur, Haridwar, India	Seychelles	www.budgetmedicines.com
Elpress-5	Elder Pharmaceuti-cals	CSEL6001	03-09	TTC Industrial Area, Navi Mumbai, India	India	www.worldremedium.com
Elpress-5	Elder Pharmaceuti-cals	CSEL 600308	07-09	TTC Industrial Area, Navi Mumbai, India	India	www.pharmacyforlife.com
Norvas	Pfizer, SA de CV	6180501101	05-10	Toluca, Mexico	Mexico	www.pharmacymex.com
Amlodipin	1A Pharma	6E0063	01-09	Oberhaching, Germany	Germany	www.tristatemeds.com
Amlomed-5	Akums Drugs and Pharmaceuti-cals, Ltd	A1004	03-08	Ranipur, Haridwar, India	India	www.generic-pharmacy-online.net
Amlokind-5	Unimax Labs	AD06-11	04-09	Faridabad, Haryana, India	India	www.pillsbasket.net
Amlogard	Pfizer Ltd, India	620-05022	05-09	Navi Mumbai, India	India	www.discount-prescription-drugs-online.com
Sildenafil						
Caverta	Not provided	Not provided	Not Provided	Not Provided	San Diego, California, United States	www.worldexpress.com
Zenegra-100	Mepro Pharm	ZA 2002	02-03	Mumbai, Maharashtra, India	Monterrey, Neuvo Leon, Mexico	www.viagrasecrets.com
Vega Asia	Not provided	B11102	10-04	Not provided	Delhi, India	www.blue-pills.net
Suhagra-100	Okasa Ltd	MR3025	01-06	Pune, Maharashtra, India	India	www.viagrageneric.tripod.com
Vega	Not provided	Not provided	04-04	Not provided	Manila, Phillippines	www.genericviagra.com

[a] Product name as displayed on package at time of delivery

[b] Prescription required as indicated by website

[c] Expired at time of delivery

Physical Characterization

Label and package characteristics of pharmaceutical products obtained from the Internet are presented in Table 3.

Table 3. Label and package characteristics of pharmaceutical products obtained from the Internet

Pharmaceutical Product Lot Number (Source)	Meets Label Standard[a]	Label Description	Meets Package Standard[a]	Package Description[b]
Simvastatin				
GP5249 (Canada)	Yes	Standard prescription label for products dispensed in the United States	No	Round plastic vial: white, light-resistant, screw-top closure, not child resistant; original container from manufacturer
AC641 (Canada)	Yes	Standard prescription label for products dispensed in the United States	No	Round plastic vial: white, light-resistant, screw-top closure, not child resistant; original container from manufacturer
20392C (Canada)	Yes	Standard prescription label for products dispensed in the United States	No	Round plastic vial: white, light-resistant, screw-top closure, not child resistant; original container from manufacturer
20329A (Canada)	Yes	Standard prescription label for products dispensed in the United States	Yes	Round plastic vial: white, light-resistant, screw-top child-resistant closure; original container from manufacturer
5C07SH (United Kingdom)	No	Standard prescription label for products dispensed in the United States; missing name of prescriber	No	Unit dose strip packages taped together; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
VO4010R (India)	No	No label affixed to drug product; label information printed on enclosed paper; missing address of dispenser and name of prescriber	No	Unit dose strip packages enclosed in envelope; sealed foil pack, light resistant, not childproof; original container from manufacturer
NS6002 (India)	No	No label affixed to drug product	No	Unit dose strip packs held together with rubber band; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
03065M (India)	No	No label affixed to drug product	No	Unit dose packages taped together; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
PMI-2001	No	Label affixed to envelope; missing name and address of dispenser, name of prescriber, name of patient, and directions for use	No	Unit dose strip packages enclosed in envelope; sealed foil pack, light resistant, not childproof; original container from manufacturer
2734F4K (Mexico)	No	No label affixed to drug product	Yes	Round plastic vial: white, light-resistant, screw-top child-resistant closures; original container from manufacturer
Z-03 (Spain)	No	No label affixed to drug product	No	Unit dose packages in box; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
V05007R (India)	No	No label affixed to drug product; label information printed on enclosed paper; missing address of dispenser and name of prescriber	No	Unit dose strip packages enclosed in envelope; sealed foil pack, light resistant, not childproof; original container from manufacturer
24205 (India)	No	No label affixed to drug product	No	Unit dose strip packs held together with staples; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
SAA602 (India)	No	No label affixed to drug product	No	Unit dose boxes with strip packages enclosed in envelope; sealed foil pack, light resistant, not childproof; original container from manufacturer

Pharmaceutical Product Lot Number (Source)	Meets Label Standard[a]	Label Description	Meets Package Standard[a]	Package Description[b]
06000065 (Thailand)	No	No label affixed to drug product	No	Unit dose strip packs in envelope; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
08124M (India)	No	No label affixed to drug product	No	Unit dose strip packs in envelope; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
02044M (India)	No	No label affixed to drug product	No	Unit dose strip packs held together with rubber band; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
Lot No. not provided (India)	No	Nonstandard label affixed to drug product contains drug name and strength	No	Capsules placed in plastic container, not light resistant or childproof
Amlodipine				
ZF1141 (India)	No	No label affixed to drug product	No	Unit dose strip packs held together with staples; blister pack with foil backing not light resistant or childproof; original container from manufacturer
NN6004 (India)	No	Label affixed to envelope; missing name and address of dispenser, name of prescriber, name of patient, and directions for use	No	Unit dose boxes with strip packages enclosed in envelope; sealed foil pack, light resistant, not childproof; original container from manufacturer
NN5007 (India)	No	Label affixed to envelope; missing name and address of dispenser, name of prescriber, name of patient, and directions for use	No	Unit dose boxes with strip packages enclosed in envelope; sealed foil pack, light resistant, not childproof; original container from manufacturer
6931003A (India)	No	No label affixed to drug product	No	Unit dose strip packs in envelope; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
55805036 (New Zealand)	No	No label affixed to drug product	No	Unit dose packages in box; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
Lot number not provided (India)	No	No label affixed to drug product	No	Unit-dose strip packs enclosed in plastic wrap and placed in envelope; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
0600652 (Thailand)	No	No label affixed to drug product	No	Unit dose boxes with strip packs enclosed in envelope; blister pack with foil backing, sealed, light resistant, not childproof; original container from manufacturer
ZF1143 (India)	No	No label affixed to drug product; label information printed on enclosed paper; missing address of dispenser and name of prescriber	No	Unit dose boxes with strip packs enclosed in envelope; blister pack with foil backing, sealed, light resistant, not childproof; original container from manufacturer
AC5J02J (India)	No	No label affixed to drug product	No	Unit dose strip packs in envelope; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
6001 (India)	No	No label affixed to drug product	No	Unit dose strip packs in envelope; blister pack with foil backing, not light resistant or childproof; original container from manufacturer

Pharmaceutical Product Lot Number (Source)	Meets Label Standard[a]	Label Description	Meets Package Standard[a]	Package Description[b]
06085AAV (India)	No	No label affixed to drug product	No	Unit dose strip packs in envelope; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
CSEL6001 (India)	No	No label affixed to drug product	No	Unit dose strip packs in envelope; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
CSEL600308 (India)	No	Label affixed to envelope; missing name and address of dispenser, name of prescriber, name of patient, and directions for use	No	Unit dose strip packs in envelope; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
6180501101 (Mexico)	No	No label affixed to drug product	No	Unit dose boxes with strip packages enclosed in envelope; blister pack with foil backing, sealed, light resistant, not childproof; original container from manufacturer
6E0063 (Germany)	No	No label affixed to drug product	No	One unit dose box with strip packages enclosed in envelope; blister pack with foil backing, sealed, light resistant, not childproof; original container from manufacturer
A1004 (India)	No	No label affixed to drug product	No	Unit dose strip packs in loose plastic; blister pack with foil backing not light resistant or childproof; original container from manufacturer
AD06-11 (India)	No	No label affixed to drug product	No	Unit dose strip packs wrapped in newspaper; blister pack with foil backing, not light resistant or childproof (front and back); original container from manufacturer
620-05022 (India)	No	No label affixed to drug product	No	Two unit dose boxes with strip packages enclosed in shipping box; blister pack with foil backing, sealed, light resistant, not childproof; original container from manufacturer
Sildenafil				
Lot number not provided (source not specified)	No	Label affixed to envelope; only contains drug name, strength, and directions	No	Loose tablets placed in small paper envelope enclosed in bubble wrap; container not light resistant, childproof, or moisture resistant
ZA 2002 (India)	No	No label affixed to drug product	No	Unit dose strip pack in envelope; blister pack with foil backing not light resistant or childproof; original container from manufacturer
B11102 (India)	No	Label affixed to envelope; only contains drug name and strength	No	Loose tablets placed in small foil unsealed envelope placed in bubble wrap envelope; container not light resistant, childproof, or moisture resistant
MR3025 (India)	No	No label affixed to drug product	No	Twenty-four unit dose boxes held together with plastic tape; blister pack with foil backing, not light resistant or childproof; original container from manufacturer
Lot number not provided (source not provided)	No	Handwritten label affixed to drug product; only contains drug name and expiration date	No	Loose tablets placed in small plastic bag; container not light resistant, childproof, or moisture resistant

[a] Required items for dispensing to patients in the United States

[b] Type of container dispensed to patients

Deviation from US federal requirements for prescription labels and manufacturer requirements for prescription packaging are noted. Among all samples obtained, significant variation was observed in external package appearance, labeling of drug product (if any), and packaging of dispensed product.

Of the 41 drug products obtained, only 1 product from Canada would meet both labeling and packaging guidelines for products dispensed in the United States. In all, 4 products from Canada were labeled in a manner that would meet US guidelines, and although the Canadian products were packaged in similar containers to those dispensed in the United States, 3 of 4 containers were not child resistant, and no offer was made to patients to dispense in this manner on the websites. A total of 7 products were dispensed in paper envelopes with a label affixed that was either handwritten or typed and contained missing information such as name and address of dispenser, name of prescriber, name of patient, and directions for use. Another 3 products did not have a label affixed to the drug product, but information was printed on a paper document enclosed in the shipping package. In all, 28 products did not have labels affixed to the drug product, while 39 of the 41 drug products' packaging would not meet guidelines established in the United States. Aside from the Canadian product, only 1 product from Mexico was dispensed in a container that woul meet US guidelines. Of the 41 products, 35 were not dispensed in plastic vials but were dispensed in unit dose packages, paper envelopes with loose dosage forms, blister packs of drugs held together with rubber bands or staples, or a combination of these packaging forms.

Discussion

Principal Results

Results of this study indicate that drug products sold on the Internet—often accessible to consumers without prescription—present insufficient labeling and packing characteristics compared with products dispensed in the United States For example, picutred in Figure 1 is a tablet formulation of generic sildenafil ("Suhagra-100") obtained from URL: http://www.viagrageneric.tripod.com. The tablets are ordinary in appearance, scored, contain no external markings with color variation from the US innovator product. Contents were packaged in unit dose plastic with foil backing, and the product appears to be from a legitimate drug manufacturer with manufacturer's labeling. The shipping source was India as indicated from the international postal service packaging.

Figure 1. Generic sildenafil tablet obtained via the Internet without prescription

Of the 41 drug products, 36 did not meet criteria for prescription drug labeling, and 39 did not meet criteria for prescription drug containers and packaging as required in the United States. For all international products, the only drug products that met US standards for labeling were those from Canada. Only 1 container from Canada and 1 container from Mexico met US guidelines. No relationship could be ascertained between packaging standards and prescription requirements.

Comparison With Prior Work

Our findings corroborate a report by Westenberger et al, where drug sample packaging was a significant concern for virtually all of the Internet purchased samples [11]. In this report, several samples had either no or minimal labeling information for proper usage or testing of these drugs. For instance, some samples had packaging with labeling in foreign languages, and others were shipped loosely in unlabeled plastic bags.

Clinical Implications

Medication errors have been attributed to improper labeling and packaging of medications. A major report from the Institute of Medicine (IOM) noted that problems with prescription drug labeling were cited as the cause of a large number of outpatient medication errors and adverse drug events (ADEs) [1]. In addition, the United States Pharmacopeia (USP) found that 33% of the reports to its voluntary Medication Errors Reporting (MER) database cited labeling or packaging as having contributed to a medication error, including almost 30% of the fatalities reported [13]. Some of the more common sources of medication errors are confusion between soundalike medication names or look-alike medication names and confusion due to similar appearances for medication packages or similar labels for different medications.

Patients may unintentionally misuse a prescribed medicine because of misunderstanding of instructions. Individuals who manage complex medication regimens were found to be at greater risk for making errors in interpreting container label instructions, particularly the elderly with limited literacy skills. The patient's ability to understand prescription label instructions can be critical to safe use of medications since other sources of information on medicines for patients may not be adequate and pharmacists may not always have the opportunity to provide counseling to patients on prescribed medications [14].

Research in health literacy underscores the high prevalence of misunderstanding of seemingly simple instructions and warnings placed on prescription container labels by patients. Studies have demonstrated that the literacy level of patients has an impact on their ability to understand directions on a label [15]. Health literacy has increasingly been viewed as a patient safety issue, and lower literacy may contribute to medication errors [16]. Lower literacy and a greater number of prescription medications were independently associated with misunderstanding the instructions on prescription medication labels [17]. Prescription drug labels should use explicit dosing intervals and clear and simple language within a patient-friendly label format—unlike the drug products received from the Internet as demonstrated in this study. Although health literacy levels of Internet drug buyers is largely unknown, it is reasonable to assume that they are not dissimilar to all patients in the population.

In addition to literacy and drug product labeling, of equal importance are the drug product's container and packaging, not only to preserve the product's integrity, but to provide ease of use for both pharmacist and patient [18]. It has been demonstrated that patients actually prefer types of packaging and labeling that are designed for safety, are easier to read, and have better organized warnings with larger type size [16].

Studies suggest that certain patient groups such as the elderly may benefit from specialized packaging for drug products [18]. Providing medications in a package that identifies the day each dose is intended to be taken and provides information on proper self-administration can improve treatment regimen adherence and treatment outcomes in elderly patients. Certain patient groups may need the most attention to their packaging needs, yet this study suggests that these needs are unlikely to be met if drugs are purchased via the Internet.

Drugs obtained from international markets via the Internet can present a health risk to patients for a variety of reasons [19]. This study has demonstrated that it is highly likely that the average US consumer may obtain an imported drug product from an Internet pharmacy website that does not meet quality specifications of packaging and labeling equivalent to US-dispensed products—another potential safety risk.

In the United States, policies and legislation are directed toward ensuring minimal health risk to patients in the use of prescription drugs, as reported by the US Food and Drug Administration [8]. This report illustrates that consumers can obtain prescription drugs via the Internet without direct oversight from a health care professional. It has been stated that this ability to purchase medications directly from a website poses the greatest risk of drug adverse effects by bypassing the traditional “visit to the physician and a review by a pharmacist” [20], and this observation may be expanded to included issues of packaging and labeling. Consumers who order drugs from the Internet do not have sufficient access to information and advice at the point of ordering and on delivery to make informed decisions about their safe and appropriate use [21]. Again, substandard packaging and labeling may compound this risk.

This study has shown that a variety of packaging and labeling exists for pharmaceuticals obtained via the Internet. Based on the findings of this study, Canadian drug products dispensed are in many respects similar if not identical to US products, with similar prescription requirements [22]. Perhaps further distinction should be made by health care authorities between drugs imported from international markets in general and from Canadian manufacturers.

Limitations

The relatively small sample size in this study may not be wholly representative of all drugs sold on the Internet and generalizing our findings to other drugs should be done with a degree of caution. However, our findings corroborate previously published work, and further studies are warranted to identify trends in quality for Internet drug product labeling and packaging.

A goal of this study was to assess quality attributes that may indirectly convey information on safety and effectiveness through packaging and labeling properties. Many factors contribute to quality of packaging and labeling and although significant, the list of attributes observed in this study was not exhaustive. Until a direct association between packaging and labeling of Internet drug products and clinical outcomes is established, again, one must interpret these findings with some reservation.

Conclusions

Our findings indicate nonequivalent labeling and packaging for drug products available to consumers via the Internet compared with prescription drug products sold in the United States. These findings suggest dissimilar and substandard distribution processes compared with the United States, which in turn offer a greater challenge to patient comprehension and health literacy and may affect patient adherence to drug treatment regimens. In the United States, consumers need to be aware that, irrespective of advertising claims on Internet pharmacy websites, consumers may receive a drug product that is not equivalent to the US. counterpart and that may be dissimilar to products that would be allowed for consumers in the United States. These findings have strong implications for drug product quality, patient outcomes, therapeutic effectiveness, and safety that should be considered by clinicians to potentially safeguard patients who choose to purchase foreign-produced drugs via the Internet.

Acknowledgments

The author wishes to thank the Texas Affiliate of the American Heart Association for their financial support in the preparation of this research report.

Conflicts of Interest

None declared

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Abbreviations

ADE:	adverse drug event
FDA:	Food and Drug Administration
IOM:	Institute of Medicine
MER:	Medication Errors Reporting
NABP:	National Association of Boards of Pharmacy
OTC:	over the counter
USP:	United States Pharmacopeia

Edited by G Eysenbach; submitted 30.12.09; peer-reviewed by E Mahe, R Levaggi; comments to author 03.03.10; revised version received 21.06.10; accepted 29.06.10; published 15.02.11.

Please cite as:
Veronin M
Packaging and Labeling of Pharmaceutical Products Obtained from the Internet
J Med Internet Res 2011;13(1):e22
URL: http://www.jmir.org/2011/1/e22/
doi:10.2196/jmir.1441
PMID:21324833

Publisher:
JMIR Publications
130 Queens Quay East.
Toronto, ON, M5A 3Y5
Phone: (+1) 416-583-2040
Email: support@jmir.org