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Original Paper

Evaluating Self-Management Behaviors of Diabetic Patients in a Telehealthcare Program: Longitudinal Study Over 18 Months

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Abstract

Background: Self-management is an important skill for patients with diabetes, and it involves frequent monitoring of glucose levels and behavior modification. Techniques to enhance the behavior changes of diabetic patients have been developed, such as diabetes self-management education and telehealthcare. Although the patients are engaged in self-management activities, barriers to behavior changes remain and additional work is necessary to address the impact of electronic media and telehealthcare on patient self-care behaviors.

Objective: The aims of this study were to (1) explore the behaviors of diabetic patients interacting with online applications, (2) determine the impact of a telehealthcare program among 7 self-care behaviors of the patients, and (3) determine the changes in glycosylated hemoglobin (HbA_{1c}) levels.

Methods: A telehealthcare program was conducted to assist the patients with 7 self-care activities. The telehealthcare program lasted for 18 months and included the use of a third-generation mobile telecommunications glucometer, an online diabetes self-management system, and a teleconsultant service. We analyzed the data of 59 patients who participated in the telehealthcare program and 103 who did not. The behavioral assessments and the HbA_{1c} data were collected and statistically analyzed to determine whether the telehealthcare services had an impact on the patients. We divided the 18-month period into 3 6-month intervals and analyzed the parameters of patients assisted by the telehealthcare service at different time points. We also compared the results of those who were assisted by the telehealthcare service with those who were not.

Results: There was a significant difference in monitoring blood glucose between the beginning and the end of the patient participation ($P=.046$) and between the overall period and the end of patient participation ($P<.001$). Five behaviors were significantly different between the intervention and control patients: being active ($P<.001$), healthy eating ($P<.001$), taking medication ($P<.001$),

healthy coping ($P=.02$), and problem solving ($P<.001$). Monitoring of blood glucose was significantly different ($P=.02$) during the 6-12 month stage of patient participation between the intervention and control patients. A significant difference between the beginning and the 6-12 month stage of patient participation was observed for the mean value of HbA_{1c} level ($P=.02$), and the differences between the overall HbA_{1c} variability and the variability of each 6-month interval was also significant.

Conclusions: Telehealthcare had a positive effect on diabetic patients. This study had enhanced blood glucose monitoring, and the patients in the program showed improvements in glycemic control. The self-care behaviors affect patient outcomes, and the changes of behavior require time to show the effects.

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KEYWORDS

Internet; diabetes mellitus; telemedicine; self-care; online systems; personal health record; patient access to records

Introduction

Background

Self-management is an important skill for patients with diabetes mellitus [1-3], involving frequent monitoring of glucose levels and behavior modification. The primary goal of self-management is to monitor glucose metabolism and induce behavioral changes to achieve better glycemic control [3,4]. However, some patients do not respond to behavior modification and some do not have sufficient knowledge to perform self-management [5-9]. Several techniques to enhance self-care behaviors for diabetic patients have been developed, such as diabetes self-management education (DSME) and telehealthcare. DSME provides patients with self-management skills, supports behavioral changes, and achieves optimal patient outcomes in diabetes care [10-13]. Telehealthcare programs promote preventive care, self-management, and clinical consultations from a distance [6,7,9,14-16]. However, self-management is challenging because it requires behavioral changes and can be easily neglected owing to a busy lifestyle and lack of support. Barriers remain for patients who carry out self-care tasks. Previous studies have also highlighted the need for additional research to address the impact of telehealthcare and electronic media on patient self-care behaviors [17,18].

In addition to routine DSME, patients in the present study completed a telehealthcare program using a third-generation mobile telecommunication (3G) glucometer, an online diabetes self-management system, and a teleconsultant service. The aim of the present study was to assess how diabetic patients used the online diabetes self-management system, determine the impact of a telehealthcare program among the 7 self-care behaviors, and measure the changes in glycosylated hemoglobin (HbA_{1c}) level. The 7 self-care behaviors are based on the definition of the American Association of Diabetes Educators 7 Self-Care Behaviors (AADE7).

Diabetes Care in Taiwan

As effective management for chronic diseases has been established, the National Health Insurance (NHI) system of Taiwan has acknowledged the value of disease screening and disease management. The NHI has broadened payment for several disease-management programs and provided financial incentives for regular diabetes follow-up visits [19-23]. In 2001, a diabetes pay-for-performance program, known as the diabetes shared care network, was implemented [24-26]. It emphasizes

the value of a multidisciplinary care team to provide DSME and regular screening to enhance self-management skills and the early detection of complications [13].

Patients are required to return for a regular visit every 3 months for laboratory monitoring and DSME courses. Certified diabetes educators (CDEs) educate patients and evaluate their self-care behaviors and skills, which is documented in their behavioral assessments. Using past medical records and laboratory results, the CDEs attempt to determine patient self-management problems. After the patients demonstrate capability in a behavior, the CDEs proceed to the next behavior. The CDEs continue this process until all potential changes are made to achieve better metabolic control. When the patients actively provide information and ask questions about self-management, the CDEs are likely to provide additional education to address the patients' needs. Typically, the CDEs provide education on and evaluate 1 to 2 behaviors per visit. The number and the distribution of the behavioral assessments are an indicator of underlying patient problems. It is, therefore, meaningful to explore the patterns of and changes in patient problems to provide more adequate health care support.

Diabetes Care at National Taiwan University Hospital

In 2001, the shared care network was implemented at the National Taiwan University Hospital (NTUH), a 2300-bed educational medical center in Taiwan. Currently, the DSME and assessments are documented in the disease management information system (DMIS), developed in 2011 [27]. The DMIS is based on the AADE7 framework and includes the following items: healthy eating, being active, monitoring, taking medication, problem solving, healthy coping, and reducing risks. The detailed contents of the AADE7 are shown in [Multimedia Appendix 1](#). In addition to the shared care network, a telehealthcare program was initiated in 2011 to explore the effectiveness of information technology interventions for individuals with diabetes.

Telehealthcare allows for the promotion of health care services outside the medical institute. Through the combination of information technology and commercial biosensor devices, telehealthcare facilitates longitudinal health status monitoring at a distance [5,14,28,29]. The effectiveness of telehealthcare has been indicated by the industry and policymakers [29-34], and online informatics applications have been widely adopted in diabetes care [1,6,35-37]. It is a promising technology for self-management and can increase patient knowledge, patient

engagement, condition monitoring, long-term follow-ups [1,7,8,16,38], and improved patient outcomes [15,16,38,39].

Methods

Overview

In addition to the routine care of individuals with diabetes mellitus, this research provided a telehealthcare program and aimed to illustrate the way patients used and interacted with the online diabetes self-management system, the impact of a telehealthcare program among 7 self-care skills, and changes in patients' HbA_{1c} levels. A diabetes telehealthcare program was conducted for 18 months, wherein patients received assistance from an online diabetes self-management system to record and manage their daily activities, a 3G glucometer to monitor their glucose, and a teleconsultant service to enhance patients' self-management activities. Behavioral assessments and HbA_{1c} levels were documented in the DMIS. We compared these parameters for those who were assisted by the telehealthcare service (intervention group) at different time points. We also compared the intervention group results to those of patients who did not participate in the telehealthcare program (control group).

The Online Diabetes Self-Management System and Teleconsultant Service

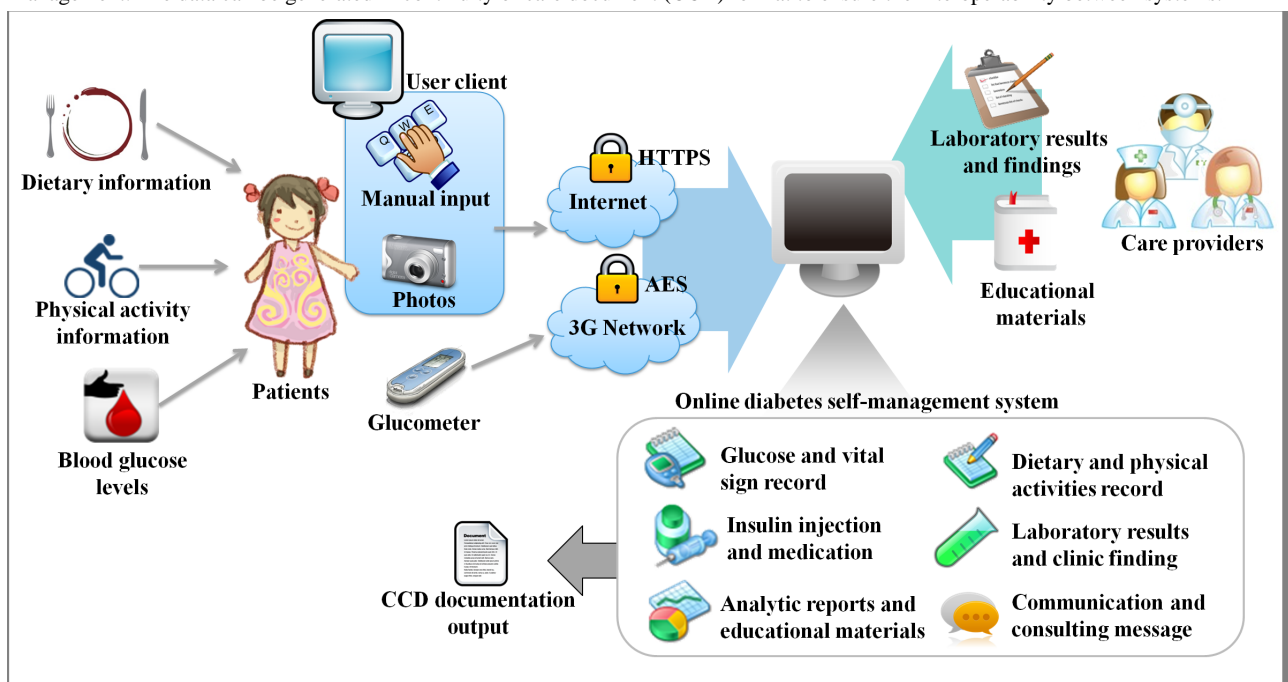
The design of the online diabetes self-management system was based on personal health record (PHR) criteria. The PHR is a health record in which patients' health data and personal information are recorded and maintained by the patients themselves [40]. It is owned, controlled, and managed by the patients [41-43], can be easily accessed, is not limited to

operating systems or devices [41-44], ensures interoperability of data between diverse systems [41,42,44-47], and facilitates easy ways of uploading information [42,43,48]. The PHR emphasizes patient privacy, providing adequate data encryption and a secured environment [38,41-44]. In addition, it improves communication and information sharing between patients and care providers [1,6,41-44,48].

The online diabetes self-management system was developed using C# programming language and a Microsoft SQL server. It was integrated with an off-the-shelf 3G glucometer [14]. The infrastructure design of the online diabetes self-management system is shown in Figure 1. According to the scheme mentioned above, each patient is assigned a unique identification and password, which allows them to log in, edit, and manage their information. The online diabetes self-management system is a Web-based system accessible on the Internet and not limited to operating systems or devices. It adopted the continuity of care document (CCD) standard to enhance the interoperability of data. The 3G glucometer facilitated easy and automatic data uploading after each measurement anywhere and combined blood pressure, blood glucose, and heart rate measurements in 1 instrument.

Encryptions were used to ensure patient privacy and for data transmission. The Web connection between a user client and the server was encrypted using the hypertext transfer protocol secure (HTTPS) protocol, and data transmission between the glucometers and the server was enciphered with advanced encryption standard (AES) encryption. Asynchronous JavaScript and XML (Ajax) and JQuery JavaScript were used to validate the format of the data input and to cooperate with different browsers.

Figure 1. Infrastructure design of the online diabetes self-management system. Patients record their daily activities through manual input, uploading photographs, and a 3G glucometer. The data are transmitted to the system through hypertext transfer protocol secure (HTTPS) and advanced encryption standard (AES) encryption. Caregivers can also enter the system and provide information and support. The system includes information to support self-management. The data can be generated in continuity of care document (CCD) format to ensure the interoperability between systems.



Asynchronous text messages were provided in the online diabetes self-management system; patients and caregivers could communicate through the online diabetes self-management system internal message service or short message service (SMS) text messaging. Application programming interfaces (API) from the Internet were used to send and retrieve information such as weather and pollution standard indexes. The online diabetes self-management system exchanged data with the hospital information system (HIS) using a service-oriented architecture (SOA) mechanism. The Health Level 7 (HL7) embedded Extensible Markup Language (XML) formatted data were used in the framework for data exchange. Patients were able to see their blood test results from the online diabetes self-management system.

The online diabetes self-management system included the monitoring items and the diabetes-related information, such as blood glucose, blood pressure, heart rate, body weight, insulin injection, daily diet, and daily physical activities. Information that was measured with equipment that did not have transmission networks required manual input. Dietary intake could be recorded through the use of either text or images. Additional information to enable self-management and goal setting for glucose control were generated (eg, the mean, median, standard deviation, and maximum and minimum daily blood glucose values). The variations in blood glucose and other parameters are presented together graphically to enable the user to observe the effect of each behavior. The frequency of self-monitoring of blood glucose (SMBG) was recorded and compared with the set goals to determine whether adjustments were needed. Body mass index (BMI) was calculated, and the suggested calorie intake and ingredient volume for each meal were displayed. An additional care-provider interface was designed so that caregivers could get a quick overview of patient status. Case managers were able to log in and view the data uploaded by the patients, identify abnormal events, and make phone calls. The online diabetes self-management system sent an SMS text message to care providers when the data exceeded the alerting range.

This study provided a teleconsultant service to support patients with diabetes self-management. The case managers for this study, including a nurse and a dietitian, were the care providers who interacted with the patients from a distance. They were responsible for monitoring patient status, answering questions about self-care activities, regularly keeping in touch with the patients through telephone calls or text messages, and encouraging them to perform self-management. The care plans and goal setting were formulated through a discussion with each patient during his or her enrollment. The case managers monitored the data uploaded by the patients. They gave advice and reminded the patients to perform self-care activities. In this study, the case managers were not involved in medication adjustments. They did, however, collate patient data and bring the information to the clinic when the patient returned for an appointment. They communicated with physicians to suggest adjustments when needed.

The assistance of the online diabetes self-management system and the teleconsultant service covered the 7 behaviors of self-management activities (shown in [Multimedia Appendix 1](#)).

During the study period, the CDEs did not know whether the patient attended the telehealthcare program.

Patient Enrollment and Data Analysis

Candidates for the study included patients diagnosed with either Type I diabetes mellitus (T1DM) or Type II diabetes mellitus (T2DM) and those with an HbA_{1c} level greater than 7.5 or identified as not well controlled. Patients with severe diabetes complications, such as diabetic foot, diabetic proliferative retinopathy, liver dysfunction, end-stage renal disease, or other medical problems that could affect the study results or trial participation were excluded. The patients were approached during regular follow-up visits in their physician's office, and informed consent was obtained from each participant. After enrollment, patients were taught to use the online diabetes self-management system and the glucometer, and they were informed how to contact the case manager for assistance. The glucometer and test strips were provided for glucose monitoring without a charge. Patients were allowed to use their own glucometer if they preferred. Those who chose not to use the provided glucometer were allowed to input their data manually. This study was reviewed and approved by the NTUH Institutional Review Board (IRB) (No. 201108018RC).

By the end of February 2013, 184 patients were enrolled in the telehealthcare program. Of the patients who participated in the telehealthcare program, 59 (32.1%) were also in the shared care network. The results of participants in the telehealthcare and shared care network were also compared to those of the participants who did not use the telehealthcare service but did complete the behavioral assessments and laboratory monitoring; these individuals served as the control participants. We recruited 103 control participants and matched their demographic characteristics with those of the telehealthcare participants to minimize the effect of potential confounding variables, including gender, age, diabetes type, duration, years of participation in the shared care network, and insulin treatment. We focused on analyzing the data of patients in the telehealthcare and the control groups, who were evaluated by behavioral assessments and laboratory monitoring every 3 months.

The evaluation of this study consisted of 3 sections (shown in [Figure 2](#)). We first analyzed the logged records of the system and illustrated the way patients used the online diabetes self-management system. For the second and third sections, the behavioral assessments and laboratory results from the DMIS for 18 months were evaluated by within-group comparisons at different time points for those participants who entered the telehealthcare program. We also compared the telehealthcare and control groups at different time points.

The data were grouped into several time ranges (see [Figure 3](#)). The time ranges included the entire 18 months of patient participation (September 2011 to February 2013, T1), the first 6 months (September 2011 to February 2012, T2), the second 6 months (March 2012 to August 2012, T3), and the last 6 months of patient participation (September 2012 to February 2013, T4). The data were grouped in 6-month intervals to obtain 1 or 2 records from regular patient visits.

The second section was the behavioral analysis. The number and distribution of the behavioral assessments indicated the problems of patients while performing self-management. In the behavioral analysis, the number of behavioral assessments was calculated for the 7 behaviors for each time range. The number of behavioral assessments of the telehealthcare participants during T1 was compared with each range (T2, T3, and T4) to demonstrate the overall variation of each time range, and the baseline (T2) was compared with T3 and T4 to see the variation across time. The differences between the telehealthcare and the control participants at each range (T1, T2, T3, and T4) were also compared.

The third section was the HbA_{1c} analysis, which consisted of calculating the HbA_{1c} mean and analyzing HbA_{1c} variability. HbA_{1c} variability represents intraindividual differences for each patient, which refers to the changes in glycemia over longer

periods of time reflected in changes in HbA_{1c} from one visit to the next [49,50]. It is defined as the standard deviation (SD) of the serial HbA_{1c} measurements. All data for blood tests within each time range were collected, and the HbA_{1c} mean and HbA_{1c} variability were calculated for each patient during each time range. The value for the telehealthcare participants at each time range (T2, T3, and T4) was compared to T1 to observe the overall variation of each time range, and the changes at T3 and T4 were observed by comparing to their baselines (T2). The differences between the telehealthcare and control participants at each time range (T1, T2, T3, and T4) were compared.

Paired *t* tests were used to analyze the differences in variables of interest between the time points of the telehealthcare participants' measures. Independent *t* tests were used to compare the telehealthcare and control results and between T1 and each time range for telehealthcare participants. We used SPSS version 17.0 (SPSS Inc, Chicago, IL, USA) for the statistical analyses.

Figure 2. A flowchart of the data analysis.

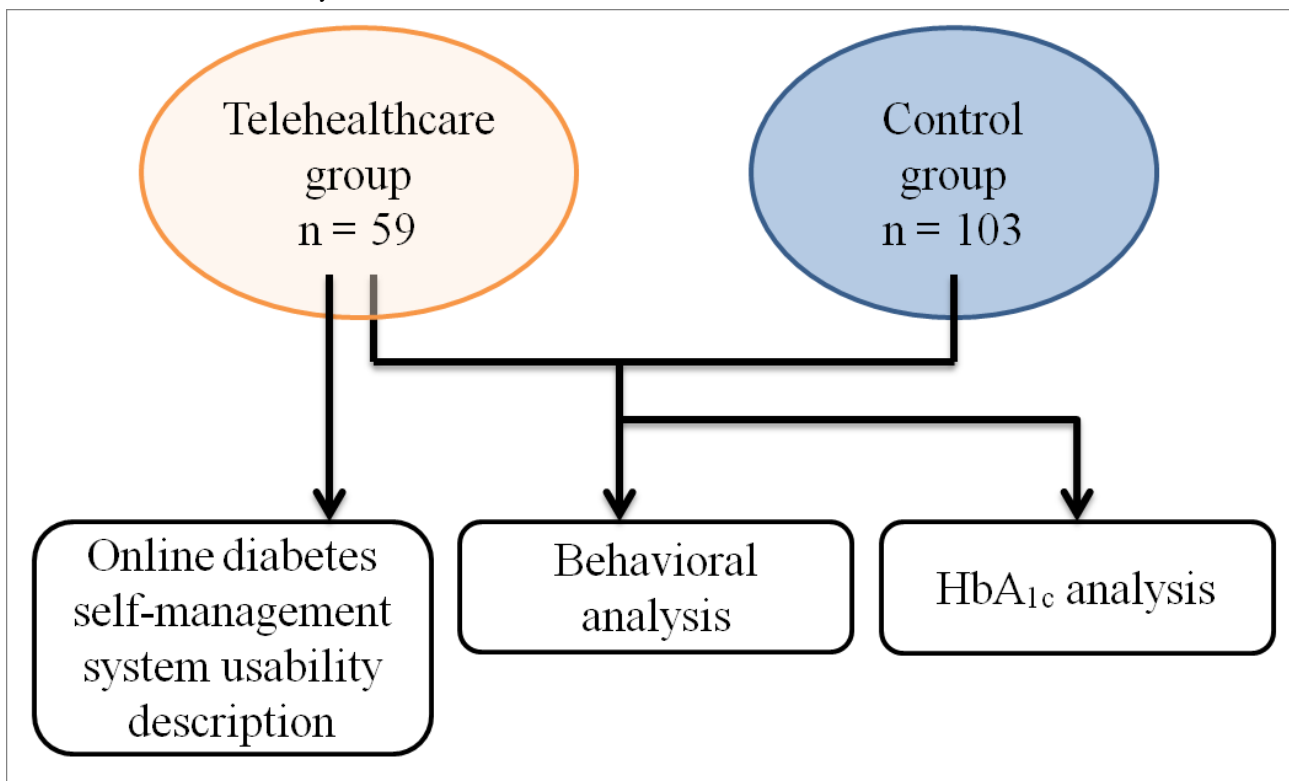
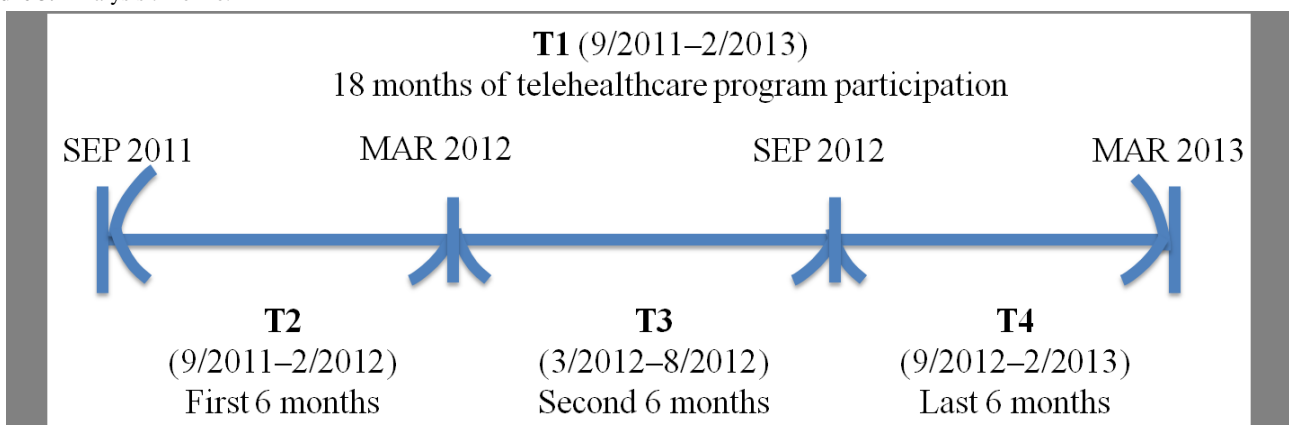


Figure 3. Analysis timeline.



Results

Table 1 and **Multimedia Appendices 2-4** show the demographic information of the telehealthcare and control participants, including gender, age, years of participation in the shared care network, disease duration, and the use of insulin injection. The telehealthcare group consisted of 18 T1DM and 41 T2DM patients. The control group consisted of 32 T1DM and 71 T2DM patients. The average age of the telehealthcare group was 51.34 years (SD 12.79). **Figure 4** shows the user interface of the online diabetes self-management system. Overall, 90% (53/59) of the patients logged in and used the online diabetes self-management system. On average, patients logged in 1.3 (SD 2.2) times every week and performed 1.1 (SD 1.3) SMBG daily. Analysis of the self-management records showed that 98% (58/59) of the patients documented blood glucose, 73% (43/59) documented blood pressure, 69% (41/59) documented heart rate, 44% (26/59) documented dietary record, 44% (26/59) documented insulin injections, and 31% (31/59) documented physical activities. In all, 61% (36/59) of the patients used telephone services to contact the case managers; 56% (33/59) used text messages.

Table 2 shows the behavioral assessments of telehealthcare group during different time ranges. SMBG was significantly

different between T1 and T4 ($P<.001$) and T2 and T4 ($P=.046$). Most of the number of assessments increased at T3 and decreased at T4, and SMBG was the only behavior that continued to increase until T4. There was a statistically significant difference between the telehealthcare and control participants in 5 behaviors at T1 (**Table 3**), including being active ($P<.001$), healthy eating ($P<.001$), taking medication ($P<.001$), healthy coping ($P=.02$), and problem solving ($P<.001$). SMBG was significantly different between the telehealthcare and control groups at T3 ($P=.02$). Notably, the telehealthcare participants had more assessments in healthy coping and reducing risk at T4 than did the control participants.

The HbA_{1c} mean and variability differences for the telehealthcare group are shown in **Table 4**. The mean HbA_{1c} level decreased significantly ($P=.02$) at T3 compared to the baseline (T2) and slightly increased at T4, and the HbA_{1c} mean decreased from 7.8 to 7.68. There was a significant difference in HbA_{1c} variability between T1 and T2 ($P<.001$), T1 and T3 ($P<.001$), and T1 and T4 ($P<.001$), and the HbA_{1c} variability decreased from 0.30 to 0.23 during patient participation. The HbA_{1c} mean and variability differences between the telehealthcare and control groups are shown in **Table 5**, and were not statistically significant.

Table 1. Patient demographics, including gender, age, and diabetes type (N=162).

Demographic information	Telehealthcare n=59	Control n=103
Gender, n (%)		
Male	29 (49.2)	52 (50.5)
Female	30 (50.8)	51 (49.5)
Age, mean (SD)	51.3 (12.8)	52.55 (12.19)
T1DM^a		
<45 years, n (%)	10 (55.6)	23 (71.9)
>45 years, n (%)	8 (44.4)	9 (28.1)
Age, mean (SD)	41.78 (9.78)	41.25 (8.16)
T2DM^b		
<65 years, n (%)	32 (78.0)	53 (74.6)
>65 years, n (%)	9 (22.0)	18 (25.4)
Age, mean (SD)	55.54 (11.73)	57.65 (10.11)

^aT1DM: Type 1 diabetes mellitus.

^bT2DM: Type 2 diabetes mellitus.

Table 2. The American Association of Diabetes Educators 7 Self-Care Behaviors (AADE7) education of patients with the telehealthcare service (n=59).

Time ^a and AADE7 behavior	Behavioral assessments, mean (SD)	Comparison with T1, <i>P</i> value	Comparison with T2, <i>P</i> value
T1 (n=59)			
AADE7 education			
Being active	0.36 (0.36)		
Healthy eating	0.60 (0.35)		
Taking medication	0.51 (0.36)		
Healthy coping	0.09 (0.22)		
Problem solving	0.31 (0.36)		
Reducing risks	0.02 (0.10)		
Monitoring	0.56 (0.15)		
T2 (n=59)			
Being active	0.34 (0.54)	.66	
Healthy eating	0.58 (0.59)	.66	
Taking medication	0.53 (0.60)	.95	
Healthy coping	0.08 (0.28)	.90	
Problem solving	0.42 (0.53)	.18	
Reducing risks	0.00 (0.00)	.10	
Monitoring	0.63 (0.69)	.68	
T3 (n=59)			
Being active	0.42 (0.56)	.44	.42
Healthy eating	0.66 (0.63)	.55	.49
Taking medication	0.54 (0.60)	.71	.89
Healthy coping	0.10 (0.30)	.82	.66
Problem solving	0.27 (0.49)	.62	.07
Reducing risks	0.03 (0.26)	.76	.32
Monitoring	0.68 (0.71)	.23	.73
T4 (n=59)			
Being active	0.31 (0.60)	.58	.86
Healthy eating	0.58 (0.60)	.75	.27
Taking medication	0.46 (0.63)	.59	.90
Healthy coping	0.08 (0.28)	.90	.90
Problem solving	0.24 (0.54)	.38	.18
Reducing risks	0.03 (0.18)	.68	.16
Monitoring	0.75 (0.63)	<.001	.046

^aT1: Entire duration of the telehealthcare program, from September 2011 to February 2013 (18 months); T2: initial stage of the telehealthcare program, from September 2011 to February 2012 (6 months); T3: middle stage of the telehealthcare program, from March 2012 to August 2012 (6 months); T4: last stage of the telehealthcare program, from September 2012 to February 2013 (6 months); T4: Last stage of the telehealthcare program, from September 2012 to February 2013 (6 months).

Table 3. The American Association of Diabetes Educators 7 Self-Care Behaviors (AADE7) education of patients with and without the telehealthcare service.

Time ^a and AADE7 behavior	Behavioral assessments per patient, mean (SD)		P value
	Telehealthcare (n=59)	Control (n=103)	
T1			
Being active	0.36 (0.36)	0.44 (0.41)	<.001
Healthy eating	0.60 (0.35)	0.72 (0.43)	<.001
Taking medication	0.51 (0.36)	0.50 (0.40)	<.001
Healthy coping	0.09 (0.22)	0.08 (0.17)	.02
Problem solving	0.31 (0.36)	0.34 (0.37)	<.001
Reducing risks	0.02 (0.10)	0.02 (0.11)	.29
Monitoring	0.56 (0.15)	0.60 (0.41)	.94
T2			
Being active	0.34 (0.54)	0.45 (0.61)	.27
Healthy eating	0.58 (0.59)	0.71 (0.67)	.20
Taking medication	0.53 (0.60)	0.49 (0.63)	.69
Healthy coping	0.08 (0.28)	0.08 (0.31)	.91
Problem solving	0.42 (0.53)	0.45 (0.70)	.84
Reducing risks	0.00 (0.00)	0.01 (0.10)	.45
Monitoring	0.63 (0.69)	0.80 (0.74)	.14
T3			
Being active	0.42 (0.56)	0.42 (0.57)	.93
Healthy eating	0.66 (0.63)	0.71 (0.73)	.65
Taking medication	0.54 (0.60)	0.52 (0.67)	.87
Healthy coping	0.10 (0.30)	0.10 (0.30)	.96
Problem solving	0.27 (0.49)	0.31 (0.50)	.66
Reducing risks	0.03 (0.26)	0.02 (0.14)	.66
Monitoring	0.68 (0.71)	0.42 (0.53)	.02
T4			
Being active	0.31 (0.60)	0.48 (0.64)	.11
Healthy eating	0.58 (0.59)	0.73 (0.70)	.18
Taking medication	0.46 (0.63)	0.50 (0.61)	.64
Healthy coping	0.08 (0.28)	0.05 (0.22)	.38
Problem solving	0.24 (0.54)	0.25 (0.44)	.80
Reducing risks	0.03 (0.18)	0.02 (0.20)	.66
Monitoring	0.75 (0.63)	1.69 (0.47)	.13

^aT1: The entire duration of the telehealthcare program, from September 2011 to February 2013 (18 months); T2: Initial stage of the telehealthcare program, from September 2011 to February 2012 (6 months); T3: Middle stage of the telehealthcare program, from March 2012 to August 2012 (6 months); T4: Last stage of the telehealthcare program, from September 2012 to February 2013 (6 months).

Table 4. The HbA_{1c} mean and variability of the patients with the telehealthcare service (n=59).

Time ^a and HbA _{1c}	Mean (SD)	Compared with T1, <i>P</i> value	Compared with T2, <i>P</i> value
T1			
Mean	7.72 (0.51)		
Variability	0.51 (0.29)		
T2			
Mean	7.80 (0.38)	.48	
Variability	0.30 (0.31)	<.001	
T3			
Mean	7.64 (0.40)	.62	.02
Variability	0.31 (0.31)	<.001	.81
T4			
Mean	7.68 (0.31)	.80	.17
Variability	0.23 (0.18)	<.001	.11

^aT1: The entire duration of the telehealthcare program, from September 2011 to February 2013 (18 months); T2: Initial stage of the telehealthcare program, from September 2011 to February 2012 (6 months); T3: Middle stage of the telehealthcare program, from March 2012 to August 2012 (6 months);

Table 5. The HbA_{1c} mean and variability of the patients with and without the telehealthcare service.

Time ^a and HbA _{1c}	HbA _{1c} , mean (SD)		<i>P</i> value
	Telehealthcare (n=59)	Control (n=103)	
T1			
Mean	7.72 (0.51)	7.65 (0.52)	.70
Variability	0.51 (0.29)	0.52 (0.32)	.78
T2			
Mean	7.80 (0.38)	7.67 (1.45)	.39
Variability	0.30 (0.31)	0.23 (0.27)	.14
T3			
Mean	7.64 (0.40)	7.67 (1.57)	.89
Variability	0.31 (0.31)	0.27 (0.26)	.45
T4			
Mean	7.68 (0.31)	7.66 (0.34)	.94
Variability	0.23 (0.18)	0.25 (0.23)	.46

^aT1: The entire duration of the telehealthcare program, from September 2011 to February 2013 (18 months); T2: Initial stage of the telehealthcare program, from September 2011 to February 2012 (6 months); T3: Middle stage of the telehealthcare program, from March 2012 to August 2012 (6 months); T4: Last stage of the telehealthcare program, from September 2012 to February 2013 (6 months).

Figure 4. Screenshot of the online diabetes self-management system user interface (note that the original user interface is in Chinese).

New Edit Delete				
Time of Measurement	Blood Glucose	Glucose Type		
2012/12/05 14:37:00	128			
2012/12/05 12:38:00	93	AC		
2012/12/04 22:39:00	104	PC		
2012/12/04 06:30:00	96	AC		
2012/12/03 22:43:00	168	PC		
2012/12/03 20:43:00	131	AC		
2012/12/03 08:27:00	115	AC		
2012/12/02 20:39:00	127	PC		
2012/12/02 10:19:00	126	AC		
2012/12/01 20:55:00	111	PC		

Discussion

Principal Findings

The aims of this study were to determine how diabetic patients use online applications, determine the impact of the telehealthcare program on the patients' 7 self-care behaviors, and examine HbA_{1c} level changes during the course of participation in such a program. Through the use of the online diabetes self-management system and the teleconsultant service, the diabetic patients managed complex information about their diseases and obtained support from their care providers. Patients were reminded to perform SMBG, and their self-care behaviors were reinforced. In all, 90% of the patients used the online diabetes self-management system, and 98% performed SMBG. On average, patients logged in every week and performed the SMBG daily. Patients who maintain insulin records are also likely to maintain dietary records, which are related to the effects of insulin injections on food intake. In this study, the use of an image uploading application did not cause more patients to maintain dietary records. One explanation for this finding is that there were more elderly patients in this program and these patients do not often use smartphones or carry a camera with them.

The case managers observed that technological difficulties were the main reason for a decline in the use of the online diabetes self-management system by elderly patients. Some of the patients claimed that they were too busy to use the online diabetes self-management system. Previous research pointed out that elderly people had poor technical skills [41]. In our study, the average age of the enrolled patients was older than 50 years; blood glucose, blood pressure, and heart rate were the 3 items most often recorded. This indicates that a proportion of

the patients only used the 3G glucometer to upload data, but seldom logged into the online diabetes self-management system. Despite the technological difficulties, patients unfamiliar with information technologies were not troubled with the computer applications used in this program, and they used the 3G glucometer to participate and obtain support from their case managers in a seamless manner. Easier ways to upload data may increase the participation of those unfamiliar with technology, enhance the completeness of the dataset, and allow them to obtain support from a distance.

According to the online diabetes self-management system logged records, more patients used the phone call service than the messaging service to contact the case managers. However, the case managers found that the younger patients used text messages more often than the elderly patients did. They used various applications, such as email, smartphone applications (eg, Whatsapp, LINE), and SMS text messages, to communicate with patients in order to accommodate the patients' busy lifestyles, which made the records difficult to trace and unavailable for presentation here. Some of the patients expressed a reluctance to let their colleagues or the people around them know about their disease, and they considered the asynchronous messages useful in allowing them to communicate with caregivers without the risk of being overheard by others. Most of the elderly patients were not familiar with keyboard typing, and they relied on phone calls to communicate. It is worth noting that providing free test strips or services created an incentive for patient participation. In fact, most of the patients were reluctant to continue their participation when told the test strips or the service may no longer be free, indicating the financial burden borne by persons with diabetes.

In the behavioral analysis, the number of SMBG assessments increased significantly in the last stage, and the patients that participated in the telehealthcare service had significantly more SMBG assessments than did those without the telehealthcare service in the 6-12 month stage. Because the telehealthcare service used was based on glucose measurements, the case managers provided support and suggestions after they observed the uploaded data. SMBG was the primary self-care ability enhanced through participation in the telehealthcare program. By performing SMBG more regularly, patients encountered problems and discussed these problems more often with the CDEs.

When the patients who participated in the telehealthcare program for 18 months were compared to those who did not, 5 of the 7 behaviors showed significant differences. Although the CDEs enhance patient education based on different considerations, patients in the telehealthcare program required less support in being active, healthy eating, and problem solving, and required more support in taking medicine and healthy coping. One explanation is that the skill of insulin injection and the overcoming of psychological obstacles still requires face-to-face interaction. Each visit was done with 1 or 2 behavior assessments, and did not cover all 7 behaviors. Some of the behaviors had not been assessed yet, and were unlikely to show differences during the 6-month period. The overall time frame concluded the 7 behaviors and also represented more time to see the changes after the education. During the last period of patient participation, the assessments of healthy coping and reducing risks were higher for those who participated in the telehealthcare program compared to those who did not. Healthy coping and reducing risks are the skills that the CDEs enhanced when the patients demonstrated that they were capable of coping with their other problems. The observation of an increase in these 2 behaviors implies that the patients were more skillful.

The mean value of HbA_{1c} of participants at 6 to 12 months improved significantly compared to baseline, and slightly declined in the last period. This result indicates that the patients experienced a “worn out” period. When the patients first entered the program, they were more conscious of their self-management behaviors because they knew that someone was watching them; as a result, they improved significantly. However, after the patients became more familiar with the service and were less anxious about the program, a slight decline was observed. The HbA_{1c} variability of each 6-month interval was significantly lower than the overall HbA_{1c} variability. The decrease of the mean HbA_{1c} value implies that patients who participated in the program improved substantially across the 18-month period, and have potentially reduced the risks of complication development with less HbA_{1c} variability [49,50]. The HbA_{1c} mean demonstrates the overall glycemic control in a 3-month period, and is limited to show the variation of glycemic control during each time interval. The behaviors affected the performance of HbA_{1c}, and the change of behaviors requires time to show its effect. Therefore, there may not be differences during each 6-month range, but significant differences in the long term.

Limitations

In this small-scale pilot study, we provided a telehealthcare program that consisted of 3G glucometers, free test strips, an online diabetes self-management system, and easy access to professional support. All the program components contributed to patient improvements, although we did not measure the individual contribution of each of the components. Unfortunately, the contribution of each of the components remains unclear; this is a limitation of this study. However, those with T1DM received free test strips from the NHI. The program did produce a small benefit of HbA_{1c} control for the T1DM patients (HbA_{1c} decreased from 7.83 to 7.74), implying that the free glucometer strips were not solely responsible for the outcomes of this program.

The mean HbA_{1c} value for the telehealthcare group during the last period dropped to 7.68 and was still considered not well controlled. This may be because of the enrollment of patients with very poor glycemic control. In addition, the therapeutic responses may require more time since HbA_{1c} is a measure of average blood glucose over the course of 3 months. The patient education in this study was based on the observations of different CDEs (3 nurses and 2 dietitians), and the evaluation result may differ from CDE to CDE. Another limitation was that before the development of the DMIS, the documentation of patient education was paper-based rather than structured in the AADE7 form. The DMIS went online in July 2011 and stabilized in August 2011; the telehealthcare program was initiated in September 2011. Hence, we were unable to obtain patients' documentation before their entry into the telehealthcare program.

While connecting the SMBG assessment and the performance of HbA_{1c} level, it could be observed that the number of SMBG assessments increased significantly and the mean HbA_{1c} level slightly increased in the last stage of patient participation. The number of SMBG assessments may refer to patients performing more SMBG and may also refer to CDEs trying to identify patient problems through encouraging them to perform more SMBG. This study has not further explored the reason of the increasing of SMBG assessment; hence, it could not explain the reason for the increasing of SMBG assessments. Further research is needed to measure the contribution of each component of the telehealthcare program and determine how to improve patient performance when they are worn out. More work is needed to demonstrate the effect of telehealthcare on specific behaviors.

Conclusions

This study showed that using a sophisticated technological design supported the patients with diabetes in self-management. It appears that telehealthcare is effective in enhancing blood glucose monitoring, and the patients in the program showed improvements in glycemic control. The self-care behaviors affected patient outcomes and the changes in behavior required time to show effects. Telehealthcare has a positive effect on patients with diabetes, and it may encourage more technological interventions for diabetes care.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

The detailed contents of the American Association of Diabetes Educators 7 Self-Care Behaviors (AADE7) education and the telehealthcare service.

[PDF File (Adobe PDF File), 29KB - [jmir_v15i12e266_app1.pdf](#)]

Multimedia Appendix 2

Patient demographics, years of participation in the shared care network.

[PDF File (Adobe PDF File), 23KB - [jmir_v15i12e266_app2.pdf](#)]

Multimedia Appendix 3

Patient demographics, duration of diabetes.

[PDF File (Adobe PDF File), 22KB - [jmir_v15i12e266_app3.pdf](#)]

Multimedia Appendix 4

Patient demographics, insulin injection frequency.

[PDF File (Adobe PDF File), 23KB - [jmir_v15i12e266_app4.pdf](#)]

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Abbreviations

- 3G:** third-generation mobile telecommunication
- AADE7:** American Association of Diabetes Educators 7 Self-Care Behaviors
- AES:** Advanced Encryption Standard
- Ajax:** Asynchronous JavaScript XML
- API:** application programming interface
- BMI:** body mass index
- CCD:** Continuity of Care Document
- CDE:** certified diabetes educator
- DMIS:** disease management information system

DSME: diabetes self-management education
HbA1c: glycosylated hemoglobin
HIS: hospital information system
HL7: Health Level 7
HTTPS: Hypertext Transfer Protocol Secure
IRB: institutional review board
NHI: National Health Insurance
NTUH: National Taiwan University Hospital
PHR: personal health records
SMBG: self-monitoring of blood glucose
SMS: short message service
SOA: service-oriented architecture
T1: entire duration of the telehealthcare program, from September 2011 to February 2013 (18 months)
T1DM: Type 1 diabetes mellitus
T2: initial stage of the telehealthcare program, from September 2011 to February 2012 (6 months)
T2DM: Type 2 diabetes mellitus
T3: middle stage of the telehealthcare program, from March 2012 to August 2012 (6 months)
T4: last stage of the telehealthcare program, from September 2012 to February 2013 (6 months)
XML: Extensible Markup Language

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Review

Use of Behavioral Change Techniques in Web-Based Self-Management Programs for Type 2 Diabetes Patients: Systematic Review

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Abstract

Background: Type 2 diabetes mellitus (T2DM) is a highly prevalent chronic metabolic disease characterized by hyperglycemia and cardiovascular risks. Without proper treatment, T2DM can lead to long-term complications. Diabetes self-management is recognized as the cornerstone of overall diabetes management. Web-based self-management programs for T2DM patients can help to successfully improve patient health behaviors and health-related outcomes. Theories can help to specify key determinants of the target behaviors and behavior change strategies required to arrive at the desired health outcomes, which can then be translated into specific behavioral techniques or strategies that patients can learn to apply in their daily life. From previous reviews of a wide range of online diabetes self-management tools and programs, it appears that it is still unclear which behavioral change techniques (BCTs) are primarily used and are most effective when it comes to improving diabetes self-management behaviors and related health outcomes.

Objective: We set out to identify which BCTs are being applied in online self-management programs for T2DM and whether there is indication of their effectiveness in relation to predefined health outcomes.

Methods: Articles were systematically searched and screened on the mentioned use of 40 BCTs, which were then linked to reported statistically significant improvements in study outcomes.

Results: We found 13 randomized controlled trials reporting on 8 online self-management interventions for T2DM. The BCTs used were feedback on performance, providing information on consequences of behavior, barrier identification/problem solving, and self-monitoring of behavior. These BCTs were also linked to positive outcomes for health behavior change, psychological well-being, or clinical parameters.

Conclusions: A relatively small number of theory-based online self-management support programs for T2DM have been reported using only a select number of BCTs. The development of future online self-management interventions should be based on the use of theories and BCTs and should be reported accurately.

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KEYWORDS

Web-based; online; self-management; review; type 2 diabetes mellitus; behavioral change techniques

Introduction

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by insulin resistance and beta cell impairment [1]. The number of people with T2DM is rising exponentially and is estimated to reach 439 million patients worldwide in 2030 [2]. Without proper treatment, T2DM can lead to long-term complications, such as neuropathy, nephropathy, retinopathy, cardiovascular disease, and a lowered quality of life [3]. The treatment of T2DM patients is largely dependent on the patient's daily self-care by means of lifestyle modification (diet and physical exercise) and taking oral blood glucose-lowering medication and/or insulin, often combined with medication to normalize blood pressure, cholesterol, and triglycerides [4,5]. Therefore, diabetes self-management is recognized as the cornerstone of overall diabetes management [6,7].

Self-management enables patients to take control of their chronic disease, such as the treatment and the physical and psychological symptoms, by making their own decisions and performing self-chosen actions aimed at improving their health [8-10]. For T2DM, the Association of American Diabetes Educators (AADE) has defined 7 key self-management behaviors: (1) healthy eating, (2) being active, (3) monitoring, (4) taking medication, (5) problem solving, (6) reducing risks, and (7) healthy coping [11].

To promote daily self-management for T2DM patients, educational and behavioral support programs have been developed and shown to be effective for behavioral and medical outcomes [7,12-15]. More recently, self-management programs for T2DM patients are also available on the Internet [16-19]. Web-based self-management programs for T2DM patients have been shown to increase the effectiveness and reach of clinical-based consultations [20]. Furthermore, these Web-based programs can help to improve patient health behaviors (eg, self-monitoring, physical activity, diet) and subsequent health outcomes (eg, weight, glycemic control, emotional distress) [21,22]. However, attrition can be problematic in Web-based interventions and should be considered during the creation process [23].

It is recognized that theory-based self-management programs are more effective than non-theory-based programs; indeed, most self-management programs are informed by theory or elements of a behavior change model [10,24,25]. Theories can help to specify key determinants of the target behaviors and behavior change strategies required to arrive at the desired health outcomes, which can then be translated into specific behavioral techniques or strategies that patients can learn to apply in their daily life [8]. Abraham and Michie [26,27] have developed a taxonomy of behavioral change techniques (BCTs) for different health behaviors, such as healthy eating and physical exercise. Such taxonomy can help to identify successful BCTs and support the development of new online self-management programs for T2DM and other chronic diseases [25-27]. From previous reviews of a wide range of online diabetes self-management tools and programs, it would appear that it is still unclear which BCTs are most used and most effective when it comes to improving self-management behaviors and related health

outcomes [21,22,28,29]. Therefore, we set out to: (1) systematically review the literature and identify which BCTs are being applied in online self-management programs for T2DM and how often, and (2) determine whether there is indication from randomized controlled trials (RCTs) for the effectiveness of applied BCTs in relation to particular health outcomes.

Methods

Search

On July 24, 2012, we searched within PubMed, EMBASE, Cochrane, PsycInfo, and Cinahl. Because of the size of the search term used, the search terms can be found in [Multimedia Appendix 1](#). Some keywords used in the search were diabetes mellitus; diabetes mellitus, type 2; Internet; eHealth; online; and Web-based. The systematic review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement where applicable [30].

Inclusion Exclusion Criteria

The retrieved articles were screened using the following inclusion criteria: written in English, published after 1994 (the introduction of the Internet), about T2DM, included patients aged 18 years or older, and concerned Web-based (online) self-management programs for which participants had to use the Internet to connect to the intervention. We only included RCTs to establish whether the BCTs used in the programs were associated with significant improvements. We defined self-management programs as systematic approaches to assist patients in their diabetes self-care, and where in some way or other patients were actively engaged and prompted to make decisions for themselves and have responsibility over their own actions [8,10]. Articles were excluded if they were not related to diabetes, reported only on technology testing, were not Web-based programs, did not target a self-management behavior, or only included type 1 diabetes mellitus (T1DM). Book chapters, abstracts, and pilot studies were not included.

Study Selection and Data Extraction

Two researchers (MvV, WHJJ) independently reviewed the articles and extracted data on demographics, care setting, type of study, duration, measurements, nature of the intervention and control condition, applied inclusion criteria, used theory or model, BCTs, target behavior(s), outcome parameters, results, limits, and adherence. The risk of bias was assessed for all included studies using a quality assessment tool as proposed by van Tulder et al [31] and can be found in the [Multimedia Appendix 2](#). The BCTs were categorized based on the checklist as proposed by Michie et al [27] which can be found in [Multimedia Appendix 3](#). Disagreements regarding defined BCTs between the researchers were resolved by discussion within the research group. The BCTs used and the statistically significant outcomes were uncovered for each study. For each study with an improved study outcome (health behaviors, clinical outcome measures, and psychological outcomes), we looked if a BCT was present in the intervention for improving that particular outcome. We used Microsoft Excel 2003 to cross-reference this data and generated a list of frequently used BCTs associated

with significant improvements in defined behavioral, clinical, and psychological outcomes.

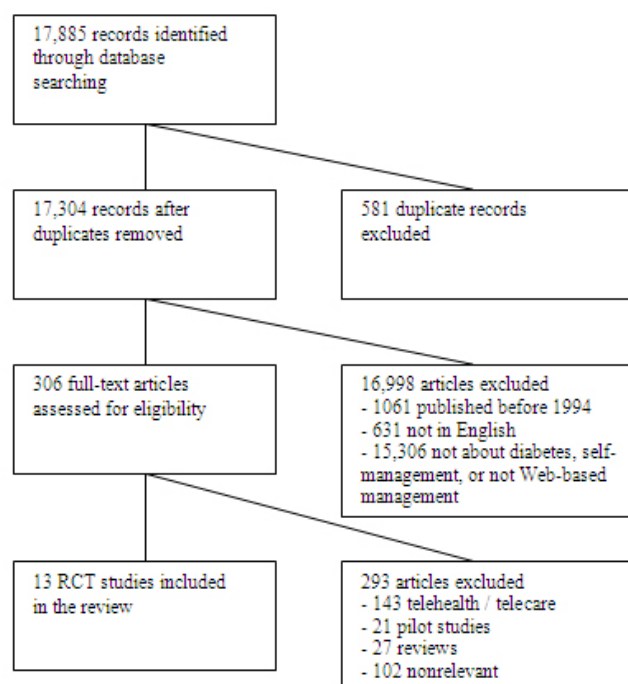
Results

Article Selection

Figure 1 shows a flowchart of the screening process. The search query resulted in 17,885 articles. After removing duplicated articles, titles and abstracts were screened for inclusion and exclusion criteria. After the first draft, 16,998 articles were

excluded because they did not meet the inclusion criteria. We categorized the remaining 306 articles as: (1) studies on Web-based self-management programs, (2) reviews, (3) telehealth, telecare, or telemedicine studies [32-34], and (4) nonrelevant studies. This resulted in 13 articles reporting on 8 different Web-based self-management interventions for T2DM patients. These articles were individually read, screened for the BCTs used, and then discussed to reach consensus. Most articles provided only a short basic description of the intervention that was used. For 1 study [35], an additional article was consulted to uncover the content of the intervention [36].

Figure 1. Flowchart screening process of articles included in review.



Study Characteristics

Tables 1 and 2 provide an overview of the included studies and their results. Of the 13 RCT studies, 10 were performed in North America [37-46], 1 in Asia [47], and 2 in Europe [35,48]. The combined total patient sample size was 3813. Demographically, on average 54.8% of the participants were female and the average age was 57.2 years (SD 7.20). Average program completion rate was 81.7% (SD 15.2%). Four studies recruited their participants from the community by using flyers and newspapers [35,39,45,48]. Five studies recruited their

participants from primary health care [37,42-44,46], 1 study recruited their participants from secondary health care [47], and 3 studies recruited their participants from primary and secondary health care [38,40,41]. All the studies included patients who had been diagnosed with T2DM for longer than a year. Five studies also included patients with T1DM [35,38,40,41,48] and 1 study also offered the intervention to people with diagnoses of chronic heart disease and chronic lung disease [45]. Average study duration was 6.69 months (SD 4.92). Adherence for all studies was high, which in itself contributes to the overall high quality of the included studies.

Table 1. Characteristics of the studies.

Study	Study description							Participants			
	Quality ^a	Country	n	Groups, n	Measurements, n	Setting ^b	Inclusion criteria ^c	Duration (months)	Ethnicity	Female, %	Age, mean
Glasgow et al (2012) [37]	83%	US	463	3	3	1	T2DM, age 25-75, BMI >25 kg/m ² , at least 1 other risk factor for heart disease, access to telephone and Internet, fluent in English or Spanish, ability to perform mild to moderate exercise	12	White, Latino	50	58.4
Van Baste-laar et al (2011) [35]	83%	NL	255	2	3	1+2	CESD>16, email address, access to Internet, no history of suicide, suicidal ideation, bipolar, psychotic, pregnancy, recent loss of significant other	3	White	61	50.0
Bond et al (2010) [38]	72%	US	62	2	2	1+2	T1DM or T2DM for at least 1 y, age ≥60, living independently, fluent in English	6	White	45	67.2
Lorig et al (2010) [39]	78%	US	761	3	3	1+2	T2DM, age ≥18, not pregnant or in care for cancer, access to the Internet	18	White, Native Indian, Alaska Native	73	54.3
Glasgow et al (2010) [46]	78%	US	463	3	2	1	T2DM, age 25-75, BMI>25 kg/m ² , at least 1 other risk factor for heart disease, access to telephone and Internet, fluent in English or Spanish, ability to perform mild to moderate exercise	4	White	50	58.4
Wang-berg et al (2008) [48]	67%	NO	61	2	2	1+2	T1DM or T2DM, access to Internet (no exclusion criteria)	1	White	57	40.1
Bond et al (2007) [40]	78%	US	62	2	2	1+2	T1DM or T2DM for ≥1 y, age ≥60, living independently, fluent in English	6	White	45	67.2
Bond et al (2006) [41]	50%	US	15	2	2	1+2	T1DM or T2DM for ≥1 y, age ≥60, living independently, fluent in English	6	White	—	—

Study	Study description								Participants		
	Quality ^a	Country	n	Groups, n	Measurements, n	Setting ^b	Inclusion criteria ^c	Duration (months)	Ethnicity	Female, %	Age, mean
Kim et al (2006) [47]	72%	KR	73	3	2	2	T2DM <20 y, age ≥20, FBS <240 mg/dL and/or HbA1c less than 10.0%, no chronic complications, no evidence of heart disease, musculoskeletal disorders, or other disabling diseases that could restrict physical activity, no insulin administration	3	Asian	47	55.1
Lorig et al (2006) [45]	78%	US	958	2	3	1+2	Age ≥18, T2DM or COPD or CHF, no active treatment of cancer for 1 y, not participated in self-management program, access to Internet (email), agree to 1-2 h per week of log-on time over at least 3 sessions/w for 6 w, able to complete the online questionnaire	12	White	71	57.5
Glasgow et al (2003) [42]	67%	US	320	3	2	1	T2DM (Welborn criteria), age 40-75, have a telephone, fluent in English, live in local area and planning to remain in the area for year of study	10	White	53	59.0
Barrera et al (2002) [43]	72%	US	160	4	1	1	T2DM (Welborn criteria), age 40-75, have a telephone, fluent in English, live in local area and planning to remain in the area for year of study	3	White	53	59.0
McKay et al (2002) [44]	72%	US	160	4	2	1	T2DM (Welborn criteria), age: 40-75, have a telephone, fluent in English, live in local area and planning to remain in the area for year of study	3	White	53	59.3

^aAssessment of study quality as proposed by van Tulder et al [31] see [Multimedia Appendix 2](#).

^b1=Primary care setting; 2=secondary care setting.

^cCESD: Center for Epidemiologic Studies Depression Scale; FBS: fasting blood sugar; HbA1c: glycated hemoglobin; COPD: chronic obstructive pulmonary disease; CHF: congestive heart failure; T2DM: type 2 diabetes mellitus; T1DM: type 1 diabetes mellitus.

Table 2. Results of the studies.

Study	Results ^a	Completion rate (adherence)	Power calculation
Glasgow et al (2012) [37]	Significant improvements in diet (fat intake), physical activity, and biological outcomes in both IGs vs baseline, and significant reduction in distress for both groups vs CG	77%	Yes
Van Bastelaar et al (2011) [35]	Significant improvements in depression and diabetes distress for IG	68%	Yes
Bond et al (2010) [38]	Significant improvements in quality of life, depression, social support, and self-efficacy for IG	100%	Yes
Lorig et al (2010) [39]	Significant improvements in HbA1c, patient activation, and self-efficacy for IGs vs CG	82%	Yes
Glasgow et al (2010) [46]	Significant improvements in diet (fat intake), physical activity, and biological outcomes in both IGs vs baseline, and significant reduction in distress for both groups vs CG	83%	Yes
Wangberg et al (2008) [48]	Significant improvements in self-care for high-efficacy group	45%	Yes (after)
Bond et al (2007) [40]	Significant improvements in HbA1c, weight, and HDL cholesterol for IG vs CG	100%	Yes
Bond et al (2006) [41]	Significant improvements in HbA1c and high comorbidities for IG vs CG	—	Yes
Kim et al (2006) [47]	Significant improvements in physical activity, FBS and HbA1c for both IGs vs CG	100%	Yes
Lorig et al (2006) [45]	Significant improvements in exercise, health distress, fatigue, pain, shortness of breath, reduction in disability for IG	82%	No
Glasgow et al (2003) [42]	Significant improvements in psychosocial and some biological outcomes for all IGs vs CG	82%	No
Barrera et al (2002) [43]	Significant improvements in diabetes-specific support measure and a general support scale for all IGs vs CG	79%	No
McKay et al (2002) [44]	Significant improvements in diet for all IGs vs CG, but no significant differences between conditions	84%	No

^aIG: intervention group; CG: control group; HDL: high-density lipoprotein; FBS: fasting blood sugar; HbA1c: glycated hemoglobin.

The Interventions

Tables 3 and 4 provide an overview of the interventions. Four of the 8 identified online interventions were developed by adapting existing (group) self-management programs into online self-management programs [35,39,45,47], and 4 interventions were newly created [37,38,40-44,46,48]. Two self-management interventions were developed as adjuncts to routine diabetes care, in which health care providers were able to have either online synchronous and asynchronous communication or telephone contact with the patient [38,40,41,47]. Six interventions were developed as standalone programs

[35,37,39,42-46,48]. Five interventions were structured as sequential lessons [35,37,39,45-47] and 3 interventions allowed the participant to navigate freely through the program [38,40-44,48]. All 8 interventions offered some form of online coaching [35,37-48]. Seven of the 8 programs reported using a psychological theory or model as the basis for the self-management program, where some programs used multiple theories [37,42,46]. The theories and models used were: self-efficacy theory, [39,42,45], social support theory [42], transtheoretical model (TTM) [47], social cognitive theory [37,46,48], social-ecological model [37,46], and cognitive behavioral therapy [35].

Table 3. Characteristics of interventions and control conditions of the intervention programs.

Study	Intervention condition 1	Intervention condition 2	Intervention condition 3	Control condition
Glasgow et al (2012), Glasgow et al (2010) [37,46]	Self-administered, Web-based diabetes self-management program with goal setting and action planning for medication adherence, physical activity, and diet; self-monitoring and feedback on progress, monitoring of blood glucose, blood pressure, and cholesterol results, a moderated forum with community resources, and barrier identification	Self-administered, Web-based diabetes self-management program with goal setting and action planning on medication adherence, physical activity, and diet; self-monitoring and feedback on progress, monitoring of blood glucose, blood pressure, and cholesterol results; a moderated forum with community resources, and barrier identification; 2 follow-up calls from interventionist and invitation to attend 3 group sessions	—	Enhanced usual care (computer-based health risk appraisal feedback and recommended preventive care behaviors)
van Bastelaar et al (2011) [35]	Eight online lessons with cognitive behavioral therapy, coaching feedback, and mood diary	—	—	Waitlist control
Bond et al (2010), Bond et al (2007), Bond et al (2006) [38,40,41]	Online library, a personal electronic log of self-management activities, advice and counseling from a nurse via email, and weekly online problem-solving group discussions	—	—	Usual care
Lorig et al (2010) [39]	Web-based diabetes self-management program, 6 weekly sessions, bulletin board feedback on action planning, problem solving, difficult emotions, and celebrations	Web-based diabetes self-management program, 6 weekly sessions, bulletin board feedback on action planning, problem solving, difficult emotions and celebrations, listserv discussion group	—	Usual care
Wangberg et al (2008) [48]	Intervention tailored to high self-efficacy aimed at self-care: blood glucose monitoring, diet and physical activity, included T2DM information, barrier identification, quizzes with feedback, videos of peers, video lectures of professionals	Intervention tailored to low self-efficacy, aimed at self-care blood glucose monitoring, diet, and physical activity, including T2DM information, barrier identification, quizzes with feedback, videos of peers, video lectures of professionals	—	Usual care
Kim et al (2006) [47]	Web-based tailored physical activity counseling, based on participants' assessed motivational stage	Printed-material physical activity intervention including the 5 stages of motivation change	—	Usual care
Lorig et al (2006) [45]	Web-based bulletin board discussion groups and a book, program contains individual exercise programs, emotion management, overview of medications, communication, healthy eating, fatigue management, action planning, feedback, and problem solving	—	—	Usual care
Glasgow et al (2003), Barrera et al (2002), McKay et al (2002) [42-44]	Goal setting with personalized feedback, barrier identification and problem solving, personalized self-management coach condition	Goal setting with personalized feedback, barrier identification and problem solving, peer support condition	Combined condition	Only diabetes information online condition

Table 4. Characteristics of the intervention programs.

Study	Theory used	BCTs ^a	Health care professional included	Evolved or new intervention	Standalone or embedded in care
Glasgow et al (2012), Glasgow et al (2010) [37,46]	Social cognitive theory, social-ecological model	1,2,4,5,7-10,13,16,17,19,29,35	No	New	Standalone
van Bastelaar et al (2011) [35]	Cognitive behavioral therapy	1,2,4,8,12,13,15,16,19,21,22,24,26,27,29,35,36,39,40	No	Evolved	Standalone
Bond et al (2010), Bond et al (2007), Bond et al (2006) [38,40,41]	—	1,2,5,6,8,10,11,16,17,19,21,23,26,28,30,36	No	New	Embedded in care
Lorig et al (2010) [39]	Self-efficacy theory	1-3,7,8,10,16,17,19,28,29,36	No	Evolved	Standalone
Wangberg et al (2008) [48]	Social cognitive theory	1,2,8,16,17,19,21,22,26,28	No	New	Standalone
Kim et al (2006) [47]	Transtheoretical model	5,6,7,17,19,20,21	Yes	Evolved	Embedded in care
Lorig et al (2006) [45]	Self-efficacy theory,	1,4,7,8,19,21,22,27,28,29,33,34,36	No	Evolved	Standalone
Glasgow et al (2003), Barrera et al (2002), McKay et al (2002) [42-44]	Self-efficacy theory, social support theory	1,2,5,8,10,16,17,19,27-29	Yes	New	Standalone

^aBCT: Behavioral change technique; see [Multimedia Appendix 3](#).

Behavioral Change Techniques Used

Only 3 studies explicitly mentioned the BCTs applied [36,37,39]. For the other studies, information on BCTs was extracted from the program description. The frequency of used BCT's found in the articles is shown in [Table 5](#). The most commonly applied BCT's were: provide feedback on performance, provide information on consequences of behavior in general, barrier identification/problem solving, provide information on consequences of behavior to the individual, and prompt self-monitoring of behavior. Some of the unused BCTs were shaping, prompting focus on past success, agree behavioral contract, and fear arousal.

Behavioral Change Techniques Linked to Improved Outcomes

Seven of 13 RCTs reported statistically significant improvements in health behaviors (diet, physical activity/exercise, medication use, smoking) [37,42,44-48]. Nine studies reported statistically significant improvements in clinical

outcomes measures, such as glycated hemoglobin (HbA1c), fasting blood glucose, cholesterol, and triglycerides [37,39-43,45-47]. Nine studies reported statistically significant improvements in psychological outcomes, such as depression, diabetes distress, psychosocial well-being, self-efficacy, stress, and communication [35,37-39,42-45,48]. [Table 6](#) provides an overview of the frequency of applied BCTs found to be associated with the statistically significant improvement of study outcomes.

The BCTs provide feedback on performance, provide information on consequences of behavior in general, barrier identification/problem solving, prompt self-monitoring of behavioral outcome, provide information on consequences of behavior to the individual, prompt self-monitoring of behavior, and plan social support/social change were all linked with improvements in health behaviors, clinical outcome measures, and psychological outcomes. Additionally, goal setting (behavior) was linked to improvements in clinical outcomes and facilitate social comparison was associated with improvements in psychological outcomes.

Table 5. Frequencies of behavioral change techniques (BCTs) used in the interventions discussed in the articles (n=8).

#	BCT	n	%
1	Provide feedback on performance	8	100
2	Provide information on consequences of behavior in general	7	88
3	Barrier identification/problem solving	7	88
4	Provide information on consequences of behavior to the individual	6	75
5	Prompt self-monitoring of behavior	6	75
6	Prompt self-monitoring of behavioral outcome	6	75
7	Provide instruction on how to perform the behavior	5	63
8	Facilitate social comparison	5	63
9	Plan social support/social change	5	63
10	Goal setting (behavior)	4	50
11	Action planning	4	50
12	Prompt review of behavioral goals	4	50
13	Stress management/emotional control training	4	50
14	Provide normative information about others' behavior	3	38
15	Model/Demonstrate the behavior	3	38
16	Prompt practice	3	38
17	Use of follow-up prompts	3	38
18	Goal setting (outcome)	2	25
19	Provide rewards contingent on successful behavior	2	25
20	Relapse prevention/coping planning	2	25
21	Provide information about others' approval	1	13
22	Set graded tasks	1	13
23	Prompt review of outcome goals	1	13
24	Prompt rewards contingent on effort or progress toward behavior	1	13
25	Prompting generalization of a target behavior	1	13
26	Provide information on where and when to perform the behavior	1	13
27	Teach to use prompts/cues	1	13
28	Environmental restructuring	1	13
29	Prompt identification as role model/position advocate	1	13
30	Prompt self-talk	1	13
31	Prompt use of imagery	1	13
32	General communication skills training	1	13
33	Stimulate anticipation of future rewards	1	13
34	Shaping	0	0
35	Prompting focus on past success	0	0
36	Agree behavioral contract	0	0
37	Prompt anticipated regret	0	0
38	Fear arousal	0	0
39	Motivational interviewing	0	0
40	Time management	0	0

Table 6. Frequency of behavioral change techniques (BCTs) per improved study outcome.

BCT	Improved health behavior outcomes (n=7)		Improved clinical outcome measures (n=9)		Improved psychological outcomes (n=9)		Combined average percentage
	n	%	n	%	n	%	
Provide feedback on performance	7	100	9	100	9	100	100
Provide information on consequences of behavior in general	6	86	8	89	9	100	92
Barrier identification/problem solving	6	86	8	89	9	100	92
Prompt self-monitoring of behavioral outcome	6	86	8	89	7	78	84
Provide information on consequences of behavior to the individual	5	71	7	78	8	89	79
Prompt self-monitoring of behavior	5	71	7	78	8	89	79
Plan social support/social change	5	71	6	67	7	78	72
Goal setting (behavior)	5	71	7	78	5	56	68
Prompt review of behavioral goals	4	57	7	78	6	67	67
Facilitate social comparison	4	57	6	67	7	78	67
Action planning	4	57	5	56	3	33	49
Use of follow-up prompts	3	43	3	33	5	56	44
Provide instruction on how to perform the behavior	3	43	4	44	4	44	44
Provide normative information about others' behavior	3	43	3	33	3	33	36
Stress management/emotional control training	1	14	4	44	4	44	34
Provide rewards contingent on successful behavior	2	29	2	22	2	22	24
Model/Demonstrate the behavior	2	29	1	11	3	33	24
Relapse prevention/coping planning	2	29	2	22	2	22	24
Prompt practice	1	14	2	22	3	33	23
Set graded tasks	2	29	2	22	1	11	21
Goal setting (outcome)	1	14	3	33	1	11	19
Prompt self-talk	1	14	1	11	1	11	12
Prompt use of imagery	1	14	1	11	1	11	12
Prompt review of outcome goals	0	0	2	22	1	11	11
Teach to use prompts/cues	0	0	2	22	1	11	11
Prompt identification as role model/position advocate	0	0	2	22	1	11	11
Provide information on where and when to perform the behavior	1	14	1	11	0	0	8
Provide information about others' approval	0	0	1	11	1	11	7
Prompt rewards contingent on effort or progress toward behavior	0	0	0	0	1	11	3
Prompting generalization of a target behavior	0	0	0	0	1	11	3
Environmental restructuring	0	0	0	0	1	11	3
General communication skills training	0	0	0	0	1	11	3
Stimulate anticipation of future rewards	0	0	0	0	1	11	3
Shaping	0	0	0	0	0	0	0
Prompting focus on past success	0	0	0	0	0	0	0
Agree behavioral contract	0	0	0	0	0	0	0
Prompt anticipated regret	0	0	0	0	0	0	0
Fear arousal	0	0	0	0	0	0	0
Motivational interviewing	0	0	0	0	0	0	0

BCT	Improved health behavior outcomes (n=7)		Improved clinical outcome measures (n=9)		Improved psychological outcomes (n=9)		Combined average percentage
	n	%	n	%	n	%	
Time management	0	0	0	0	0	0	0

Discussion

Overall Findings

To the best of our knowledge, this is the first review of BCT use in online diabetes self-management support programs. This information should prove helpful in designing effective online self-management programs for people with T2DM. We identified 13 RCT studies reporting on 8 different online self-management interventions of which 4 pre-existed as group-based programs. Despite the introduction of the Internet in 1994, only a relatively small number of Internet-based self-management interventions for T2DM patients have been studied. We did find 143 studies on various forms of diabetes telehealth and telecare interventions. These studies were excluded from our review because they did not qualify for our definition of self-management programs. Rather these programs stimulated patients to self-monitor their blood glucose, followed by professional feedback and advice. To our knowledge, these programs do not explicitly prompt or support patients to make decisions [32-34,49].

The majority of the included studies that reported on self-management interventions only gave a very basic description of the program and its background. Indeed, it has been noted before that very few studies provide a detailed description of the actual behavioral change intervention [50-52]. This could be caused by the limited space authors have to describe the intervention in certain journals, making it difficult to replicate the study or allocate an effect size to specific parts of the intervention.

The Use of Theories and Behavioral Change Techniques

We observed that 7 of 8 interventions were grounded in a theoretical model, of which one of the used models (TTM), although popular, had limited evidence to support its assumptions [53,54]. Self-regulation theory with monitoring, action planning, and evaluating as its key features [55], and social learning theory, characterized by learning in social context [56], were most commonly used to inform development of the online interventions. However, only 3 studies specifically substantiated their choice for the use of specific BCTs to support their intervention [35,37,39]. After distilling the BCTs from the articles, the BCTs feedback on performance, providing information on consequences of behavior, barrier identification/problem solving, and self-monitoring of behavior and outcomes seemed to contribute the most to the effectiveness of the online self-management programs. These techniques also seemed to be key components for healthy eating and increasing physical activity [57], and were also commonly found in offline T2DM self-management programs [14,58]. However, being used frequently is in itself not a guarantee that these BCTs will

actually contribute to the improvement of patients' self-management in a particular domain. Nor does it mean that these BCTs fit the theory that was chosen to guide the intervention [59]. To further the development of effective online self-management interventions for T2DM and other chronic conditions, it is important to understand the underlying learning process [59]. Appropriate use of theories and supporting BCTs can prevent future interventions to be wrongly interpreted or executed by participants thereby improving treatment fidelity. This is particularly important for online programs, where confusion and misinterpretation on the part of the participant is more difficult to detect and address than in a group setting, for example, because of the more distant and static nature of the Web-based intervention. Therefore, it is crucial that the theoretical framework and BCTs are carefully chosen before a Web-based self-management intervention is created [60].

A number of potentially effective BCTs appear to be used rarely or never in online self-management programs for T2DM despite a good theoretical basis. For instance, only a selection of BCTs derived from social theories, which have a great influence on the self-management of T2DM [61], were represented in the reviewed studies that claimed to use these social theories. Although planning social support and having some form of coaching to provide feedback are frequently used, other BCTs that seem to affiliate with social cognitive theories, such as identification of a role model, model/demonstrate the behavior, and provide information about others' approval, were not frequently used. The same is true for BCTs such as coping planning and use of imagery that have been shown to be effective in stimulating self-management of T2DM in an offline program [62]. Similarly BCTs that seem to be based in the classical and operant conditioning theories (characterized by associations and rewards), such as prompt rewards contingent on effort or progress toward behavior and teach to use prompts/cues, were also barely used, but have shown to be associated with improving physical activity [63]. Just because these theories and BCTs were not used in the reviewed interventions does not mean that they are of no value to an online self-management program.

The question then arises why researchers only use a limited number of BCTs and why the chosen BCTs do not always match the theories underlying their intervention. One explanation could be that current online interventions are being copied from published successful online or offline interventions based on a selection of theories and BCTs. By copying existing self-management programs, other relevant theories and BCTs are slowly phased out, narrowing the spectrum of BCTs used. Another obvious reason why certain BCTs are not being used could be that they are too complex or too technologically demanding and, therefore, too costly to integrate into an online environment. For instance, integrating elements of social support

into the intervention, such as a forum, email messaging, and chatting functionality, demands large databases and continuous moderator involvement. The maintenance costs of these parts could influence the choice of using these elements. Finally, another reason for underuse of effective BCTs may be that the development of Web-based interventions for T2DM patients are driven primarily by technological advancements rather than being based on a BCT [64].

Limitations

The number of articles uncovered in this review was limited to 13 RCTs, covering 8 different diabetes self-management interventions. By only including English studies there is a possibility we limited the amount of available interventions for this review. This, in combination with multiple BCTs used and a variety of outcome measures, made it difficult to allocate an effect size to a specific BCT. Furthermore, because of the fact that self-management interventions contain multiple modules with interactive components, it is difficult to attribute an improvement in a particular study outcome to one specific BCT.

Conclusions/Future Recommendations

The development of online self-management interventions for T2DM patients brings with it a responsibility of correctly constructing and choosing the working components to specifically target diabetes self-management goals and outcomes. To avoid a further narrowing of applied BCTs, we recommend developers of online self-management programs to not only copy existing successful programs, but also critically review and consider less frequently used BCTs in the context of their theoretical background and the chosen target behaviors.

Ideally, the creation process should follow the order of choosing a theory first, then matching BCTs, and lastly the technology to support the intervention. BCTs can be selected from the taxonomy of 40 BCTs as proposed by Michie et al [27]. By using this strategy, online theory-based self-management programs for T2DM patients can be developed without making unnecessary compromises or biased choices caused by existing technology. Furthermore, reporting detailed information on used theories and BCTs in research protocols and articles will benefit researchers in the creation and understanding of new effective Web-based self-management interventions for T2DM and other chronic disorders.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Search terms.

[PDF File (Adobe PDF File), 27KB - [jmir_v15i12e279_app1.pdf](#)]

Multimedia Appendix 2

Study quality assessment.

[PDF File (Adobe PDF File), 23KB - [jmir_v15i12e279_app2.pdf](#)]

Multimedia Appendix 3

Behavioral change techniques proposed by Michie et al (2011).

[PDF File (Adobe PDF File), 19KB - [jmir_v15i12e279_app3.pdf](#)]

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Abbreviations

AADE: Association of American Diabetes Educators
BCT: behavioral change technique
CG: control group
IG: intervention group
RCT: randomized controlled trial
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus
TTM: transtheoretical model

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Review

A Lot of Action, But Not in the Right Direction: Systematic Review and Content Analysis of Smartphone Applications for the Prevention, Detection, and Management of Cancer

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Abstract

Background: Mobile phones have become nearly ubiquitous, offering a promising means to deliver health interventions. However, little is known about smartphone applications (apps) for cancer.

Objective: The purpose of this study was to characterize the purpose and content of cancer-focused smartphone apps available for use by the general public and the evidence on their utility or effectiveness.

Methods: We conducted a systematic review of the official application stores for the four major smartphone platforms: iPhone, Android, Nokia, and BlackBerry. Apps were included in the review if they were focused on cancer and available for use by the general public. This was complemented by a systematic review of literature from MEDLINE, Embase, and the Cochrane Library to identify evaluations of cancer-related smartphone apps.

Results: A total of 295 apps from the smartphone app stores met the inclusion criteria. The majority of apps targeted breast cancer (46.8%, 138/295) or cancer in general (28.5%, 84/295). The reported app purpose was predominantly to raise awareness about cancer (32.2%, 95/295) or to provide educational information about cancer (26.4%, 78/295), followed by apps to support fundraising efforts (12.9%, 38/295), assist in early detection (11.5%, 34/295), promote a charitable organization (10.2%, 30/295), support disease management (3.7%, 11/295), cancer prevention (2.0%, 6/295), or social support (1.0%, 3/295). The majority of the apps did not describe their organizational affiliation (64.1%, 189/295). Apps affiliated with non-profit organizations were more likely to be free of cost ($\chi^2_1=16.3$, $P<.001$) and have a fundraising or awareness purpose ($\chi^2_2=13.3$, $P=.001$). The review of the health literature yielded 594 articles, none of which reported an evaluation of a cancer-focused smartphone application.

Conclusions: There are hundreds of cancer-focused apps with the potential to enhance efforts to promote behavior change, to monitor a host of symptoms and physiological indicators of disease, and to provide real-time supportive interventions, conveniently and at low cost. However, there is a lack of evidence on their utility, effectiveness, and safety. Future efforts should focus on improving and consolidating the evidence base into a whitelist for public consumption.

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KEYWORDS

mobile; Internet; cancer; software applications; apps

Introduction

Since the beginning of the 21st century, mobile phones have become nearly ubiquitous. At the end of 2011, there were an estimated 6 billion mobile subscriptions, accounting for approximately 87% of the global population [1]. Rapid technological convergence has led to the emergence of smartphones—feature-rich phones that combine the voice and text messaging functions of basic phones with powerful computing technology that can support third-party applications, sensing, Internet access, and wireless connectivity with other devices. According to a 2012 report from the Pew Internet and American Life Project, 85% of US adults own a cell phone of some kind and 53% own a smartphone [2]. The combination of their popularity, technical capabilities, and proximity to their owners makes them an attractive platform for the delivery of health promotion and disease management interventions [3].

Basic mobile phone-based interventions have shown promise in improving outcomes for a variety of health conditions and behaviors. A systematic review of controlled trials of health care interventions delivered by cell phones with basic features such as voice or text-messaging capabilities reported improvements in 61% of outcomes measured [4]. Process improvements included improved attendance at medical appointments, quicker time to diagnosis and treatment, and enhanced communication skills. Behavioral changes included smoking cessation, improved medication adherence, and more timely vaccinations. Clinically significant changes included improvements in blood sugar control, asthma symptoms, stress levels, and self-efficacy. Most of these mobile interventions used “push” technology, where participants received personalized text or automated voicemail messages such as appointment, medication, or symptom assessment reminders, or educational messages to encourage preventive health behaviors or self-management activities.

Less is known about smartphone-based interventions, which offer new possibilities for health promotion and disease management. Technical capabilities include: text messaging, cameras, Internet access, automated sensing, and native applications. All major smartphone platforms—Apple iOS, Google Android, BlackBerry, Nokia’s Symbian, and Nokia and Microsoft Windows Phone—provide third-party developers with application programming interfaces (APIs) that they can use to build special purpose applications, known as native applications (apps). The launch of the Apple App Store in 2008, along with its software development kit shortly thereafter, led to an explosion in app development and subsequent downloads. As of April 2012, the total number of consumer health apps for the iPhone was estimated to be 13,600 [5]. Klasjna and Pratt [2] have identified five strategies used in smartphone-based health interventions that take advantage of the technical capabilities of the mobile phone to various extents; these include: (1) tracking health information (eg, through text messaging, native apps, or automated sensing), (2) involving the health care team (eg, remote coaching, symptom monitoring), (3) leveraging social influence (eg, peer-to-peer support, modeling, or influence), (4) increasing the accessibility of health information (eg, short messages or reminders), and

(5) utilizing entertainment (eg, games to motivate health management).

Researchers have begun to characterize the smartphone apps that are available to consumers for pain management [6], diabetes management [7], smoking cessation [8], cancer [9], and melanoma detection [10]. Cancer is a leading cause of death and disability worldwide, accounting for 7.6 million deaths (13% of all deaths) in 2008 [11]. Recent advances in detection, prevention, and treatment have led to increased survival rates for patients living with the disease, with an estimated 28 million survivors around the world [12]. A large majority of cancer survivors experience distressing symptoms and adverse long-term consequences related to their disease and unmet supportive care needs are frequently reported [13]. As a result, many people affected by cancer regularly seek health-related information online [14-16]. The review of cancer apps by Pandey et al [9], although informative, was restricted to those available on the iPhone market and lacked detail on the content or features of apps. For example, consumer apps were described as “general information about the disease” or “patient assistant tools”.

The purpose of this study was to characterize the purpose and content of cancer-focused smartphone apps available for use by the general public and the evidence on their utility or effectiveness. We present a systematic review and characterization of the cancer-focused apps that are available in four leading smartphone application stores. This was complemented by a systematic review of the health literature to identify evaluations of cancer-focused smartphone apps. We also discuss the reported purpose and features of smartphone apps in relation to health behavior change theory, with the goal of identifying gaps, which could inform intervention development.

Methods

Overview

Systematic review methodology, as described by Moher et al [17], was used to guide the collection and characterization of eligible apps from the official smartphone stores and the evidence on app utility or effectiveness from the health literature. We developed a systematic search strategy that attempted to identify all relevant apps and studies and we provide a systematic presentation and synthesis of the characteristics of the apps and the studies.

Mobile Application Market Search

Overview

On February 14, 2012, we conducted a search of the online stores for iPhone (App Store), Android (Google Play), BlackBerry (App World), and Nokia/Symbian (Ovi) using the keyword “cancer” in the main search engine. We searched across all store categories (eg, we did not restrict our search to the health/ lifestyle category). We restricted our search to applications that had “cancer” in the title or store description of the app. One author (LD) searched the Android and BlackBerry markets in France and another author (RY) searched

the iPhone and Nokia markets for eligible apps in Canada. All eligible apps from the French Android and BlackBerry stores were checked against the Canadian Android and BlackBerry stores to ensure their availability in the Canadian market. The two reviewers then swapped a random selection of 5% (a total of 64 apps) of their search yields to verify their eligibility.

Selection Criteria

Apps were included if they were focused on cancer and were intended for people affected by cancer defined as cancer patients or survivors, their family caregivers, or the general public concerned about cancer; had an English-language interface; and were available for smartphones. If an app had an English interface, the app, and its title and description appeared in English regardless of the store in which the search was conducted. Some apps were available in multiple languages. Apps were excluded if they were only available on tablet computers or were aimed at health care professionals. We excluded apps related to smoking cessation, radiation exposure, or general symptom management because they were not focused on cancer and many did not include “cancer” in their title or store description. Moreover, recent reviews have been published on smoking cessation apps [8] and pain management apps [6]. Inter-rater reliability of the 64 apps (5%) reviewed for eligibility as determined by standard Cohen’s kappa was acceptable (.74). Disagreements were resolved by consensus involving a third reviewer when necessary.

Data Extraction

We collected information from the store description of the app and only downloaded or examined the websites of those apps that had unclear store descriptions or did not provide screenshots. We extracted information on: year of release, cost, affiliation (eg, commercial, non-profit, university, or medical center), condition information (eg, type of cancer), source of app information, features (eg, calendar, journaling software, etc), and multimedia used (eg, text, audio, visual, video).

Data Coding and Analysis

We generated a preliminary coding scheme to describe the purpose of the app by collectively (JLB, RY, LD) analyzing the content of the first 50 (16.2%, 50/309) eligible apps. Using this coding scheme, one author (RY) extracted the study data and coded the main purpose of the apps. Another author (MT) independently reviewed a random selection of 25.6% (79/309) of apps to verify the information coded. Inter-rater reliability of the coded data, as determined by Cohen’s kappa was high (.87), but revealed that minor changes to the coding scheme were required. RY used the revised coding scheme to re-code all apps. The final coding scheme was based on the following seven identified categories of apps:

1. Awareness-raising: tools to raise public recognition of cancer as a societal problem.
2. Fundraising: tools to attract financial resources for cancer control.
3. Promote an organization: encourage awareness about a charitable organization raising awareness and funds for cancer or providing support to people affected by cancer.

4. Disease and treatment information: provide general information about cancer (eg, disease or treatment options)
5. Prevention: provide information and practical tools to avoid cancer, including the recurrence of cancer.
6. Early detection: provide information and tools to assist in the identification of cancer before the emergence of symptoms or signs.
7. Disease management: provide information and practical tools to deal with the medical, behavioral, or emotional aspects of cancer.
8. Support: provide access to peer or professional assistance.

Apps were coded into one category based on their main purpose as described in the store description.

Health Literature Search

Overview

Articles were identified through a search of MEDLINE (1990-June 18, 2012), Embase (1990-June 24, 2012), and all of the databases in the latest available version of The Cochrane Library (1990-June 24, 2012). The search strategy, developed in consultation with a medical librarian (ME), included a string of mobile technology search terms cross-matched with terms “cancer” and “neoplasm” ([Multimedia Appendix 1](#)). The yield from the bibliographic databases was supplemented with a review of reference lists from eligible articles and recent reviews. Two of the authors of this study (MT and JLB) independently reviewed the titles and abstracts of the total search yield to identify eligible articles. The full text of the article was retrieved if any reviewer considered a citation potentially relevant.

Selection Criteria

Articles were considered potentially relevant if they: described an evaluation of a mobile phone app for cancer patients/survivors, family caregivers, or the general public; included original data on the use of the mobile phone app by cancer patients/survivors, family caregivers, or the general public; and were published in English. To be eligible for inclusion in the final analysis, the article must have described an evaluation of a cancer-focused smartphone app. We excluded articles that described or evaluated basic mobile phone and personal digital assistant (PDA) interventions, the reliability of paper versus mobile phone-based assessments, as well as articles that evaluated apps tested exclusively on laptops, netbooks, or tablet computers. As described, a smartphone is a feature-rich phone that offers more computing capability than a basic mobile phone or a PDA.

Data Extraction and Coding

Two of the authors of this study (MT and JLB) independently reviewed the full text of the articles meeting the eligibility criteria and extracted information on the following: general study characteristics (eg, primary author, year of publication, country of study, and source of funding); participants (age, gender, and sociodemographic data); condition (eg, cancer type); intervention (eg, device, main purpose, and features); study design, and findings. Disagreements were rare and were easily resolved by consensus.

Results

General Characteristics

The search of the mobile phone market yielded 1314 potentially relevant apps, of which 309 apps met our selection criteria (Figure 1); 90.3% (279/309) of apps were available on the iPhone or Android markets (Figure 2). Twelve apps were available on more than one platform (10 were available in two stores and 2 in three stores). Therefore, there were a total of 295 unique apps.

Release date information was available for only 38.0% (112/295) of the apps from Apple, Android, and BlackBerry, as the remainder had produced updated versions and only published their date of update. Release date information was not available for apps on the Nokia market.

Half of the apps (50.2%, 148/295) were free to download. Of those free-to-download apps, 8 were trial versions of the full

pay-for-download applications. These free apps offered limited versions of the full apps, restricting access to the full suite of features. The remainder of the apps (47.1%, 139/295) ranged from \$1 to \$12 CAD and the majority were priced at a median of \$1.01 CAD.

The majority of the apps did not describe their organizational affiliation (64.1%, 189/295). Of those that provided organizational information, 63.2% (67/106) were affiliated with a non-profit, 26.4% (28/106) with a commercial company (eg, Health Monitor Network), 9.4% (10/106) with a university or medical institution, and 1 app was affiliated with a government institution (eg, National Institutes for Health). Apps affiliated with not-for-profit organizations (non-profit, university, medical institution, or government) were more likely to be free ($\chi^2_1=16.3, P<.001$). Apps that did not disclose their affiliation were more likely to have a price ($\chi^2_1=50.1, P<.001$).

Figure 1. Flow diagram.

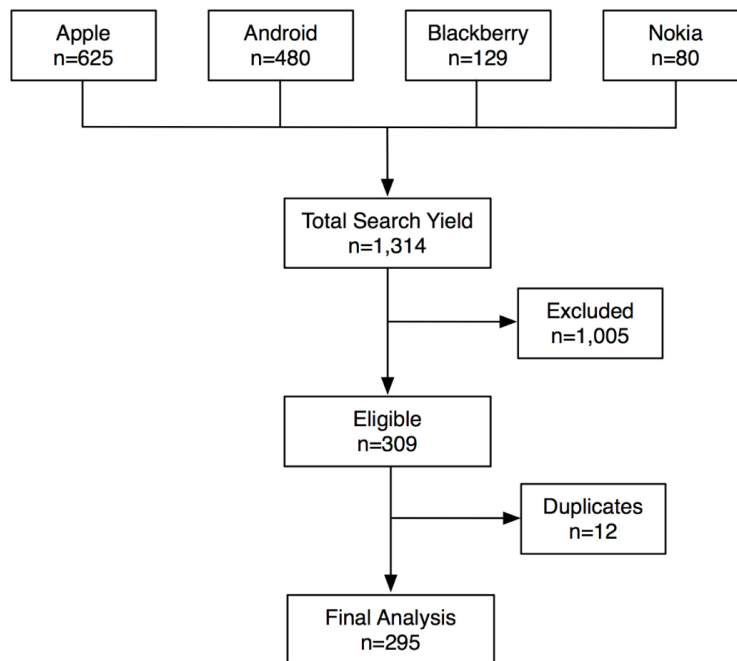
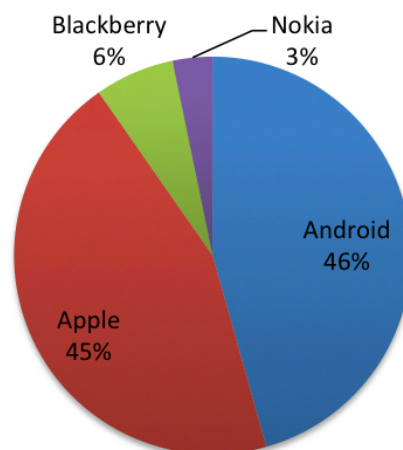


Figure 2. Distribution of cancer apps across the four mobile markets.



Target Cancer Type

Overall, the apps targeted 15 types of cancer, as well as broadly

targeting pediatric cancers, female cancers, and cancer in general. The majority of apps targeted breast cancer (46.8%, 138/295) (Figures 3 and Figure 4).

Figure 3. Number of apps by target cancer type.

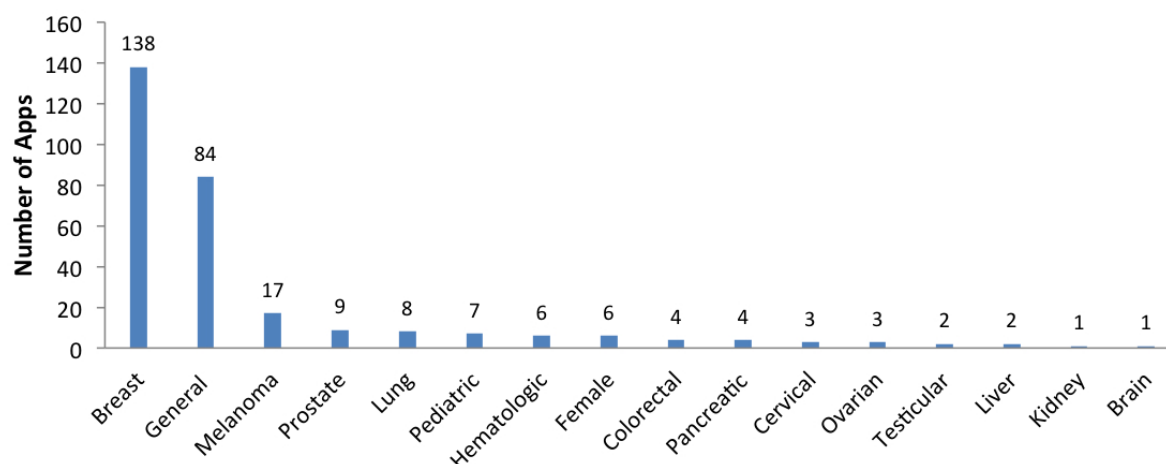
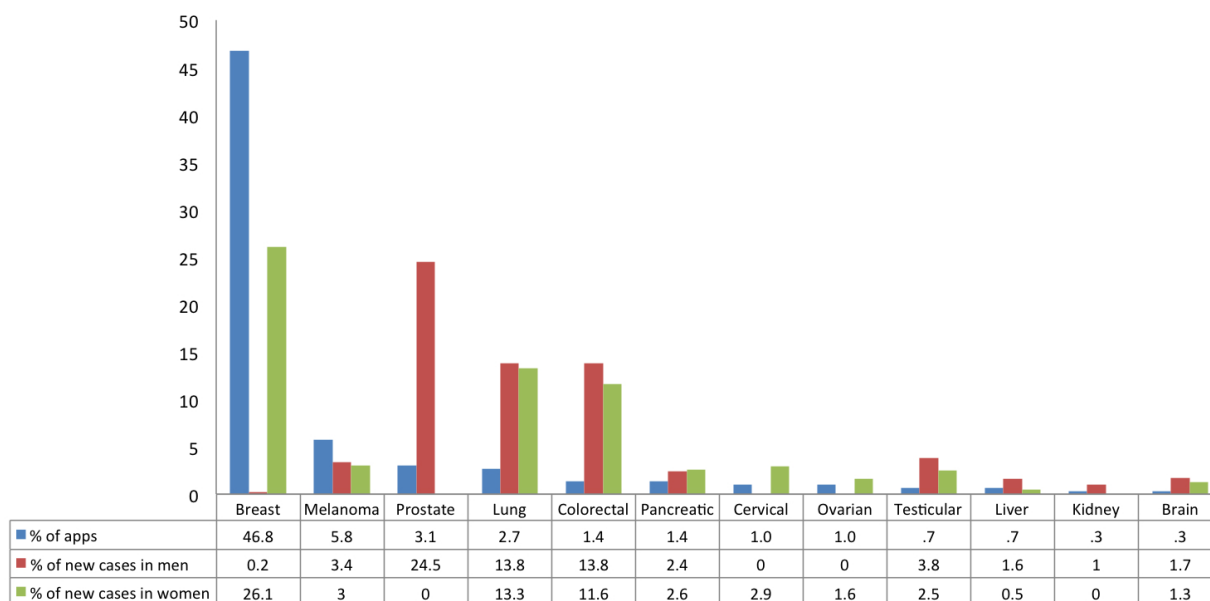


Figure 4. Percent distribution of apps in comparison to estimated new cases of cancer, by gender, Canada 2013. Data on cancer incidence drawn from Figure 1.2 of Canadian Cancer Statistics by the Canadian Cancer Society (2013).



Application Purpose and Content

The reported app purpose was predominantly to raise awareness about cancer (32.2%, 95/295) or provide information about cancer (26.4%, 78/295). A considerable proportion of apps were designed to support fundraising efforts (12.9%, 38/295) or promote a charitable organization raising awareness or funds for cancer (10.2%, 30/295). A minority of apps aimed to assist in the prevention (2.0%, 6/295), early detection (11.5%, 34/295), or management of cancer (3.7%, 11/295), and only 3 apps (1.0%, 3/295) enabled users to communicate with or learn from other cancer survivors. Apps affiliated with a commercial company were more likely to have an informational purpose, while apps affiliated with a not-for-profit were more likely to have a fundraising, awareness, or promotional purpose ($\chi^2=13.3$,

$P=.001$). Application purpose and features are summarized in Table 1.

The majority of apps utilized the visual media capability of the smartphone to deliver content. The top three multimedia formats were: visual media-only (36.7%, 108/295), text-only (28.9%, 83/295), and a combination of text and visual media (22.6%, 65/295). The apps that contained only visual media consisted of themed backgrounds or icons (eg, pink ribbons), which were intended to raise awareness of cancer. Many apps (31.5%, 93/295) used a combination of multi-media content. (Data not shown.)

Screenshots of representative apps from each category are shown in Multimedia Appendix 2.

Table 1. Primary function and features of cancer apps (n=295).

Purpose	Description	Features ^a	Apps, n (%)
Awareness	Images, information, or games to raise awareness about cancer or issues related to cancer	<ol style="list-style-type: none"> 1. Cancer-themed wallpaper, icons, fonts, or programs (eg, pink ribbon background) 2. Basic information to raise awareness about cancer 3. Cancer-themed games (eg, chemo drug shooting at cancer cells) 4. Interactive activities to raise awareness about cancer (eg, trivia about cancer) 	95 (32.2)
Disease and treatment information	Educational information, in some cases supplemented by visual or video media, regarding: disease, diagnosis, symptoms, treatment, prevention, screening, alternative therapy, behavior management, cancer terminology, psychosocial issues, or up-to-date news.	<ol style="list-style-type: none"> 1. eBook 2. Newsfeed 3. Glossary of terms 4. Directory of information with search functionality 5. Instructional images or videos 	78 (26.4)
Fundraising	Tools to raise funds for cancer or support management of fundraising efforts.	<ol style="list-style-type: none"> 1. Promote fundraising efforts (eg, Twitter, Facebook) 2. Monitor fundraising progress 3. Update personal fundraising page 4. Fundraising event information 5. Donate funds 	38 (12.9)
Early detection	Educational information, skills training, and tools to assist in the detection of cancer.	<ol style="list-style-type: none"> 1. Information, images, or videos on how to screen 2. Monitor screening results (eg, notes or pictures) 3. Medical screening reminder 4. Forms or image capture tools with built-in GPS locator of screening or cancer centers 5. Image capture tool with algorithm that calculates skin cancer risk 	34 (11.5)
Promote an organization	Encourage awareness about a charitable organization raising awareness and funds for cancer or providing support to people affected by cancer.	<ol style="list-style-type: none"> 1. Newsfeeds 2. Information about the organization 3. Organizational contact information 4. Direct links to contact the organization (eg, hyperlink to a contact form on a website) 	30 (10.2)
Disease management	Information and tools to manage the medical, behavioral, or emotional aspects of cancer	<ol style="list-style-type: none"> 1. Appointment tools: reminder/ organizer, medical team contact list, tools to prepare questions, tools to store lab results, journal for notes, tools to track medical expenses 2. Self-monitoring/ tracking tools: physical symptom tracker, psychosocial symptom tracker, medication tracker 3. Communication (eg, email) 	11 (3.7)
Prevention	Educational information, skills training, and tools to prevent cancer.	<ol style="list-style-type: none"> 1. Grocery list of foods that may prevent cancer 2. Recipes based on recommend cancer-fighting foods 3. Quiz on reducing behavior and dietary risk factors 4. Information and images on how to exercise 	6 (2.0)
Peer support	Tools to communicate with or learn from the experiences of other cancer patients.	<ol style="list-style-type: none"> 1. Asynchronous communication tools 2. GPS locator of social network members 3. Text or audio-based cancer survivor stories 	3 (1.0)

^aThe features listed here are illustrative of the main app content in each category.

Prevention, Early Detection, and Disease Management Apps

Six apps (2.0%, 6/295) reported that their purpose was to assist in the prevention of cancer by promoting healthy lifestyle behaviors. Five of these apps aimed to promote healthy eating behaviors; one app promoted exercise. These apps targeted breast cancer (n=4), prostate cancer (n=1), and cancer in general (n=2). The healthy eating apps offered educational information and skill-building tools to assist in the performance of healthy eating behaviors. Features included lists of cancer preventative foods, recipes based on recommended foods, and tips on healthy eating practices. The exercise app offered instruction on how to perform exercises to promote increased circulation in breast tissue.

Thirty-four apps (11.5%, 34/295) reported that their purpose was to assist in the early detection of cancer. The majority of these apps targeted breast cancer (n=17) or skin cancer (n=9), followed by hematologic cancers (eg, leukemia, lymphoma, myeloma; n=3), testicular cancer (n=2), cervical (n=1), and colorectal (n=1). Most of the former apps offered practical guidance on how to perform self-exams, reminders for self-exams or screening appointments, and features to track assessment results. A handful of apps offered cancer risk scores based on completion of a questionnaire. Skin cancer detection apps included tools that captured and tracked images of skin lesions and generated cancer risk scores based on built-in algorithms.

Eleven apps (3.7%, 11/295) provided tools to support the management of cancer. The majority of these apps were not specific to a particular cancer type (n=7), three were tailored for breast cancer (2 of which also targeted colorectal cancer), and one was tailored for prostate cancer. These apps offered a combination of tools to assist in the management of (1) medical appointments (eg, appointment organizers or reminders, team contact lists, question list builders, note taking, recoding of lab results, tracking of medical costs), or (2) self-monitoring of symptoms or medication consumption (eg, using forms or journaling features). One app was focused entirely on assisting in the preparation of question lists to guide conversations with health professionals, including an inventory of over 100 typical questions, and tools to add a question, build question lists, and record answers.

Evaluation

No app reported an evaluation of any form in their store description.

The search strategy yielded 594 articles. After independent review by two authors, none of these were deemed eligible. We did not find an evaluation of a cancer-focused smartphone app. But we did find evaluations of three unique mobile device interventions for cancer: a symptom management system to facilitate monitoring of toxicity symptoms in patients undergoing chemotherapy, which produces tailored self-management feedback and alerts the care team alerts when alarming symptoms arise [17-19]; a generic symptom assessment system that prompts patients to perform and record assessments and forwards completed assessments to clinicians for review [20];

and a problem-solving skills system for parents of children with cancer with prompts to perform and log problem-solving activities [21]. One of these was designed for a basic mobile phone and the others were PDA-based interventions.

Discussion

Principal Findings

In summary, a total of 295 unique apps were identified across the four leading smartphone markets. The majority of apps targeted breast cancer or cancer in general and aimed to raise awareness about cancer or provide educational information about cancer. Most apps affiliated with a non-profit organization were free. However, most apps did not report their organizational affiliation. Last, a systematic review of the health literature found no evaluations of cancer-focused smartphone applications.

This study demonstrates, as have others [6-9], the increasing number of native health apps that are available to the public. The majority of reviewed apps were available on Android or iPhone smartphones, which is unsurprising given the dominance of Google and Apple in the smartphone market [18]. Some early reviews of health apps focused exclusively on iPhone apps [6,8,9]. This study demonstrates the importance of considering Google's Android platform, which accounted for 75% of the worldwide smartphone market share as of the third-quarter of 2012 [18].

Despite increasing interest in mobile phones as platforms for the delivery of health behavior-changing interventions, this study suggests that the cancer apps available in the app stores, on their own, have limited potential value in this regard. It is well recognized that information alone is insufficient to change behavior, particularly when complex behavior change is the aim [19]. To be effective, health promotion efforts must also: teach the self-management skills necessary to translate that knowledge into effective practices; build a sense of self-efficacy or confidence in performing the behaviors; and create the social supports necessary for the initiation and maintenance of the desired behavior [20]. Yet, the majority of identified apps focused exclusively on raising awareness or delivering information about cancer. Only 17.2% (51/295) of apps provided information in combination with skill-building tools to assist in the performance of preventive, detection, or self-management behaviors. Similarly, Rosser and Eccleston [6] found that the majority of pain-related apps were designed to deliver information about pain and its treatment, with little integration of features to promote coping or self-management behaviors. In contrast, Chomutare et al [7] found an under-representation of education in their review of diabetes apps, which were rich in self-management features. Their review, on the other hand, was restricted to apps that had a blood glucose self-monitoring component, which could have excluded educational apps.

Overall, the reviewed cancer apps did not take advantage of the smartphone's technical capabilities. For example, the main feature offered by the subset of apps that aimed to support preventative or self-management behaviors was health information tracking, often referred to as self-monitoring. This

was primarily achieved through native journaling applications custom-designed to support logging of appointment information or health-related behaviors. Self-monitoring has been shown to be an effective health behavior intervention, particularly for weight loss [21]. However, the effort involved in tracking one's activities can be a significant barrier to adoption and sustained use. Mobile phones can reduce the effort involved in self-monitoring by using photos to document complex behaviors and using sensors connected wirelessly to measuring devices that automatically log behaviors and physiologic states [2]. Most of the apps included in this review relied on textual entry or touch screen completion of predetermined response options. A handful of the skin cancer detection apps enabled users to document and track their skin lesions using the phone's built-in camera and three of the question-building apps enabled users to audio record health professionals' responses. There were no apps that used automated sensing for tracking.

Although there are fewer clear physiologic indicators for cancer that are amenable to user self-collection, mobile sensing platforms could assist in the automated logging of symptoms (eg, fatigue, pain, nausea) or health behaviors such as exercise. The threat of regulation, which is costly and time-consuming, could have discouraged app developers from using the smartphone's technical capabilities, particularly automated sensing. Regulatory bodies in the United States and the European Union are increasing scrutiny over mobile apps, with the United States opting for a larger scope [22]. On September 25, 2013, the US Food and Drug Administration (FDA) issued guidelines for the oversight of mobile medical apps that meet the regulatory definition of "device" and that (1) are intended to be used as an accessory to an FDA-regulated medical device (eg, an app that could enable a health professional to view a medical image), or (2) transform a mobile platform into a regulated medical device (eg, apps that use sensors to measure and track vital signs) [23]. However, some mobile sensing apps that meet the definition of a medical device will not require FDA review, for example, apps that allow users to collect (electronically or manually entered) blood pressure data and share these data through email or upload it to a personal or medical health record. Although these FDA guidelines were not available at the time the search was conducted, draft guidelines of a similar nature were available and could have influenced app developers.

Effective self-management requires effective communication with and support of the health care team [19,20]. Only a few apps included features that could facilitate communication with the health care team. These were limited tools to identify and prioritize questions to ask your doctor and journaling apps to take notes during medical appointments. In their review of pain apps, Rosser and Eccleston [6] found no apps that facilitated communication with the health care team, which they attributed to the lack of involvement of health professionals in app development. Health professionals can also support self-management efforts through regular assessment of their patients' health status and providing encouragement to perform healthy behaviors, as well as problem-solving support [19]. Involvement of health professionals has also been shown to increase adherence to Web-based interventions [24]. Mobile

phones can keep health professionals informed of the patient's condition and progress and facilitate health professional-patient interactions, through remote coaching, remote symptom monitoring, and automated feedback [2]. As discussed, the mobile smartphone's connectivity to the Internet facilitates remote monitoring efforts by enabling user's data to be uploaded to a server as soon as they are captured, allowing for early detection of critical events. For example, Kearney et al [25] developed a PDA-based symptom management system to facilitate monitoring of toxicity symptoms in patients undergoing chemotherapy. The system uses phone-based questionnaires to assess six chemotherapy-related symptoms (nausea, vomiting, fatigue, mucositis, hand-foot syndrome, and diarrhea). Patients' responses are uploaded to a server and the system generates specific strategies for managing the particular symptoms. If the software determines that the symptoms are alarming, the system generates an alert that is sent to the health care team. Reported benefits of the system based on patients' evaluations include: improved communication with health professionals, improvements in management of symptoms, and feeling reassured their symptoms were being monitored. While apps that enable patients to self-record their symptoms and to upload that information to a server for health professionals are considered medical devices according to the FDA, the agency has decided to waive regulation of these apps.

The reviewed apps also failed to fully take advantage of the smartphone's social networking capabilities. Only three apps enabled users to connect with similar others to exchange information and support. Two of these apps enabled users to post questions and responses to other users of the app in the form of a mobile community of support, and the third consisted of a book of survivors' experiences with the disease. None of the prevention and disease management apps included features that enabled the exchange of supportive information with other users of the app. Similarly, Chomutare et al [7] documented a lack of social media functionality in their review of diabetes apps. Most diabetes apps that claimed to include social media features only provided a link to the device's group page in social networking sites such as Twitter and Facebook. Online health communities have repeatedly demonstrated their value in bringing together cancer patients and survivors to exchange information and support [26]. While the exact mechanisms by which social relationships affect health remains unclear, nearly 30 years of research has consistently demonstrated that they have a powerful effect on physical and mental health and may extend survival [27]. Social support is also a critical factor in the initiation and maintenance of health behaviors [20]. Mobile phones have the potential to connect users with their support networks anytime and anywhere.

The lack of evidence of app effectiveness and description of the procedures or data sources (eg, evidence, theory, or user-centered design) used to develop the app is also concerning. All five previous reviews of health apps have raised this concern [6-10], two of which demonstrated discrepancies between information generated on smartphone applications and evidence-based guidelines [7,8]. Pandey et al [9] found that significantly more iPhone apps designed for health care professionals had scientifically valid information compared to

those designed for patients (96% vs 32%). Although evaluating the credibility of app content was out of scope, and in our view sufficiently addressed in previous reviews, the “iEAT” app in [Multimedia Appendix 2](#) provides a good example of questionable content that lacks cited source material. Our study found that the majority of apps failed to report their organizational affiliation (64.1%, 189/295).

Last, compared to cancer incidence in Canada [28], there is a nearly two-fold over-representation of the percent distribution of breast cancer apps (eg, 45% of apps compared to 26.1% new cases of breast cancer), and a considerable under-representation of prostate, lung, and colorectal apps. In part, this is likely because a large proportion of the apps were intended as awareness-raising tools as opposed to addressing perceived or real need and there is greater charitable activity around breast cancer. The breast cancer fundraising movement is one of the largest and most successful social movements, which other groups seek to emulate [29]. In addition, the overwhelming majority of investment in cancer research in Canada (27%) is focused on breast cancer [30].

There is a need for a whitelist of regulatory body-approved (when necessary), scientifically evaluated, and consumer-recommended mobile health apps. Our study found several apps for melanoma detection that would likely fall under FDA regulation. These apps aim to aid users in determining their melanoma risk by analyzing a digital image of the user’s lesion based on built-in algorithms. A use case study of the accuracy of four of these types of apps to correctly classify 60 melanoma and 128 benign control lesions, found the results to be highly variable: 3 of the 4 apps incorrectly classified 30% or more of the melanoma lesions as un concerning [10]. These types of apps have the potential to cause distress and harm if they provide the patient with advice that is misleading. The FDA maintains a list of apps on its website that have been approved by the agency [23]. The National Health Service (NHS) in the United Kingdom has gone one step further in producing a Library of Health Apps [31] that are reviewed by the NHS to ensure that they are clinically safe and rated by consumers. There are also CONSORT-eHealth reporting guidelines for randomized controlled trials of Web-based and mobile health interventions [32]. Currently lacking is a synthesis

of this information for consumers, reporting standards for app store descriptions, and a set of criteria to aid consumers in selecting health apps. This information could be beneficial to developers, funders, and health professionals as well, and may improve the development of future apps and stimulate work in neglected areas.

Limitations

Our study had certain limitations. First, the review of the smartphone apps was restricted to the commercial descriptions of the apps in the online stores; as a result, certain apps may have been overlooked. Second, a considerable proportion of apps included in this review did not report their release dates, content source, or organizational affiliation in the store description. It is possible that some of this missing information is documented within the app. Third, the search results are dependent on the terms included in the search strategy and the search engines used. We attempted to overcome this limitation by choosing common terms, including multiple smartphone markets, as well as conducting the health literature review. Fourth, we conducted the searches in the Canadian and French mobile markets and, as a result, may have missed cancer apps available in the markets of other countries. Last, our selection criteria (eg, restricting to apps with “cancer” in the title or store description) likely excluded many prevention-related apps. Moreover, we intentionally excluded apps that were not focused on cancer or intended for people affected by cancer. Thus, the apps in the prevention category are likely not representative of all cancer prevention apps.

Conclusions

Overall, this study found a considerable number of cancer-focused apps, available to consumers, of unknown utility and effectiveness. Although mobile devices offer remarkably low-cost, real-time ways to encourage preventive strategies, monitor a host of behaviors, symptoms and physiological indicators of disease, and provide interventions, the evidence base in support of these apps is lacking. Future efforts should focus on improving and consolidating the evidence on the utility, safety, and effectiveness of mobile cancer apps into a whitelist for public consumption.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Mobile app review - literature search strategy.

[\[PDF File \(Adobe PDF File\), 3KB - jmir_v15i12e287_app1.pdf\]](#)

Multimedia Appendix 2

Examples of representative iPhone apps from each category.

[\[PDF File \(Adobe PDF File\), 485KB - jmir_v15i12e287_app2.pdf\]](#)

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Abbreviations

API: application programming interfaces

FDA: Food and Drug Administration

PDA: personal digital assistant

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Original Paper

Text Messaging Data Collection for Monitoring an Infant Feeding Intervention Program in Rural China: Feasibility Study

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Abstract

Background: An effective data collection method is crucial for high quality monitoring of health interventions. The traditional face-to-face data collection method is labor intensive, expensive, and time consuming. With the rapid increase of mobile phone subscribers, text messaging has the potential to be used for evaluation of population health interventions in rural China.

Objective: The objective of this study was to explore the feasibility of using text messaging as a data collection tool to monitor an infant feeding intervention program.

Methods: Participants were caregivers of children aged 0 to 23 months in rural China who participated in an infant feeding health education program. We used the test-retest method. First, we collected data with a text messaging survey and then with a face-to-face survey for 2 periods of 3 days. We compared the response rate, data agreement, costs, and participants' acceptability of the two methods. Also, we interviewed participants to explore their reasons for not responding to the text messages and the reasons for disagreement in the two methods. In addition, we evaluated the most appropriate time during the day for sending text messages.

Results: We included 258 participants; 99 (38.4%) participated in the text messaging survey and 177 (68.6%) in the face-to-face survey. Compared with the face-to-face survey, the text messaging survey had much lower response rates to at least one question (38.4% vs 68.6%) and to all 7 questions (27.9% vs 67.4%) with moderate data agreement (most kappa values between .5 and .75, the intraclass correlation coefficients between .53 to .72). Participants who took part in both surveys gave the same acceptability rating for both methods (median 4.0 for both on a 5-point scale, 1=disliked very much and 5=liked very much). The costs per questionnaire for the text messaging method were much lower than the costs for the face-to-face method: ¥19.7 (US \$3.13) versus ¥33.9 (US \$5.39) for all questionnaires, and ¥27.1 (US \$4.31) versus ¥34.4 (US \$5.47) for completed questionnaires. The main reasons for not replying were that participants did not receive text messages, they were too busy to reply, or they did not see text messages in time. The main reasons for disagreement in responses were that participants forgot their answers in the text messaging survey and that they changed their minds. We found that participants were more likely to reply to text messages immediately during 2 time periods: 8 AM to 3 PM and 8 PM to 9 PM.

Conclusions: The text messaging method had reasonable data agreement and low cost, but a low response rate. Further research is needed to evaluate effectiveness of measures that can increase the response rate, especially in collecting longitudinal data by text messaging.

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KEYWORDS

text messaging; data collection; program evaluation; child nutrition sciences

Introduction

Globally, the proportions of stunting, underweight, and wasting of children younger than 5 years are estimated to be 26%, 16%, and 8%, respectively, and they have attributed to more than 40% of child deaths [1]. In China, the prevalences of underweight and stunting in children younger than 5 years are also high, amounting to 12.6% and 9.4%, respectively, in 2012 [2]. Inadequate breastfeeding and complementary feeding causes undernutrition in young children; thereby, affecting children's survival [3]. The World Health Organization (WHO) recommends exclusive breastfeeding for 6 months and then providing safe and appropriate complementary foods with continued breastfeeding for children up to 2 years of age and beyond [4]. During the past decade, China has adopted the WHO's feeding recommendations and implemented programs to improve feeding practices [5]. However, infant and young child feeding is still suboptimal: the proportion of infants younger than 6 months who were exclusively breastfed was only 27.6%, the proportion of infants aged 6-9 months who received complementary feeding was 43.3%, and the proportion of children aged 12-15 months who received continued breastfeeding was 37.0% [6].

Planning and management are essential for health programs to achieve high coverage of key interventions. Program monitoring aims to evaluate the extent to which activities are completed, such as training, supervision, home visits, and distribution of medicines, supplies, and counseling materials. Indicators related to availability, access, demand, and quality can be obtained through program records and routine reports. Monitoring is crucial for process evaluation of intervention programs, but often difficult to perform in rural areas because there are no adequate primary care records in paper or electronic format that could enable us to monitor indicators such as knowledge of caregivers or proportion of children with anemia who received iron supplements [7].

The quality of data collection is affected by different sources of bias, which together are referred to as the *total survey error* [8]. Total survey error consists of sampling errors and nonsampling errors. The choice of data collection mode influences the extent to which the data are affected by each type of nonsampling error (coverage error, nonresponse error, and measurement error) [9]. There are a wide range of data collection methods for both interviewer-administered questionnaires (including face-to-face and telephone interviews) and self-administered questionnaires (including mailed surveys and computer-assisted surveys) [9]. The face-to-face mode has long been recognized as the gold standard for its effectiveness in securing high levels of participation and, hence, to reduce

nonresponse error [9]. However, in face-to-face surveys, respondents are more likely to modify the true answer to certain types of survey questions to present themselves in a more favorable light than in self-administered surveys [10,11]. In addition, the face-to-face mode is labor intensive, expensive, and time consuming [12], and the increased costs makes it very challenging and extremely costly to be used in large surveys [13], especially in resource-limited settings.

The number of mobile phone holders has increased rapidly worldwide, including in China. By May 2013, there were almost as many mobile phone subscriptions as people in the world (estimated 6.8 billion mobile subscriptions) [14]. In China, there were more than 1.1 billion mobile phone subscriptions in May 2013 [14]. There is a growing interest in using text messages in medical research and this could be an innovative way to collect data for self-administered interviews [15]. Previous studies have evaluated using text messaging for data collection. Haberer et al [16] showed in their qualitative study that participants expressed a high level of acceptance of text message data collection about antiretroviral therapy adherence in a resource-limited setting. Whitford et al [17] found that participants perceived text messaging as an acceptable way of providing data and that researchers found it an easy and functional method of gathering data. Other studies demonstrated that it was feasible to use text messaging to document bleeding episodes in children with hemophilia [18], to collect data on pain after tonsillectomy [19], and to collect frequent data for monitoring the clinical course of low back pain [20]. Studies also indicated that text messaging data collection has many advantages: it is accessible for many people regardless of time, place, or setting, and it can collect information in real time without interviewer bias [12]. In certain cases, it makes it possible to collect longitudinal data [21-23] and can give access to a migrating population and to other participants that are difficult to reach [24,25].

The choice between modes of data collection is guided by data quality, but also by the available organizational infrastructure, estimated costs, predicted nonresponse rate, and length of data collection period [26]. As far as we know, data collection by text messaging has not yet been studied in China. Our study describes a text messaging survey and compares text messaging to face-to-face data collection to monitor an infant feeding program in rural China. We aimed to explore the feasibility of data collection through text messaging to monitor child health programs. If this method is feasible, it can be used to monitor health programs more effectively and guide planning of successful health interventions that can improve child health.

Methods

Overview

This study is part of the evaluation of a large-scale child health intervention program in Zhao County, China. As part of nutrition counseling in this program, we developed a feeding calendar and distributed it to all caregivers to explain the WHO feeding recommendations.

Study Design

All caregivers who received the calendars with information on infant feeding were eligible for recruitment if they met our inclusion criteria. We used the test-retest method [27] and asked participants to complete a survey questionnaire for program monitoring twice: first by text messaging and then by face-to-face interviews. We compared differences between the 2 data collection methods in response rate, data agreement, costs, and acceptability to caregivers. We also explored caregivers' reasons for not replying to text messages, reasons for answer disagreement between the two methods, and the most appropriate time during the day for sending text messages.

Study Setting

This study was conducted in all 16 village clinics in Wangxizhang Township, Zhao County, Hebei Province, China. In Zhao County, approximately 75% of the population has mobile phones and nearly all households have at least 1 mobile phone [28]. Detailed information on the study setting can be found elsewhere [29].

Participants

Before the study, we distributed the infant feeding calendars to pregnant women and caregivers of all children aged 0-23 months in Wangxizhang Township in January 2012. We included participants according to the following criteria: (1) had a child younger than 2 years, (2) received the infant feeding calendar prior to the study, (3) provided their mobile phone number, (4) were willing to receive text messages, and (5) had a mobile phone number that was validated by our text messages from village doctors. We excluded caregivers if their mobile phone number was wrong, if they refused to participate, or if they participated in the pilot study.

Recruitment

We asked village doctors to distribute the infant feeding calendars in their catchment areas supervised by a doctor from Zhao County Maternal and Child Health Hospital. Village doctors were established to introduce health care in rural areas in the 1960s when a village-level cooperative medical scheme was started. However, the quality of care varied widely because funding was variable and most village doctors only received a short period of training or no training at all. Nowadays, village doctors usually have at least primary school or junior high school education and they have a good relationship with villagers [30,31]. We also asked village doctors and the hospital doctor to collect demographic information of children and their caregivers, mobile phone numbers of caregivers, and their willingness to receive text messages. We obtained a list with names of children after distribution of infant feeding calendars.

Then, we sent text messages to all caregivers to validate mobile phone numbers. For those caregivers who did not respond to our text messages, we asked the village doctors to visit caregivers in their homes to verify their mobile phone numbers. We paid the village doctors and the hospital doctor for their efforts. Each village doctor was paid ¥50.0 (US \$7.95) for completion of their work and the hospital doctor was paid ¥50.0 (US \$7.95) per day for 2 days.

Pilot Study

Before the formal study, we conducted a pilot study on caregivers' willingness to receive and reply to text messages. We selected a convenience sample of 38 caregivers aged 22 to 37 years, who were raising a child aged 0-23 months in our study area. After obtaining informed consent and demographic information, we sent text messages to caregivers to test the survey. We asked caregivers about their mobile phone use, experience with text messaging surveys, and how they interpreted our questions. We found that almost every caregiver (94.7%) had their own mobile phone and that almost all (94.7%) were willing to reply to the messages for research. We revised our survey's text messages according to the caregivers' feedback. We added more information to the first and the second message to make it more accurate, included information about the message sender, fees for replying to messages, how to reply to a text message survey, and reduced the total number of questions from 10 to 8. In addition, we made some small changes to the wording of the text messages.

Training of Interviewers

We recruited 3 recent graduates with Bachelor's degrees from medical universities (2010-2011) as interviewers for this study and trained them for half a day on the procedures of the face-to-face survey. We did role-play exercises with the interviewers and discussed problems they encountered to ensure they felt comfortable and confident in conducting interviews and would conduct them with consistency.

Data Collection and Entry Process

We first asked caregivers to participate in the text messaging survey for a period of 3 days (April 15-17, 2012), and then in the face-to-face survey for a second period of 3 days (April 18-20, 2012). According to Hermann Ebbinghaus's test, only approximately 27.8% of newly learned meaningless syllables will be remembered after 48 hours [32]. Our study was about whether caregivers received and read the feeding calendar, their perception of the feeding calendar, and their knowledge on infant feeding, which were meaningful; therefore, we prolonged the time interval to 3 days. Participants were not allowed to look up their answers during the interview. During the study, a team member recorded all the costs data and another team member checked the data.

Text Message Method

Before the formal text messages were sent, we asked village doctors to inform participants. We first conducted the text messaging survey for 3 days. A team member used a smartphone (ME525, Motorola, Tianjin, China) with an Android 2.2 system to send text messages to all participants individually. During the first day, we sent the first question to all participants from

10 am to 8 pm. We sent the next text messages immediately after participants responded between the hours of 8 am and 12 pm. A supervisor (a team member) checked the messages individually to ensure that the messages sent out were correct and that each message had been successfully sent. We sent the messages again if they failed to be sent, if we did not receive a reply within 1 day, or if we received an unclear response. The smartphone automatically saved all original messages and the sending and receiving time. When replying to our text messages, participants were charged ¥0.1 (US \$0.02) per message; for all 8 messages that needed a reply, they were charged ¥0.8 (US \$0.13) at most. In the first survey message, instead of reimbursing text messages' fees, we told participants that caregivers who completed the text message survey (responded to all 8 questions) would receive an infant recipe as a gift for their efforts after the face-to-face interview 3 days later. This was only a small incentive for caregivers; it was worth ¥2.0 (US \$0.32) and the per capita annual net income of rural households was ¥7119.7 (US \$1132.29) in 2012 according to the China Statistical Yearbook [33].

Face-to-Face Method

After the text messaging survey, we did a face-to-face survey during a second period of 3 days. Village doctors informed all 258 participants (including 159 caregivers who did not participate in the text messaging survey) to gather at the village clinics for the interviews and told them the interviews were about infant feeding knowledge. Each interview was conducted in a quiet place where an interviewer asked each participant questions and recorded answers using pen and paper. Each interview lasted approximately 8 to 10 minutes. After the face-to-face survey, a team member checked if the participant had responded to the text messaging survey and if the results were the same for both surveys. Then, interviewers asked the participants questions about their reasons for not replying and about any differences between the text messages and face-to-face responses. For caregivers who participated in both surveys, we

asked them to rate the two methods on a 5-point scale to assess acceptability (1=dislike very much, 2=dislike, 3=ok, 4=like, 5=like very much) [34]. After the interview, the supervisor checked the completeness of all the questionnaires. We gave a towel, worth ¥2.0 (US \$0.32), to the participants for their participation.

Questionnaire

As shown in [Textbox 1](#), the first question participants were asked was about informed consent (only in text messaging survey); there were an additional 7 core questions in both surveys. Participants were not sent any other questions/text messages if they replied "no" to the informed consent question. The 7 core questions were divided into 3 categories: participants' feedback on the infant feeding calendar, participants' feeding knowledge, and the main source of their feeding knowledge. Two questions about participants' feeding knowledge were from the Breastfeeding and Nutrition module of the Maternal, Newborn, and Child Health household survey developed by the WHO; we developed the other 5 questions. All these questions were tested in the pilot study and revised according to the feedback of caregivers.

The text messaging survey consisted of 11 messages: 2 introduction messages which did not need replies, 1 informed consent message which asked whether the participant was willing to participate, 7 messages with the 7 core questions, and 1 thank you message. In the introduction messages, we informed participants who we were, what the aim of the study was, and what benefits (an infant feeding recipe) they could get after completing the text messaging survey.

The face-to-face survey had 27 questions in total: 10 questions about general information of children and participants, the 7 core questions, 7 questions about reasons for disagreement between the same questions, one question about reasons for nonresponse or incomplete replies, and 2 questions about participants' perceptions of the 2 survey methods.

Textbox 1. Text messaging survey content.

Text message 1: Hello! This is the Capital Institute of Pediatrics and Zhao County Maternal and Child Health Hospital. We have given you a feeding calendar and now would like to know how you use the feeding calendar.

Text message 2: This survey does not require extra expenses apart from your normal text message costs, which is 1 jiao per message. Please reply to our text messages. Caregivers who reply to all these messages will get a feeding recipe in a couple of days (do not reply to the previous 2 messages).

Text message 3 (question 1): Please reply to questions one by one. After replying to a question, you will receive the next question. There are 8 questions in total. Do you agree to participate in the survey? Please write the number of your choice below, and then send the message.

1. Yes
2. No

Text message 4 (question 2): Have you or other members of the family read the feeding calendar? Please write the number and send.

1. Yes, I have read it carefully
2. Yes, I have read it
3. Yes, I have read part of it
4. No, I have not read it
5. No, I did not get it

Text message 5 (question 3): In your opinion, is it easy for you to understand the feeding knowledge? Please write the number and send.

1. Yes, it is very easy.
2. Yes, it is easy.
3. Yes, it is ok.
4. No, it is difficult.
5. No, it is very difficult.

Text message 6 (question 4): In your opinion, is the feeding knowledge calendar useful for you to feed your child? Please write the number and send.

1. Yes, it is very useful.
2. Yes, it is useful.
3. Yes, it is ok.
4. No, it is useless.
5. No, it is completely useless.

Text message 7 (question 5): In your opinion, until what age should a child be given only breast milk, without any other food or liquids (including water)? Please write your answer in months, and send.

Text message 8 (question 6): In your opinion, at what age should a child be given meat (such as pork, beef, mutton, chicken, and duck)? Please write your answer in months, and send.

Text message 9 (question 7): In your opinion, until what age should a child be breastfed? Please write your answer in months and send.

Text message 10 (question 8): Where did you receive this feeding knowledge? Please choose the most important one below. Please write the number and send.

1. The feeding calendar
2. Township hospital doctors
3. Village doctors
4. By yourself
5. Relatives or friends
6. Other

Text message 11: You have completed all questions, thank you for your cooperation!

Outcomes

The primary outcomes were the response rate, data agreement, and costs. The secondary outcomes were acceptability, reasons for nonresponse to text messages, reasons for disagreement between the 2 survey methods, and the appropriate time to send text messages.

Response Rate

In both surveys, we defined the response rate in 2 ways: (1) the proportion of participants who answered at least 1 core question, and (2) the proportion of participants who completed all the core questions.

Data Agreement

Data agreement could only be assessed when the same participant participated in both the face-to-face and text messaging surveys. We reported intraclass correlation coefficient (ICC) and kappa values, and the percentage of agreement of responses that were the same for both methods [35].

Costs

We assessed the total costs, costs per questionnaire, the costs per completed questionnaire, and the incremental cost effectiveness ratio (ICER), which was calculated for the proportion of participants who completed all the core questions. The costs included expenses for the two methods from 9 sources: transportation, food, hotel, printing, text message, renting a mobile phone, data entry, payments for interviewers, supervisors, and local coordinators, and gifts for interviewees.

Acceptability of Text Messaging and Face-to-Face Surveys

We defined acceptability as the rating that participants who participated in both surveys gave. We report the median points of caregivers' acceptability scores (on a 5-point scale; 1=dislike very much, 2=dislike, 3=ok, 4=like, 5=like very much) for both surveys.

Reasons for Not Responding to Text Messages

Reasons for not responding were reasons participants gave for not replying to text messages.

Reasons for Disagreement Between the Survey Methods

Reasons for disagreement were reasons caregivers thought may be the reason they gave different answers.

Appropriate Times to Send Text Messages

A better time to send text messages is the time interval when most text messages are replied to. We defined the best time as the time when at least 75% of text messages were replied to within 1 hour of being received.

Data Analysis

We entered data for both surveys into EpiData 3.1 (The EpiData Association, Odense, Denmark). We checked the 2 files and resolved discrepancies by checking the original data in the smartphone or face-to-face questionnaires.

We used the McNemar test to detect differences between the survey methods in the overall response rate. We assessed the data agreement by kappa value (simple kappa for categorical variable, Fleiss-Cohen for ordinal data), ICC for quantitative variables, and percentages of the same answers in both methods [36]. We used the pairwise Wilcoxon rank test and kappa value to compare the caregivers' acceptability for both survey methods. Two team members read and discussed reasons for both nonresponse and inconsistent answers and then classified the answers into different categories. We calculated percentages to describe provided reasons for not responding to the text messaging survey, disagreement in responses between the 2 survey methods, and the appropriate time for sending messages. We used SAS 9.1 (SAS Institute, Cary, NC, USA) for the analysis and we considered a *P* value less than .05 as statistically significant.

Ethical Approval

We obtained ethical approval from the Ethical Committee of the Capital Institute of Pediatrics in Beijing. For face-to-face survey, all surveyed participants read the informed consent form and gave their written consent. For the text messaging survey, participants gave their consent through a text message.

Results

Participants

Figure 1 shows the flowchart of the enrollment of participants. We included 258 (62.6%) participants in our study out of the 412 caregivers who received feeding calendars. Of those 412 caregivers, we had to exclude 62 (15.0%) caregivers because we did not have the mobile phone number for the following reasons: no numbers (35/62, 56%), wrong numbers (3/62, 5%), participated in pilot study (22/62, 35%), or had children aged older than 2 years (2/62, 3%). We sent validation messages to the remaining 350 caregivers and we were able to validate the mobile phone numbers of 71 (20.3%) caregivers who responded. For the 279 (79.7%) caregivers who did not respond to our messages, village doctors were able to recollect 187 mobile numbers. We compared the numbers they found with our own records, but we did not send text messages again to caregivers to validate the numbers. The remaining 92 caregivers whose mobile numbers were not recollected by village doctors were excluded. In all, a total of 258 caregivers were included in this study.

Table 1 lists the total number of participants in the text messaging survey and face-to-face survey and the characteristics of participants and their children. Among the 258 included participants, 99 (38.4%) participated in text messaging survey, 177 (68.6%) participated in the face-to-face survey, and 43 participants (16.7%) participated in both surveys. The age and sex ratios of the youngest child in families were similar for the 2 surveys. Participants who participated in our surveys included primarily mothers, but also fathers, grandparents, and other family members. There were a higher proportion of grandparents in the face-to-face survey (29.4%) than in the text messaging survey (1.0%).

Figure 1. Flowchart of participant enrollment.

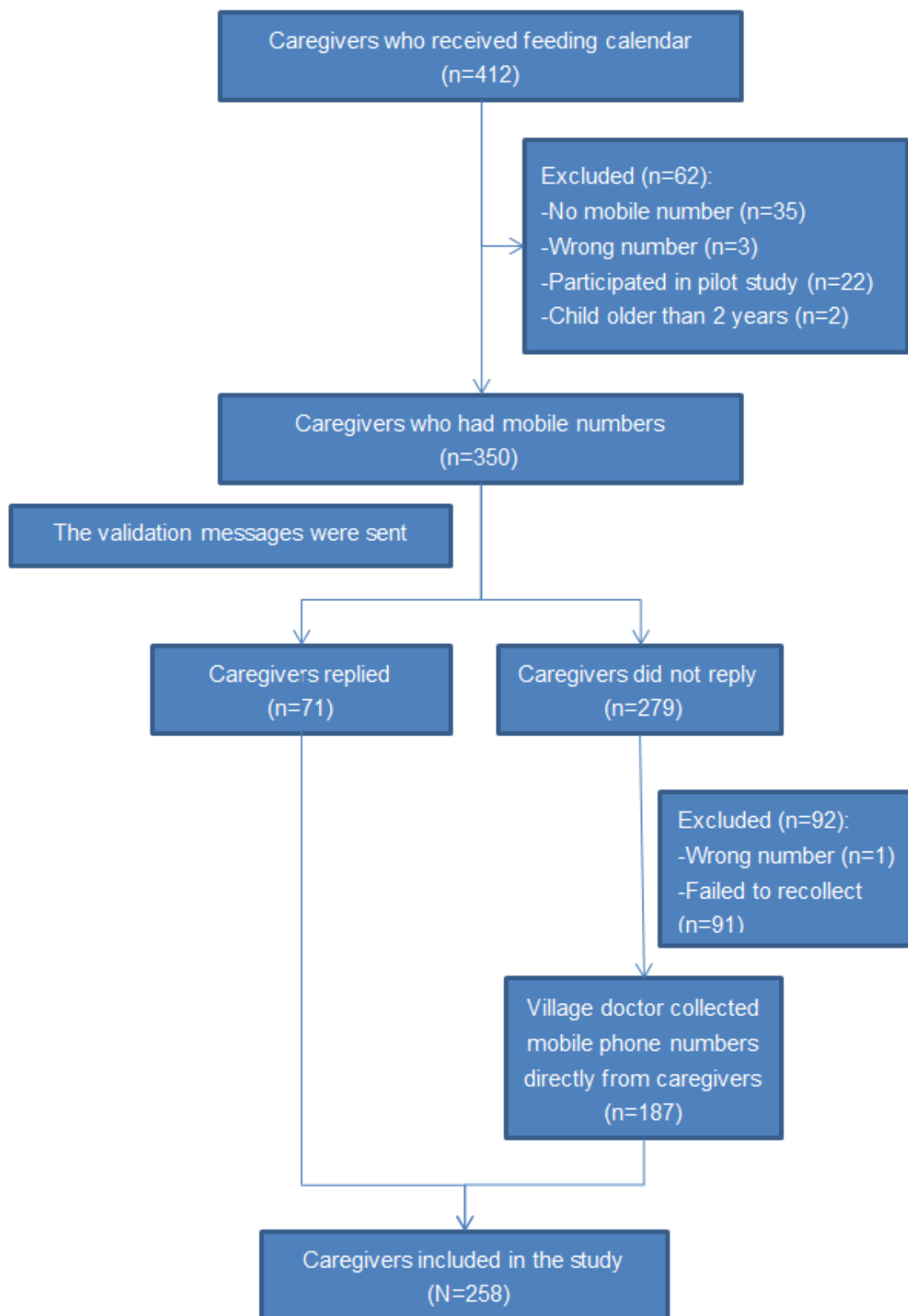


Table 1. Characteristics of survey participants and their children (N=258).

Characteristics	Text messaging survey (n=98)	Face-to-face survey (n=177)
Children		
Age in days, mean (SD)	359.6 (154.5)	359.8 (155.7)
Sex (male/female)	62/37	116/61
Participants, n (%)^a		
Mother	86 (87.8)	115 (65.0)
Father	10 (10.2)	7 (3.9)
Grandparent	1 (1.0)	52 (29.4)
Other	1 (1.0)	3 (1.7)

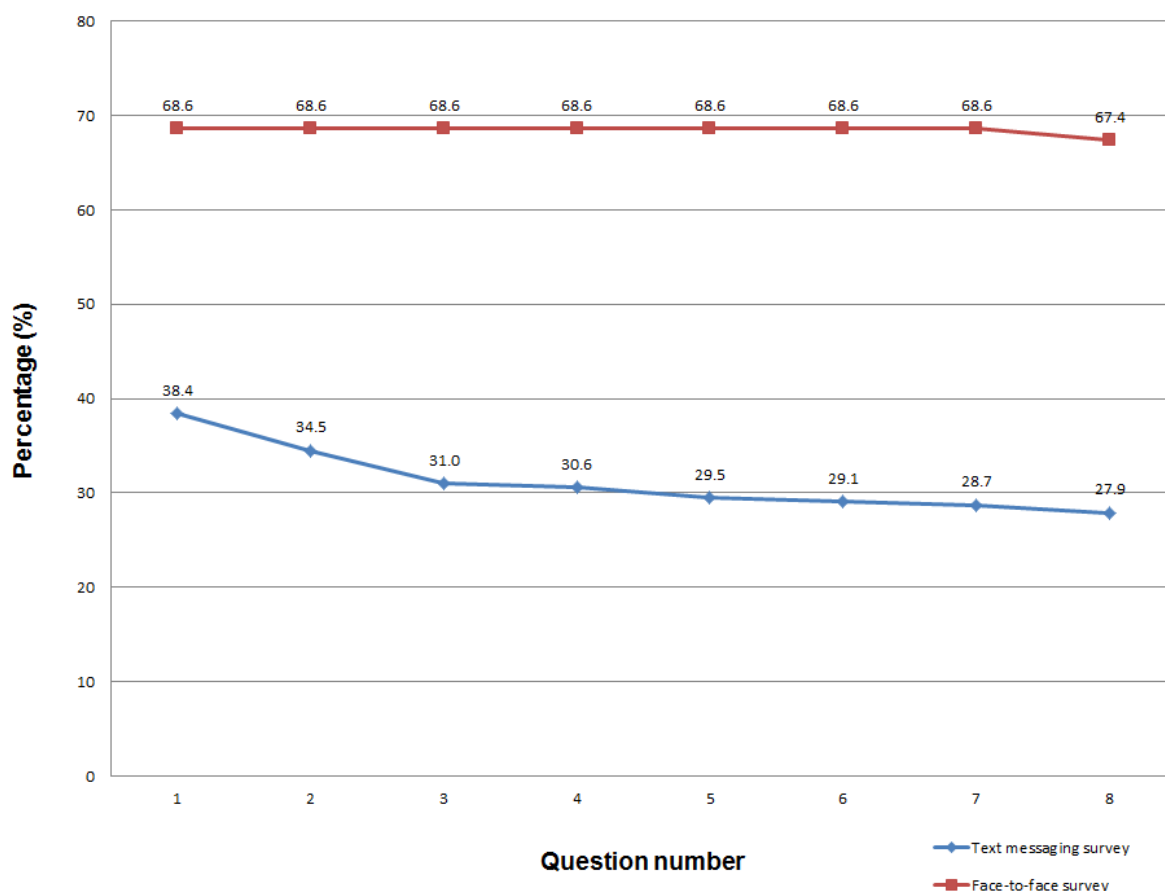
^aData missing for 1 participant in the text message survey group because the interviewer forgot to ask this question.

Response Rate

For the text messaging survey, 99 (38.4%) of 258 participants responded to our first question and 72 (27.9%) completed all 8 questions (72.7% of participants who responded to the first question). For the face-to-face survey, 177 (68.6%) participants

participated and 174 (67.4%) completed all questions. There was a significant difference in the response rate for the first question between the 2 surveys (McNemar test $\chi^2_1 = 46.8$, $P < .001$) and also for the response rate for all questions (McNemar test $\chi^2_1 = 68.6$, $P < .001$). Figure 2 shows the response rates for both surveys.

Figure 2. Response rates for each question in the text messaging and face-to-face surveys.



Data Agreement

There were a total of 255 questions answered by the same participants in both surveys. Table 2 shows that 159 (62.4%) questions had the same answers for both surveys. The lowest proportion of agreement was for the fourth question, with 19 (56%) of 34 responses having the same answers; the highest proportion of agreement was for the last question, with 28 (85%) of 33 responses having the same for both methods. The

Fleiss-Cohen kappa values and ICCs showed a moderate to good agreement for most questions. The Fleiss-Cohen kappa values were .68 (95% CI 0.43-0.92), .50 (95% CI 0.21-0.79), and .23 (95% CI -0.12 to 0.58) for ordinal data (questions 2-4), respectively. The ICC for quantitative data (questions 5-7) were .53 (95% CI 0.29-0.76), .72 (95% CI 0.51-0.86), and .69 (95% CI 0.50-0.83), respectively. Simple kappa for categorical data (question 8) was .76 (95% CI 0.56-0.96).

Table 2. Questions with the same answers in both surveys by the same participants.

Question	Questions by same person, n	Questions with same answers, n (%)	Survey method, median (interquartile range)		Kappa/ICC (95% CI)
			Face-to-face	Text messaging	
2	43	25 (58)	2.00 (1.00, 2.00)	2.00 (1.00, 2.00)	.68 (0.43, 0.92) ^a
3	35	23 (66)	2.00 (1.00, 3.00)	3.00 (1.00, 3.00)	.50 (0.21, 0.79) ^a
4	34	19 (56)	1.00 (1.00, 2.00)	1.50 (1.00, 2.00)	.23 (-0.12, 0.58) ^a
5	29	18 (62)	6.00 (5.00, 6.00)	6.00 (5.00, 6.00)	.53 (0.29, 0.76) ^b
6	29	19 (66)	7.00 (6.00, 8.00)	6.00 (6.00, 7.00)	.72 (0.51, 0.86) ^b
7	31	22 (71)	18.00 (12.00, 24.00)	18.00 (12.00, 24.00)	.69 (0.50, 0.83) ^b
8	33	28 (85)	—	—	.76 (0.56, 0.96) ^c
Total	255	159 (62)	—	—	—

^aFleiss-Cohen kappa

^bICC

^cSimple kappa

Costs

The costs shown in Table 3 are all directly related to the data collection project. The total costs of the face-to-face survey were much higher than the costs of the text messaging survey: ¥5993.1 (US \$953.12) and ¥1954.5 (US \$310.84), respectively. Costs per questionnaire for the face-to-face survey were also higher than for the text messaging survey: ¥33.9 (US \$5.39)

and ¥19.7 (US \$3.13) for all questionnaires, respectively, and ¥34.4 (US \$5.47) and ¥27.1 (US \$4.31) per completed questionnaires, respectively. Table 3 shows the total costs and costs per questionnaire for both surveys. The ICER was calculated to be ¥102.2 (US \$16.25), meaning the cost of the face-to-face survey for each percentage increase of completion rate was ¥102.2 (US \$16.25) compared to the text messaging survey.

Table 3. Cost^a comparison of both surveys.

Item	Face-to-face (¥/US \$)	Text message (¥/US \$)
Transportation	1606.0 (255.41)	0.0 (0.00)
Food for interviewer and supervisor	600.0 (95.42)	300.0 (47.71)
Hotel for interviewer and supervisor	1440.0 (229.01)	0.0 (0.00)
Printing of questionnaires and informed consent form	150.0 (23.86)	0.0 (0.00)
Text message	0.0 (0.00)	166.8 (26.53)
Renting mobile phone	0.0 (0.00)	150.0 (23.86)
Data entry	53.1 (8.44)	29.7 (4.72)
Payment for interviewers, supervisor, and local coordinators ^b	1790.0 (284.67)	1110.0 (176.53)
Gift for participants	354.0 (56.30)	198.0 (31.49)
Total	5993.1 (953.07)	1954.5 (310.84)
Per questionnaire (all questionnaires)	33.9 (5.39)	19.7 (3.13)
Per questionnaire (completed questionnaires)	34.4 (5.47)	27.1 (4.31)

^aBased on ¥/US \$ exchange rate on April 15, 2012.

^bWe asked township health workers and village doctors as local coordinators to collect and validate the mobile phone numbers for text messaging survey and to recruit interviewees for face-to-face survey.

Acceptability of the Text Messaging and Face-to-Face Surveys

Participants who participated in both surveys gave their acceptability scores for both surveys. As indicated in [Table 4](#),

the medians for both the text messaging and face-to-face surveys were the same (median 4) and there was no significant difference between the surveys (Wilcoxon signed rank test=15, $P=.41$, $\kappa=.512$, 95% CI 0.301-0.724).

Table 4. Participants' perceptions of the text messaging and face-to-face surveys (N=43).

Perceptions ^a	Text messaging survey, n			Total
	3 (ok)	4 (like)	5 (like very much)	
Face-to-face survey, n				
3 (ok)	3	2	1	6
4 (like)	3	12	1	16
5 (like very much)	1	5	15	21
Total	7	19	17	43

^aFor both surveys, no participants chose 1 (dislike very much) or 2 (dislike).

Reasons for Not Responding to Text Messages

A total of 159 participants did not reply to our text messages. Of these, 104 (65.4%) participated in the face-to-face survey. Of the 104 participants, 51 (49.0%) were not the holder of mobile phones to which we sent the text messages. We asked

the remaining 48 participants about their reasons for not replying to our text messages (data missing for 5 caregivers because interviewers forgot to ask this question). [Table 5](#) indicates that 19 of 48 (40%) caregivers reported that they did not receive our text messages, and 16 (33%) of them reported that they were too busy to reply or did not see the text message in time.

Table 5. Participant reasons for nonresponse to text messages (n=48).

Reasons	n	%
Did not receive text message	19	40
Too busy to reply or did not see text messages in time	16	33
Did not know how to reply	5	10
Did not want to reply	4	8
Other ^a	2	4
Do not know	2	4

^aOne “did not know that this message needed a reply” the other “forgot to reply.”

Reasons for Disagreement Between Survey Methods

There were 43 participants who answered 255 questions in total: 159 (62.4%) questions with the same answers and 96 (37.6%) questions with different answers when comparing the face-to-face and text message questions. We asked participants for the reasons for disagreement. We obtained 69 answers;

participants did not provide their answers for the remaining 27 questions. Table 6 indicates that for questions with different answers, approximately two-thirds (67%) of participants said they had forgotten their text message answers in face-to-face interview, 1 in 6 participants (17%) changed their answers, and 1 in 10 participants' (10%) said that they misunderstood the text message question.

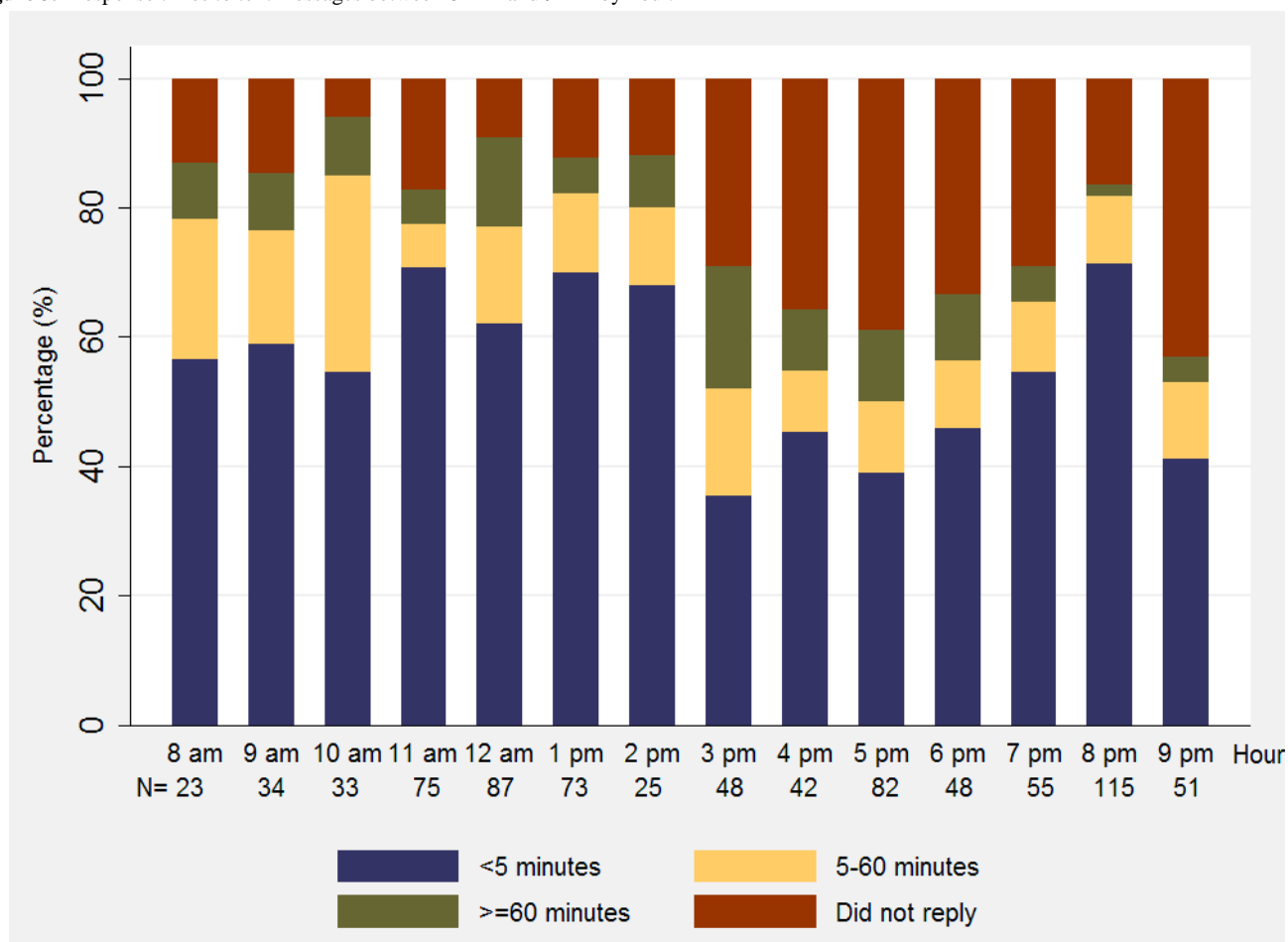
Table 6. Reasons for disagreement between the survey methods (n=69).

Reasons	n	%
Forgot the answer to this question	46	67
Changed ideas	12	17
Writing wrong numbers because misunderstood question in text messaging survey	7	10
Gave wrong answer because misunderstood question in face-to-face survey	2	3
Do not know	2	3

The Appropriate Time to Send Text Messages

The smartphone automatically recorded the time sent and the reply time of each text message. Instead of sending all questions to participants at the same time, we sent the next question only after we received a reply message to the previous question; therefore, some questions were not sent to all participants because of nonresponse for the previous question. We sent 806 text messages in total and received 628 reply messages from

caregivers. Figure 3 shows the time interval between sending and replying to messages across the day (each column represents 1 hour). In this chart, we excluded 10 pm to 11 pm because only 7 messages were sent at 10 pm and 8 messages at 11 pm. Participants responded quicker from 8 am to 3 pm and from 8 pm to 9 pm. During these periods of time, more than 50% of the replied text messages were replied to within 5 minutes and more than 75% were replied to within 60 minutes.

Figure 3. Response times to text messages between 8 AM and 9 PM by hour.

Discussion

Principal Results

Our study showed the text messaging method had a lower response rate, moderate to good data agreement, and lower cost compared to the face-to-face method. Participants who participated in both surveys found the methods similarly acceptable. The main explanations the participants provided for not replying were not receiving text messages, being too busy to reply, or not seeing the text message in time. The main explanations provided by the participants for disagreement were that participants forgot their text message answers and they changed their minds. We also found that participants were more likely to reply immediately after they received text messages in 2 time periods: from 8 am to 3 pm and between 8 pm and 9 pm.

Comparison With Prior Work

A low response rate of a survey sample leads to nonresponse error; therefore, it is a key issue for text messaging data collection. Studies in the literature indicated different response rates, varying from 14% to 100% [12,15-17,37-41]. A study with 2400 randomly selected mobile phone numbers from the Swedish population registry achieved a response rate of 14% [37]. Another study with a small sample size had a response rate of 100% [15]. The response rate in our study was modest, 38.4% for the first question (consent) and 27.9% for all 8

questions in the survey. Among 99 caregivers who replied to the first text message, 74 (74.7%) of them completed all 8 questions. It is promising that interviewees are more likely to complete the text messaging survey when they respond to the first text message question, but the initial response is a key to recruit interviewees. Therefore, there is a need to explore how the response rate can be increased.

Many factors can affect the response rate of text messaging surveys. The initial contact with participants is the first step; however, this often fails because of difficulties in finding functioning mobile phone numbers [37]. An advance letter to introduce the aim and meaning of the survey, benefits to participants, and who the surveyors are could contribute to a higher response rate [42], whereas a foreign phone number might decrease the trustworthiness and lower the response rate [37]. Participants' awareness of the survey and their trust in the surveyors can increase their willingness to respond [15,37]. We asked village doctors, whom most caregivers trust, to verbally inform interviewees in advance, and we sent an introduction message. Participants' professions and education levels also affect the response rate. The participants of the study that had a 100% response rate were undergraduate college students [15], whereas the collection of human immunodeficiency virus (HIV) treatment adherence data by text messaging from HIV-infected children's caregivers who only completed primary school in Uganda indicated very low response rate [16]. In our study, participants were caregivers, including parents and grandparents,

in rural areas and most were farmers with a junior high school education. The illiteracy rate for people aged 15 years and older was 4.07% in rural areas in Hebei province in 2010 [43]. In our pilot study, we did not find that illiteracy was a problem and we expected our target study population was mainly literate. However, this may be different in other study settings. Our pilot study showed that most caregivers could reply to messages, but in our study, approximately 10% of those who did not respond reported that they did not know how to reply to the text messaging survey. This has to be taken into consideration for future research. Sending text messages at an appropriate time could also increase the response rate. Some studies on telephone surveys showed that targeting the call time or calling at an anticipated time was an effective strategy to increase response rate [42]. Bexelius et al [44] found that a lower proportion of participants responded to text messages that were sent at 5 pm, which is usually a time when many people are in transit. Some participants in our study reported that they were too busy to reply or they did not see our text messages in time, which meant that our text messages were not sent to them at a convenient time. However, we found that participants responded more quickly between 8 am and 3 pm and between 8 pm and 9 pm, which could potentially be an appropriate time for sending text messages to our study population. Reminders can increase the response rate. In Kew's study, they sent 3 text message reminders to participants and if that did not work, they reminded participants by calling them [15]. However, in a trial in which a daily reminder message was sent for taking a vitamin C pill for 1 month, only 45% of participants would continue to use it for a longer period of time [45]. Therefore, in our study we sent only 1 reminder message and gave participants 3 days to respond. Further research is needed to test the usefulness and tolerance for reminders in a text messaging survey.

We found that the most important reasons participants' gave for not responding to text messages were that they did not receive the survey text messages or that they were too busy to reply followed by they did not know how to reply or they did not want to reply. Example interventions to solve these problems are to make more effort to have personal contact with participants, let village doctors inform caregivers more actively, send information messages on the research and how to reply, update mobile phone numbers regularly, and send text message at the appropriate times. Further studies need to be conducted to explore in-depth the reasons for not responding and the effectiveness of these approaches on increasing response rates of text messaging surveys.

Data validity is the prerequisite for text messaging to be accepted as a data collection method, and it has been addressed by a small number of studies. Whitford et al [17] found that a text messaging survey had excellent agreement compared to a telephone interview for collecting information on infant feeding. A study comparing telephone interviews and text message data collection for disease symptom reporting also acquired a high degree of agreement [12]. Our study compared a text message survey with a face-to-face survey and found moderate agreement. However, by exploring the reasons for disagreement

between the two methods, we found that nearly 20% of disagreement was because of participants' changing their minds and only 10% was reported to be directly caused by the text messaging method (primarily because of writing the wrong numbers or misunderstanding questions sent by text messages). Further research needs to be done on a larger sample of participants so that kappa values can be calculated.

The cost of the study would change with different study designs. In our study, the costs could be less if a number of factors changed. Firstly, there were fees for data entry because there was no software that could transfer data from the mobile phone text messages to the computer at that time. Therefore, these costs could be deducted for data entry. Secondly, an automated text messaging system can avoid fees by renting the mobile phone and deducting the messages' fees. Thirdly, the nonresponse rate and text message reminders increased the average fees for every questionnaire. Therefore, the higher the response rate, the lower the costs of the survey. Fourthly, the fees for text messages and renting mobile phones will decrease with the rapid development of technology. However, we expect that fees for transportation will increase, and that the fees for food and hotel for interviewers and supervisors, printing, data entry, and gifts for caregivers will not change dramatically in China within a relatively short period. Overall, text messaging data collection methods can potentially save money on program monitoring.

Strength and Limitations

The strength of our study is that we explored the reasons for nonresponse and disagreement between the 2 survey methods. This gave us more insight into why some participants did not respond and why responses were different, and this information could be used for further studies to increase the response rate or validate text messaging surveys. In our study population, the highest responses were achieved from 8 am to 3 pm and between 8 pm and 9 pm, which can guide future text messaging data collection. However, our study had some limitations. First, we used a mobile phone to manually send text messages because we could not find an appropriate text message platform at the time of the study. Second, our sample size for data agreement analysis was small because of the low response rate of the text messaging survey. The reasons for nonresponse and responding differently in the 2 survey methods were asked face-to-face and provided by caregivers, but we have no way to verify their answers. Interviews might be needed to explore the real reason for nonresponse and inconsistent answers.

Conclusions

To our knowledge, this is the first study that explored the feasibility of using text messaging as a data collection method for program monitoring in rural China. Although the text messaging survey was acceptable to interviewees who participated in both surveys and costs were lower than for the traditional face-to-face method, it had a lower response rate than the face-to-face method. Future research needs to evaluate the effectiveness of strategies that can increase the response rate, especially in collecting longitudinal data by text messaging.

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Conflicts of Interest

None declared.

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Abbreviations

HIV: human immunodeficiency virus
ICC: intraclass correlation coefficient
ICER: incremental cost effectiveness ratio
WHO: World Health Organization

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Original Paper

Leveraging Text Messaging and Mobile Technology to Support Pediatric Obesity-Related Behavior Change: A Qualitative Study Using Parent Focus Groups and Interviews

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Abstract

Background: Text messaging (short message service, SMS) is a widely accessible and potentially cost-effective medium for encouraging behavior change. Few studies have examined text messaging interventions to influence child health behaviors or explored parental perceptions of mobile technologies to support behavior change among children.

Objective: Our aim was to examine parental acceptability and preferences for text messaging to support pediatric obesity-related behavior change.

Methods: We conducted focus groups and follow-up interviews with parents of overweight and obese children, aged 6-12 years, seen for “well-child” care in eastern Massachusetts. A professional moderator used a semistructured discussion guide and sample text messages to catalyze group discussions. Seven participants then received 3 weeks of text messages before a follow-up one-on-one telephone interview. All focus groups and interviews were recorded and transcribed verbatim. Using a framework analysis approach, we systematically coded and analyzed group and interview data to identify salient and convergent themes.

Results: We reached thematic saturation after five focus groups and seven follow-up interviews with a total of 31 parents of diverse race/ethnicity and education levels. Parents were generally enthusiastic about receiving text messages to support healthy behaviors for their children and preferred them to paper or email communication because they are brief and difficult to ignore. Participants anticipated high responsiveness to messaging endorsed by their child’s doctor and indicated they would appreciate messages 2-3 times/week or more as long as content remains relevant. Suggestions for maintaining message relevance included providing specific strategies for implementation and personalizing information. Most felt the negative features of text messaging (eg, limited message size) could be overcome by providing links within messages to other media including email or websites.

Conclusions: Text messaging is a promising medium for supporting pediatric obesity-related behavior change. Parent perspectives could assist in the design of text-based interventions.

Trial Registration: Clinicaltrials.gov NCT01565161; <http://clinicaltrials.gov/show/NCT01565161> (Archived by WebCite at <http://www.webcitation.org/6LSaqFyPP>).

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KEYWORDS

child; obesity; overweight; health behavior; text messaging; telemedicine

Introduction

The public health significance of childhood obesity is well-known, as are the complexities involved in supporting obesity-related behavior change in clinical practice. The ubiquitous use of mobile phones in the United States [1] may provide opportunities to support families in health behavior change through the innovative use of applications such as short message service (SMS) text messaging. Text messaging is a widely accessible and potentially cost-effective medium for facilitating behavior change through support and immediate feedback capabilities. In 2012, over 2.3 trillion text messages were sent, and there were more active cell phones than people in the United States [2]. Rates of mobile phone use are highest among historically difficult to access populations including adolescents, young adults, low-income populations, less educated adults, and those with less stable home addresses [3-6].

Prior studies have assessed the influence of text messaging on adult weight loss [7-9], smoking cessation [10,11], asthma management [12], sunscreen application [13], heart failure self-management [14], prenatal care [15], and medication adherence [16]. Fewer studies have been conducted among children and/or their parents. For example, text messaging to support weight management was found to be feasible and acceptable among adolescents [17,18] and has been used to promote adolescent sexual health [19], physical activity [20], and diabetes self-management [3,21,22]. Text messaging directed to adolescents and parents was found to reduce “no-show” rates to medical appointments [23] and promote adherence to vaccination schedules [24,25]. These studies show promising results, yet few studies have assessed text messaging to parents to support ongoing and complex health behaviors such as overweight and obesity management for their children. Parents play a key role in helping their children navigate obesogenic environmental and media influences and as agents of change in modifying weight-related behaviors [26]. Further information is needed to facilitate the design of mobile technology-powered pediatric obesity interventions that target parents as agents of change.

The purpose of this study was to explore parental acceptability and preferences regarding the use of text messaging and other mobile technologies to support pediatric obesity-related behavior change.

Methods

Study Setting and Population

We conducted five focus groups and seven follow-up interviews with parents of overweight or obese children, aged 6-12 years, receiving care at one of two pediatric practices in eastern Massachusetts. We purposively selected two pediatric practices for recruitment in order to obtain heterogeneity in the sociodemographic characteristics of participants. One practice was a part of Cambridge Health Alliance (CHA), a safety net

institution [27] caring for an ethnically diverse and traditionally underserved population. The other was part of Atrius Health, a private institution serving families with a broad range of socioeconomic backgrounds.

Focus group eligibility included parents who (1) had a child 6.0-12.9 years old with a body mass index (BMI) $\geq 85^{\text{th}}$ percentile for age and gender at the most recent “well-child” visit with no other chronic conditions, (2) could communicate in English, and (3) had a cell phone capable of text messaging. The study focused on parents of overweight and obese children in order to obtain opinions and preferences relevant to this high-risk population. Further, the study was limited to school-age children rather than younger children or adolescents, who are distinct in their levels of autonomy over their behaviors and environments.

Recruitment and Enrollment

Participants were recruited from a sample of parents with children meeting the eligibility criteria who had a well-child visit at CHA’s Somerville Pediatrics practice between July 2010 and August 2011 or at Atrius Health’s Dedham Medical Associates (DMA) between April 2011 and September 2011. Study staff sent recruitment letters, with an opt-out phone number, to the parents of 388 children seen at CHA and 297 children seen at DMA. Two parents from CHA and three from DMA called to opt-out. Seven days after mailing the letter, two research assistants began recruitment calls starting from the top and bottom of an alphabetical list of remaining children to establish eligibility, explain the study, answer questions, and schedule parents for focus groups. After attempting calls to over 60% of the CHA sample and the entire DMA sample, they scheduled 39 participants for three focus groups at CHA and 30 parents for two groups at DMA. Calls were discontinued once 12-15 participants were recruited for each group.

During focus groups, the moderator invited parents to submit their contact information voluntarily for potential inclusion in a 3-week mock text messaging intervention and follow-up interview. Participants were selected through stratified random sampling from among volunteers to ensure that 1-2 participants from each focus group were included in interviews. From 11 volunteers, 8 parents were selected and 7 completed interviews.

Data Collection

The study team, which included pediatricians, health services and public health researchers, and an anthropologist, created the focus group guide informed by standard focus group techniques [28] and existing literature on text messaging and mobile technologies. Through several iterations, the focus group guide ultimately included 26 open-ended core questions derived from the study aims and research questions. These questions were supplemented by spontaneous probes and follow-up questions during the focus group discussions. Prior to starting the focus groups, participants completed a brief, anonymous survey on demographic characteristics and mobile technology use and preferences. The focus group questions addressed

parents' perspectives regarding the use of mobile technologies to support them in helping their children adhere to evidence-based behavior goals for obesity prevention (eg, reducing sugar-sweetened beverages and fast food, increasing physical activity, ensuring adequate sleep, and limiting screen time) [29]. Discussion questions focused on message design, clarity, content, relevance, personalization, and potential effectiveness in supporting behavior change. In order to catalyze

discussion during focus groups, parents received six sample text messages about health behaviors on their own mobile phones, including tips and self-monitoring messages to which they were encouraged to reply via text in real time (Textbox 1). In one focus group, text messaging failed and participants received all messages on paper. The focus groups lasted between 90 and 120 minutes, and participants received a light meal and a \$30 gift card for their time.

Textbox 1. Sample text messages received by participants during focus groups and before follow-up interviews.

Sample text messages received by participants during the focus groups

- Most juices and sports drinks are loaded with sugar and calories -- even 100% juice is. When your child is thirsty, water should be the drink of choice.
- How many hours or minutes did your child watch or use screen media on an average day in the last week? *Please text back your response* Thanks!
- Responses (*reviewed on paper*)
 - If meeting goal: Keep it up! You're off to a great start.
 - If almost there: That's not far off the recommended amount. The goal for this behavior is within reach!
 - If needs work: There is work to be done to reach the recommended amount for this goal, but your child can do it. Start with small changes and build up.
- Your child's doctor suggests less than 2 hours a day of screentime. This is time on TV, DVDs, movies, computer & video games. Handheld devices count too!
- Well-rested children make for happier parents. 6-12 year-olds need 10-11 hrs of sleep, and enough sleep can make for better moods and better learning.
- Run, walk, ride, skate, dance, play. What exercise does your child enjoy? The goal is 1 hr/day. If it sounds like a lot, start slowly and build up.

Sample text messages received by participants during the 3-week mock intervention

Week 1:

- Work on the 10-2-1-0 goal for kids! That's 10 hours of sleep, less than 2 hours of TV, 1 hour of physical activity, and 0 sugary drinks.
- How many hours did your child sleep in an average night in the last week? *Please text back your response* Thanks!
- Self monitoring response

Examples:

- Great job! Congratulate your child for being on target with this behavior.
- Your child is close to meeting the recommendation. Work together to think of small steps to help them reach the goal.
- There's a ways to go to meet the goal, but work with your child to start slowly and keep at it.

Week 2:

- Just say no to TV in kids bedrms. Studies show that your child may be more willing to go to sleep, fall asleep faster, & sleep longer w/o TV in the bedrm.
- Skip sugary drinks for kids. Choose water instead. Seem too plain? One parent told us she makes it fun with orange or lemon slices or sparkling water.
- Kids need 1+ hrs moderate-vigorous activity a day. What's that? If moderate, you can talk, not sing. If vigorous, you can say 3 words, then need a breath.

Week 3:

- How many hours or minutes did your child do moderate to vigorous physical activity on an average day in the last wk? *Please text back your response* Thanks!
- Self monitoring response (see examples above)
- Remember, you are your child's role model! Limit your own TV time to help your children do the same.

Focus group volunteers chosen to participate in the mock text messaging intervention received three text messages a week for 3 weeks (Textbox 1) before a one-on-one telephone interview approximately 3-4 weeks after the focus group. In order to deliver the text messages, we contracted with Mobile Commons (Brooklyn, NY), a mobile technology vendor that offers a Web-based platform to support text messaging programs. The follow-up interview guide was informed by findings from the focus groups and further explored parents' real-life experience receiving text messages. Interviews lasted about 30 minutes, and participants received a \$30 gift card for their time.

All participants gave written consent to participate in focus groups and interviews. The Harvard Pilgrim Health Care Institute Human Studies Committee and the CHA Institutional Review Board for Human Subjects Protection approved this study.

Analysis

We used descriptive statistics to summarize participant characteristics based on survey data. The focus groups and interviews were audio-recorded, transcribed verbatim, and imported into QSR International's NVivo 9 software, a qualitative data analysis program. Using a framework analysis approach [30], 2 members of the research team (MS and ED) developed an initial codebook of themes that included a priori themes of interest and new themes that arose after both researchers attended all focus groups and read all transcripts in their entirety. Three research team members (including a qualitative research expert, ED) then coded two transcripts independently and met to reach consensus about the codes to be used. Additional codes were then included in the codebook as new themes emerged. The same team members coded the remaining focus group and interview transcripts while meeting periodically to review and discuss any discrepancies in coding. Analysis involved the systematic comparison of coded segments across the five focus groups and seven interviews transcripts to identify convergent, salient, and/or unique themes. Research staff compiled and shared these interpretations with the larger research team for their final review.

Results

Participant Characteristics and Mobile Technology Use and Preferences

We completed five focus groups with 31 parents (28 mothers and 3 fathers) and seven follow-up interviews with focus group

participants of diverse race/ethnicity and education levels. Table 1 shows results from the brief survey of participants on demographic characteristics as well as mobile technology use and preferences.

The majority of participants had unlimited text messaging cell phone plans (77%, 24/31) and reported text messaging at least once a day (71%, 22/31). A small minority reported any mobile service interruptions (10%, 3/31). Eleven participants (35%, 11/31) reported enjoying texting "a lot" with the remainder reporting "somewhat" (48%, 15/31) or "a little" (13%, 4/31). Only one parent reported ever having signed up to receive text messages about health information. Barriers to more frequent texting listed by parents included cost, preference for talking on the phone, and lack of interest. Among the 19 smartphone owners in the group, 16 reported ever having downloaded and used apps (applications) on their smartphone, and only 2 had ever downloaded a health-related app such as a weight or fitness tracker. All 31 parents reported that they would like to receive text messages from their pediatrician's office with advice about their children's health, and all but one parent were willing to reply via text regarding their children's health behaviors.

Text Messaging Acceptability

Table 2 presents the major themes and representative quotes that emerged from the focus groups regarding text messaging acceptability. Parents were enthusiastic about text messaging interventions and most commonly cited convenience and "ease of use" as advantages. Many characterized text messaging as more effective than other types of communication because its brevity, immediacy, and "hard to ignore" quality make parents more likely to read messages. While some reported more comfort with email than text messaging, many felt inundated with emails and reported consequently ignoring or overlooking many. Some considered the asynchronous nature of text messaging a benefit because you can read and reply to messages when convenient. Many mentioned that text messages are easy to share and show to others, allowing quick dissemination of health messages to family and friends.

Limitations of text messaging described by parents included the difficulty of referring back to messages at a later time and message size constraints. A few parents described less comfort with the technology, and some felt cost would be a barrier for those without unlimited text messaging plans.

Table 1. Participant characteristics and mobile technology use and preferences among 31 participants in parent focus groups.

Characteristics	Mean (SD) or n (%)
Participant characteristics	
Parent age, yrs (range 28-51)	41.1 (6.3)
Child age, yrs	8.7 (1.9)
Race/Ethnicity	
White	20 (65%)
Black	3 (10%)
Hispanic	3 (10%)
Other	5 (16%)
English primary language	20 (65%)
Education completed	
High school	10 (32%)
College	11 (35%)
Post-graduate	8 (26%)
Mobile technology use & preferences	
Text once per day or more	22 (71%)
Enjoy texting “a lot” or “somewhat”	26 (84%)
Unlimited text messaging plan	24 (77%)
Ever signed up for texts about health information	1 (3%)
Own a smartphone that can connect to the Internet	19 (61%)
Ever downloaded an app	16 (52%)
Ever downloaded a health-related app	2 (6%)
Mobile service interruptions (last 12 months)	
Never	27 (87%)
1-2 times	3 (10%)
How frequently would you like to get text messages from your pediatrician’s office with tips/advice about your child’s health?	
Daily	1 (3%)
4-6 times per week	2 (6%)
1-3 times per week	9 (29%)
1-3 times per month	17 (55%)
Less than once per month	2 (6%)
Never	0 (0%)
Willing to reply to text messages from your pediatrician’s office about your child’s health behaviors?	30 (97%)

Table 2. Perceptions of text messaging to parents to support child behavior change.

Perceptions	Representative quotations
Advantages of text messaging	
Convenient	<p>“I don’t have to try to find the information. It comes to me.”</p> <p>“I’m always on my phone. It’s just easier.”</p> <p>“You get a better chance of me getting the message immediately if it’s a text...I just have to read so many emails.”</p>
Brief	<p>“You text people because you don’t want to pick up the phone and get into a half an hour conversation. You want it to be brief.”</p> <p>“I think the pro is that text is brief and it’s done and it’s over with”</p>
Hard to ignore	<p>“It’s immediate, and there’s something about a text that makes you just have to look at it.”</p> <p>“pay more attention...read it right away”</p>
Asynchronous	“My favorite form of communication is the text message just because...you don’t have to answer it immediately.”
Reminder	“I already know that but it’s kind of like...the little angel and devil on your shoulder.”
Easy to Share	“I wouldn’t mind them seeing some of this so it’s not constantly, ‘Mom says I can’t do this, mom says I can’t do this.’”
Limitations of text messaging	
Space limits	“harder to consume a lot of information”
Variable comfort	<p>“I didn’t start to text until the last year or two.”</p> <p>“If she had texted me, I wouldn’t have been able to respond.”</p>
Hard to reference	“If I go and delete that text message, I can’t get it back.”
Cost	“They should know who has the [unlimited text messaging] plan... like not presuming everybody has [it].”

Text Messaging Preferences and Intervention Recommendations

Overview

Table 3 shows participants’ preferences and recommendations for text messaging interventions to support healthy behaviors for children summarized in the following categories.

Content

Parents expressed a need for specific, action-oriented advice and strategies to achieve goals rather than general information on healthy behaviors. Examples of useful information included alternatives to screen time, a “do this, not that” list (eg, a list comparing the effectiveness of a variety of physical activities), lists of healthy snacks, tips/recipes for healthy yet inexpensive meals, and local physical activity events/programs. Initially, some felt they would appreciate messages only about behaviors needing improvement; yet, the sample text messages about behaviors in which their children were excelling were found to be “encouraging”. These parents ultimately stated they would prefer a mix of messages about behaviors their child was doing well and ones that needed work. Participants recommended keeping messages focused on one goal (or set of related goals) at a time to avoid making parents feel overwhelmed with numerous health behaviors; some suggested having weekly themes for message topics. Several parents expressed concerns about creating body image issues and disordered eating habits among their children and wanted sensitive and non-stigmatizing strategies to prevent these issues.

Frequency/Timing/Duration

After receiving the sample text messages, the majority of parents felt that receiving messages twice per week would be appropriate; some parents said they preferred daily messages. This was a notable shift in preference toward more frequent messages compared to the results of the survey completed prior to beginning the groups. There was no consensus on the best time of day to receive messages or even on unacceptable times. Participants felt strongly that they could continue to receive messages indefinitely if the content remained relevant and novel. There was consensus that there should be an option to increase or decrease the frequency of messages.

Voice of Authority

Participants frequently noted that a text from a health care provider would have a “voice of authority”. They anticipated high responsiveness from children simply because the source is someone other than the parent and felt that showing a child or other caregiver a text message could serve as proof to validate the parents’ efforts to encourage behavior change.

Personalization/Customization

Parents felt that the more relevant messages are to their child, the more effective they will be in supporting behavior change. Suggestions for creating and maintaining relevance included tailoring messages to the child’s age, gender, neighborhood, health conditions, preferred goals, and current knowledge. Some imagined messages with the child’s name and even their doctor’s name to make them personal and direct.

Table 3. Parent preferences for text messaging interventions to support child behavior change.

Topic area	Representative quotations
Content	
Specific strategies, “how-to” advice, and resources	<p>“I know what’s good to do [but] how do I get my son to do things I want him to do.”</p> <p>“Everything I get is very generic...‘Let’s eat more vegetables, and let’s not go to McDonald’s’, which doesn’t actually apply. So it’s not necessarily directives or ideas or strategies”. “‘Your kid should exercise.’ Really? I know that. Or, like, ‘Drink water.’ Come on, we know that. Give me something interesting, like there was a new study out, and your kids should eat more of this.”</p>
Weekly themes targeting one health behavior	<p>“I like the idea of themes...If I had to deal with food and screen time and bed time all in the same week, we’d all end up in the nuthouse.”</p> <p>“If it’s random stuff all week, I mean, every week, I would probably be like, ‘OK, enough,’ you know?”</p>
How to prevent issues with body image and disordered eating	<p>“I’m really nervous on how to talk to her...because I don’t want her to feel like there is anything wrong with her... figuring out the best way to approach it so she’s OK with herself and her body image while embracing the correct behaviors to make sure she stays healthy.”</p> <p>“...how would I approach my daughter about food because I don’t want her to keep worrying about ‘I have to eat this, I’m not supposed to eat that.’ I don’t want to stress her out about that.”</p> <p>“How do you make this not something about shame and how do you make it something about healthy eating habits? “...to say, ‘Well, you’re a little overweight,’ that would really crush him. You have to be very careful”</p>
Duration and frequency	
Contingent on relevance	<p>“If it follows your child as your child ages, it could go on until the child is an adult...there could always be new things to say.”</p> <p>“If you are getting these once a week and now its six weeks later and you haven’t really gotten any information that’s interesting to you, then I think I would text stop.”</p> <p>“It starts repeating, you’d be like, ‘OK, I’ve heard it all’.”</p>
Authoritative source	<p>“I think some kids will listen to their doctor better than their parents”</p> <p>“Neither my son nor my husband listen to anything I have to say unless, like, I show them on a website.”</p> <p>“It’s not like your parents are telling you because, of course, whatever your parents say, it’s obviously never true...”</p>
Personalized	<p>“Choose your own adventure”</p> <p>“Here’s a great thing you can do with an avocado...and they’re on sale at [the nearby] Market Basket.”</p> <p>“Have the option to change because sometimes one thing is working real well and then ... you might need more information on another topic.”</p> <p>“What if you filled like a little survey and...I get to pick [the topics]. Don’t send me information about this...Every once in a while you can throw some in, but I really want to focus on these.”</p>
Interactive	<p>“I would love to ideally be able to have someone on-call on text...whatever your question is and then there’s someone that it pops up and they can text you right back.”</p> <p>“If you wanted to get more information that you could reach out. So if at the end of one of the texts it said have questions, call.”</p> <p>“It should go back somehow to the pediatrician, some way, so that we’re almost held accountable during the visit.”</p> <p>“I think if it becomes a mechanism for you to have some kind of ongoing dialogue—a way that you feel connected to your primary care physician, then I think that would extend the longevity of how long I would stay invested in the program.”</p>
Multimodal	<p>“You could text back ‘more’ and maybe something automatically shoots off to your email. You could say ‘to see more, go to this website.’ You can get that within 160 characters.”</p> <p>“If you had it all go to the same website, you could have a little blog. Somebody could say, ‘hey, do you have a healthy Halloween snack?’ And then somebody could tap in if they want to answer back.”</p> <p>“I think if you’re collecting data, there’s some kind of dashboard you see where...you have a graph that shows you your screen time use at the same time show you everybody else’s... I think that could help a lot in terms of helping people change.”</p> <p>“A supportive website that had these exact texts with an area for more resources if you wanted...I don’t need a person. Just a place to go for more information would be fine.”</p>

Interactivity

Most parents preferred an option for “live” support to answer questions. While some envisioned telephone support, most indicated that responses to questions via text message would be sufficient. Some participants preferred that their pediatrician receive their responses and eventually discuss progress with them.

Multimodal

Parents suggested supplementing text messages by linking to email, websites, mobile apps, or patient health portals. Most parents wanted email in conjunction with texts, reasoning that email is widely available, can contain a large amount of information, and may be easier to use for those newer to text messaging. Participants felt that the use of mobile phone apps would be attractive to younger parents. We observed that the discussion around mobile apps was more active among parents at DMA than CHA with an apparent higher acceptability for mobile apps and mobile interventions directly targeted to their children among DMA parents.

Parents frequently discussed integration of text messaging with a website that could record and track progress, perhaps in relation to how others are doing, and serve as a “one-stop shop” for supportive advice, information on local resources and activities, and access to forums, support groups, and research findings. Some reported positive experiences using patient health portals, and one parent recommended tracking parent responses to text messages within their child’s patient portal to facilitate communication with the doctor.

Experiencing the Mock Text Messaging Intervention

The focus groups included rich discussions about hypothetical text messaging interventions. Follow-up interviews with 7 focus group participants who experienced a 3-week mock text messaging intervention ([Textbox 1](#)) substantiated most of the themes generated during the focus groups. These participants felt strongly that text messaging is a convenient way to receive health messages and reiterated the benefits of the immediacy and asynchronous nature of texts. While very little of the information was new to them, they found the majority of information received to be helpful reminders of positive health goals. One parent reported that she “liked the attention [from] people interested in how we manage it with the kids.” Receiving three messages a week between the times of 8 a.m. and 5 p.m. seemed appropriate to most. Two participants would have liked to receive even more messages, while one said they were “kind of a little too many” and stopped responding to messages because she found it burdensome to do so during the holiday season. Many suggestions mirrored those from focus groups: more specific suggestions, personalization, access to a “real person” for questions, and integration with email and Web to enhance interactivity and provide access to more information.

Some parents reported behavior change among their children during the 3-week mock intervention. The ability to share messages, which the children perceived to be from their doctor, was felt to be quite powerful. One parent said, “Every time I tell her she doesn’t listen to me. I said this came from your doctor’s office, and she was happy and said, now I have to start

drinking water.” Two others reported that their children started going to bed earlier, drinking more water, and exercising more. Another participant related a conversation with her son prompted by a text message about the difference between moderate and vigorous exercise. The result of the conversation was that her son chose to go running that afternoon with her because it was more vigorous.

Discussion

Principal Findings

In this qualitative study, parents of overweight and obese children aged 6-12 years reported general acceptability and enthusiasm for text messaging interventions supporting healthy behaviors for children. Parents found text messaging innovative and preferable to paper or email communication because it is immediate, brief, and difficult to ignore. Keys for creating and maintaining relevance included providing novel, relevant information with specific strategies for implementation and personalization of information specific to the child and local community. Most parents favored multimodal interventions utilizing text messaging to relay information and as a trigger or link to other forms of media including email and Web-based platforms.

Prior studies have demonstrated the promise of text messaging interventions in promoting behavior change [3,6-25,32,33], and interventions with features such as tailoring/personalization and a two-way interaction to reduce attrition have observed better results. Yet, few studies have explored the use of mobile technologies directed at parents to support complex, ongoing healthy behaviors in children. In one of the few published studies involving 31 parents and children, investigators observed greater adherence to self-monitoring of sugar-sweetened beverage consumption, physical activity, and screen time among those receiving text messages compared to those keeping paper diaries [34]. Although the study did not evaluate actual behavior or acceptability and preferences among participants, it supports the potential of text messaging as a tool for communication and health behavior tracking.

This study represents a novel exploration of parent preferences regarding text messaging and other technologies to support obesity-related behavior change for their children and presents themes that can guide future interventions. The implementation of such interventions leveraging mobile technologies presents unique opportunities as well as some challenges. Although the ubiquity of cellular telephones is increasing and bridging socioeconomic divides in access, any intervention utilizing mobile technologies like text messaging requires consistent telephone service, reliable and up-to-date contact information, and participant consent to receive text messages per Federal Communications Commission regulations [35]. Furthermore, the interest we observed among parents to receive tailored messages with options for interactivity and eventual feedback from their children’s physicians requires appropriate clinical information systems and demands policies to protect patient confidentiality. The resource implications and incremental benefit of these factors merit further evaluation.

Strengths and Limitations

Strengths of the study design included the sample texts provided during focus groups as well as the mock intervention and follow-up interviews. A few limitations should be considered. The qualitative design and sample size are not intended to determine exact percentages of parents holding a given belief. However, themes recurred in multiple groups and interviews supporting their salience. The results may not be broadly generalizable, although participants were purposively sampled from two practices serving diverse populations. Similar themes emerged at both sites, although participants at DMA indicated higher acceptability for mobile apps and mobile interventions directly targeted to their children. Given the risk for social desirability bias wherein participants seek to appease

investigators and/or conform to dominant opinions, the moderator guides were developed to facilitate frank and open discussions. Finally, information is lacking about parents who did not participate, thus response bias is also possible, that is, participants may not hold representative views regarding mobile communication technologies to support healthy behaviors.

Conclusions

Text messaging is a promising and low-cost medium for supporting pediatric obesity-related behavior change that is easily scalable within a health care system and appears to have high acceptability among parents of overweight and obese children 6-12 years old. Studying actual behavior change in response to text messaging will be a critical next step.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index
CHA: Cambridge Health Alliance
DMA: Dedham Medical Associates
SMS: short message service

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Original Paper

Use of a Text Message Program to Raise Type 2 Diabetes Risk Awareness and Promote Health Behavior Change (Part I): Assessment of Participant Reach and Adoption

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Abstract

Background: There are an estimated 25.8 million American children and adults, equivalent to 8.3% of the US population, living with diabetes. Diabetes is particularly burdensome on minority populations. The use of mobile technologies for reaching broad populations is a promising approach, given its wide footprint and ability to deliver inexpensive personalized messages, to increase awareness of type 2 diabetes and promote behavior changes targeting risk factors associated with type 2 diabetes. As a part of the Beacon Community Cooperative Agreement Program, txt4health, a public-facing mobile health information service, was launched in 3 Beacon Communities: the Southeast Michigan Beacon Community in Detroit, MI, the Greater Cincinnati Beacon Community in Cincinnati, OH, and the Crescent City Beacon Community in New Orleans, LA. Txt4health is a mobile health information service designed to help people understand their risk for type 2 diabetes and become more informed about the steps they can take to lead healthy lives.

Objective: The purpose of this investigation was to use the RE-AIM framework to document txt4health reach and adoption by focusing on enrollment and participant engagement in program pilots in Southeast Michigan and Greater Cincinnati.

Methods: We conducted a retrospective records analysis of individual-level txt4health system data from participants in Southeast Michigan and Greater Cincinnati to determine participant usage of txt4health and engagement with the program.

Results: Results from the retrospective records analysis revealed that 5570 participants initiated the 2-step enrollment process via 1 of 3 enrollment strategies: text message, website, or directly with Beacon staff who signed participants up via the website. In total, 33.00% (1838/5570) of participants completed the 2-step enrollment process and were fully enrolled in the program. All participants (100.00%, 1620/1620) who enrolled via text message completed the entire 2-step enrollment process versus 5.52% (218/3950) of participants who enrolled via website or a Beacon staff member. Of those who fully enrolled, 71.00% (1305/1838) completed the diabetes risk assessment and 74.27% (1365/1838) set an initial weight loss goal. Overall, 39.06% (718/1838) of participants completed all 14 weeks of the program and 56.26% (1034/1838) dropped out before completing all 14 weeks, with the bulk of dropouts occurring in the first 4 weeks. Length of participation varied greatly, ranging from 0-48.7 weeks (median 8.6, mean 15.8, SD 15.8). Wide variability of participant engagement in regards to weekly weight and physical activity was documented.

Conclusions: Although broadly focused public health text message interventions may have the potential to reach large populations and show high levels of engagement among some users, the level of individual engagement among participants varies widely, suggesting that this type of approach may not be appropriate for all.

KEYWORDS

diabetes mellitus, type 2; mobile health; cellular phone; text messaging; risk reduction behavior; program evaluation

Introduction

According to 2011 estimates from the Centers for Disease Control and Prevention, there are 25.8 million American children and adults, the equivalent of 8.3% of the US population, living with diabetes [1]. Moreover, 79 million American adults older than 20 years of age (35%) have prediabetes, a condition characterized by higher than normal blood glucose or glycated hemoglobin levels (a measure of long-term blood sugar control) not yet in the diabetic range [1]. Prediabetes is associated with increased risk for developing type 2 diabetes, heart disease, and stroke [1]. These staggering rates pose a population-level health problem because diabetes is a leading cause of heart disease and stroke, and it is the seventh leading cause of death in the United States [1]. Diabetes is particularly burdensome on minority populations, including African Americans [2-4]; after adjusting for population age differences, 12.6% of non-Hispanic African American adults older than 20 years have diagnosed diabetes and a 77% greater risk of diabetes diagnosis compared to non-Hispanic White adults [1].

Targeting diabetes prevention and self-management of current diabetes is essential for reducing health care expenditures. The total costs attributed to diabetes in the United States is estimated at \$174 billion and estimated medical expenses for diabetics are more than double that of patients without diabetes [1]. Results from the Diabetes Prevention Program (DPP) indicate that counseling and behavior changes that result in modest weight loss and increased physical activity dramatically lower the risk of developing type 2 diabetes, and are more effective than the pharmacologic intervention metformin in the short term and comparable in the long term [5,6]. Despite the effectiveness of the DPP, costs to deliver the program are high. As a result, numerous attempts to adapt and translate the program into alternative, more affordable settings have been made [7-9] and these approaches have been shown to be effective at promoting similar results [10-12]. One strategy for promoting behavior change with the potential to reach a large population is through the use of mobile health (mHealth) interventions delivered via cell phone. With the ubiquity of cell phones in the United States, mHealth approaches have been gaining momentum as a viable intervention delivery modality.

According to recent estimates from the Pew Internet & American Life Project, 91% of American adults own a cell phone and 56% own a smartphone [13]. Moreover, among cell phone users, 80% have used their phone for text messaging, 43% have downloaded apps, and 31% have looked for health or medical information online [14]. The use of mobile approaches for reaching broad populations is a promising strategy given the high penetration and interactive capability of cell phones across diverse populations, particularly in African American and Latino populations, which have traditionally experienced great health disparities. Cell phone adoption has become so pervasive that access in low-income groups is also common, with 86% of

adults with annual household incomes below \$30,000 owning a cell phone [15]. Evidence for the use of mHealth to support behavior change is growing. Systematic reviews of cell phone behavior change interventions utilizing text messaging have shown positive behavior change [16,17], and text message interventions for diabetes [18-22], smoking cessation [23-26], medication adherence [19,21,27,28], and weight loss [29-31] have been documented.

To raise awareness of type 2 diabetes at the population level and to inform individuals of their risk for developing type 2 diabetes, 3 pilots of txt4health, a free automated and personalized 14-week text message program focused on diabetes, were launched in the Detroit, MI, Cincinnati, OH, and New Orleans, LA metropolitan areas through funding from the Beacon Community Cooperative Agreement Program [32]. The purpose of this 2-part investigation was to evaluate the txt4health pilots in Southeast Michigan and Greater Cincinnati through the lens of the RE-AIM framework. In the present paper (Part I), we seek to document the program's reach and adoption; in Part II, we seek to document the program's efficacy in terms of perceptions of program satisfaction, ease of use, and usefulness. In comparison to the majority of previous work that has focused on small scale implementations of mHealth programs [33,34], this txt4health evaluation represents an effort to understand user usage and perceptions of a program operating at scale.

Methods

Overview

This evaluation of txt4health was conducted in 2 parts. In Part I, we conducted a retrospective records analysis of individual-level txt4health system usage data from participants in Southeast Michigan and Greater Cincinnati to determine participant usage of the program, with specific focus on intervention reach and participant adoption. This is the focus of the present paper. In Part II, we conducted a multimodal user survey with Southeast Michigan and Greater Cincinnati txt4health users recruited through txt4health to understand participant perceptions of program satisfaction, use, and behavior change as a result of using txt4health. Results from Part II of this evaluation are provided in the companion paper.

Program Description

Txt4health is an automated, personalized, interactive text message service with a primary goal of helping people understand their risk for type 2 diabetes by offering a diabetes risk assessment. Txt4health further seeks to inform users about the steps they can take to reduce their diabetes risk through sending individually tailored messages over 14 weeks. These messages are tailored according to an individual's diabetes risk profile and focus on diet and exercise, connections to local resources, and educational messages that promote behavior change through weight and physical activity self-monitoring. Moreover, txt4health participants are encouraged to participate

in weekly weight and physical activity tracking. Although the cost to register for txt4health was free to participants, standard text message rates applied. The txt4health intervention has been more fully described previously [32]. To be eligible to participate in the txt4health pilots, users had to self-report residing in a ZIP code in 1 of the 7 Southeast Michigan Beacon Community (SEMBC) or the 16 Greater Cincinnati Beacon Collaborative (GCBC) counties.

Program Enrollment

To enroll in txt4health, users were required to complete a 2-step enrollment process, which could be completed in 1 of 3 ways. First, participants could initiate enrollment through texting the word “health” to the short code 300400, which generated an automated text response requiring users to text back their ZIP code to validate their participation and complete the enrollment process. Second, participants could enter their cell phone number and ZIP code into an online enrollment utility available on the txt4health website. Once registered online, an automated text response requesting users to validate their cell phones by texting a reply was generated and sent via text message to the participant’s cell phone. Third, participants could initiate enrollment through providing a cell phone number and ZIP code directly to SEMBC and GCBC staff members who entered this information for potential participants into the online enrollment utility. This would then generate the same automated text response requiring users to validate their cell phone and confirm their participation by texting a response to txt4health. Enrollment procedures have been fully described previously [32].

Upon enrollment in txt4health, participants were offered a diabetes risk assessment that included an optional health profile,

consisting of self-reported weight and height, from which a suggested weight loss goal was calculated (for individuals for whom weight loss was recommended). Participants were then asked to set a target weight goal. Once the health profile was complete, participants were asked to complete an optional 8-item diabetes risk assessment via text message (1 question per text message). Diabetes risk assessment items included self-reported age, daily physical activity level, gender, gestational diabetes screen of having diabetes while pregnant or having given birth to a baby more than 9 lb (if the participant was a woman), sibling history of diabetes, parental history of diabetes, ethnicity, and smoking status. See Table 1 for the full list of assessment items.

Although participants were asked to complete the health profile and diabetes risk assessment questions, these were not required for enrollment. Once enrolled, participants received approximately 5 to 7 messages per week for 14 weeks. Depending on an individual’s health profile and the level of interactivity, participants received tailored messages from 1 of 2 message streams: high risk messages or low/unknown risk messages. At the end of each week, all participants were asked to report their current weight and the number of days they were physically active over the past week. Individuals also received geographically localized text messages that included information on issues and events locally relevant to the audience (ie, advertisement of local health fairs, health-related resources, or time-sensitive subject matters). Finally, every 4 weeks, participants received a text message that reiterated instructions on how to opt out of txt4health or to access assistance.

Table 1. Items from the txt4health diabetes risk assessment.

Topic	Message from txt4health
Age	This is a sensitive question, but stick with me, it’s important. How old are you? Reply with your current age in years (for example, 57).
Physical activity	How much exercise do you get in a usual day? Reply 1 if you get little or no exercise or Reply 2 if you are very active most days.
Gender	In order for me to give you helpful information, I need to know if you are a male or a female. Reply 1 for Male or 2 for Female.
Gestational diabetes screen	Your past helps determine your risk for diabetes. Did you have diabetes while pregnant OR give birth to a baby over 9 lbs? Reply YES or NO.
Family history (sibling)	Tell me about your family history. Do you have a brother or sister with diabetes? Reply 1 for Yes; 2 for No; or 3 if you do not know.
Family history (parental)	You only have 3 more questions left! What about your parents? Do either of them have diabetes? Reply 1 for Yes; 2 for No; or 3 if you do not know.
Ethnicity	What is your ethnicity? Reply 1 for White; 2 for Black/African American; 3 for Hispanic/Latino; 4 for Asian/Pacific Islander; 5 for Other.
Smoking status	Let’s talk about smoking for a minute. You can be honest with me. Do you smoke cigarettes? Reply YES or NO.

Program Rollout

The txt4health pilots launched in February 2012. In Southeast Michigan, txt4health was launched as a part of a larger, broad-based public health campaign called Fighting D in the D, a public health campaign launched by the SEMBC in the greater Detroit area to promote type 2 diabetes awareness.

Txt4health was used as a call to action within the larger Fighting D in the D campaign. This campaign began with a kickoff event featuring a keynote address by US Surgeon General Regina Benjamin, MD, and a community roundtable featuring health care leaders of Southeast Michigan. The campaign was further disseminated via earned and paid media in the form of newspapers, radio, and television commercials, high-profile

awareness-based “street teams,” partner-based communications, social media, health fairs/expositions, and a variety of other avenues across the 7 county service areas for txt4health in Southeast Michigan. Although txt4health was available throughout the entire 7-county region in Southeast Michigan, particular dissemination emphasis was strategically focused on microtargeting 36 ZIP codes identified via third-party syndicated data as having high concentrations of individuals living with diabetes. At the outset, SEMBC staff members developed target enrollment estimates of at least 3000 individuals from the 7-county region.

In the Greater Cincinnati area, txt4health was launched with a kickoff event featuring Tim Ingram, Hamilton County Public Health Commissioner, and hosted by Kroger, a prominent grocery store chain in the region. Cincinnati efforts were coordinated by GCBC and Hamilton County Public Health and marketed with the slogan: “A text a day keeps the doctor away.” The Greater Cincinnati area txt4health pilot was disseminated via social media and health fairs/expositions, earned media, and outdoor and radio advertising, in addition to other outreach tactics across the 16-county GCBC catchment area. At the outset, GCBC staff members developed target enrollment estimates of at least 10,000 primary care patients with obesity, hypertension, and/or other prediabetic indicators. Additional information regarding the SEMBC and GCBC marketing strategies for txt4health have been more fully described previously [32].

Program Evaluation Framework: RE-AIM

Overview

We utilized the RE-AIM framework to guide this evaluation, which is a model that provides a systematic approach to guiding the planning, evaluation, reporting, and review of health promotion interventions. Since its development in 1999 by Glasgow et al [35], the RE-AIM framework has been utilized extensively in the planning, evaluation, reporting, and review of health promotion interventions with a public health and community-based focus. The RE-AIM framework includes 5 dimensions: reach, efficacy, adoption, implementation, and maintenance. When considering each of these 5 dimensions independently, this systematic approach can lead to a more comprehensive understanding of the public health impact of a health promotion intervention. In this paper, we focus on the reach and adoption elements of RE-AIM.

Reach

Reach is an individual-level measure referring to the number of intended participants in a program [35]. By systematically considering participants who utilize a program in comparison to the target population, an understanding of the representativeness of a sample can be achieved. Within the present txt4health evaluation, reach refers to the individuals from subject service areas that initiated enrollment in txt4health.

Adoption

Adoption is an organizational measure that refers to the proportion and representativeness of settings that adopt a program [35]. Because txt4health targets individuals, not clinics

or specific settings, we assessed adoption on an individual level. Within the present evaluation, adoption refers to individual participant enrollment, dropout, and engagement with txt4health.

Procedures

We performed a retrospective data analysis of existing deidentified system-level usage data compiled through txt4health. The Wayne State University Institutional Review Board approved this study with a waiver of written consent for the retrospective records analysis.

Measures

The system-level dataset contained information collected from participants including ZIP code, date of enrollment, and the date the participant dropped out (if applicable), as well as any available health profile (height and weight) and diabetes risk assessment (age, physical activity level, gender, gestational diabetes screen of having diabetes while pregnant or having given birth to a baby over 9 lb if participant was female, parental family history of diabetes, sibling history of diabetes, ethnicity, and smoking status) information. Because providing diabetes risk assessments to participants was the chief focus of txt4health, the number of participants who completed their risk assessment was our primary engagement measure of interest.

As secondary measures of engagement, we calculated the number of times a participant responded to their weekly weight and physical activity assessment, which was used to classify adherence with weight or exercise tracking. Participants who did not log any data were considered nonadherent to tracking, whereas participants who logged 4 times or less were classified as low adherers, 5 to 8 times were classified as medium adherers, and 9 or more times were classified as high adherers. In addition, from enrollment date to dropout date, we calculated the length of time that a participant was enrolled in txt4health. To better understand the influence of race, self-reported race data was recategorized into White and non-White classifications. Unfortunately, because Beacon staff members who were assisting potential participants with enrollment used the same website interface as an individual who was attempting to sign up via the website on their own, there was no way to determine which website enrollment initiations were assisted by Beacon staff and which were initiated by individual users.

Data Analysis Strategies

We conducted descriptive statistics to describe participant enrollment, dropout, engagement, and participant characteristics based on health profile and diabetes risk assessment data. Continuous variables were expressed as mean (SD) and means were compared using 2-tailed unpaired independent samples *t* tests. Categorical data were displayed as frequencies and percentages, and chi-square tests were used for comparison. Multiple regression analyses were used to predict time spent in txt4health, whereas logistic regressions were used to predict program completion, weight goal setting, weekly activity tracking, and weekly weight tracking. Because of the highly skewed nature of weekly weight and activity tracking, we dichotomized these outcome variables into those participants who tracked 2 or more times versus those who did not. All regression models controlled for the continuous variables body

mass index (BMI) and age, as well as the dichotomous variables gender, amount of exercise in a usual day, Beacon Community affiliation (Southeast Michigan or Greater Cincinnati), White or non-White race, and smoking status. Moreover, chi-square analyses were used to explore potential differences between participants affiliated with the Southeast Michigan or Greater Cincinnati Beacon Communities. Significance levels were set at a *P* value equal to or less than .05. All statistical analyses were carried out using STATA version 11.0 (StataCorp LP, College Station, TX, USA).

Results

Reach

During the 10-month txt4health pilots, 5570 people initiated enrollment by using 1 of the 3 2-step enrollment processes: 1834 in Southeast Michigan and 3736 in Greater Cincinnati. In Southeast Michigan, enrollment was initiated equitably between text message (47.38%, 869/1834) and website sign-up (52.62%, 965/1834); whereas in Greater Cincinnati, 79.90% (2985/3736) of enrollments were initiated through the website. Across both pilots, 33.00% (1838/5570) of participants who initiated enrollment completed the 2-step enrollment process. Of participants who initiated enrollment via text message, 100.00% (1620/1620) completed the 2-step enrollment process, compared to 5.52% (218/3950) of participants who initiated enrollment via the website. Refer to Figure 1 for an illustration of participant flow.

In Southeast Michigan, 14.1% (136/965) of participants who initiated enrollment via website completed the 2-step enrollment process, compared to 2.75% (82/2985) in Greater Cincinnati. Website-initiated sign-ups included both participant-initiated website enrollments as well as participants who signed up with Beacon staff members, who later initiated enrollment on the website on behalf of the participant (which anecdotally comprise the vast majority of these enrollment initiations). Because both enrollment mechanisms used the same website interface, it is not possible to distinguish between participants who enrolled through either of these mechanisms.

In total, 71.00% (1305/1838) of participants furnished sufficient personal information to be categorized by diabetes risk level. From the data that was available, txt4health users were an average age of 41.2 years (SD 12.4), predominantly female (67.0%, 641/957), nonsmokers (83.36%, 912/1094) who engaged in little or no exercise on a typical day (62.48%, 701/1122), were obese with a BMI ≥ 30 kg/m² (52.31%, 828/1583) and an average BMI of 32.1 kg/m² (SD 9.2), and had an average weight of 203 lb (SD 60.0). The participant sample was racially diverse; 58.0% participants were White (472/814) and 35.4% were African American (288/814). In addition, of those with an assigned risk for developing diabetes based on the txt4health diabetes risk assessment, the majority were at high risk for developing diabetes (65.29%, 852/1305). See Table 2 for a complete breakdown of txt4health participant characteristics.

Figure 1. Participant flow through txt4health.

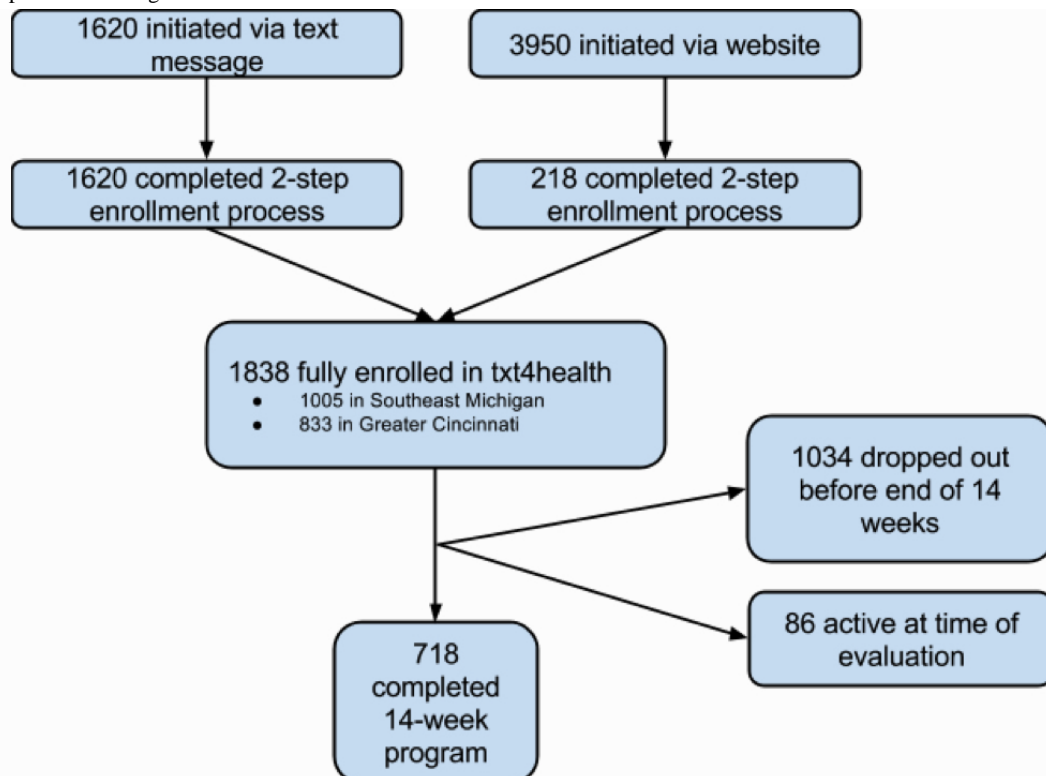


Table 2. Characteristics of txt4health users (N=1838).

Participant characteristic	Southeast Michigan	Greater Cincinnati	Total
Gender, n	509	448	957
Female, n (%)	329 (64.6)	312 (69.6)	641 (67.0)
Male, n (%)	180 (35.4)	136 (30.4)	316 (33.0)
Age, n	763	602	1365
Mean (SD) ^a	42.9 (12.4)	39.1 (12.0)	41.2 (12.4)
Ethnicity, ^a n	421	393	814
White, n (%)	193 (45.8)	279 (71.0)	472 (58.0)
Black/African American, n (%)	197 (46.8)	91 (23.2)	288 (35.4)
Hispanic/Latino, n (%)	13 (3.1)	8 (2.0)	21 (2.6)
Asia/Pacific Islander, n (%)	10 (2.4)	6 (1.5)	16 (2.0)
Other, n (%)	8 (1.9)	9 (2.3)	17 (2.1)
Physically active, n	601	521	1122
Very active, n (%)	222 (36.9)	199 (38.2)	421 (37.5)
Little or no exercise, n (%)	379 (63.1)	322 (61.8)	701 (62.5)
Current weight category, n	888	695	1583
Underweight, n (%)	6 (0.7)	12 (1.7)	18 (1.1)
Normal, n (%)	164 (18.5)	146 (21.0)	310 (19.6)
Overweight, n (%)	238 (26.8)	189 (27.2)	427 (27.0)
Obese, n (%)	480 (54.1)	348 (50.1)	828 (52.3)
Parents family history, ^b n	421	379	800
No, n (%)	238 (56.5)	250 (66.0)	488 (61.0)
Yes, n (%)	168 (39.9)	113 (29.8)	281 (35.1)
Do not know, n (%)	15 (3.6)	16 (4.2)	31 (3.9)
Sibling family history, ^a n	421	379	800
No, n (%)	311 (73.9)	318 (83.9)	629 (78.6)
Yes, n (%)	86 (20.4)	39 (10.3)	125 (15.6)
Do not know, n (%)	24 (5.7)	22 (5.8)	46 (5.8)
Gestational diabetes screen, ^c n	314	308	622
No, n (%)	256 (81.5)	256 (83.1)	512 (82.3)
Yes, n (%)	58 (18.5)	52 (16.9)	110 (17.7)
Smoker, ^a n	612	482	1094
No, n (%)	531 (86.8)	381 (79.0)	912 (83.4)
Yes, n (%)	81 (13.2)	101 (21.0)	182 (16.6)
Risk category, ^a n	725	580	1305
High, n (%)	496 (68.4)	356 (61.4)	852 (65.3)
Low, n (%)	229 (31.6)	224 (38.6)	453 (34.7)

^aSignificant difference ($P < .001$) found between Southeast Michigan Beacon Community (SMBC) and Greater Cincinnati Beacon Collaborative (GCBC) participants.

^bSignificant difference ($P < .05$) found between SMBC and GCBC participants.

^cGave birth to baby >9 lb.

Adoption

Overview

To assess txt4health adoption, we focused on 2 domains: participant dropout and engagement.

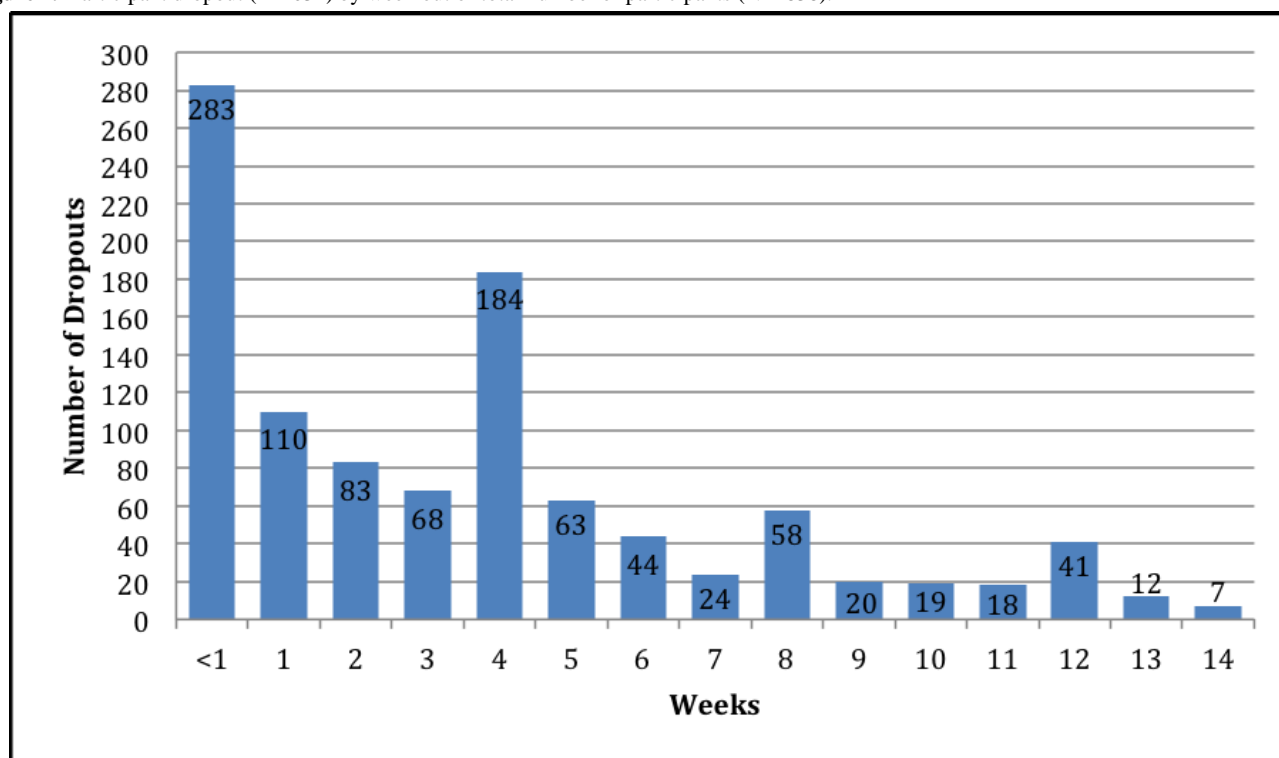
Participant Dropout/Retention

Of the 1838 participants who completed the 2-step enrollment process, 39.06% (718/1838) completed the program by receiving 14 weeks of messages, 56.26% (1034/1838) dropped out before the end of the 14-week program, and 4.68% (86/1838) were still active at the end of 2012 (Figure 1). Length of participation varied greatly, ranging from 0 to 48.7 weeks (median 8.6 weeks; mean 15.8 weeks, SD 15.8). In total, 718 participants were retained throughout the program. Participant dropout was highest within the first 7 days of the program. Of the 1034 people who dropped out, 27.37% (283/1034) exited the program before the participant completed the first week of txt4health. The bulk of participant dropout occurred within the first month of the program, with 70.41% (728/1034) occurring before the end of the fourth week. Although rates of participant dropout had a relatively steady decline over the course of the 14-week

program, there were spikes in dropout rates during weeks 4, 8, and 12, which coincided with the scheduled messages reminding participants how to opt out of the program. See Figure 2 for a breakdown of participant dropout by week.

No significant differences were found in rates of dropout between participants who enrolled via text message versus other enrollment pathways. Using logistic regression and controlling for the continuous variables BMI and age, as well as the dichotomous variables gender, amount of exercise in a usual day, Beacon Community affiliation (Southeast Michigan or Greater Cincinnati), White or non-White race, and smoking status, race was the only participant characteristics that was a significant predictor of program completion, with non-White participants being more likely to complete the program than White participants (OR 2.35, 95% CI 1.66-3.31, $P<.001$). Regarding the length of time spent in txt4health, age ($\beta=.10$, $P=.048$) and non-White race ($\beta=5.42$, $P<.001$) were significant predictors of the number of weeks in the program with non-White participants completing more weeks of the program than White participants (mean 21.5 weeks, SD 14.7 and mean 16.0 weeks, SD 14.4, respectively; $t_{812}=5.28$, $P<.001$).

Figure 2. Participant dropout (n=1034) by week out of total number of participants (N=1838).



Participant Engagement

To determine participation engagement, we looked at 4 different measures: diabetes risk assessment completion (primary measure of participant engagement), weight goal setting, weekly weight reporting, and weekly activity reporting (secondary measures of participant engagement). Of the 1838 participants who completed the 2-step enrollment process, 71.00% (1305/1838) completed the diabetes risk assessment. Moreover, 74.27% (1365/1838) set an initial weight loss goal at the beginning of the program. Using logistic regression analysis, several

demographic variables were found to be significant predictors of weight goal setting. For each 1 kg/m² increase in BMI, there was a 15% increase in likelihood of setting a weight goal (OR 1.15, 95% CI 1.09-1.21, $P<.001$), and for each 1 year increase in age, there was a 5% increase in likelihood of weight goal setting (OR 1.05, 95% CI 1.02-1.07, $P<.001$). In addition, females were more likely to set initial weight goals (OR 2.40, 95% CI 1.43-4.03, $P=.001$), as were White participants (OR 1.76, 95% CI 1.04-2.98, $P=.04$).

Over the course of the program, 89.17% (1639/1838) of enrolled participants tracked their current weight and 54.62%

(1004/1838) tracked the number of days they had been physical active over the previous week at least once. When categorizing participants into low, medium, and high adherers to weekly weight and physical activity reporting, most participants were considered to be low adherers (logging 4 times or less over 14 weeks) for weight tracking (80.25%, 1475/1838), whereas most participants were either low adherers for activity tracking (30.58%, 562/1838) or not adherent at all, having never logged a weekly activity report throughout their program (45.38%, 834/1838). Although 13.60% (250/1838) of participants were highly adherent to weekly activity tracking, only 1.20% (22/1838) of participants were considered to be high adherers to weekly weight tracking.

When looking strictly at participants who completed the 14-week program (excluding dropouts and currently active participants), adherence rates for tracking weekly weights were low for program completers. Among txt4health users who received the full complement of tailored messages over the 14-week period, 71.4% (513/718) were categorized as low adherers for weight tracking and 6.8% (49/718) were completely nonadherent to weight tracking. Only 3.1% (22/718) of completers were highly adherent to weekly weight tracking. Patterns of tracking adherence varied for weekly activity reporting with 28.6% (205/718) of txt4health completers classified as low adherers and 22.7% (163/718) classified as completely nonadherent, yet 31.9% (229/718) were classified as high adherers, having logged a weekly activity amount at least 9 or more times. Using logistic regression, age was found to be a significant negative predictor of tracking weight 2 or more times (OR 0.98, 95% CI 0.97-1.00, $P=.03$) and physical activity 2 or more times (OR 0.98, 95% CI 0.96-0.99, $P=.001$). In addition, White participants were more likely to track weekly weights 2 or more times than non-White participants (OR 1.6, 95% CI 1.15-2.26, $P=.006$). Finally, females were less likely than males to track weekly activity 2 or more times (OR 0.64, 95% CI 0.45-0.91, $P=.01$).

Discussion

Reach

The campaigns launching txt4health in Southeast Michigan and Greater Cincinnati were broadly disseminated through a variety of different mechanisms, including high-profile kickoff events and other launch-related activities that garnered significant local, regional, and even national media attention. Because of the tremendous amount of earned media press on top of other dissemination avenues used by the Beacon Communities, it is near impossible to estimate the number of people who were exposed to txt4health. Despite this, we can make a fair generalization that given the estimated population of Detroit and Cincinnati (approximately 700,000 and 300,000, respectively) [36,37], which represent only a small portion of the entire catchment areas of these Beacon Communities, the actual reach of txt4health, as estimated by the number of individuals who initiated the 2-step enrollment process ($n=5570$), was small. Undoubtedly, the number of people who enrolled in txt4health was a fraction of the number estimated by both Beacon Communities at the outset. Although we do not

know why actual enrollment numbers were far lower than initial expectations, it is possible that either initial estimates were too high, or that campaign exposure and community response was lower than expected. Currently, the Crescent City Beacon Community in New Orleans, LA (the third Beacon Community to pilot txt4health), is attempting to shed light on this matter by undertaking efforts to measure campaign exposure of their own txt4health rollout within their community. Future work should seek to more acutely measure public health campaign exposure for txt4health by surveying a random sample of community members about txt4health awareness because the actual rates of program enrollment initiation may be a poor proxy for campaign reach. By obtaining better estimates of campaign exposure, it may be possible to tease out whether the campaigns promoting txt4health in the greater Detroit and Greater Cincinnati areas were not as effective as they could have been, or if consumer interest in txt4health was low. Despite the small enrollment numbers in comparison to the larger communities, according to the demographic information users supplied to the program for tailoring purposes, it appears that txt4health did reach the diverse target population at risk for developing type 2 diabetes.

Although the literature is sparse in regards to users of public health-focused text message programs, 2012 estimates from the Pew Internet & American Life Project reveal that only 9% of cell phone owners receive health/medical information via text message. In comparison to other cell phone owners, women and adults aged 30-64 years are more likely to receive health/medical text messages [38]. These trends were reflected in our findings. Although there exist examples in the literature of public health-focused mHealth interventions operating at scale, these often do not provide a good evidence base for what to expect in terms of user demographics of these types of interventions in the United States because they often originate internationally, such as the txt2stop program in the United Kingdom [24], or have only reported on regional usage of large programs, such as txt4baby [39]. Because the literature on broad-based public health-focused text messaging programs operating at scale is still underdeveloped, future research should strive to establish estimates of reach among the larger US population.

Distilling further down into the enrollment process reveals that only 33.00% of individuals who initiated enrollment completed both steps in the 2-step process. Previous work with Internet-mediated interventions has found similar patterns of potential participants not completing enrollment processes [40]. We attribute the fact that approximately two-thirds of our potential participants did not complete the enrollment process to the combination of the 2-step enrollment process and the website-initiated enrollment avenue. The 2-step enrollment process required participants to double opt-in to ensure that they were really willing to participate. Although slight, this process places additional burden on participants, which is exactly what this interaction was meant to do. Double opt-in procedures are common for text message programs because of regulatory requirements and are intended to ensure that participants really do want to participate in these programs.

Because of the added burden of the double opt-in enrollment process on participants, it seems logical that alleviating this burden by utilizing Beacon staff to initiate enrollment on behalf of potential participants, who signed up at community events, would yield higher rates of enrollment. After consideration of our results, we believe that this strategy was not effective; in fact, we believe this strategy artificially overinflated the number of individuals who did not complete the 2-step enrollment process. Although both the Southeast Michigan and Greater Cincinnati Beacon Communities used this strategy, this method was employed in Greater Cincinnati to a much greater extent, and the failure to shuttle potential participants through both steps of the 2-step enrollment process was particularly striking. As noted previously, approximately 80% of potential participants from Greater Cincinnati initiated enrollment via the website (the vast majority are attributed to participants signing up directly with Beacon staff who completed the online registration on behalf of the participant), yet only approximately 3% of these potential participants completed the 2-step enrollment process. Across both Beacon Communities, 100% of participants who initiated enrollment via text message completed the 2-step enrollment process, compared to 5.52% who initiated via website or Beacon staff member.

Although reasons for the failure to convert website-initiated potential participants into fully enrolled participants are not known, we believe that in many cases, potential participants who signed up with Beacon staff had low investment in program participation and had little or no intention to enroll. Whether it was because of peer pressure, etiquette, or other psychosocial reasons, we believe that the majority of those individuals were not likely to enroll, thus artificially lowering our enrollment completion rate. Moreover, there was no way for Beacon staff to verify that the phone numbers given by potential participants were legitimate, belonged to the participant themselves, or were for a cell phone and not a landline, all of which might have added to the failure to fully enroll some participants.

It is also likely that the failure of participants to fully enroll when initiating enrollment via website can be partially attributed to the lag time between the steps of the enrollment process. For those who enrolled via text message, the enrollment process was seamless and enrollment could be completed in under a minute although it contained multiple steps. For those who enrolled via the website, the enrollment process was broken up between a website or Beacon staffer sign-up, as well as a subsequent text message interaction. Individuals initiating enrollment themselves via the website were likely able to complete the 2-step enrollment process almost seamlessly by switching from one device (desktop computer, tablet, laptop, etc) to another (cell phone), and it is anticipated that very few of these people failed to complete the process. In contrast, those individuals who initiated enrollment through signing up with Beacon staff at health fairs likely experienced a considerable lag in the 2-step process where initial sign-up occurred in person, but the second text message confirmation step occurred at a later point in time. This lag in the enrollment process placed additional burden on participants and likely filtered out those with low investment by providing an opportunity to back out, or allowing potential participants to lose interest over time

before enrollment. Enrollment via this mechanism may have been increased had mobile devices been used to initiate enrollment for potential participants in the moment, thereby generating a confirmation text message to the participant cell phone immediately.

Complex enrollment procedures have been previously related to barriers to enrollment [40,41]. For these reasons, we now believe that manually initiating enrollment on behalf of potential participants may boost the number of people who initiate enrollment, but this method is not likely to return a significant number of participants who fully enroll; in fact, it may overinflate the number of participants who do not complete enrollment. Because the majority of current literature focused on mHealth programs is still focused on relatively small demonstration projects versus larger public health-focused implementations, best practices for participant recruitment and enrollment are not known. Future work should seek to identify strategies to increase recruitment and enrollment in mHealth programs. In particular, future work should seek to determine the effectiveness of recruitment strategies originating from trusted sources and key opinion leaders, such as health care providers, health care organizations, other authority figures, all of which center prominently in models of persuasion and adoption, such as the 2-step flow of communication [42,43], the elaboration likelihood model [44], and the diffusion of innovations [45].

Adoption

Participant Engagement

Nearly three-quarters of the enrolled participants completed the diabetes risk assessment, which was the primary focus of txt4health. It appears that txt4health was able to draw the intended target population, as 65.3% of participants with a risk profile were categorized as having high risk for developing diabetes. In terms of secondary measures, participant engagement in txt4health was varied, but this is expected given that many participants likely joined txt4health for the diabetes risk assessment and not the additional 14 weeks of tailored messages. Most participants set a weight loss goal (74.27%), and tracked their weight (89.17%) and physical activity (54.62%) at least once during the program. Adherence rates to weekly weight and physical activity tracking were variable. Although a greater proportion of participants tracked their weight at least once, as opposed to physical activity, there were a greater proportion of participants highly adherent to physical activity tracking (13.6%) than to weight tracking (1.20%). Among those who completed the 14 weeks of tailored messaging, these proportions increased to 31.9% highly adherent to physical activity tracking and 3.1% highly adherent to weight tracking. Reasons for these patterns of tracking are unknown, but it is possible that participants more frequently reported physical activity because they had engaged in some form of exercise over the previous week and had new information to report, whereas participants failed to engage in weekly weight tracking because they were not losing weight. Moreover, it is possible that some individuals may have no, or limited access, to a scale when requests to enter weekly weights were received. In the short term, physical activity goals that are related to the

number of days of physical activity over the previous week are likely more easily achieved than weight loss goals. Future research should focus on determining strategies for increasing adherence to weekly tracking within mHealth programs because this has not yet been documented.

It should be noted that several changes were made to txt4health based on the lessons learned both during and after the 3 pilots, and the program has been significantly refined. To reduce barriers to enrollment, a need documented in this evaluation, several steps have been taken to streamline enrollment through partnerships with mobile carriers and health plans. To make txt4health relevant to a wider audience, the current iteration of txt4health now focuses on prevention more broadly because promotion and encouragement of health behaviors that are appropriate for decreasing risk for type 2 diabetes also apply to a broader audience. Finally, the program has taken steps to increase the level of participant engagement through mechanisms such as more interactive weight and exercise challenges, quizzes and other more interactive educational content, and encouraging and sending reminders for appropriate health screenings for diabetes and other conditions.

Dropout/Retention

Overall, txt4health retained 39.06% of participants throughout the 14-week program and lost 56.26% to drop out, which was most frequent within the first week of the program. Given that 71.00% of the enrollees completed the diabetes risk assessment, which was the primary purpose txt4health, it comes as no surprise that many people did not continue on to receive messages for 14 weeks. The bulk of participant dropout occurred before the end of the fourth week of the program, and followed a predictable pattern of declining dropout rates with each subsequent week of program participation, with small spikes in dropout rates in weeks 4, 8, and 12 corresponding to the weeks that opt-out instructions were automatically sent. Moreover, it is likely that dropout rates were underestimated. To formally drop out of txt4health, participants had to text “stop” to the program short code. Although slight, the act of formally dropping out of the program posed a burden on participants. It is likely that a subset of active users stopped reading messages during their program and never formally dropped out. This nonusage attrition is not directly measurable, but has been documented in the literature on Internet-mediated interventions [46-50]. Support for the presence of nonusage attrition may be found in the txt4health participants who never logged any weekly weight or physical activity data.

Although the literature documenting participant dropout in text message programs is sparse, the literature on Internet-mediated behavior change interventions documents lower retention rates, yet similar patterns of attrition [51-55]. Moreover, although recent estimates from 2012 reveal that smartphone users download an average of 41 apps to their smartphones [56], reports from the mobile analytics firm Localytics suggest that apps are often downloaded but abandoned after first use, with 22% of newly downloaded apps only being used once [57]. Although a text message-based intervention is not run via an app platform, attrition rates from that realm may provide some insight into what patterns of use may be expected from text

message interventions. Given that we retained 39.06% of participants through at least 14 weeks, even allowing for some amount of nonusage attrition that is not accounted for, we believe that this program was comparable or better in regards to retention rates when compared to many Internet-mediated and app-based programs.

Although reasons for the high dropout rates exhibited in this investigation are unclear, we speculate several possible explanations. First, because the primary intention of txt4health was to provide participants with a diabetes risk assessment, it is possible that many dropout participants enrolled to determine their risk, but were not interested in receiving additional messages, prompting them to drop out shortly into the program. Another possible reason for attrition was the frequency and duration of messaging. Although 5-7 messages per week for 14 weeks does not sound like a high burden on participants, 7% of survey participants self-reported in the participant survey that there were too many messages sent within the program (see Part II of this evaluation). In addition, it is possible that too many messages may dilute the power of the messages that are sent. Little is currently known about the optimum frequency and duration of text message interventions, and although likely to be dependent on the nature of the program, future work should seek to better understand these factors.

Another potential reason for high dropout rates is the possibility that txt4health did not meet the expectations of all participants. For example, it is possible that a text message program is appropriate for conducting a one-time diabetes risk assessment for a broad base of participants, but that enthusiasm among a general audience for a 14-week behavior change intervention delivered via text message is tempered. In comparison to other successful, broad-based text message campaigns, such as txt4baby [58] targeting pregnant moms and txt2stop [24] targeting smoking cessation, that both have time-specific messages and information to convey, behavior changes regarding diet and physical activity are lifelong pursuits and individual needs regarding these behavior changes may not always be met with this sort of program. Also, participant needs may not have been met in regards to the subject matter. Although txt4health is focused on diabetes risk awareness and reduction, and was marketed as such by SEMBC with their Fighting D in the D campaign, this was not necessarily the case in the Greater Cincinnati area where GCBC’s marketing efforts billed “A text a day keeps the doctor away.” Without utilizing the word “diabetes” in the txt4health program name, or in the marketing slogan used by GCBC, it is possible that not all participants realized that txt4health was focused on diabetes.

Finally, it is also possible that dropout was spurred by costs associated with text messaging. Although text messaging is highly pervasive among American cell phone users, not all have access to free unlimited text messaging. This means that some individuals incur a nominal fee of upwards of US \$0.20/message for each text message sent or received. In a program that targets at-risk individuals, many of which are low-income minorities, the delivery of a minimum of 5-7 text messages per week for 14 weeks could translate to significant participation costs. Although there exist examples of health-related text message programs that have worked with cell phone carriers to provide

free text message delivery, such as txt4baby [58], this was not the case for txt4health at the time of this evaluation.

Strengths and Limitations

The major strength of this investigation is that we were focused on better understanding the use of a public health–focused text message program operating at scale. Through this work, we have started to identify the challenges with enrolling and maintaining participation of individuals in this type of program. This strength also happens to be a double-edged sword, in that it is precisely the nature of our community-based program that causes us to have a profound lack of information regarding our participants. Because we had to rely solely on participant self-reported data from diabetes risk assessments, we have no understanding of who failed to complete the 2-step enrollment process (because they never made it to that step) or why they failed to fully enroll. Furthermore, the self-reported demographic data gathered through the diabetes risk assessment was very basic and does not allow us to build a complete picture of the participants who used txt4health. Future work with large, public health–focused text message programs operating at scale should incorporate a stronger evaluation component from the outset so that more robust measures can be tracked from all stages of the program.

One of our goals was to measure the reach of txt4health. Because we had no way to measure the amount of campaign exposure within the community, and because we were not able to survey random community members about their awareness of the public health campaigns within their respective communities, it is impossible to determine an accurate measure of reach. Despite this, given the relatively small enrollment numbers in comparison to the population of the major metropolitan centers within the SEMBC and GCBC service area, it is safe to say that the reach of txt4health was small. Future work should seek to understand what type of enrollment rates and what patterns of participant engagement we could expect to see in similar text message programs marketed as a part of a larger public health campaign.

Conclusions

This evaluation of the txt4health pilots in Southeast Michigan and Greater Cincinnati contributes greatly to the growing body of mHealth literature as it represents an effort to gain deeper understanding of individual use of a large-scale public health–focused text message–based intervention promoting behavior change. Although this type of program may not be appropriate for all, it is an appropriate delivery modality for reaching large populations, can retain a large proportion of users, and may provide some users with the tools needed to make necessary behavior changes.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index

DPP: Diabetes Prevention Program

GCBC: Greater Cincinnati Beacon Collaborative

mHealth: mobile health

SEMBC: Southeast Michigan Beacon Community

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Original Paper

Use of a Text Message Program to Raise Type 2 Diabetes Risk Awareness and Promote Health Behavior Change (Part II): Assessment of Participants' Perceptions on Efficacy

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Abstract

Background: Although there is great enthusiasm in both the public and private sector for the further development and use of large-scale consumer-facing public health applications for mobile platforms, little is known about user experience and satisfaction with this type of approach. As a part of the Beacon Community Cooperative Agreement Program, txt4health, a public-facing, mobile phone-based health information service targeting type 2 diabetes, was launched in 3 Beacon Communities: the Southeast Michigan Beacon Community in Detroit, MI, the Greater Cincinnati Beacon Community in Cincinnati, OH, and the Crescent City Beacon Community in New Orleans, LA. This program was marketed via large public health campaigns and drew many users within the respective communities.

Objective: The purpose of this investigation was to use the RE-AIM framework to document txt4health efficacy by focusing on perceptions of satisfaction, usage, and behavior change among individuals who used txt4health in pilot studies in Southeast Michigan and Greater Cincinnati.

Methods: We conducted a multimodal user survey with txt4health users recruited via text message through the program to understand participant perceptions of program use and satisfaction, as well as self-reported perceptions of behavior change as a result of using txt4health.

Results: Txt4health users reported very high levels of program satisfaction, with 67.1% (108/161) reporting satisfaction scores of ≥ 8 on a 10-point scale, with 10 equivalent to most satisfied (mean 8.2, SD 1.6). All survey participants agreed/strongly agreed that the messages included in txt4health were clear and easy to understand (100.0%, 160/160), and most found txt4health made them knowledgeable about their risk for type 2 diabetes (88.1%, 140/159) and made them conscious of their diet and physical activity (88.8%, 142/160). Most participants reported that txt4health helped them to make behavior changes related to diet; after having completed txt4health, most agreed/strongly agreed that they are more likely to replace sugary drinks, such as juice or soda, with water (78.0%, 124/159), have a piece of fresh fruit instead of dessert (74.2%, 118/159), substitute a small salad for chips or fries when dining out (76.1%, 121/159), buy healthier foods when grocery shopping (79.7%, 126/158), and eat more grilled, baked, or broiled foods instead of fried (75.5%, 120/159).

Conclusions: Results from this study suggest that participants in txt4health, a large-scale, public health-focused text message program targeting type 2 diabetes, have positive perceptions of the program and that participation has led to positive behavior change.

KEYWORDS

diabetes mellitus, type 2; mobile health; cellular phone; text messaging; risk reduction behavior; program evaluation

Introduction

In an era of health care reform occurring at a time when cell phones and mobile devices are near ubiquitous within the United States population [1], it is not surprising to see the rapid expansion of mobile health (mHealth) for the delivery of health information and services. Although there is great enthusiasm in both the public and private sector for the further development and use of consumer-facing health-related applications for mobile platforms, the momentum of mHealth is quickly outpacing the evidence base documenting the efficacy of these endeavors, as well as the traditional research designs used in the creation of the evidence base [2-4]. The efficacy of text message-based interventions to promote behavior change within the context of chronic illness has been previously documented within small-scale contexts [5-7], but most of the available evidence base is focused on underpowered small-scale pilot studies with few participants [4-6]. This fact leads many to believe that, similar to other innovations within the health care industry, moving beyond the pilot phase to operating at scale is an issue plaguing the mHealth field today.

Because of the affordances of a large-scale text message campaign, such as wide reach, low participant costs, and a small time investment on the part of participants, these types of programs appear to be perfectly suited to broad-based public health campaigns. Txt4baby is an example of this type of public health approach [8], which has garnered significant attention in the popular press and many people are attempting to replicate its successes. Txt4health, a text message program that offers participants a type 2 diabetes risk assessment followed by 14 weeks of tailored messaging focused on behavior changes for physical activity and diet, is one such program that was piloted in the Detroit, MI, Cincinnati, OH, and New Orleans, LA metropolitan areas through funding from the Beacon Community Cooperative Agreement Program. Although text message programs are well documented at the pilot stage, large-scale applications in the United States, such as txt4baby, are largely missing from the evidence base and little is known about participant experiences with these types of interventions. To better understand participant experiences within a large-scale, public health-focused, text message program targeting chronic illness, we conducted a multimodal survey of participants who had engaged in txt4health.

The purpose of this 2-part investigation is to evaluate the txt4health pilot studies in Southeast Michigan and Greater Cincinnati through the lens of the RE-AIM framework. In the present paper (Part II), we seek to document program efficacy in terms of participant perceptions of program satisfaction and usage, as well as its effects on behavior change. In our companion paper (Part I), we sought to document program reach and adoption. In comparison to the majority of previous work that has focused on small-scale implementations of mHealth programs [4-6], this txt4health evaluation represents an effort

to understand user perceptions of a program that is operating at scale.

Methods

Overview

This evaluation of txt4health was conducted in 2 parts. In Part I, we conducted a retrospective records analysis of individual-level txt4health system usage data from participants in Southeast Michigan and Greater Cincinnati to determine intervention reach and participant adoption of the program. Findings from Part I of the evaluation are presented in the companion paper. In Part II, we conducted a multimodal user survey with Southeast Michigan Beacon Community (SEMBC) and Greater Cincinnati Beacon Collaborative (GCBC) txt4health users recruited through the program. This survey sought to understand participant perceptions of program satisfaction and use, and self-reported perceptions of behavior change as a result of using txt4health. Txt4health is an automated, personalized, interactive, 14-week text message service targeting vulnerable at-risk populations, designed to help people understand their risk for type 2 diabetes and become more informed about the steps they can take to reduce that risk. Txt4health has been more extensively described in the Part I companion paper, as well as in recent work by Abebe et al [9].

Program Evaluation Framework: RE-AIM

We used the RE-AIM framework to guide this evaluation of the txt4health pilots in Southeast Michigan and Greater Cincinnati. As previously described in the companion paper, RE-AIM incorporates the dimensions of reach, efficacy, adoption, implementation, and maintenance, and is a framework that has been extensively used to guide the planning, evaluation, reporting, and review of health promotion interventions [10]. Within the present paper, we focus strictly on the dimension of efficacy of the RE-AIM framework. Efficacy is an individual-level measure that refers to the degree to which use of an intervention creates the desired outcomes [10]. Within the context of the present txt4health evaluation, efficacy refers to participant perceptions of txt4health, as well as perceptions of the effect of txt4health on behavior.

Participant Recruitment

To be eligible to participate in this study, individuals had to be at least 18 years and enrolled in the txt4health program for at least 10 weeks. Beacon employees enrolled in txt4health were excluded from participation in this survey. For recruitment purposes, we sent a text message to all txt4health users in the SEMBC and GCBC pilots who were subscribed to the program at the time of solicitation. In total, 814 participants were active in the txt4health system when survey recruitment text messages were sent. Six batches of recruitment texts were sent to all active participants between September and December, 2012 (approximately every 2 weeks), and asked txt4health users to

indicate whether or not they would be interested in participating in the survey. Those individuals who responded yes were contacted via phone to coordinate survey completion. Phone calls were not made to potential participants until at least 10 weeks had passed after a participants' initial txt4health enrollment date. This allowed for participants to complete most of the program before taking the survey. Those individuals who responded no were removed from our solicitation list and they never received another recruitment text message. Participants who did not respond to the recruitment text messages remained on our solicitation list and continued to receive recruitment text messages. Up to 5 attempts were made by phone to contact all participants who expressed interest in survey participation.

Once contact was established, potential participants were again asked if they were interested in participating. Any individual no longer interested was thanked for their time. All eligible participants willing to participate were given the option of completing the survey via phone, Internet (survey hosted on SurveyMonkey [11]), or US Mail. Individuals who wished to take the survey via Internet or US Mail received periodic reminders via email or phone for up to 6 weeks, or until survey

completion. All survey respondents were eligible to receive a US \$10 gift card to a local retailer for completing the survey. The Wayne State University Institutional Review Board approved the user survey portion of this study with a waiver of documentation of written consent. In lieu of written consent, all participants who completed the survey were given information pertaining to the study, including study procedures, risks/benefits, and incentives. This information was distributed in electronic form for online survey participants, in hard copy for US Mail participants, and over the phone with a statement of oral consent for phone survey participants.

Measures

The investigator-developed user survey took approximately 20 minutes to complete and included questions assessing txt4health use and perceptions, health and health behaviors, mobile phone use, demographics, and activation as measured by the Patient Activation Measure (PAM). The PAM is a 13-item instrument that has been validated to assess individuals' knowledge, skill, and confidence with managing their health. The PAM characterizes people into 1 of 4 levels of activation, with descriptions of each level as follows in Table 1 [12,13].

Table 1. Description of Patient Activation Measure (PAM) level categorizations.

PAM level	Description ^a
1	Does not feel in charge of their own health and care. Managing health is overwhelming for them with all of life's other challenges. Lacks confidence in their ability to manage health. Has few problem-solving skills and poor coping skills. They may not be very aware of own behaviors.
2	May lack basic knowledge about their condition, treatment options, and/or self-care. Have little experience or success with behavior change. Look to their doctor to be the one in charge. Low confidence in their ability to manage health.
3	Have the basic facts of their conditions and treatments. Some experience and success in making behavioral changes. Some confidence in handling limited aspects of their health.
4	Have made most of the necessary behavior changes, but may have difficulty maintaining behaviors over time or during times of stress.

^aDescriptions from PAM licensing materials packet from Insignia Health [13].

Data Analysis

We conducted descriptive statistics to describe participant characteristics, perceptions of txt4health, self-reported text4health usage, and self-reported effects of txt4health. Continuous variables were expressed as mean (SD) and means were compared using 2-tailed unpaired independent samples *t* tests. Categorical data were displayed as frequencies and percentages, and chi-square tests were used for comparison. It should be noted that because participants were not required to answer all items within the survey, the denominator of many of our analyses fluctuates slightly. Multiple regression analyses were used to predict satisfaction with txt4health controlling for the continuous variables age and body mass index (BMI), as well as the categorical variables gender, White or non-White race, income, education, level of activation as measured by the PAM, and Beacon Community affiliation (Southeast Michigan or Greater Cincinnati). Moreover, chi-square analyses were used to explore potential differences between participants affiliated with the Southeast Michigan or Greater Cincinnati Beacon Communities. Significance levels were set at a *P* value

<.05. All statistical analyses were carried out using STATA version 11.0 (StataCorp LP, College Station, TX, USA).

Results

Overview

We conducted a survey of Southeast Michigan and Greater Cincinnati txt4health participants recruited via text message. Of the 814 active txt4health participants who were sent recruitment text messages, 47.7% (388/814) expressed initial interest in participating in the survey via text message. We successfully contacted 70.4% (273/388) of those individuals by phone and asked again if they would be willing to participate. Overall, 14.7% (40/273) of txt4health users who previously expressed interest in our survey declined participation, and an additional 6 (2.2%) individuals were excluded from participation because they were Beacon employees. Of the remaining 227 eligible individuals still interested in survey participation, 70.9% (161/227) of participants completed the approximately 20-minute survey; 64.0% (103/161) completed it via the Internet, 31.1% (50/161) completed it via phone, and 5.0% (8/161)

completed it via US Mail. Refer to [Figure 1](#) for a complete chart of participant flow.

Of the 161 participants who completed the user survey, the sample was predominantly female (73.7%, 115/156), African American (51.6%, 81/157) or White (44.6%, 70/157), smartphone users (78.5%, 124/158), with a mean age of 42.4 years (SD 11.6) and a mean BMI of 33.1 kg/m² (SD 8.6). Most survey respondents were obese with a BMI ≥30 kg/m² (53.9%, 82/152), or overweight with a BMI between 25.0 and 29.9 kg/m² (31.6%, 48/152). In addition, 30.6% (48/157) had a history of diabetes. Most survey participants (75.6%, 121/160) self-reported good, very good, or excellent health. Overall, this sample was well educated with 58.6% (92/157) reporting that they were college graduates or had completed postgraduate work, and an additional 28.0% (44/157) reporting that they had completed some college classes. Only 8.9% (14/157) reported

that they were high school dropouts, or had completed high school. Annual income of survey participants was well distributed, with 22.2% (34/153) reporting annual household incomes of less than US \$25,000, and 20.9% (32/153) with more than US \$100,000. Regarding levels of activation, 63.5% (101/159) of respondents were categorized as level 4 on the PAM, which is characterized as individuals who “have made most of the necessary behavior changes, but may have difficulty maintaining behaviors over time or during times of stress” [13]. An additional 22.6% (36/159) were categorized as level 3 on the PAM, which is characterized as individuals who “have the basic facts of their conditions and treatments, some experience and success in making behavioral changes, and some confidence in handling limited aspects of their health” [13]. For 53.8% (85/158) of respondents, txt4health was the first text message program that they had used. See [Table 2](#) for a complete breakdown of survey respondent characteristics.

Figure 1. Participant flow.

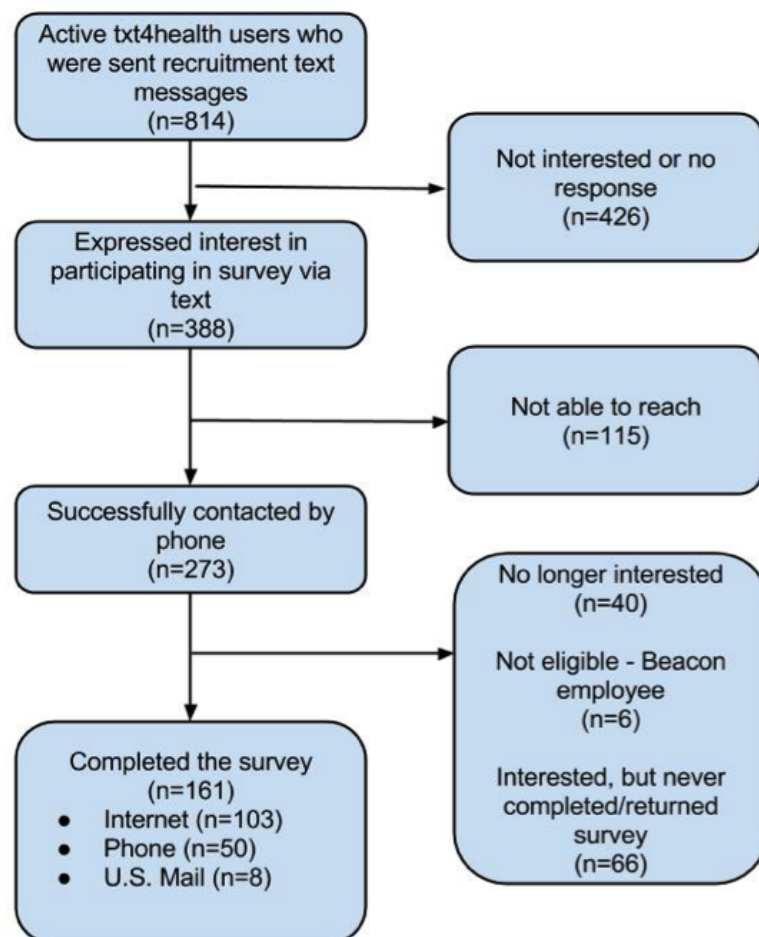


Table 2. Characteristics of txt4health user survey respondents (N=161).

Participant characteristic	Southeast Michigan	Greater Cincinnati	Total
Gender, n	94	62	156
Female, n (%)	65 (69.1)	50 (80.6)	115 (73.7)
Male, n (%)	29 (30.9)	12 (19.4)	41 (26.3)
Age (years), n	93	62	155
Mean (SD)	43.3 (11.8)	41.0 (11.3)	42.4 (11.6)
Hispanic or Latino origin, n	92	61	153
Yes, n (%)	2 (2.2)	0 (0.0)	2 (1.3)
No, n (%)	89 (96.7)	61 (100.0)	150 (98.0)
Don't know, n (%)	1 (1.1)	0 (0.0)	1 (0.7)
Race,^a n	94	63	157
White, n (%)	30 (31.9)	40 (63.5)	70 (44.6)
Black or African American, n (%)	62 (66.0)	19 (30.2)	81 (51.6)
Other, n (%)	2 (2.1)	3 (4.8)	5 (3.2)
Don't know, n (%)	0 (0.0)	1 (1.6)	1 (0.6)
Income (US \$), n	92	61	153
<25,000, n (%)	18 (19.6)	16 (26.2)	34 (22.2)
25,000-49,999, n (%)	20 (21.7)	10 (16.4)	30 (19.6)
50,000-74,999, n (%)	21 (22.8)	9 (14.8)	30 (19.6)
75,000-99,999, n (%)	13 (14.1)	9 (14.8)	22 (14.4)
100,000-124,999, n (%)	5 (5.4)	3 (4.9)	8 (5.2)
≥125,000, n (%)	10 (10.9)	14 (23.0)	24 (15.7)
Don't know, n (%)	5 (5.4)	0 (0.0)	5 (3.3)
Education, n	94	63	157
Some high school, n (%)	2 (2.1)	0 (0.0)	2 (1.3)
High school diploma or GED, n (%)	5 (5.3)	7 (11.1)	12 (7.6)
Trade or vocational school, n (%)	5 (5.3)	2 (3.2)	7 (4.5)
Some college, n (%)	27 (28.7)	17 (27.0)	44 (28.0)
College graduate, n (%)	27 (28.7)	19 (30.2)	46 (29.3)
Postgraduate work or degree, n (%)	28 (29.8)	18 (28.6)	46 (29.3)
Where you go to for health care services, n	93	62	155
Family doctor/nurse or clinic, n (%)	82 (88.2)	53 (85.5)	135 (87.1)
Emergency department, n (%)	4 (4.3)	4 (6.5)	8 (5.2)
Urgent care clinic, n (%)	4 (4.3)	2 (3.2)	6 (3.9)
Internet, n (%)	2 (2.2)	1 (1.6)	3 (1.9)
Nowhere, n (%)	1 (1.1)	2 (3.2)	3 (1.9)
Diabetes history,^a n	94	63	157
Yes, n (%)	39 (41.5)	9 (14.3)	48 (30.6)
Yes, but only during pregnancy, n (%)	2 (2.1)	3 (4.8)	5 (3.2)
No, n (%)	44 (46.8)	43 (68.3)	87 (55.4)
No, but prediabetes or borderline diabetes, n (%)	9 (9.6)	8 (12.7)	17 (10.8)
Prediabetes history,^b n	84	56	140

Participant characteristic	Southeast Michigan	Greater Cincinnati	Total
Yes, n (%)	20 (23.8)	4 (7.1)	24 (17.1)
Yes, but only during pregnancy, n (%)	3 (3.6)	3 (5.4)	6 (4.3)
No, n (%)	61 (72.6)	49 (87.5)	110 (78.6)
BMI category, n	91	61	152
Normal, n (%)	11 (12.1)	11 (18.0)	22 (14.5)
Overweight, n (%)	26 (28.6)	22 (36.1)	48 (31.6)
Obese, n (%)	54 (59.3)	28 (45.9)	82 (53.9)

^aSignificant difference ($P<.01$) found between Southeast Michigan Beacon Community (SMBC) and Greater Cincinnati Beacon Collaborative (GCBC).

^bSignificant difference ($P<.05$) found between SEMBC and GCBC.

Survey Participants' txt4health Use

Survey participants first learned of txt4health through a variety of channels, including health fairs (20.0%, 32/160), radio advertisements (14.4%, 23/160), and directly from health care providers (13.8%, 22/160). Despite the number of respondents who first learned of txt4health through health fairs where individuals were able to initiate enrollment by providing a phone number and ZIP code to Beacon staff members, only 4.4% (7/160) of respondents initiated enrollment through that mechanism. Rather, 92.5% (148/160) self-reported initiating enrollment through texting the word "health" to the txt4health short code. Regarding use of the program, 83.2% (134/161) of survey participants reported using txt4health to set physical activity goals, and 67.5% (108/160) reported setting weight loss goals. The vast majority of survey participants (82.5%, 132/160) reported that they always read the text messages they received from txt4health, and 26.3% (42/160) of survey participants reported discussing txt4health messages with their health care provider. One component of txt4health was the inclusion of messages regarding resources of potential interest, such as contact information for community resources and organizations, links to additional health-related information, etc. Survey respondents reported using these resources never (25.0%, 40/160), rarely (30.0%, 48/160), occasionally (26.3%, 42/160), or frequently/very frequently (15.0%, 24/160).

Survey Participants' Perceptions of txt4health

All survey participants agreed/strongly agreed that the messages included in txt4health were clear and easy to understand (100.0%, 160/160). Most reported txt4health made them knowledgeable about their risk for type 2 diabetes (88.1%, 140/159) and the program made them conscious of their diet and physical activity habits (88.8%, 142/160). Most survey participants reported that they agreed/strongly agreed that they enjoyed participating in the program (88.1%, 140/159). Although 6.9% (11/159) indicated that there were too many messages sent in the program, most participants indicated that the number of messages sent each week was just the right amount (79.9%, 127/159). See [Table 3](#) for a complete breakdown of participant responses to the txt4health perception items. Perceptions of satisfaction among survey participants were very positive with 67.1% (108/161) reporting satisfaction scores of 8 or higher on a 10-point scale, with 10 equivalent to most satisfied (mean 8.2, SD 1.6). Using multiple regression analyses, race was a significant predictor of satisfaction scores ($\beta=.81$, $P=.008$) with non-White participants reporting higher mean satisfaction scores than White participants (mean 8.6, SD 1.5 and mean 7.7, SD 1.6, respectively; $t_{155}=-3.79$, $P<.001$). In addition, PAM level was also predictive of satisfaction scores ($\beta=.33$, $P=.03$) with individuals at PAM level 4 rating their satisfaction higher than those with PAM levels less than 4 (mean 8.5, SD 1.6 and mean 7.7, SD 1.6, respectively; $t_{157}=-2.96$, $P=.004$).

Table 3. Participant response to behavior change items.

Item	Disagree/strongly disagree n (%)	Neutral n (%)	Agree/strongly agree n (%)
Perceptions of txt4health			
The text messages were clear and easy to understand (n=160)	0 (0.0)	0 (0.0)	160 (100.0)
Txt4health made me knowledgeable about my risk for type 2 diabetes (n=159)	4 (2.5)	15 (9.4)	140 (88.1)
Txt4health made me conscious of my diet and physical activity habits (n=158)	4 (2.5)	12 (7.6)	142 (89.9)
Txt4health helped me become more physically active (n=158) ^a	17 (10.8)	35 (22.2)	106 (67.1)
Txt4health helped me lose weight (n=160)	37 (23.1)	50 (31.3)	73 (45.6)
I enjoyed participating in the program (n=156) ^a	1 (0.6)	15 (9.6)	140 (89.7)
Text4health helped improve the way I manage my mental health (n=157)	26 (16.6)	50 (31.8)	81 (51.6)
Behavior change			
After having completed txt4health, I am more likely to replace sugary drinks such as juice or soda with water (n=158) ^a	8 (5.1)	26 (16.5)	124 (78.5)
After having completed txt4health, I am more likely to have a piece of fresh fruit instead of dessert (n=158)	7 (4.4)	33 (20.9)	118 (74.7)
After having completed txt4health, I am more likely to substitute a small salad for chips or fries when dining out (n=159)	10 (6.3)	28 (17.6)	121 (76.1)
After having completed txt4health, I buy healthier foods when grocery shopping (n=158) ^a	4 (2.5)	28 (17.7)	126 (79.7)
After having completed txt4health, I eat more grilled, baked, or broiled foods instead of fried (n=158)	5 (3.2)	33 (20.9)	120 (75.9)

^aDoes not equal 100% due to rounding error.

Self-Reported Behavior Change Attributed to txt4health

Because the goal of txt4health is to promote behavior change among participants, survey respondents were asked to reflect on how txt4health may have changed their behavior. The majority of the participants agreed/strongly agreed that after having completed txt4health, they were more likely to replace sugary drinks, such as juice or soda, with water (78.0%, 124/159), have a piece of fresh fruit instead of dessert (74.2%, 118/159), substitute a small salad for chips or fries when dining out (76.1%, 121/159), buy healthier foods when grocery shopping (79.7%, 126/158), and eat more grilled, baked, or broiled foods instead of fried (75.5%, 120/159). Of those individuals who set goals within txt4health, most reported meeting their physical activity goals most of the time or always (60.6%, 80/132), whereas 25.7% (28/109) reported meeting weight goals most of the time or always. In addition, most (66.3%, 106/160) agreed/strongly agreed that the program helped them become more physically active, and almost half reported that txt4health helped them to lose weight (45.6%, 73/160). See Table 3 for a complete breakdown of participant response to behavior change items.

Discussion

Among txt4health users who participated in the user satisfaction and perceptions survey, participants reported very positive

perceptions of txt4health. Overall, the majority of survey participants reported enjoying the program and rated their satisfaction as 8 or higher on a 10-point scale, with 10 equivalent to most satisfied. In addition to positive perceptions of the program, survey respondents self-reported making behavior choices related to diet and physical activity as a result of their participation, and approximately half of respondents self-reported that txt4health helped them to lose weight. Many of these positive perceptions were echoed in the open-ended response section of the survey, in which participants were given an opportunity to provide additional comments. Overall, the tone of these comments was positive, and survey respondents offered helpful and constructive suggestions on how to improve the program rather than any overtly negative feedback. Given our recruitment strategy solicited individuals who were active within the program and excluded any individuals who dropped out before recruitment, it is not surprising that participant response regarding the program was overwhelmingly positive. Undoubtedly, this recruitment strategy introduced a fair amount of bias into the survey results because only individuals who had not dropped out of the program received the invitation to participate. This, coupled with the self-selection bias that occurs from participants who were likely skewed toward favoring txt4health, is potentially problematic. Future research should seek to conduct an evaluation with a stronger research design that includes random sampling of both active and dropout participants to reduce the amount of bias within the sample.

Despite these limitations related to sampling, it is clear that for a subset of individuals who initially enrolled in txt4health, this approach to a behavior change program was met with great satisfaction from many participants, and suggests that this is a feasible and acceptable method to promote behavior change to large numbers of individuals who may derive some perceived benefit from participation. There appears to be a relatively discrete subset of individuals who responded very well to this type of program in terms of both program usage (see our companion paper, Part I) and overall perceptions of txt4health. In particular, it appears that minority participants respond more favorably to the txt4health intervention. Results from Part I of this investigation showed that non-White participants stayed in txt4health longer than White participants (see Part I companion paper), and results from the present user survey show that non-White participants had higher ratings of satisfaction than White participants.

Because it is unlikely that there exists a one-size-fits-all approach to behavior change programs that will be met with universal acceptance, future work should seek to understand which types of people are best suited to different types of programs, as well as to develop instruments for identifying these individuals. This may allow for better targeting of programs to those individuals who are likely to derive the most benefit. Throughout our analysis, demographic characteristics seldom predicted participant perceptions or usage of txt4health. This suggests that with the exception of non-White race predicting length of participation and satisfaction, demographics are not the drivers of use/acceptability in text message-based programs, and perhaps more psychological factors may be key.

In addition to positive perceptions of txt4health among survey respondents, many participants also self-reported that participation in the program led to positive behavior changes, which we hope will ultimately lead to positive health outcomes. Recent work by Ramachandran et al [14] supports the use of text messaging to gain positive health outcomes related to diabetes. In that study, 537 working men in India were randomized to a text message program (similar to txt4health) or usual care. The authors found after 2 years of program use,

the text message program was effective at preventing type 2 diabetes; 27% of control group participants developed type 2 diabetes by the end of the trial compared to 18% of the text message group participants [14]. This recent finding in India has increased the desire to more concretely establish the efficacy of this type of program among Americans, and to see if these findings could be replicated here. Unfortunately, in the present study, because of the limitations of our research design, we lack objective measures that would reveal whether txt4health actually caused people to change their behavior; thus, we are not able to make a judgment regarding the efficacy of text4health on health outcomes. Rather, our evaluation relies on self-reported survey data that only provides limited insight into participant perceptions of the program. Reasons for the limitations regarding research design have been previously described [9], but briefly include issues related to program dissemination strategies, as well as limited time and financial resources. Although small-scale pilot studies exist that indicate text message programs can be effective at promoting behavior change, well-powered randomized controlled trials establishing efficacy of these types of programs among American adults are largely missing from the literature [4-6]. Given the participant response regarding self-reported behavior change from this study, future work should seek to test the efficacy of txt4health and similar broad-based, large-scale, public health text message interventions using well-thought-out experimental designs with appropriate controls.

Despite the proliferation of small-scale pilot studies demonstrating the efficacy of text message mHealth programs for chronic disease, little is known about user perceptions of these types of programs among American adults while operating at scale. Results from this study suggest that participants in txt4health, a large-scale public health-focused text message program targeting type 2 diabetes, have positive perceptions of the program and that participation has led to positive behavior change. Although these results come from a seemingly biased sample of txt4health users who self-selected to participate in the user survey, these findings do suggest that a large subset of individuals who participate in a broad-based, public health-focused intervention may respond quite favorably.

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Conflicts of Interest

None declared.

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Abbreviations

BMI: body mass index

GCBC: Greater Cincinnati Beacon Collaborative

mHealth: mobile health

PAM: Patient Activation Measure

SEMBC: Southeast Michigan Beacon Community

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Original Paper

Exploring the Use and Effects of Deliberate Self-Harm Websites: An Internet-Based Study

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Abstract

Background: In the United Kingdom, rates of deliberate self-harm (DSH) are rising. Alongside this, there has been an increase in the number of websites available with DSH content, and the Internet is known as a valuable resource for those who feel isolated by their condition(s). However, there is little and contradictory evidence available on the effects of using such websites. Further research is therefore required to examine the use and effects of DSH websites.

Objective: Our objectives were to explore (1) the reasons people engage in the use of self-harm forums/websites, (2) the beliefs of users of self-harm forums regarding the role of such websites, (3) how the use of self-harm forums/websites modulates self-harm behaviors, and (4) other ways that self-harm forums affect the lives of individuals who use them.

Methods: Data were collected by a questionnaire hosted on 20 websites with self-harm content. Participants were self-selected from users of these sites. Results were analyzed using descriptive statistics and simple thematic analysis.

Results: In total, 329 responses were received with 91.8% (302/329) from female site users. The majority of participants (65.6%, 187/285) visited these sites at least twice per week, and most participants used the sites to find information (78.2%, 223/285) or participate in the forums (68.4%, 195/285). Positive effects of website use such as gaining help and support, isolation reduction, and a reduction in self-harm behaviors were reported by a large number of participants. However, smaller but important numbers reported negative effects including worsened self-harm, being triggered to self-harm, and additional negative physical and psychological effects.

Conclusions: This is the first multisite study to explore DSH website use in depth. There are clear and important benefits to engaging in website use for many individuals; however, these are not experienced by all website users. Negative effects were experienced by moderate numbers following website use, and clinicians should consider the impact of a patient's website use when consulting.

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KEYWORDS

Internet; websites; deliberate self-harm; self-injury

Introduction

The term deliberate self-harm (DSH) can be defined as “the intentional destruction of body tissue without suicidal intent” [1]. DSH encompasses a range of behaviors including cutting, burning, scalding, hair pulling, banging body parts, breaking

bones, needle-sticking, scratching, preventing wound healing, and self-poisoning [1-4], although it has been suggested that cutting is the most common behavior [5].

Prevalence of DSH in the United Kingdom has been estimated to be between 4.6% and 6.6% [6,7]; however, it is thought actual

rates may be higher due to suspected levels of unreported behavior. The Adult Psychiatric Morbidity in England 2007 [7] report indicated an increase in the proportion of people reporting DSH between 2000 and 2007, particularly in women. Gender disparity is most evident in data from 16-24 year olds with 17.0% of young women self-harming compared to 7.9% of men in the same age group [7].

The Internet has been shown to be a valuable resource for individuals who feel isolated by their condition(s), such as those who self-harm, by providing anonymous support and information [8]. Internet access has increased greatly over the last decade with an estimated 80% of British households having Internet access [9]. The diversity of the Internet means it has innumerable uses, and health information has been shown to be more frequently accessed on websites than in the past [10].

Prasad et al researched the type of information and help available on the Internet for those who self-harm and concluded that the majority of websites offered information on self-harming, suicide, and related psychological issues, but that little support and discussion opportunities were available [11]. More recently, the number of Internet-based discussion pages available for self-harm has increased [12] and this, along with the increase in Internet accessibility and developments in online communication, means that opportunities for Internet-based self-harm discussion are more widely available than ever before.

Online discussion forums and health websites have generated concerns, and studies of similar websites, such as those for sufferers of eating disorders, have suggested behaviors encouraged by the use of such sites may be of concern. However, such sites are also seen as a source of support for users [13]. Previous research looking at self-harm discussion sites has concluded that there are positive aspects associated with use of these websites. For instance, evidence suggests such websites provide valuable emotional support for individuals who self-harm [8,14] and that these websites can be used as a coping mechanism for self-harm behaviors [15].

However, concerns have been raised over perceived negative effects of such websites, such as encouragement or triggering of DSH behaviors [8,14], normalization of DSH behaviors that may prevent individuals from seeking professional help [14,15], and the fact that support offered on such websites follows a very different model and style from support offered by health care professionals [14]. It has been suggested such websites could facilitate the learning of new self-harm behaviors [8].

Three main reasons for why such websites are used have been identified: users viewed them as places of support and understanding, as a community to which they could belong and as offering coping mechanisms for the social and psychological distress associated with self-harm [15]. Additionally, users of self-harm websites have reported they believe use of these sites had a positive effect on their self-harm behavior, particularly in terms of reducing frequency and severity [12].

Current evidence on this topic, however, is significantly limited by users being drawn from only one website and small sample sizes, meaning results cannot be generalized to the wider self-harm website-using population and highlighting the need

for further research. Websites vary greatly in terms of intent and content, and therefore wider reaching research is required including a broader selection of the websites available.

In order to explore the use of and effects of using these websites, this study had four aims: (1) to explore the reasons people engage in the use of self-harm websites/forums, (2) to explore the beliefs of users of self-harm forums regarding the role of such websites, (3) to explore how the use of self-harm websites/forums modulates self-harm behaviors, and (4) to identify other ways that self-harm websites/forums affect the lives of individuals who use them.

Methods

Data Collection

This study received ethical approval from the University of Birmingham BMedSc Internal Ethics Committee prior to commencement.

All data were collected via an anonymous questionnaire developed after a review of the available literature. The questionnaire gathered data on DSH behaviors, DSH website/forum use, and reasons for use of such websites/forums, using both closed and open questions. Closed questions, where participants selected the most appropriate answer(s) from a list of options, were used where there was robust prior evidence about the subject. Open questions with free-text response were used where little was known on the subject. The format of the questionnaire was standard for all participants, and participants were able to review or change their answers once a question had been completed. Responses to the questionnaire were reviewed on the first day of posting to ensure comprehension by participants and that no changes were deemed necessary.

The questionnaire, hosted by SurveyMonkey, was accessed by participants via a link posted on websites with self-harm content (see [Multimedia Appendix 1](#) for the questionnaire). A Google search using terms such as “self-harm forums” and “self-harm websites” identified 22 websites, of which 10 initially granted permission to post the questionnaire. In each case, permission was sought from the administrator/moderator of the sites before attempting to post the link. Where possible, the link was posted as a “sticky”, or permanent, post. If this was not possible, websites were regularly checked to ensure the link had not gotten lost in the forum and if necessary was reposted.

The questionnaire was available to access for 6 weeks between January and March 2013. Participants were invited to access the questionnaire by clicking a link and reading the participant information sheet before clicking on a second link to confirm willingness to proceed to the questionnaire and participate in the study. On completion of the questionnaire, responses were automatically sent to the SurveyMonkey account. Duplicate completions of the questionnaire were prevented by SurveyMonkey to only allow one response per IP address.

One question asked participants to list the websites they currently use. When new websites were provided as answers, these websites were investigated as possible hosts for the questionnaire as described above, to ensure that the widest

selection of websites possible was included in the study. In total, the questionnaire was hosted on 20 separate websites ([Multimedia Appendix 2](#)).

Analysis

The data collected comprised both quantitative and qualitative data. Quantitative data were used to describe the sample in terms of age, ethnicity, gender, DSH behavior, and DSH website use. Simple descriptive statistics were used to describe the frequency of DSH and types of behavior (see analysis maps in [Multimedia Appendix 3](#)).

Initial analysis of qualitative data was carried out during the data collection phase; responses were analyzed by a simple thematic coding and counting method. Coding categories were developed by a single researcher, but a subsample (n=50) was reviewed by a second researcher (LR) to confirm agreement with the coding framework and individual codes. After the data collection phase, coding categories were reviewed and collapsed to give the best thematic representation of categories to address the research questions. Given the large dataset, some indication of strength of expression of themes was possible. Researchers have chosen not to report percentages in the results section as coding infers a degree of subjectivity, and therefore quantifying of data in this way would be inappropriate. However, for some key themes an approximation of the weight of reporting participants is given.

Results

Description of Sample

Overall, 329 participants consented to complete the questionnaire. Due to the nature of the Internet hosting of the questionnaire, participants were free to exit the questionnaire at any point resulting in some uncompleted submissions; however, these submissions were still included in the analysis. Additionally, due to the filtering of the questionnaire, participants did not necessarily answer every question. Therefore, for questions described below, the number of participants who answered each question has been detailed (n).

Demographics

329 participants answered the demographic questions. Of these, 91.8% (302/329) were female and the average age of the sample was 23.06 years (SD 8.62). The majority of participants reported their ethnicity as white (90.3%, 297/329). Of the remaining participants, 3.3% (11/329) reported mixed ethnicity, 1.5% (5/329) Asian, 1.5% (5/329) Chinese, 0.6% (2/329) black, and 2.7% (9/329) reported "other". Most participants selected United Kingdom as their country of residence (69.9%, 230/329). A further 7.6% (25/329) selected Europe and 22.5% (74/329) selected "other". Participants were invited to specify if they selected "other", and the most commonly reported countries were Canada, Australia, and New Zealand.

Self-Harm History

Of the 329 participants who answered the question about prior self-harm, 98.5% (324/329) reported that they had previously self-harmed. No definition of DSH was provided for this question. Instead, participants were allowed to apply their own personal definition of DSH when determining whether they had previously carried out DSH or not. Further clarification of this personal definition was sought in later questions.

Of the 5 participants with no self-harm history, 3 provided reasons for their website use. One reported use for work purposes, while 2 reported use to prevent starting self-harm behavior. [Table 1](#) reports the methods of self-harm employed as reported by 323 participants. The most common method of self-harming was cutting with 94.7% (306/323) of participants reporting this. Of the 14.6% (47/329) of participants who selected "other" for this question and were invited to specify the methods they used, biting and overdosing were most commonly reported.

There were 321 participants who indicated the age at which they started to self-harm. The average age of starting self-harm was 14.07 years (SD 5.05); 67.9% (220/324) indicated that they were currently self-harming.

Table 1. Methods of self-harm used by participants^a (N=329).

Method	n	%
Cut self	306	94.7
Burn self	100	31.0
Scald self	21	6.5
Bang body parts	135	41.8
Pull hair	69	21.4
Scratch self	166	51.4
Prevent wound healing	133	41.2
Ingest toxic substances	42	13.0
Break bones	6	1.9
Other (please specify)	47	14.6

^aParticipants could select multiple methods to fully reflect personal self-harm history.

Website/Forum Use

There were 295 participants who indicated when they had first looked at deliberate self-harm websites. The majority of participants reported initially looking at self-harm websites/forums *after* starting self-harming (90.5%, 267/295). Of these, 15.0% (40/267) reported looking at the websites within 1 month of starting self-harming, 10.5% (28/267) within 2 months of self-harming, 17.2% (46/267) between 2 months and 1 year of starting self-harming, and 57.3% (153/267) after self-harming for longer than 1 year.

Table 2 shows website use by participants in terms of time spent using them in an average week. Information was provided by

285 participants for how long they spent looking at/using websites in an average week. The largest group of participants reported using the websites “daily but for less than 4 hours per day” (31.6%, 90/285).

Table 3 shows the activities carried out when using the websites. 283 participants provided information about what they did when using the websites. “Viewing threads in the forum” was the most commonly reported activity (78.8%, 223/283). Of the 15.5% (44/283) of participants who selected “other” as their answer and were invited to provide more detail, the most commonly reported activities were “staffing/moderating” and “looking for pictures/images”. Generally, most participants used the websites to either find information or participate in forums.

Table 2. Time spent looking at or using DSH websites/forums in an average week (N=329).

Time	n	%
Daily (for longer than 4 hours per day)	20	7.0
Daily (but less than 4 hours per day)	90	31.6
2-6 times per week	77	27.0
Once per week	17	6.0
Less than once per week but more than once per month	32	11.2
Once per month	11	3.9
Less than once per month	38	13.3

Table 3. Activities carried out when using DSH websites/forums (N=329).

Activity	n	%
Search for information	195	68.9
View threads in the forum	223	78.8
Contribute to threads in the forum	158	55.8
Start threads in the forum	117	41.3
Chat	103	36.4
Send private messages	110	38.9
Play games	22	7.8
Other	44	15.5

Reasons for DSH Website Use and Initial Motivators for Engagement With Sites

To explore these issues, four free-text questions were asked. Data were coded, categorized, and then conceptualized into themes based on the relationship of categories to each other. From this analysis, two main predominating themes were identified.

The theme with the highest strength of reporting was that of “help and support”. Participants spoke of the value they placed on the levels of support derived from use of the websites and how they felt this had contributed to their recovery:

It keeps me focused on recovery, placing importance on good mental health strategies and expressing my feelings. It helps me cope with self-harm thoughts or

behavior. It's a place helping me deal with day-to-day issues. [Participant 59—female, 29]

“Isolation reduction and community engagement” was the theme with the second highest strength of reporting. Around half the participants described their experiences of self-harm as being highly isolating and lonely. They therefore used the websites to connect with other people who shared experiences/feelings and to reduce the sense of isolation they felt resulting from their self-harm:

They make me feel less alone and isolated, and make me realize there are other people who have similar feelings to me. [Participant 85—female, 18]

Outside of these two predominating themes, the theme of “distraction and expression” was also apparent in large numbers of participants’ answers. Participants described the websites as

places enabling expression of their feelings or providing distraction from carrying out self-harm behaviors:

They allow me to express myself and to gain some peer support. They're also good distractions from self-harm thoughts, and games especially are helpful with that. [Participant 185—female, 30]

Some participants also wrote about their desire to “help others”, a desire often driven by wanting to offer others the same support they had derived from website use:

I used it to ask for help and advice because I didn't feel I could ask in my own life. I continue to use the site because I like to give back and give advice to those who post threads and are struggling just as I used to. [Participant 291—female, 21]

After these themes, the theme of “triggering material/tips” was the next most commonly reported. While significantly fewer participants mentioned this theme, compared to other reasons for use/engagement, it was still relatively common with around 10% of participants reporting this. This theme included answers detailing looking for written material as well as images and artwork:

I wanted triggering. That sounds weird but I felt the harm I was doing was not bad enough and I needed to make it worse. [Participant 176—female, 19]

Do Self-Harm Websites/Forums Modulate Self-Harm Behaviors?

Some participants reported an increase in self-harm, some participants reported their self-harm decreased, and other participants reported no change in self-harm behaviors. The largest of these groups, approximately 40%, felt they now self-harmed less as a result of using the websites. The theme of “self-harm reduction” included the categories of reduced severity, reduced frequency, and website use to prevent self-harm. Participants described websites as having played a critical role in their recovery and helping them to find other, less destructive ways of managing their feelings:

It's reduced my self-harm—I've learned other ways to cope, and these websites have taught me to think rationally about what I'm doing to myself. They've given me a new perspective on my self-injury, to view it as a coping mechanism and something I need help for. [Participant 22—female, 18]

Although many reported reduced self-harm resulting from website use, just under a third of participants indicated that using the websites/forums had not affected their behaviors and that no connection existed between their Internet use and self-harm patterns:

I don't feel using forums has innately changed my self-harm behavior. I feel the two are pretty independent. [Participant 154—female, 18]

A similar number of participants indicated increased self-harm resulting from website use. The “increased self-harm” theme included the categories of increased severity, increased frequency, new methods learned, and competition with other users. Some participants reported the unhealthy nature of the

websites and highlighted the comparison and competition they led to:

Using the forums leads to competitiveness. I see other's scars, look at my own and think 'I'm not like them, I'm not ill' and it makes the whole situation worse. [Participant 50—female, 19]

Outside of these three key areas, small numbers of participants reported, as a result of website/forum use, they either had sought external help or now took better care of their wounds.

Other Impacts of Self-Harm Websites/Forums Use

Participants were asked whether DSH website/forum use had any other impacts for them. The majority indicated that the websites/forums had no additional effects apart from those upon self-harm behaviors. However, an important number did indicate “positive psychological effects”. This theme included categories such as improved self-esteem, reduced isolation, and feeling better able to cope. Participants spoke positively of the impact of the websites upon their lives and the key role they felt they had played in their recovery:

[The websites/forums] made me realize how much others do care, that I'm not alone, and recovery is possible. [Participant 282—female, 17]

Participants also reported social effects and particularly described how the websites had facilitated the formation of new friendships and kindled positive involvement in the website/forum community:

When I was very isolated, participating in forums allowed me to feel I belonged somewhere, and have the social interaction that I was desperate for. [Participant 36—female, 23]

Smaller numbers of participants detailed the perceived “negative effects” resulting from website/forum use, in terms of both physical and psychological effects. These included categories such as increased isolation, being hurt emotionally, and feeling triggered. Some participants wrote about how they felt the sites constructed unhealthy environments where the only topic of conversation was self-harm and how this could lead to feeling triggered to self-harm:

I used [the websites] as a teenager and in retrospect I can see that it made my self-harming worse because the only thing the users had in common was self-harm. It's good to talk about it, but it was all that we talked about. I do not believe that surrounding myself with other self-harmers was good for me. [Participant 323—female, 23]

Beliefs of Users of Self-Harm Forums Regarding the Role of Such Websites

To further validate responses, participants were asked to describe in their own words the purpose of the website(s) they use to someone who does not self-harm. In line with reasons given for website use, the predominating theme in participants' answers was “help and support”. Participants described websites as sources of valued support and information for those who personally self-harmed as well as those looking for information

for friends/family members. Participants wrote passionately about support derived from such websites and how beneficial they found them to be in aiding recovery:

It's a site aimed at supporting people who self-harm, aiming to help find 'healthier' ways of coping. Self-harm isn't 'forbidden', and there isn't a timescale in which you 'have' to stop self-harming, but the ultimate aim is that help and support helps people to stop. Moderators are watchful to make sure that people aren't 'comparing' self-harm stories, and photos/images of self-harm aren't allowed too. [Participant 58 – female, 53]

Supporting wider impacts of sites, participants spoke of the “non-self-harm content” present on websites/forums used. Participants commonly reported that the websites used did not just contain information related to self-harm. They described advice relating to other mental health issues as well as general life advice found on these websites:

The website I most commonly use is a large support forum where people can get advice or support for a variety of different issues on many topics (not just self-harm). The site also has a chat room, articles and videos. [Participant 147—male, 16]

Similar numbers reported the theme of “community” in their answers further evidencing the value of this to users. This included categories such as friendships, social networking, and isolation reduction. Participants described the websites as places they could turn to in order to connect with similar others who would understand their own feelings and places where they could always find someone to talk to. Participants wrote about website use as a method of reducing the isolating and lonely experience of self-harming:

[The website used] is a community of people who vary in age, profession and lifestyle related by the fact that they use self-harm as a coping mechanism, it's NOT a teenage community where we egg each other on and share tips and photos. It's a supportive community where we listen to each other and try to support people's choices, some don't want to stop self-harming, some do, and we listen and help where we can whatever the choice. It's a community where we play games, have fun and make lifelong friends, not every conversation is dominated by self-harm, or talk of it. We are a microcosm of society, but we share a common pain, and support each other as much as we can. [Participant 118—female, 24]

Discussion

Principal Findings

This is the first multisite study to examine the use and effects of using DSH websites. It recruited a large sample size from a broad range of websites and has produced several findings for discussion.

From the demographic questions it is evident the sample is typical compared to the self-harming population as previously described in the literature, seen in terms of gender [7] and DSH

behaviors [1-5], highlighting the validity of this study. Results have been grouped into two key areas for discussion, which naturally address the two sides of the debate about DSH website impact: benefits and worsening self-harm.

Benefits

This study's results suggest there are several benefits of engaging in website/forum use in terms of recovery or reduction of self-harm behaviors. Analysis of responses shows that the majority of participants are using self-harm websites/forums for recovery-based reasons, either to seek help or to reduce self-harm.

The theme with the highest strength of reporting was “help and support” for both why individuals engage in website use and their beliefs regarding the role of such websites. Participants detailed how important they felt support gained from the websites is and wrote about the significant role of websites in facilitating their recovery, clearly highlighting the positive impacts of website use. This finding is in keeping with the findings of previous studies by Whitlock et al [8] and Messina et al [14] who identified such websites as providing valuable support for those who self-harm. This predominating positive theme can help to explain why, when looking at the effects of using self-harm websites, most felt their self-harm behavior(s) had improved since using the websites, in terms of both frequency and severity.

Another commonly reported theme for website use was “distraction and expression”. Participants detailed feelings of frustration and an inability to express feelings to people outside of the virtual community. The websites were described as places where participants felt they could “be themselves” and “vent” without feeling judged or stigmatized. Participants felt this enabled exploration of reasons behind their self-harm and provided alternative methods of dealing with their feelings, demonstrating the benefit of such sites in terms of reducing self-harm behaviors. Similarly, individuals described how they would use the websites instead of self-harming when they felt the urge to do so, showing how website use can be a useful distraction strategy from the desire to self-harm and for reducing self-harm.

Increased awareness and understanding of other mental health issues, such as depression and eating disorders, was commonly reported as a result of engaging in website use. This is significant as other mental health issues are highly likely to be comorbid with self-harm. The deepened understanding and awareness gained could help explain why the websites were felt to be places without judgment and stigmatization as participants had personal or first-hand experience of such issues themselves.

Additionally, there appear to be social benefits from engaging in website use. Many individuals wrote about website use as a way of forming friendships and how this reduced the isolation and loneliness they felt either as a result of or concurrent to their self-harm. This in turn led to improved self-esteem and confidence, demonstrating the positive psychological changes that can be associated with website use.

The idea of social benefits is supported by the theme of “isolation reduction and community engagement”, having the

second highest strength of reporting. Many wrote of the isolating experience of self-harm and how website use was the only way of being able to communicate with others offering understanding. Similarly, many individuals reported they initially engaged in DSH website use to know they “weren’t alone” and seek other people feeling/behaving in the same way, clearly demonstrating the role of these websites in providing a community. Such findings, highlighting the importance of the virtual community among people who self-harm, are in line with previous research identifying sense of community as a key reason as to why people engage in such website use [8,15].

Some individuals reported that as a result of feeling less isolated and reassured that they weren’t the only person who self-harmed, they were encouraged to tell people outside of the virtual community and seek professional help. This shows the benefits of the online community in promoting recovery.

Worsening Self-Harm

Despite the predominantly positive findings, some wrote that they used the websites to look for triggering material or tips. Additionally, answers revealed the competitive nature of self-harm that can be fueled through engaging in website/forum use, highlighting the dangers of website use for this vulnerable population. These findings are in line with previous research that has identified that use of such websites can result in encouragement or triggering of self-harm behaviors [8,14]. Participants wrote about how some websites did not moderate material posted, and while many indicated avoidance of these types of sites, others wrote that this was a reason for engaging in use. This highlights the need for research in this area to be inclusive in terms of websites used.

Although the sites are clearly used by some to trigger self-harm behaviors, it is interesting to note that when participants were asked when they had first looked at DSH websites, the majority reported they had viewed the websites only *after* starting self-harming. This shows that for most participants, it is not the websites themselves providing the trigger for the initiation of self-harm behaviors, although they can contribute to the maintenance or worsening of behaviors for some.

As mentioned, the majority felt that website use had either improved or not changed their self-harm behaviors; however, a significant number felt that website use had worsened their self-harm behavior. This group cannot be ignored, and answers suggest that competition between users and triggering posts by others detailing methods and extent of injuries are key factors contributing to worsened self-harm behavior.

Some individuals felt that using the websites had resulted in negative psychological effects such as increased isolation and worsened mood. These participants wrote of being shunned by other website users and being made to feel inadequate, highlighting that acceptance into virtual communities carries some of the same risks and etiquette as real communities and is a challenge for some individuals.

Limitations

This questionnaire was solely available in English, meaning results may not be generalizable outside of the English-speaking community. Furthermore, research insurance restrictions meant this study did not include citizens from the United States. If a US citizen tried to complete the questionnaire, SurveyMonkey directed them to the end of the questionnaire after completing the demographic questions.

Participants for the study were recruited via DSH websites and forums. This may mean that the study underestimates the harmful effects of such sites as those who felt significant negative effects resulting from use may no longer do so, and they therefore would not have been able to access the questionnaire. Additionally, the results of this study suggest that the sample was highly active in terms of their use of DSH websites. We acknowledge that this may not be representative of all users of DSH websites. We also recognize that all data collected were retrospective and self-reported.

DSH websites/forums are diverse in content and ethos, and there were several sites that the questionnaire was not posted on due to restricted access or not being able to gain permission to post. Therefore, the results do not apply to all websites in existence, and other harms/benefits may exist relevant to specific sites. It should be remembered that the virtual world is constantly changing and websites are regularly created or deleted, which highlights this as an evolving area for future research. This is particularly relevant in terms of new types of sites and social media, such as Tumblr and Twitter, which many participants reported using more frequently now than the forums they previously used.

Despite these, this study gained a large and valid sample and has generated many important results and key points for discussion, demonstrating its worth. The results have implications for clinicians and from a public health perspective.

Conclusions

Overall, the results of this study show that there are benefits to engaging in use of DSH websites/forums in terms of gaining help and support, reducing self-harm behaviors, reducing isolation, and other positive psychological changes such as improved self-esteem. However, negative aspects of website use have also been reported in terms of worsening self-harm behaviors, triggering material, and negative psychological effects such as increased isolation, highlighting the dangers of engaging in website/forum use. Clinicians should be mindful of the existence of these websites/forums when engaging with patients who self-harm, and discussion of an individual’s reasons for using such sites and the benefits/harms derived would be appropriate. If necessary, treatment plans should include strategies to maximize benefits and minimize harm derived from these sites.

Given the fluid and rapidly changing nature of the virtual world, further research into sites and the new platforms available facilitating self-harm material is recommended.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

The questionnaire.

[[PDF File \(Adobe PDF File\), 17KB - jmir_v15i12e285_app1.pdf](#)]

Multimedia Appendix 2

Websites that hosted a link to the questionnaire.

[[PDF File \(Adobe PDF File\), 3KB - jmir_v15i12e285_app2.pdf](#)]

Multimedia Appendix 3

Analysis maps.

[[PDF File \(Adobe PDF File\), 251KB - jmir_v15i12e285_app3.pdf](#)]

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Original Paper

The Sexunzipped Trial: Optimizing the Design of Online Randomized Controlled Trials

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Abstract

Background: Sexual health problems such as unwanted pregnancy and sexually transmitted infection are important public health concerns and there is huge potential for health promotion using digital interventions. Evaluations of digital interventions are increasingly conducted online. Trial administration and data collection online offers many advantages, but concerns remain over fraudulent registration to obtain compensation, the quality of self-reported data, and high attrition.

Objective: This study addresses the feasibility of several dimensions of online trial design—recruitment, online consent, participant identity verification, randomization and concealment of allocation, online data collection, data quality, and retention at 3-month follow-up.

Methods: Young people aged 16 to 20 years and resident in the United Kingdom were recruited to the “Sexunzipped” online trial between November 2010 and March 2011 (n=2036). Participants filled in baseline demographic and sexual health questionnaires online and were randomized to the Sexunzipped interactive intervention website or to an information-only control website. Participants were also randomly allocated to a postal request (or no request) for a urine sample for genital chlamydia testing and receipt of a lower (£10/US\$16) or higher (£20/US\$32) value shopping voucher compensation for 3-month outcome data.

Results: The majority of the 2006 valid participants (90.98%, 1825/2006) were aged between 18 and 20 years at enrolment, from all four countries in the United Kingdom. Most were white (89.98%, 1805/2006), most were in school or training (77.48%, 1545/1994), and 62.81% (1260/2006) of the sample were female. In total, 3.88% (79/2036) of registrations appeared to be invalid and another 4.00% (81/2006) of participants gave inconsistent responses within the questionnaire. The higher value compensation (£20/US\$32) increased response rates by 6-10%, boosting retention at 3 months to 77.2% (166/215) for submission of online self-reported sexual health outcomes and 47.4% (118/249) for return of chlamydia urine samples by post.

Conclusions: It was quick and efficient to recruit young people to this online trial. Our procedures for obtaining online consent, verifying participant identity, automated randomization, and concealment of allocation worked well. The optimal response rate

for the online sexual health outcome measurement was comparable to face-to-face trials. Multiple methods of participant contact, requesting online data only, and higher value compensation increased trial retention at 3-month follow-up.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 55651027; <http://www.controlled-trials.com/ISRCTN55651027> (Archived by WebCite at <http://www.webcitation.org/6LbkxdPKf>).

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KEYWORDS

Internet; randomized controlled trials as topic; outcome assessment (health care); sexual health; sexually transmitted diseases; behavioral research

Introduction

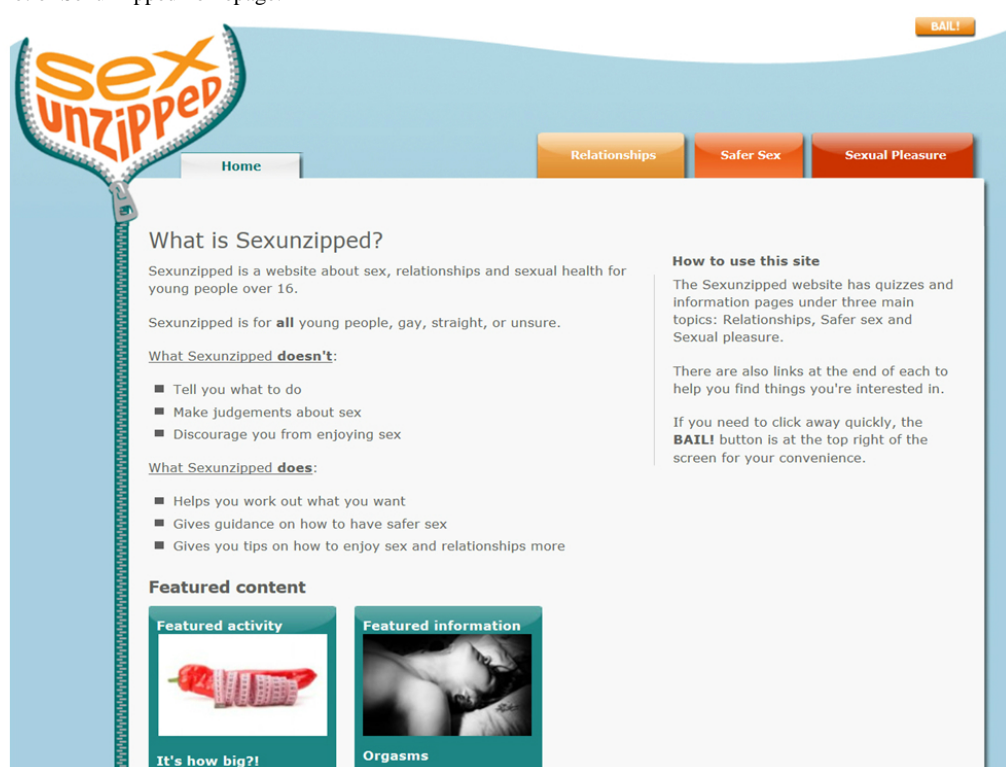
Sexually transmitted infection (STI), unwanted pregnancy, and abuse within relationships are public health problems that have a high impact on young people [1,2]. There are high social and economic costs, making it important to identify cost-effective interventions [3]. Digital media interventions for sexual health have great potential because of the reach and popularity of technology such as the Internet and mobile phones, especially with young people [4]. Such interventions offer advantages over face-to-face interventions since they can be accessed privately and at users' convenience [5] and programs can be tailored to meet users' needs [6].

Interactive computer-based interventions for sexual health promotion can lead to improved knowledge, self-efficacy, intention, and sexual behavior (including increased condom use and reduced numbers of partners), and reduced STI [7-9], although more evidence is needed to be certain of these effects. Online trials are increasingly being used to evaluate online interventions since they offer the advantage of ease of access

to large numbers of potential participants, the facility for automated randomization, reminders, data collection, and facility for blind allocation to intervention or control [10]. There is a strong argument that interventions delivered online should also be evaluated online to maximize the trial's external validity (generalizability) [10]. However, there can be very high loss to follow-up in online trials [10], with some studies losing two-thirds of participants or more [11-13]. There is also the challenge of verifying participant identity online (to prevent repeat registrations) [14] and potential concerns about the internal validity (trustworthiness) of online data [15].

The "Sexunzipped" website is an interactive, theory-based website that aims to give young people the tools to make informed decisions about their sexual well-being (see [Figure 1](#)) [16-18]. We conducted a randomized controlled trial to inform the feasibility of a future definitive online randomized controlled trial to evaluate the Sexunzipped website and to contribute to knowledge about the optimal design of online trials [10] including the best ways to measure sexual health outcomes online [15].

Figure 1. Screenshot of Sexunzipped homepage.



Methods

Study Objectives

This study addressed the feasibility of several parameters of online trial design: recruitment route, online consent, participant identity verification, randomization procedures, concealment of allocation, online data collection, data quality, and trial retention at 3-month follow-up. Two sub-studies were conducted: (1) effect on overall response rates of asking participants to return a chlamydia urine sample by post in addition to online sexual health outcome measurement, and (2) effects on response rates of two different levels of compensation.

Online Trial Design

Ethical committee permission was granted by the University College London ethics committee (reference 1023/002). This trial was registered with International Standard Randomized Controlled Trial Number (ISRCTN55651027).

Participant Recruitment

We used a number of different avenues to invite young people aged 16 to 20 years to participate in the study. We emailed and telephoned staff in schools throughout the United Kingdom, asking their help to disseminate study information to pupils aged 16 years and over. Several youth organizations disseminated information, including the UK Youth Parliament and PACE (a charitable organization for lesbian, gay, bisexual, and transgender people). We also distributed printed flyers in three London sexual health clinics for young people and gave out flyers outside a large inner city school for 16 to 19 year olds. We posted an advertisement on the social networking website Facebook, making the advertisement visible only to Facebook users who were 20 years or younger and resident in the United Kingdom. Facebook imposes restrictions on sex-related advertising (including sexual health), so we could not post the advertisement to those under 18. The advertisement featured the Sexunzipped logo and asked, "Interested in sexual health? Willing to help us with our research?" Those interested clicked on the advertisement to take them to the Sexunzipped enrolment splash page. We paid a fee per click and the advertisement was withdrawn once a pre-specified daily cost limit was reached. Study information was also posted online by a number of sexual health bloggers and the study was advertised on the UK National Health Service SHO-Me website. Finally, we emailed study participants to ask them to invite friends to participate.

Online Enrolment and Consent

Young people were invited to enroll for the research by clicking on a button on the Sexunzipped website that asked, "Are you interested in sexual health? Willing to help us with our research? Sign up for the Sexunzipped sexual health study and receive a £10 voucher for participating. Click below to find out what's involved." This led to two eligibility screening questions that allowed only those who said they were currently resident in the United Kingdom and aged between 16 and 20 years to register. Participants were then presented with study information and a consent form online (with checkboxes to agree or disagree with statements) and given a researcher email address and telephone

number for queries. Participants were told that they (1) would be asked to complete an online sexual health questionnaire at baseline and in three months' time, (2) would be allocated to one of two versions of a sexual health website, and (3) might also be asked to provide a urine sample for chlamydia testing to return by post. Those consenting to the research created a username and password and were then directed to an online questionnaire that elicited demographic information and measured baseline sexual health outcomes.

Compensation Offered

Participants were offered a £10 (US\$16) shopping voucher for complete follow-up data (either online questionnaire only or both online questionnaire and chlamydia urine sample). We opted for a voucher sent by post in order to ensure that participants gave valid addresses and to reduce the risk of repeat registrations in order to get the incentive. Participants allocated to receive a chlamydia test kit were sent £5 (US\$8) of the compensation in advance, enclosed with the chlamydia kit. The voucher could be redeemed in a variety of different stores including clothes shops, news agents, bookshops, etc. During collection of 3-month follow-up data, we reviewed retention rates and decided to test whether a higher value voucher of £20 (\$32) would increase retention. From this point onwards, the remaining participants were individually randomized to receive either a £10 or a £20 voucher (n=902) ([Multimedia Appendix 1](#)).

Methods of Randomization

There were three individual one-to-one randomizations in the study. At recruitment, all participants were randomized in a factorial (2x2) design to either the intervention or control website and to receive or not receive a urine sample kit for chlamydia testing at follow-up. In addition, the final 902 participants were randomized after recruitment to a £10 or £20 voucher to complete follow-up as requested. The first two randomizations were performed using an automated computer algorithm and the third was performed off-site by random permutation of participant identifiers.

Concealment of Allocation

Participants were automatically allocated by computer to control or intervention after submitting baseline data, with their passwords allowing access to either intervention *or* control website only. Neither participants nor researchers were aware of allocations in advance. There was no compensation offered for submitting baseline data. All participants were offered a £10 voucher for complete follow-up data (the 3-month online questionnaire plus the urine sample for chlamydia testing if allocated). Allocation to receipt of a chlamydia testing kit was disclosed in an email at 6 weeks, which revealed whether a chlamydia sample would be requested at 3-month follow-up. For those later allocated to the increased compensation of £20, this was revealed in the 3-month follow-up email. The trial manager (OM) was aware of allocations to the voucher and urine sample after the event, since she was responsible for postage of chlamydia test kits and appropriate value vouchers. The trial manager was not aware of allocation to intervention or control.

Identity Verification and Consistency Checks

Participants were asked for their email address and postal address and informed that the voucher would be sent by post. We excluded participants who gave registration information that appeared fraudulent, for example, multiple registrations using the same postal address or multiple similar names or email addresses. Possible duplicate registrations were checked by manually sorting data within an Excel file. We requested date of birth and gender at baseline and also at 3-month follow-up, on the assumption that if those facts were falsified at baseline, participants may not have recalled the falsified date or gender three months later. We checked responses for inconsistent or unlikely answers (for example, selecting the first or last response option available and inconsistent responses to questions about sexual activity and condom use).

Online Sexual Health Outcome Measurement

Demographic information including age, gender, ethnicity, and employment was collected at baseline via an online survey instrument. We used the “Sexunzipped sexual health questionnaire” to capture sexual health outcomes at baseline and again at 3-month follow-up. The Sexunzipped questionnaire contained items from available validated sexual health outcome measurement instruments including indicators for AIDS prevention programs [19], the National Survey of Sexual Attitudes and Lifestyles [20,21], and the HARK four-question scale to assess intimate partner abuse [22]. The survey instrument measured mediators of sexual behavior change (sexual health knowledge, self-efficacy, and safer sex intentions) as well as sexual behavior (condom and contraception use, use of services, and partner numbers), self-reported sexually transmitted infections, pregnancy, sexual problems, partner abuse, regretted sex, sexual pleasure, relationship satisfaction, and sexual satisfaction (Multimedia Appendix 2). All questions required mandatory responses except for questions on sexual practices. A “not applicable” option was available for the majority of the sexual health questions.

Intervention and Control Websites

Participants were given unlimited access to their allocated website during the course of the trial. An automated email was sent to participants at 6 weeks and 9 weeks after registration to encourage exploration of the website. There was no compensation offered for engagement with the intervention or control websites.

Website usage (individual page views) was tracked through Google analytics and using bespoke (custom) software to track page views by participant unique identifier (on log-in to the website with a self-chosen username and password). We did not record time spent on the allocated websites. We chose not to track Internet Protocol (IP) addresses, since users may have received IPs that were dynamically assigned to them by Internet service providers, so they would have been liable to change.

The Sexunzipped intervention website focused on safer sex, relationships, and sexual pleasure, aiming to give young people the tools to make informed decisions about their sexual health

[16]. The site content and design was informed by the integrated behavioral model and other theory, addressing mediators of behavior change such as beliefs, attitudes, perceived norms, and sense of personal agency as well as safer sex behavior and communication skills [17]. The website was structured to encourage active engagement with material, for example, quizzes that gave tailored feedback and activities that invited participants to enter personally relevant data and to reflect on decisions.

The trial control condition was an information-only control website that shared the same logo and colors as the Sexunzipped intervention site, but had no interactive activities. The website gave brief information on topics such as sexually transmitted infections, contraception, and sexual practices, but did not encourage self-reflection, decision-making, or the development of communication skills.

Outcome Data Collection and Compensation Offered

Participants were sent an email at 13 weeks after registration, which provided a Web link to the 3-month online questionnaire. The questions asked at follow-up were identical to sexual health outcomes elicited at baseline. Non-responders were sent five further reminders by email or post (with the chlamydia test kit), and then sent a shortened version of the online questionnaire by post, containing 11 questions to be returned in a stamped addressed envelope in return for the voucher. We sent a final email to non-responders, which contained three key outcome questions in the body of the email instead of a Web link to the full survey. No compensation was offered for response to this final email. There were initial technical problems in submitting the questionnaire online, so the first 106 participants were sent the £10 voucher regardless of whether they had succeeded in submitting it.

Participants randomized to receive a urine sample kit by post at three months for genital chlamydia testing (n=1030) were sent a kit containing instructions, a urine sample container, and a prepaid envelope addressed to the laboratory. Non-responders received one repeat kit by post. Samples were analyzed by The Doctors Laboratory (TDL), using the Becton Dickinson BD Viper chlamydia Trachomatis Polymerase Chain Reaction DNA test. Results were sent by text, by telephone, or posted by mail according to participant preferences stated on the chlamydia test request form. Most participants chose to receive test results by text. Those with positive results were telephoned by the trial manager and were advised to seek treatment from local health services.

Sample Size

A sample size of 1200 participants was estimated to provide 80% power to detect a difference in retention at the 5% significance level such as 45% vs 35% in retention rates between groups. Recruitment on Facebook was so straightforward and cheap that we decided to exceed this target number. However, this resulted in large numbers of participants aged 18 years and over and a much smaller proportion of younger participants (see Table 1).

Table 1. Participant age at enrolment (by gender, male or female).

Age in years	Female, n=1259, n (%)	Male, n=735, n (%)	Total, n=1994, n (%)
16	41 (3.26)	29 (3.95)	70 (3.51)
17	72 (5.72)	32 (4.35)	104 (5.22)
18	448 (35.58)	213 (28.98)	661 (33.15)
19	410 (32.57)	268 (36.46)	678 (34.00)
20	287 (22.80)	192 (26.12)	479 (24.02)
21 or more	1 (0.08)	1 (0.14)	2 (0.10)
Total	1259 (100)	735 (100)	1994 (100)

Data Analysis

The primary outcome for this feasibility study was retention of valid participants at 3-month follow-up, that is, completion of the online sexual health questionnaire only or both sexual health questionnaire and chlamydia urine sample (according to prior allocations). We analyzed measures of feasibility and process including numbers recruited by source, number of rejected ID verifications, numbers responding to email and postal follow-up prompts by level of compensation and allocation to chlamydia test kit, and proportion of urine samples testing positive for genital chlamydia. For the entire group of participants, the probability of retention was modeled in terms of group allocation, website usage, level of compensation, demographic variables, and sexual behavior determinants, using univariate and multivariate logistic regression. Retention was defined as response to requests for follow-up data (online or postal questionnaire and chlamydia test sample) at 3 months. In univariate analysis, we explored how each variable was individually associated with retention (see [Multimedia Appendix 3](#)). We subsequently performed multivariate logistic regression where all the variables were included concurrently in the regression model. Significant predictors of retention were then identified using a forward stepwise selection procedure (the significance levels for removal and addition to the model were .1 and .05, respectively) starting with all predictors in the model (see [Multimedia Appendix 3](#)). A *P* value of .05 or less was considered statistically significant. Statistical analyses were conducted using STATA Version 12.

Results

Online Trial Eligibility, Recruitment, and Retention

[Multimedia Appendix 1](#) indicates the numbers eligible, recruited, excluded, and retained at follow-up. Since the outcome of interest was retention at 3 months, *all* participants (including non-responders at 3 months) were included in analyses.

Participant Identity Verification and Data Quality

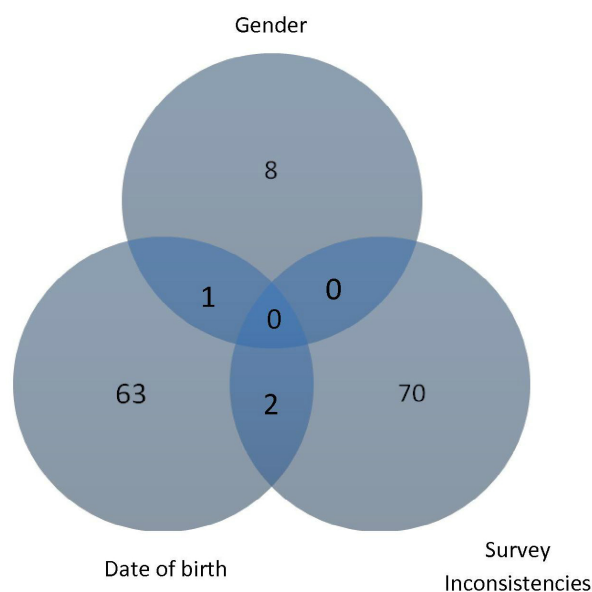
After registration, 18 participants asked to be withdrawn from the study. Of these, 7 gave a reason: 3 did not want to give a urine sample, 2 were concerned about mail coming to the house, and 2 said their friends had enrolled them as a joke. There were

12 participants who appeared to have registered more than once (on the basis of the same or very similar names, email, or postal addresses). These participants were removed, leaving 2006 participants retained in the analysis of the effect of voucher compensation.

No participants chose extremes of response option for every question (for example, selecting the first or last response option available). In total, 66 participants (3.29%, 66/2006) gave discrepant dates of birth at baseline and 3 months later, and one person wrote nonsense (unintelligible content) in many of the free-text boxes. In addition, some participants gave inconsistent answers within the baseline questionnaire: 15 participants (0.75%, 15/2006) indicated that they were in a sexual relationship but also that they had never had sex (involving genital contact), 50 participants (2.49%, 50/2006) said that they had not used a condom at last vaginal sex but also reported no episodes of unprotected vaginal sex in the last three months, and 11 participants supplied answers to questions that should have been skipped (on the basis of their previous answers). Furthermore, 9 participants reported discrepant genders at baseline and follow-up, and 2 participants were 21 or over, suggesting they must have entered an age between 16 and 20 years in response to the initial eligibility screening questions, but later submitted dates of birth out of this range in the online questionnaires.

It is difficult to evaluate these inconsistencies—there may have been data entry mistakes, technical problems with the questionnaire skip pattern, questions may have been interpreted in ways that we had not anticipated, and it is possible that some participants may have changed gender identity between baseline and follow-up. A total of 3.88% (79/2036) entries were therefore deemed invalid on the basis of repeat contact details, discrepant dates of birth, or nonsense responses, and a further 4.00% (81/2006) participants gave an inconsistent gender at two time points or inconsistent responses to sexual health questions. There was little overlap between these inconsistencies (see [Figure 2](#)).

Our analyses excluded participants who appeared to have registered more than once, but retained those with inconsistent responses (total n=2006), since these respondents contribute to understanding the effect of increased compensation.

Figure 2. Numbers of participants giving discrepant or inconsistent responses.

Participant Recruitment

Most of the 2006 participants were recruited via an advertisement on Facebook (84.00%, 1685/2006), with 8.97% (180/2006) via friends or relatives, 3.99% (80/2006) via email, and only 1.99% (40/2006) through school or college. There were an estimated 2,846,204 Facebook users resident in the United Kingdom who were aged 18-20 years in 2010 (47% female and 53% male) [23], but we do not know how many of the target audience actually saw the advertisement, since it was withdrawn once a daily cost limit was reached. An estimated 6705 people viewed the Sexunzipped enrolment website (figure estimated from Google analytics and bespoke page view tracking software). Of these, 4926 met the eligibility criteria for age and UK residence, 2600 went on to submit online consent forms, 2207 created user accounts (supplying usernames and passwords), and 2036 submitted baseline demographic and sexual health data (41.33%, 2036/4926) of people meeting the eligibility criteria. After participant withdrawals and removal of those who appeared to have registered more than once, 2006 people remained (see [Multimedia Appendix 1](#)).

Online Trial Participants

Trial participants (n=2006) were recruited between November 2010 to March 2011. Two-thirds of the sample (62.81%, 1260/2006) were female, 36.59% (734/2006) male, 0.25% (5/2006) female to male transgender, 0.99% (2/2006) male to female transgender, and 0.25% (5/2006) “other”. Participants ranged in age from 16 to 21 years, with a median age of 19 years (see [Table 1](#), presented by gender). Participants were recruited

from all four countries in the United Kingdom, with 81.40% (1633/2006) from England, 7.63% (153/2006) from Scotland, 3.84% (77/2006) from Wales, and 4.64% (93/2006) whose location could not be deduced from the postal code supplied. The majority of participants were white (89.17%, 1778/1994) (see [Table 2](#), presented by gender). Most participants were students at school, college, or university (77.48%, 1545/1994), with 28.18% (562/1994) in employment, 8.02% (160/1994) unemployed, 2.00% (40/1994) in a “gap year” before college or university, 1.00% (20) sick or disabled, and 1.00% (20/1994) full-time parents or caregivers.

At baseline, 1229/2006 participants (61.27%) reported being in a relationship with one person, 65/2006 (3.24%) were in relationships with more than one person, and 711/2006 (35.44%) were not in a relationship. Of the latter group, 80 (3.99% of the whole sample, 80/2006) had never been in a relationship. The majority of current or past relationships were sexual (92.00%, 1772/1926) and only 108/2006 of the sample (5.38%) had never had (genital) sex. Most participants reported predominantly opposite-gender sexual attraction (87.45%, 1101/1259 of female participants and 77.14%, 567/735 of male participants) (see [Table 3](#)).

We were concerned that participants might re-register to gain access to the intervention site, but there was no evidence of this: 51.54%, 1034/2006 were allocated to the intervention site, which is consistent with random variation in allocations (95% CI 49.4-53.7). The majority of participants (75.77%, 1520/2006) visited the intervention or comparator websites, with 29.91% (600/2006) visiting 11 or more web pages (see [Table 4](#)).

Table 2. Ethnicity (by gender, male or female).

Ethnicity	Female, n=1259, n (%)	Male, n=735, n (%)	Total, n=1994, n (%)
White British	1051 (83.47)	628 (85.44)	1679 (84.20)
White Irish	26 (2.07)	20 (2.72)	46 (2.31)
White other	30 (2.38)	23 (3.13)	53 (2.66)
Asian British, South East Asian, Chinese	27 (2.14)	26 (3.54)	53 (2.66)
Black British, African, Caribbean	40 (3.18)	8 (1.09)	48 (2.40)
Mixed cultural background	48 (3.81)	15 (2.04)	63 (3.16)
Other background	2 (0.16)	0 (0.0)	2 (0.10)
Prefer not to say	35 (2.78)	15 (2.04)	50 (2.51)
Total	1259 (100)	735 (100)	1994 (100)

Table 3. Sexual attraction (by gender, male or female).

Sexual attraction	Female, n=1259, n (%)	Male, n=735, n (%)
Only to females, never to males	14 (1.11)	443 (60.27)
More often to females and at least once to males	49 (3.89)	124 (16.87)
About equally often to females and to males	88 (6.99)	32 (4.35)
More often to males and at least once to females	488 (38.76)	51 (6.94)
Only to males and never to females	613 (48.69)	81 (11.02)
I have never felt sexually attracted to anyone	7 (0.56)	4 (0.54)
Total	1259 (100)	735 (100)

Table 4. Number of pages of intervention or comparator websites viewed.

Number of pages viewed	Allocated to intervention website, n=1034, n (%)	Allocated to comparator website, n=972, n (%)	All participants, n=2006, n (%)
0	251 (24.27)	235 (24.18)	486 (24.23)
1-5	346 (33.46)	229 (23.56)	575 (28.66)
6-10	176 (17.02)	169 (17.39)	345 (17.20)
11 or more	261 (25.24)	339 (34.88)	600 (29.91)
Total	1034 (100)	972 (100)	2006 (100)

Outcome Data Collection

We reported the response rates to each round of prompting for the online sexual health questionnaire (n=2006) and postal chlamydia samples (n=1030) at 3-month follow-up.

Online Questionnaire

The overall response rate for the 3-month online sexual health outcome questionnaire was 71.78% (1440/2006), combining responses to emailed and postal follow-up invitations.

Follow-Up Emails With Web Link to the Online Questionnaire

In total, 60.22% of participants (1208/2006) completed the online questionnaire in response to an email at 3 months with a Web link to the survey instrument: 36.09% (724/2006)

responded to the first emailed request; 11.62% (233/2006) to the second reminder (by email or postal, with the chlamydia sample); 4.99% (100/2006) to the third; 3.39% (68/2006) to the fourth; and 4.09% (82/2006) to the final email reminder.

Follow-Up by Post

Non-responders (798 participants) were sent the shortened 11-question version of the online questionnaire by post. In total, 208/798 (26.07%) responded to this postal follow-up, boosting the overall response rate by 10.37% (208/2006); 79 paper questionnaires were returned uncompleted (9.90%, 79/798), marked by the UK Royal Mail as "Addressee gone away" or "Incorrect or incomplete address or name"; and 11 people returned the questionnaire without completing it.

Follow-Up Emails With Questions in the Email Body

We sent one final email to the 560 remaining non-responders, with three key outcome questions in the body of the email text instead of a Web link to the full online survey. Of these emails, 42/560 (7.50%) bounced back (ie, were invalid email addresses), 27 people (4.82%, 27/560) responded (1.35%, 27/2006 of the total sample), providing data on self-reported chlamydia in the last 3 months and condom use at last anal and vaginal sex.

Postal Urine Sample for Chlamydia Testing

In total, 1030 participants were asked to return a urine sample for chlamydia testing: 32.14% (331/1030) returned the urine sample after the first postal invitation, one sample required a second posting following damage in the post, and a further 12.72% returned the urine sample after the second request (131/1030). Five additional samples were returned but could not be processed: two were mislabeled, two were insufficient samples, and the laboratory was “unable to process” one sample, giving an overall response rate of 44.95% for processed samples (463/1030). There was no response from 54.56% of participants (562/1030); of these non-responders, 15 sample kits were returned with wrong or incomplete addresses, 14 were returned “addressee unknown” or “gone away”, and 20 sample kits were returned uncollected from post offices. Of the urine samples that could be processed, 11/463 (2.38%) tested positive for

chlamydia Trachomatis on a Nucleic Acid Amplification Test (NAAT).

Impact on Response Rates of Requesting a Urine Sample by Post

Of the 976 participants who were asked only to complete the 3-month questionnaire, 736/976 (75.41%) completed it. Requesting a chlamydia test urine sample in addition to the online sexual health questionnaire reduced the retention rate considerably, with only 429 out of the 1030 (41.65%) completing both. A total of 31/1030 participants (3.01%) sent back the urine sample but did not complete the 3-month questionnaire, and 275/1030 (26.70%) completed the 3-month questionnaire but did not send back the urine sample. Being asked to return a urine sample as well as to fill in the online questionnaire significantly reduced the overall response rates for complete outcome data (41.65%, 429/1030 vs 75.41%, 736/976, $P < .001$).

Levels of Compensation Offered

To test the effect of compensation offered, 902 participants were randomized to receive either a £10 or a £20 voucher for complete follow-up data. Table 5 shows the effect of doubling the compensation to £20 and the effect of being asked to fill in the online questionnaire and return a urine sample for chlamydia testing. A higher value voucher boosted response rates by 6-10%.

Table 5. Response rates at 3-month follow-up by level of compensation offered and chlamydia sample request.

Allocation (total n=902)	Asked to fill in online questionnaire and chlamydia sampling (n=485)				
	Asked to fill in online questionnaire only (n=417)	Questionnaire completion rate n (%)	Questionnaire completion rate n (%)	Chlamydia sample response rate n (%)	Complete data set (both questionnaire and chlamydia sample) n (%)
£10 voucher	144/202 (71.29)		149/236 (63.14)	97/236 (41.10)	91/236 (38.56)
£20 voucher	166/215 (77.21)		183/249 (73.49)	118/249 (47.39)	111 ^a /249 (44.58)
<i>P</i> value (chi-square significance test)	.20		.01	.19	.21

^aIncludes one sample returned but not processed (insufficient sample).

Analysis of Retention at Three Months

There was no differential retention by allocation to control or intervention group, age, living in London, recruitment route (Facebook vs other routes including email, known contacts, leaflets, or posters), being in a sexual relationship, time since last sex, safer sex (defined as condom use at last vaginal or anal sex), last sex with a regular/non-regular partner, having talked about sexual desires, sexual problems, regretted sex, vaginal or anal sex at last sex, nor by range of sexual activities (see Multimedia Appendix 3). We found significantly lower retention for males compared to females (OR 0.61, 95% CI 0.49-0.75), “non-white” participants compared to white (OR 0.58, 95% CI 0.44-0.75), participants who had ever had sex (OR 0.47, 95% CI 0.27-0.81), and allocation to receive a chlamydia test kit (OR 0.65, 95% CI 0.53-0.79), and significantly higher retention among those who were attracted only to same-gender partners

(OR 1.84, 95% CI 1.28-2.65), those at school, college, university, or training (OR 1.73, 95% CI 1.37-2.20), in a relationship with one person (OR 1.38, 95% CI 1.11-1.71), and in relationships of more than one week (OR 2.65, 95% CI 1.15-6.11). Higher engagement with the control/intervention websites was associated with increased probability of retention at 3-month follow-up and, as expected from the results reported above, participants who were given the higher value voucher (£20) were more likely to submit follow-up data than participants in the £10 voucher group (OR 1.29, 95% CI 1.03-1.61).

Discussion

Principal Findings

The online trial methodology used to test the Sexunzipped website proved acceptable to young people, as evidenced by retention at three months, which was comparable with retention rates in a school-based longitudinal cohort study [24]. Online recruitment to the trial was quick and easy [12,13]. A low proportion (3.88%) of apparently fraudulent enrolment was detected by manually checking contact details, checking for unlikely response options or meaningless free-text responses, and requesting date of birth at baseline and follow-up. The internal validity of our online data was good, with 96.0% supplying consistent responses within the sexual health questionnaire.

Higher value compensation increased response rates by 6-10%, yielding a maximal retention rate at 3-month follow-up of 77.21% for the online questionnaire and 47.39% for the postal chlamydia sample with a £20 shopping voucher. Online sexual health outcome measurement is therefore an efficient method of gathering self-reported outcome data of good quality. Our findings align with other studies that report higher retention with repeated reminders, multiple routes of contact (including email, text message, post, and telephone), and higher value compensation [25,26].

Recruitment and Participants

The simplest and most effective route for recruitment was an advertisement on the social networking website Facebook, displayed only to a specific target population. However, since Facebook does not permit advertising with references to sex or sexual health to be displayed to those under 18, there are proportionately fewer of the younger age groups (16-17 year olds) in our sample (Table 1). Young women were over-represented (two-thirds of the sample), despite an even distribution in the gender of young adult Facebook users [23]. Young men were less likely to participate in this study and more likely to drop out by 3 months. We would have liked to have conducted this research with young people under 16 because Sexunzipped website content is particularly appropriate for those around the age of sexual debut (which is at a median age of 16 in Britain [21]), but this would require parental consent. Recruitment via Facebook was much cheaper, quicker, and easier than other avenues of recruitment; however, restriction on advertising to those 18 and over resulted in recruitment of participants with a higher mean age than intended. Since our Facebook advertisement was displayed only to those within our target age group and living in the UK, this will have helped to limit the possibility for fraudulent enrolment by those not meeting these criteria.

Feasibility of Online Outcome Data Collection

A particular challenge for online trials is attrition, with online studies often recruiting large numbers of participants but losing the majority by follow-up [11-13]. Our maximal retention rate for the online questionnaire (77.21%) is comparable with rates achieved in another online trial that also offered compensation and multiple follow-up reminders (79% retention at one month

and 53% at two-month follow-up) [25]. This aligns with others' findings that an online questionnaire (via a Web link in an email) produces better response rates than the same questionnaire sent by post and that offering increased compensation does have a significant impact on response rates [27]. Route of recruitment (Facebook vs other more personal routes of contact) had no effect on retention at 3 months, which supports the use of online advertising for participant recruitment.

The Sexunzipped online questionnaire was long (a maximum of 103 sexual health questions depending upon skip patterns, plus 8 questions for demographic information and contact details). Young people involved in field work for this project had previously said that they would not be willing to fill in a long questionnaire [16], but only 7.75% (171/2207) of people who created user accounts did not go on to submit baseline demographic and sexual health data. In our parallel qualitative evaluation of the trial design, young people said that they enjoyed responding to questions that they felt were relevant to them (companion paper, [28]) and our retention rates support this finding. Data sets were complete for those who submitted questionnaires online and the proportion of inconsistent responses was small (4.00%). By their nature, quantitative survey questions cannot capture subtleties of meaning for individual respondents [29]; however, our analysis of qualitative comments on the questionnaire indicated that for the most part it was judged appropriate and acceptable [28].

It is difficult to evaluate questionnaire inconsistencies since it is impossible to know whether an inconsistency represents a data entry error, misunderstanding of a question, or dishonest reporting. We removed from analysis those with repeat contact details, discrepant dates of birth, or nonsense responses, judging these to indicate possible dishonesty. Removing *all* participants with inconsistent responses would exclude those whose responses were dishonest but also those who made genuine errors on a minority of questions. This would increase the internal validity of data, but could also result in a selection bias.

Feasibility of Chlamydia Sampling

While the Sexunzipped trial was conducted principally online, a sub-sample were asked to return chlamydia test samples by post since biological outcomes are the most reliable indicators of the impact of sexual health interventions [30]. We chose to measure Genital chlamydia infection since it is the most prevalent STI in young people [31] and a Polymerase Chain Reaction test on a urine sample is non-invasive and has high accuracy. To maximize return of the samples for chlamydia testing, we implemented many of the techniques known to increase postal response rates for questionnaires [32]: we emailed participants before dispatching test kits, provided stamped return envelopes, included clear, short, personalized covering letters and chlamydia request forms, offered half of the compensation in advance, and posted second sample kits to non-responders. A proportion of sample kits (1.46%, 15/1030) were returned because of an incorrect address and 1.94% (20/1030) were not collected from post office delivery offices; the secure "biohazard" packaging may have meant that the chlamydia samples did not fit through some household letter boxes.

Chlamydia screening is opportunistic in the United Kingdom. Most screening is done via clinics or outreach schemes, but in some areas young people are contacted by post for chlamydia screening and there are also websites through which those under 25 years of age can request a postal chlamydia testing kit. Our overall response rate of 44.66% (460/1030) for chlamydia urine samples compares favorably with postal chlamydia screening initiatives (typically about 25% return rate after two postal invitations without compensation) [33], but requesting a postal chlamydia sample as well as online questionnaire data almost halved the overall response rates at 3-month follow-up. Our qualitative evaluation suggests that those who had had a recent chlamydia test may have been less motivated to receive another test result [28]. In our data, those who reported an STI check-up within the last 3 months were less likely to return a sample (41.28%, 116/281), than those who had not had a recent check-up (46.56%, 332/713), but this difference was not statistically significant ($P=.132$).

We found a similar point prevalence of chlamydia (2.38%) to that found by the UK national chlamydia screening program, which reported 2.1% positive diagnoses in 15 to 25 year olds screened in 2011 [31]. One-quarter of our sample (24.32%, 293/1205) reported an STI check up in the last 3 months (26.13%, 208/796, of female participants and 21.14%, 85/402, of male); in comparison, the UK chlamydia screening program reached an estimated 42.7% for young women and 22.6% of young men over the entire year 2010-11. The cumulative incidence of self-reported genital chlamydia (diagnosis and/or treatment over the previous 3 months) was 6.39% (77/1205), taking data from the 3-month follow-up online questionnaire.

Efforts to Increase Retention

We found that multiple reminders via two methods of contact (by email and by post) were acceptable to young people [28] and increased overall response rates from 36.09% (724/2006) to 71.78% (1440/2006) for the sexual health questionnaire and from 32.14% (331/1030) to 44.95% (463/1030) for the postal chlamydia test sample. We could have sought mobile phone numbers as a third avenue for contact [25]; however, contact by post and telephone is more resource intensive than automated emails. Outcome data collected via mobile phone may incur a cost for participants and there is more of a limit on the number of questions that can be asked. Young people may change email addresses and postal addresses frequently, so mechanisms are needed to keep these up to date, for example, requesting two different email addresses and using an email address to log in, which would prompt users to keep the address up to date.

A higher level of compensation increased the response rates by 6 to 10% for the postal chlamydia test sample and the online questionnaire at 3-month follow-up (Table 5), but these differences were not statistically significant for the most part. Requesting a chlamydia sample as well as the online questionnaire had an adverse impact on the response rate for the online questionnaire, but a higher level of compensation mitigated this, increasing the response rate from 63.14% (149/236) to 73.49% (183/249) ($P=.01$).

Limitations

The sample was a convenience sample, with participants self-selecting into this trial. This means that the sample is not representative of UK youth nor of Facebook users, which limits the generalizability of the overall findings. We recruited a diverse sample in terms of geographical location and ethnicity: 10.78% of trial participants were “non-white”, which compares with a 14% non-white population in England and Wales [34] and 2% in Scotland [35].

While our best retention rate compares favorably with many other online trials, any drop-out at follow-up limits the validity of data on intervention efficacy [10]. There was no differential retention by allocation to control or intervention group, which is important in terms of assessing the impact of the intervention. However, bias may be introduced by the fact that those retained in the trial were more engaged with the intervention/control and were more likely to be female, white, attracted to the same gender, at school/college/university, to have never had sex, and to be in relationships with one person for more than a week.

We under-recruited younger participants (aged 16-17 years); while Facebook is quick and cheap, it is probably necessary to invest more resources to attract younger participants specifically, perhaps through sexual health websites. Ideally, we would have liked to recruit 13-16 year olds, but the necessity for parental consent for participation in research makes this group hard to reach. We decided that an online form for parental consent would not be adequate, since this could be completed fraudulently by participants.

The first 106 participants experienced technical problems with the submission of the questionnaire; technical problems are a constant threat to online research and can be minimized by rigorous testing before systems go live. We designed the questionnaire with skip patterns so that irrelevant questions would not be presented. Despite pre-trial questionnaire testing, a small percentage of participants (0.55%, 11/2006) supplied answers to questions that should have been skipped, which we cannot explain.

This feasibility trial was strengthened considerably by the change of protocol on compensation level at mid-point. We decided to offer the higher incentive on review of the retention data and this has allowed us to report the success of this approach. The mid-point randomizations were generated by computer and were conducted off-site, so we have no concerns about the robustness of our trial procedures.

Future Directions

Recommendations for the conduct of online randomized controlled trials and online sexual health research can be found in Multimedia Appendix 4. These recommendations were derived from this quantitative evaluation and from the linked qualitative evaluation of the Sexunzipped trial procedures reported in a companion paper [28].

Conclusions

There is increasing realization of the potential for digital interventions for sexual health promotion [36] and for innovative data collection methods via digital media [37]. Online evaluation

offers many advantages including access to hard-to-reach populations and user-friendly, efficient, and cost-effective research administration and data collection mechanisms [15]. This paper contributes to understanding how to improve retention and ensure good quality sexual health outcome measurement in an online research environment.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Flow diagram – recruitment, allocations, and retention.

[PDF File (Adobe PDF File), 43KB - [jmir_v15i12e278_app1.pdf](#)]

Multimedia Appendix 2

Sexunzipped sexual health questionnaire.

[PDF File (Adobe PDF File), 287KB - [jmir_v15i12e278_app2.pdf](#)]

Multimedia Appendix 3

Predictors of retention at 3-month follow-up.

[PDF File (Adobe PDF File), 23KB - [jmir_v15i12e278_app3.pdf](#)]

Multimedia Appendix 4

Recommendations for the conduct of online trials and sexual health research.

[PDF File (Adobe PDF File), 73KB - [jmir_v15i12e278_app4.pdf](#)]

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Abbreviations

IP: Internet Protocol

NAAT: Nucleic Acid Amplification Test

STI: sexually transmitted infection

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Original Paper

The Effect of Patient Narratives on Information Search in a Web-Based Breast Cancer Decision Aid: An Eye-Tracking Study

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Abstract

Background: Previous research has examined the impact of patient narratives on treatment choices, but to our knowledge, no study has examined the effect of narratives on information search. Further, no research has considered the relative impact of their format (text vs video) on health care decisions in a single study.

Objective: Our goal was to examine the impact of video and text-based narratives on information search in a Web-based patient decision aid for early stage breast cancer.

Methods: Fifty-six women were asked to imagine that they had been diagnosed with early stage breast cancer and needed to choose between two surgical treatments (lumpectomy with radiation or mastectomy). Participants were randomly assigned to view one of four versions of a Web decision aid. Two versions of the decision aid included videos of interviews with patients and physicians or videos of interviews with physicians only. To distinguish between the effect of narratives and the effect of videos, we created two text versions of the Web decision aid by replacing the patient and physician interviews with text transcripts of the videos. Participants could freely browse the Web decision aid until they developed a treatment preference. We recorded participants' eye movements using the Tobii 1750 eye-tracking system equipped with Tobii Studio software. A priori, we defined 24 areas of interest (AOIs) in the Web decision aid. These AOIs were either separate pages of the Web decision aid or sections within a single page covering different content.

Results: We used multilevel modeling to examine the effect of narrative presence, narrative format, and their interaction on information search. There was a significant main effect of condition, $P=.02$; participants viewing decision aids with patient narratives spent more time searching for information than participants viewing the decision aids without narratives. The main effect of format was not significant, $P=.10$. However, there was a significant condition by format interaction on fixation duration, $P<.001$. When comparing the two video decision aids, participants viewing the narrative version spent more time searching for information than participants viewing the control version of the decision aid. In contrast, participants viewing the narrative version of the text decision aid spent less time searching for information than participants viewing the control version of the text decision aid. Further, narratives appear to have a global effect on information search; these effects were not limited to specific sections of the decision aid that contained topics discussed in the patient stories.

Conclusions: The observed increase in fixation duration with video patient testimonials is consistent with the idea that the vividness of the video content could cause greater elaboration of the message, thereby encouraging greater information search. Conversely, because reading requires more effortful processing than watching, reading patient narratives may have decreased participant motivation to engage in more reading in the remaining sections of the Web decision aid. These findings suggest that

the format of patient stories may be equally as important as their content in determining their effect on decision making. More research is needed to understand why differences in format result in fundamental differences in information search.

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KEYWORDS

personal narratives; decision aids; eye tracking; breast cancer

Introduction

Narratives (ie, personal stories about health experiences) are a popular vehicle for patients to learn about diseases and treatments, and they are commonly available on the Internet, on social media sites, and in patient decision support tools [1,2]. The proliferation of patient stories through Web-based outlets has provided researchers cause for concern given that there are strong theoretical reasons to believe that narratives have powerful effects on decision making [3,4]. Research on attitudes and persuasion suggests that patient stories are likely to be more influential than other message formats because (1) narratives have the ability to “transport” the reader or viewer into the story [5,6], (2) narratives are likely to cause greater elaboration [7], and (3) people are more likely to rely on case studies than statistical information [8]. Further, research on dual process models and the affect heuristic suggest that narratives may facilitate different modes of information processing than other message formats, which could result in greater weight given to narrative information during the decision process [9-14].

Although several recent studies have explored the role of narratives, there is still little consensus about how patient stories impact decisions about health care [3,15-22]. One likely reason for the discrepant findings is that many of these studies focused on outcomes such as treatment intentions or decisions. However, recent work suggests that narratives may also influence decision processes such as information search. Therefore, uncovering the true impact of narratives involves measuring decision processes along with outcome measures [17].

In this paper, we report the results of a study examining the effect of patient narratives on information search in a Web-based decision aid during a hypothetical breast cancer treatment task. Women in this study were asked to imagine they had been diagnosed with early stage breast cancer and needed to choose between two surgical treatments—lumpectomy with radiation or mastectomy. Participants were provided access to a Web-based decision aid about surgical treatments for early stage breast cancer and were allowed to freely browse the aid until they developed a preferred surgical treatment. Some of the women viewed a decision aid with patient narratives; others viewed a decision aid without narratives. To track information search, we monitored participants’ eye movements while viewing the Web decision aid.

Our primary research question was whether including narratives in Web decision aid would alter information search strategies. Broadly, we hypothesized that providing patient stories would increase the breadth and depth of information search. Without narratives, we expected that participants would focus on information related to survival (eg, local recurrence and survival

rates). By contrast, we predicted that patient stories about their decision process and their experiences with treatment would draw attention to other attributes of the treatments that are unrelated to survival but may be important for subjective experience and post-treatment satisfaction (eg, length of recovery time). Therefore, we predicted participants would spend more time searching for information discussed in the narratives.

Methods

Recruitment

We recruited 56 women from Wichita, Kansas, via ads in a local newspaper and on the Wichita State University website. Participants were required to be 18 years of age or older, be native English speakers, and have normal or corrected-to-normal vision. Participants were excluded from the study if they were pregnant, had previously been diagnosed with breast cancer, reported wearing bifocal or trifocal corrective lenses, reported wearing lenses with reflective coatings, or had serious eye injuries. The age and pregnancy restrictions were chosen to avoid recruiting members of vulnerable populations, as defined by the Institutional Review Board. Native English speakers were recruited to ensure adequate comprehension of the material presented in the Web decision aid. We restricted the sample to women without a personal history of breast cancer because we wanted to avoid biases in information search due to prior treatment choices. We also avoided recruiting participants with major vision problems because of the difficulties associated with eye tracking calibration.

Screening for these criteria was conducted via an online survey. Invitations to participate in the study were extended to a portion of those who completed the survey and met the eligibility requirements. However, preference was given to older adults to more accurately reflect the distribution of age among new breast cancer patients. Participants were compensated US \$100 for their study participation.

Study Materials

Participants in this study were asked to imagine that they had been diagnosed with early-stage breast cancer following the detection of a lump during a breast self-exam. A 1-page description of the diagnostic process was provided; see [Multimedia Appendix 1](#). To help with the treatment decision, participants were given one of four versions of the Web decision aid; assignment to condition was random. They were instructed to take as much time viewing the website as necessary. When they finished viewing the Web decision aid, participants indicated their preferred treatment using a 7-point Likert scale (1=Extremely likely to choose lumpectomy with radiation, 7=Extremely likely to choose mastectomy).

Web Decision Aid

The Web decision aid used in the study was constructed from a US website produced by Health Dialog that provides information about surgical treatments for early stage breast cancer and includes video interviews with patients and physicians. This website is the companion to their video decision aid, BCR001 v03. All versions of the Web decision aid included 17 pages of content that provided detailed information about lumpectomy and mastectomy using text, images, and (in some versions) videos. See [Multimedia Appendix 2](#) for a screenshot of the first page of the Web decision aid.

To examine the effect of patient narratives, we created two versions of the decision aid. In the two video conditions, participants were provided access to video controls that allowed them to play, pause, and move to different positions in the video timeline. The *video narrative* version of the Web decision aid was a replica of the Health Dialog website, which included videos of patients sharing their stories about deciding between treatments and their experiences with those treatments. The decision aid also included videos of physicians providing didactic information about early stage breast cancer and the treatments. There were 18 videos of interviews with patients or physicians included in this version of the decision aid. Videos were embedded in 7 of the 17 webpages in the decision aid. These pages provided information about (1) decisions to be made after being diagnosed with breast cancer, (2) different types of breast cancers, (3) pathology reports, (4) mastectomy, (5) lumpectomy and radiation, (6) lymph node surgery, and (7) working with your doctor. Many of these videos were clips of interviews from a single patient or physician. However, several videos included clips from multiple patient and/or physician interviews. The narratives were not tailored to the participants with respect to race, ethnicity, or other individual characteristics.

To create the *video control* version of the decision aid, we removed any videos containing patient interviews. However, the four video clips of physician interviews remained in the decision aid. These videos appeared on pages that provided information about (1) decisions to be made after being diagnosed with breast cancer, (2) different types of breast cancers, (3) pathology reports, and (4) lymph node surgery.

To distinguish between the effect of narratives and the effect of videos, we created two additional versions of the Web decision aid. We constructed a *text narrative* version of the Web decision aid by replacing the patient and physician interviews with text transcripts of the videos and a *text control* version by removing the transcripts of the patient stories. Examples of two video transcripts are provided in [Multimedia Appendix 3](#).

Participants were randomly assigned to view one of the four Web decision aids (video narrative, video control, text narrative, or text control); however, we overweighed assignment to the video conditions, with about two-thirds of participants viewing either the video narrative or video control decision aids (n=36). We chose to oversample the video conditions because they represented the naturalistic version of this decision aid. About one-third of participants (n=20) were randomized to one of the two text decision aids (text narrative or text control).

Eye Tracker

To assess information search in the Web decision aid, we used a Tobii 1750 eye-tracker integrated with a 96dpi 17-inch monitor to record participant eye movements. The Tobii 1750 samples eye movements every 20 milliseconds and has a spatial resolution of $.25^\circ$ and a spatial accuracy of $.5^\circ$. The resolution of the monitor was set to 1280 x 1024 pixels. This eye tracker is situated nonintrusively within the monitor enclosure and provides the ability to record eye movements without the use of a chinrest or head mount. In conjunction with the eye-tracker, an Intel-based computer with 2GB of RAM running Microsoft Windows Vista was used to operate the eye-tracker. All participants were calibrated on the eye-tracker using the Tobii Studio 9-point calibration routine to aid tracking accuracy. Eye movements during the study were recorded with Tobii Studio software.

Statistical Analyses

To create manageable units of analysis, we a priori divided the Web decision aid into 24 areas of interest (AOIs). Most webpages within the decision aid were defined as a single AOI. However, some webpages contained multiple subheadings with content directly related to material covered in the patient narratives. Because we wanted to assess whether information search differed for material explicitly discussed in the narratives, we examined these areas separately. To do this, we defined multiple AOIs on webpages where this occurred. For example, the webpage describing mastectomy contains several subheadings including what to expect after mastectomy, appearance after mastectomy, and local recurrence after mastectomy. Because there were two patient stories about appearance after mastectomy on this page, we expected information search about appearance to differ from information search about local recurrence for the conditions with patient stories. Therefore, we defined these three subheadings as separate AOIs within the page.

The primary outcome in this study was total fixation duration per AOI, measured in milliseconds. This represents the total amount of time that a participant was looking at information in a predefined AOI, yielding 24 total fixation duration measurements per person. Our measures of fixation duration exclude looking time associated with the physician and patient interviews. Each of the interviews, whether they were a video or a transcript, opened a separate webpage that was not one of the predefined AOIs. Time spent viewing these pages was not included in the analyses so that we could focus on differences in information search in the remaining sections of the Web decision aids that were common across conditions. Fixation duration was log transformed to reduce the positive skew in the distribution. Our secondary outcome was treatment preference.

We used multilevel modeling to examine the impact of narratives on information search. For these analyses, the log-transformed fixation durations associated with the 24 AOIs were nested within study participants (N=56) providing over 1300 measurement occasions. We tested models with both random and fixed slopes and intercepts with AOI as the Level 1 variable and participant as the Level 2 variable. Condition (patient stories present vs patient stories absent) and format

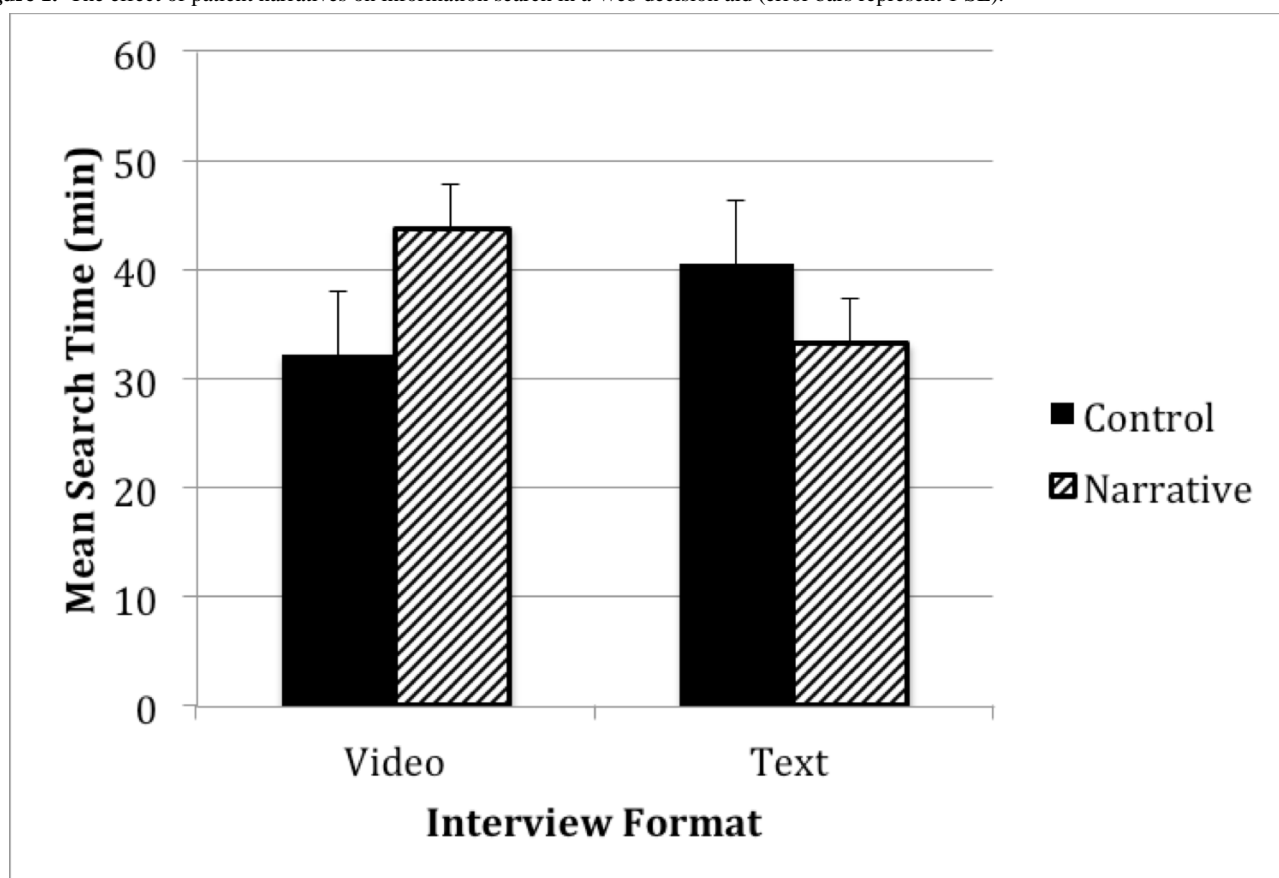
(text vs video) were included as Level 2 predictors. Multilevel models were assessed using the restricted maximum likelihood estimate with the lme4 package in R [23]. The best model, as judged by Akaike information criterion and Bayesian information criterion, is described below. All analyses were two-tailed and a P value of .05 was considered significant.

In this model, there was a significant main effect of condition, $P=.02$. Participants viewing decision aids with patient narratives spent more time searching for information (mean 39.88 min, SD 15.62 min) than participants viewing the decision aids without narratives (mean 35.08 min, SD 16.09 min). The main effect of format was not significant, $P=.10$. However, there was a significant condition by format interaction on fixation duration, $P<.001$; see Figure 1 for an illustration of this effect. When

comparing the two video decision aids, participants viewing the narrative version spent more time searching for information than participants viewing the control version of the decision aid. The opposite pattern emerges when comparing the two text versions of the decision aid. Participants viewing the narrative version spent less time searching for information than participants viewing the control version of the decision aid.

Despite the difference in search time between conditions, the difference in treatment preference between the control and narrative decision aid conditions was not significant, $t_{54}=0.98$, $P=.33$. However, it should be noted that with this sample size, the study was powered to detect only a large effect (Cohen's $d=0.8$) for this outcome measure.

Figure 1. The effect of patient narratives on information search in a Web decision aid (error bars represent 1 SE).



Results

Participants

Participants ranged from 30-71 years of age (mean 48.7, SD 9.4). Of the sample, 96% (54/56) were Caucasian, and 74%

(41/56) were college graduates. Although no participants had a personal history of breast cancer (this was an exclusion criterion), approximately 41% (23/56) of participants had a family history of breast cancer and 64% (36/56) had a friend who had previously been diagnosed with breast cancer. See Table 1 for complete participant demographics.

Table 1. Participant characteristics (N=56).

Characteristics	n (%)
Age, years (mean 48.7)	
30-39	10 (17.9)
40-49	20 (35.7)
50-59	20 (35.7)
Above 60	6 (10.7)
Race	
White	54 (96.4)
Black or African American	2 (3.6)
Education	
High school graduate	6 (10.8)
Some college	9 (16.1)
College graduate	21 (37.5)
Some graduate school	2 (3.6)
Graduate degree	18 (32.1)
Income (in USD)	
Less than \$30,000	6 (10.7)
\$30,001 to \$50,000	11 (19.6)
\$50,001 to \$75,000	17 (30.4)
\$75,001 to \$100,000	13 (23.2)
Above \$100,000	9 (16.1)
History with breast cancer	
Family history of breast cancer	23 (41.1)
Friends with breast cancer	36 (64.3)

Effect of Narratives on Fixation Duration

The best fitting multilevel model was a random intercept, fixed slope model. The intercept varied by webpage and individual,

and slopes were fixed for condition (control vs narrative), format (text vs video), and their interaction. Parameter estimates for the model are provided in [Table 2](#).

Table 2. Parameter estimates for the multilevel models of log-transformed fixation duration.

Parameters	β	SE	<i>t</i>	<i>P</i>
Intercept	10.92	0.20	55.25	<.001
Condition (control vs narrative)	0.36	0.15	2.43	.02
Format (text vs video)	0.29	0.18	1.64	.10
Condition x Format	0.80	0.25	3.23	.001

Use of Narratives

Although the patient narratives were available to all participants in the narrative conditions, not all participants chose to view the narratives while reviewing the decision aid. [Table 3](#) describes the content of each narrative, indicates the proportion of times that narrative was viewed in both the text and video narrative conditions, and displays the mean time spent on the

webpage with that narrative. Note each narrative was located on a separate webpage that would open when users clicked on the content. This allowed us to track use of narrative information separately from information search in the rest of the decision aid. The narratives were accessed at a similar rate in both the text and video narrative conditions. However, participants in the video narrative conditions spent more time with the narratives than participants in the text narrative conditions.

Table 3. Time spent viewing the patient and physician interviews.

Title of content	Includes patients	Includes physicians	Text narratives (n=10)		Video narratives (n=17)	
			% View (n)	Mean time on page, seconds	% View (n)	Mean time on page, seconds
Description of Diagnosis	✓	✓	60 (6)	67.28	47 (8)	117.19
A Woman's Preference is Important		✓	50 (5)	18.79	35 (6)	30.92
Take Your Time Making a Decision	✓	✓	60 (6)	27.96	35 (6)	87.09
Types of Breast Cancer		✓	30 (3)	20.93	59 (10)	44.70
Pathology Report		✓	40 (4)	16.39	59 (10)	36.37
Why Two Patients Chose Mastectomy	✓		50 (5)	23.74	65 (11)	48.98
Appearance After Mastectomy	✓		80 (8)	21.24	53 (9)	50.57
Breast Reconstruction	✓		70 (7)	7.75	53 (9)	19.14
Why Patient A Chose Lumpectomy	✓		50 (5)	5.00	53 (9)	15.11
Why Patient B Chose Lumpectomy	✓		50 (5)	11.38	59 (10)	27.86
Radiation After Lumpectomy	✓	✓	50 (5)	23.50	65 (11)	57.71
Side Effects of Radiation	✓		40 (4)	15.71	47 (8)	30.15
Appearance After Mastectomy	✓		50 (5)	17.60	41 (7)	29.10
Sentinel Node Biopsy		✓	30 (3)	34.32	47 (8)	51.77
Side Effects of Lymph Node Surgery	✓		40 (4)	16.62	41 (7)	35.16
Being Involved in Treatment Decisions	✓		70 (7)	8.13	53 (9)	28.64
Making Decisions	✓		60 (6)	25.29	47 (8)	73.42
Life After Breast Cancer	✓		50 (5)	15.71	53 (9)	47.56

Local Versus Global Differences in Search Patterns

The inclusion of random slopes did not improve the fit of either model suggesting the pattern of information search described above is consistent across AOIs. Although participants spent more or less time in a particular AOI, the relative difference in search time between groups remained constant. Although we predicted that patient stories would influence search for specific pieces of information (eg, appearance after surgery), the narratives instead appeared to influence information search more globally. These search patterns are illustrated in [Multimedia Appendices 4 and 5](#). Both appendices display heat maps depicting group differences in information search patterns on a summary page of the Web decision aid that compares the two treatments. Heat maps use color to illustrate fixation duration for a specific section of a text or image. The colors of a heat map should be interpreted like radar maps used by meteorologists where color represents precipitation intensity as an increasing ordinal function from blue to purple to white.

[Multimedia Appendix 4](#) illustrates differences in search for information about local recurrence, and [Multimedia Appendix](#)

[5](#) shows differences in search for information about appearance after surgery. In both appendices, narratives increase information search in the video conditions but decrease information search in the text conditions. We chose these two AOIs because they differ with respect to the amount of time these topics were discussed within the patient narratives. Specifically, appearance was mentioned more frequently than local recurrence. Thus, the fact that the same information search patterns exist in both AOIs provides evidence for the impact of narratives on global (across the entire decision aid) rather than local (within a specific section of the decision aid) information search.

Discussion

Principal Findings

This study was designed to examine the impact of patient narratives on information search in a Web-based decision aid. Using an eye tracker to gather search data, we found that the presence of patient narratives increased search time by more than 4 minutes. Further, this increase in search time was seen globally (across all pages of the Web decision aid) and was not

specific to pages covering information addressed in the narratives.

In addition, we assigned a subsample of our participants to two text-based versions of the Web decision aids, one with patient stories and one without. This allowed us to examine the effect of narrative format and the interaction between narrative presence and format on information search. There was no significant main effect of format; however, there was a significant narrative presence by format interaction. While the presence of video-based narratives increased information search, text versions of the patient stories decreased search time. Again, the differences in search patterns between the versions with and without narratives were not limited to areas of the decision aid that included narratives or specifically addressed issues discussed in the narratives.

The difference in the effect of video and text-based patient narratives is somewhat surprising. Although we anticipated that there might be differences in the magnitude of the effects of video and text-based stories, we had not predicted that the direction of the effects would also differ. However, there is a fairly parsimonious, albeit post hoc, explanation for the observed differences. Reading involves a significantly greater amount of cognitive resources than simply watching. Reading requires more active involvement with the material, while watching typically requires only passive involvement. Because of this, we hypothesize that the more effortful act of reading patient narratives decreased participant motivation to engage in more reading in the remaining sections of the Web decision aid. In contrast, watching the patient narrative videos may have had the opposite effect on cognitive load by giving participants a break from reading. This is supported by [Table 3](#), which shows that participants in the video narrative conditions spent more time viewing the narratives than participants in the text narrative conditions. This may have allowed one of the major messages of the stories, “take your time in making a decision”, to have a greater effect on information search by motivating participants to ensure they were fully informed about the treatments.

Limitations

This study had some limitations that may affect the generalizability of the results. First, participants in the study were engaged in a hypothetical decision task that may differ from the decision process associated with a “real” treatment decision. Second, because we used a decision aid that had been previously produced for other purposes (ie, clinical not experimental use), we were able to manipulate only the presence of patient stories, not their content. Third, our sample had very limited racial and ethnic diversity. Future research is needed to replicate these effects in a more heterogeneous sample.

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A recent paper outlining a taxonomy of patient narrative types [17] argues that the precise effect of a patient story is closely tied to its purpose for inclusion in the decision aid, its specific content, and its evaluative valence. Because we did not systematically manipulate these dimensions in this study, we can only speculate about how these characteristics of the stories used in this decision aid may have impacted our results. The content of the stories could be best characterized as a mixture of “process” (ie, descriptions of the process of making a treatment decision) and “experience” (ie, descriptions of a treatment experience) narrative elements. Recent work has shown that process narratives can increase information search in an artificial lab search task [24]. Thus, some of the impact of the video narratives may be due to the process elements covered in the stories. Future studies should examine the specific impact of these three dimensions on information search.

Finally, only about one-third of our sample was used to explore the impact of text-based patient narratives on information search. Although this still resulted in a very rich dataset due to the number of observations nested within each participant, future work should focus on replicating this finding and testing our post hoc hypotheses about the relationship between the cognitive effort associated with reading versus watching narratives and information search.

Conclusions

In a Web decision aid, videos of patient stories embedded within the larger text-based decision aid increased information search during a hypothetical breast cancer decision task. However, transcripts of the patient videos had the opposite effect. Participants spent about 5 fewer minutes searching for information in the Web decision aid when text-based narratives were included. These findings suggest that the format of patient stories may be equally as important as their content in determining their effect on decision making. Although it is unsurprising that video narratives would be more engaging than text-based narratives (as evidenced by the amount of time spent with each in this study), it is instructive that this engagement generalizes to the remainder of the Web decision aid, which itself was text-based. This suggests that engagement may not be specific to modality, and video narratives may be used to increase involvement with both text and video formats of health messaging. Although video narratives are more expensive to create than text versions, the additional funds may be cost-effective when engagement with the material is critical. However, more research is needed to replicate these findings and to test our hypotheses about why differences in format result in fundamental differences in information search.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Scenario used in the study describing the diagnostic process.

[PDF File (Adobe PDF File), 47KB - [jmir_v15i12e273_app1.pdf](#)]

Multimedia Appendix 2

Example webpage from the decision aid.

[PNG File, 457KB - [jmir_v15i12e273_app2.png](#)]

Multimedia Appendix 3

Transcripts of patient and physician interviews from decision aid (patient and physician names removed).

[PDF File (Adobe PDF File), 34KB - [jmir_v15i12e273_app3.pdf](#)]

Multimedia Appendix 4

Heat maps of an information search on a webpage comparing the two treatments (this section of the webpage highlights differences in local recurrence between the two treatments).

[PNG File, 1MB - [jmir_v15i12e273_app4.png](#)]

Multimedia Appendix 5

Heat maps of an information search on a webpage comparing the two treatments (this section of the webpage highlights differences in appearance post-surgery between the two treatments).

[PNG File, 625KB - [jmir_v15i12e273_app5.png](#)]

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Abbreviations

AOI: area of interest

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Original Paper

Perceived Barriers and Facilitators of Using a Web-Based Interactive Decision Aid for Colorectal Cancer Screening in Community Practice Settings: Findings From Focus Groups With Primary Care Clinicians and Medical Office Staff

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Abstract

Background: Information is lacking about the capacity of those working in community practice settings to utilize health information technology for colorectal cancer screening.

Objective: To address this gap we asked those working in community practice settings to share their perspectives about how the implementation of a Web-based patient-led decision aid might affect patient-clinician conversations about colorectal cancer screening and the day-to-day clinical workflow.

Methods: Five focus groups in five community practice settings were conducted with 8 physicians, 1 physician assistant, and 18 clinic staff. Focus groups were organized using a semistructured discussion guide designed to identify factors that mediate and impede the use of a Web-based decision aid intended to clarify patient preferences for colorectal cancer screening and to trigger shared decision making during the clinical encounter.

Results: All physicians, the physician assistant, and 8 of the 18 clinic staff were active participants in the focus groups. Clinician and staff participants from each setting reported a belief that the Web-based patient-led decision aid could be an informative and educational tool; in all but one setting participants reported a readiness to recommend the tool to patients. The exception related to clinicians from one clinic who described a preference for patients having fewer screening choices, noting that a colonoscopy was the preferred screening modality for patients in their clinic. Perceived barriers to utilizing the Web-based decision aid included patients' lack of Internet access or low computer literacy, and potential impediments to the clinics' daily workflow. Expanding patients' use of an online decision aid that is both easy to access and understand and that is utilized by patients outside of the office visit was described as a potentially efficient means for soliciting patients' screening preferences. Participants described that a system to link the online decision aid to a computerized reminder system could promote a better understanding of patients' screening preferences, though some expressed concern that such a system could be difficult to keep up and running.

Conclusions: Community practice clinicians and staff perceived the Web-based decision aid technology as promising but raised questions as to how the technology and resultant information would be integrated into their daily practice workflow. Additional research investigating how to best implement online decision aids should be conducted prior to the widespread adoption of such technology so as to maximize the benefits of the technology while minimizing workflow disruptions.

KEYWORDS

colon cancer; colonoscopy; cancer screening; early detection of cancer; reminder systems; decision support techniques; focus groups; health information technology

Introduction

Colorectal cancer (CRC) screening is recommended for all average-risk adults aged 50 years and over [1]. Several CRC screening options are available for average-risk adults, including stool blood test and colonoscopy [1]. While up-to-date CRC screening rates of asymptomatic adults aged 50-75 years in the United States have increased from 54% in 2002 to 64.5% in 2010 [2], millions of eligible people remain unscreened by any method [3]. Given evidence that no single CRC screening test is superior at reducing CRC mortality [1], current recommendations advise CRC screening should be based on each patient's preference and chosen using shared decision making [1,3-5]. Decision aids may help to facilitate shared decision making by reducing patient decisional conflict, improving patient knowledge, and stimulating patients to be more active in decision making without increasing anxiety [6,7]. Studies utilizing decision aids on CRC screening have shown variable results, with seven showing an increase [6,8-14], one showing a decrease [6,15], and five showing no difference in CRC screening [6,16-20].

Colorectal Web was developed as a Web-based interactive decision aid to help adults aged 50 years and over make a choice among several medically appropriate CRC screening options [21,22]. In addition to helping patients understand their CRC risk by providing information on risk factors, a key feature of Colorectal Web is the interactive values clarification exercise where users identify their top three areas of concern from a menu of 10 concerns often cited about CRC screening: cost, discomfort, embarrassment, frequency, accuracy, convenience, additional testing, preparation, risk, and sedation. [Figures 1](#) and [2](#) illustrate how Colorectal Web works. In the example illustrated by [Figure 1](#), the user identified their three top concerns as frequency, accuracy, and need for additional tests. For this user, a colonoscopy would have been recommended because colonoscopies are recommended only every 10 years, have the best accuracy, and require no additional tests. In the example illustrated by [Figure 2](#), the user identified their three top concerns to be cost, discomfort, and embarrassment. For this user, a stool blood test would have been recommended

because stool blood tests are the most cost-effective screening tool, have the least discomfort, and are commonly perceived as the least embarrassing.

As reported by Ruffin, Fetters, and Jimbo (2007), patients using Colorectal Web were more likely to follow through with CRC screening when compared to controls [10]. As summarized in [Figure 3](#), we hypothesize that linking patients' screening preferences directly to the clinical encounter would enable clinicians to more effectively engage patients in personalized conversation about CRC screening, which in turn would help improve patient-clinician communication, shared decision making, and patients' CRC screening follow-through. We further posit that the combined use of the patient-led decision aid and clinician-directed computerized reminder system would help to streamline care in real world settings where efficiency and strict time management are essential. And finally, by improving patient-clinician communication, fostering shared decision making, and improving patient follow-through, we believe the effective use of the Web-based decision aid can help promote the early detection of CRC and improve patient outcomes.

Before these hypotheses can be tested, it is important to gain a better understanding of how those working in community practice settings perceive Web-based decision aids, a corresponding computerized reminder system, and the integration of these tools in the clinics' daily operation. Of particular importance are the perceptions of clinicians and other staff regarding perceived facilitators and barriers to implementation, as well as how the tools might impact the clinical milieu. To this end, we conducted focus groups with both clinicians and nonclinical office staff to elucidate their perceptions, concerns, ideas, and opinions about the proposed use of Colorectal Web and the linking of patients' identified screening preference to a computerized reminder system already piloted in each of the practice settings. We anticipate findings from this research will help inform policies that shape the development and implementation of Web-based decision aids, computerized reminder systems, and other health information technologies that promote patient activation, shared decision making, and a more patient centered patient-clinician encounter.

Figure 1. Colonoscopy selected as preferred screening method.

Colorectal Web

- 1 What is Colorectal Cancer?
- 2 How can I check for it?
- 3 Frequently Asked Questions
- 4 Where can I get more information?
- Glossary

Test Summaries: Flexible Sigmoidoscopy, Fecal Occult Blood Test (FOBT), Double Contrast Barium Enema (DCBE), Colonoscopy

There are a number of things to consider when choosing a test to check for colon cancer. Listed below are several areas that you might consider when trying to choose a test for checking for colon cancer.

Pick three that are most important to you we'll show you the test that best addresses your concerns. You can read more about that that test, or choose other concerns.

Cost	Colonoscopy: Moderate Fecal Occult Blood Test: None Flexible Sigmoidoscopy: Mild-Moderate Double Contrast Barium Enema: Mild-Moderate
Discomfort	Colonoscopy: Moderate Fecal Occult Blood Test: Mild Flexible Sigmoidoscopy: Moderate Double Contrast Barium Enema: Moderate
Embarrassment	Colonoscopy: Most accurate Fecal Occult Blood Test: Least accurate Flexible Sigmoidoscopy: Moderate accuracy Double Contrast Barium Enema: Moderate accuracy
Frequency	
Inaccurate Results	
Inconvenience	
Need for Additional Tests	
Preparation	
Risk	
Sedation	

Based upon the three factors you just selected, your preferred method of screening would be: **Colonoscopy**

Choose other factors on the left or click on the arrow to learn more.

Figure 2. Fecal occult blood test selected as preferred screening method.

Colorectal Web

- 1 What is Colorectal Cancer?
- 2 How can I check for it?
- 3 Frequently Asked Questions
- 4 Where can I get more information?
- Glossary

Test Summaries: Flexible Sigmoidoscopy, Fecal Occult Blood Test (FOBT), Double Contrast Barium Enema (DCBE), Colonoscopy

There are a number of things to consider when choosing a test to check for colon cancer. Listed below are several areas that you might consider when trying to choose a test for checking for colon cancer.

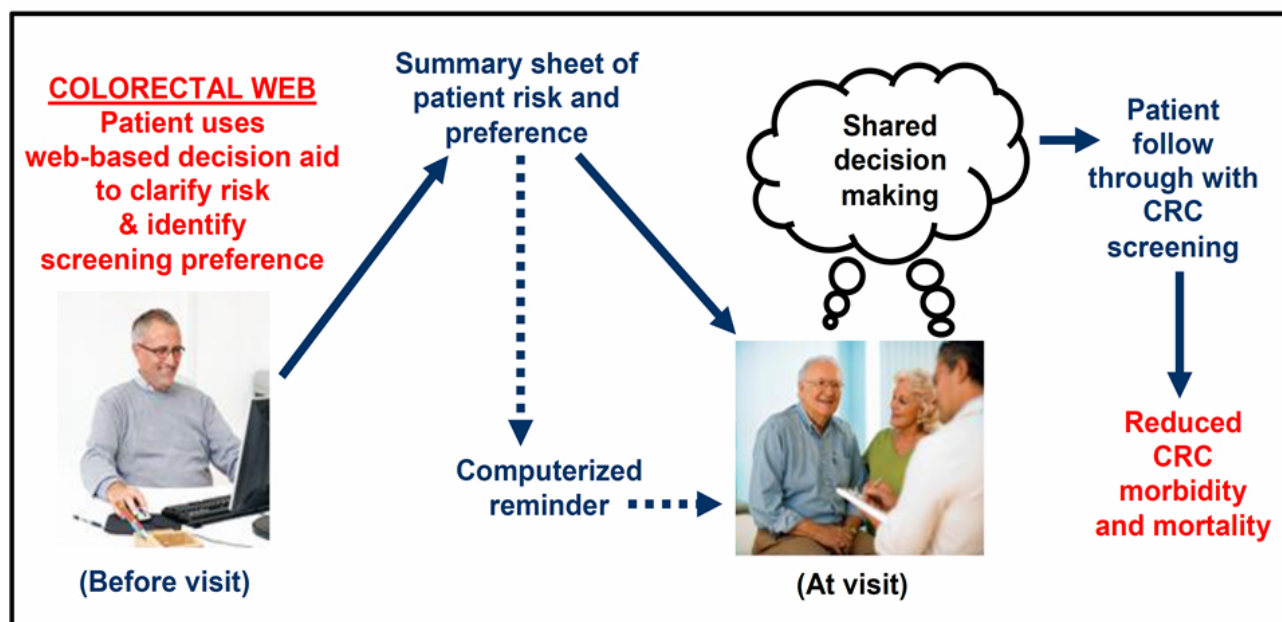
Pick three that are most important to you we'll show you the test that best addresses your concerns. You can read more about that that test, or choose other concerns.

Cost	Colonoscopy: \$800-\$1,600 Fecal Occult Blood Test: \$10-\$25 Flexible Sigmoidoscopy: \$150-\$300 Double Contrast Barium Enema: \$250-\$500
Discomfort	Colonoscopy: Most Fecal Occult Blood Test: Least Flexible Sigmoidoscopy: Moderate Double Contrast Barium Enema: Moderate
Embarrassment	Colonoscopy: Small Fecal Occult Blood Test: None Flexible Sigmoidoscopy: Very Small Double Contrast Barium Enema: Very Small
Frequency	
Inaccurate Results	
Inconvenience	
Need for Additional Tests	
Preparation	
Risk	
Sedation	

Based upon the three factors you just selected, your preferred method of screening would be: **Fecal Occult Blood Test**

Choose other factors on the left or click on the arrow to learn more.

Figure 3. Linkage of colorectal Web to clinical encounter (solid lines show a sequence where the patients may print out their summary sheets to take to their clinicians; dotted lines show a sequence where the computerized reminder also generates the summary sheet for clinicians' use).



Methods

Design

This qualitative study utilized data collected from five focus groups involving both clinicians and key office staff from community practice settings. We employed focus groups because they are an efficient means to gather information while allowing participants to interact with each other as topics are explored. Allowing for give-and-take interactions between participants was critical for this research, as changes in clinical practice often affect the work of both clinicians and staff members alike. To adequately capture participants' concerns, ideas, and opinions as to how the Web-based decision aid would affect the daily operations of the community-based practice, the perspectives of all key individuals who would likely be involved with implementation were invited to participate. Approval from the University of Michigan Institutional Review Board was obtained prior to the study's execution.

Setting

We conducted the focus groups in five community-based primary care settings across Michigan from August 2006 to May 2007.

Sampling Frame

As the study's purpose was to better understand the factors that mediate and impede the use of a Web-based CRC screening decision aid, it was decided to recruit from only those sites having previous experience using health information technologies. Such sites were also of interest because they likely typify early adopters of health information technology in community-oriented primary care. By focusing on these early adopters, we anticipated that reported barriers and facilitators would represent participants' perspectives about the actual use

of the Web-based tool rather than about the use of electronic health information technology per se. The reported barriers and facilitators would be based more on practical experience (ie, actual past use of health information technology) and less on assumptions (ie, guesses or presuppositions in the absence of previous use). To this end, we used an intentional sampling approach to recruit from 12 practice sites that previously had implemented a computerized reminder system as part of a National Cancer Institute-funded study examining the utility of a computerized reminder system to promote CRC screening [23]. Each site was affiliated with the Great Lakes Research Into Practice Network, a voluntary association of Michigan-based primary care practices that have expressed an interest in participating in health services research. Because clinicians and staff from these sites had previous experience using a computerized reminder system, they were uniquely positioned to provide an informed perspective on how the addition of the Web-based decision aid might affect the patient-clinician encounter and related processes of care.

Of the 12 candidate sites, one had previously indicated a desire to not participate in future research. Using the remaining 11 sites, a purposive recruitment strategy was employed to maximize variability in terms of practice size, location, and the site's technological sophistication (eg, sites using and not using an electronic health record [EHR]). Based on their demographic profiles, seven sites were selected for recruitment. The study's principal investigator (PI) subsequently contacted the clinical lead (either a lead physician or clinic manager) at each site by phone to discuss the aims of the study, the approach (ie, a focus group with clinic physicians and staff), and logistics (eg, the study's time frame). Clinical leads from five sites expressed an interest in having their clinic participate.

Discussion Guide Development

The semistructured discussion guide (available upon request) was developed to assess the four following areas: (1) current CRC screening approaches, (2) perceptions/opinions about Colorectal Web, (3) feasibility of implementing and linking the decision aid and computerized reminder system, and (4) anticipated influences on practice workflow and logistics. The discussion guide underwent several iterations until the study's investigators reached 100% agreement.

Recruitment

After the clinical leads at each of the five sites agreed to have their clinic participate, the focus group moderator scheduled focus groups for a time identified by the lead as convenient. All clinicians (physicians, and physician assistants), clinical support staff (registered nurses, licensed practical nurses, and medical assistants), and nonclinical support staff (clinic managers, receptionists, and billing clerks) were invited to participate in the focus group. Written informed consent was secured from each participant prior to the start of the focus group. While all clinicians and support staff from each site were invited to participate, some clinicians or staff by choice or circumstance may not have been present at the time of scheduled visit. Of those onsite at the time of the scheduled visit, all joined the focus group.

Data Collection

A single focus group was conducted at each of the five participating sites, and the same discussion guide was used to ensure that each session was conducted in a similar manner. The same experienced moderator facilitated all focus groups and was trained in the use of Colorectal Web as well as the computerized reminder system piloted in each site. Each focus group, lasting between 60 and 90 minutes, was audiorecorded and then transcribed verbatim by a professional transcriptionist. To protect the identity of focus group participants, the only demographic characteristics collected were role (clinician vs office staff) and gender.

Analysis

To test for differences between participating ($n=5$) and nonparticipating ($n=7$) practice sites, two-tailed Student's t tests were employed.

The focus group transcripts were analyzed using an iterative process to identify overarching patterns and salient themes. Using four main topics from the discussion guide as an initial organizing framework, the authors carefully read and analyzed the transcripts using the immersion/crystallization method [24]. This method requires those reviewing the transcripts to immerse themselves in the data by closely reading the transcript in great detail, followed by periods of reflection and deliberation to identify patterns and themes. Overarching patterns, themes, and subthemes were documented by the study's investigators and then submitted to the principal investigator (PI). The PI then integrated these themes into a cohesive framework by identifying consistency between investigators and corroborating these themes with salient text. Next, each investigator reviewed this integrated summary, and discrepancies between the PI's

framework and investigators' interpretations were negotiated until 100% agreement was achieved. The framework was then used to systematically review each transcript to identify inter-site variation. To illustrate recurrent themes, subthemes, and variation between sites, representative and especially salient quotations were selected (a complete summary of quotations is available upon request).

The following convention was used to indicate the frequency in which a particular theme or subtheme was expressed: a small number = one to two clinicians or one to two clinic staff, a moderate number = three to four clinicians or three to four clinic staff, a majority = five or more clinicians or five or more clinic staff. Direct quotes from respondents are presented in italics. To help minimize the length of quotations, ellipses are used liberally (three periods indicate a break within a sentence and four periods a break between sentences). Some longer quotations are included to ensure speakers' meaning or context remains intact.

Results

Overview

Differences between the five participating and seven nonparticipating sites are presented in Table 1. All sites specialized in family medicine and were distributed throughout Michigan. With one exception—where participating sites were less likely to have self-pay patients compared to nonparticipating sites—the small sample size limited our ability to detect statistically significant differences. The participating sites tended to have fewer clinicians (physicians and nonphysician clinicians), higher clinician-to-patient ratios, larger proportion of patients from racial/ethnic minority groups, and more patients covered through managed care.

Demographic characteristics of participating sites and of focus group participants are outlined in Table 2. Two sites were located in suburban communities in the state's west central or east central regions, one site was in a rural Upper Peninsula community, and two were in rural communities in the state's east central or southern regions. As shown, one rural and one suburban site utilized EHRs. Each site was independently operated; that is, the sites were neither affiliated with one another nor with a larger health system. Among clinicians, five were male and four were female; all nonclinical office staff were female.

During focus group sessions, clinicians more actively shared their perspectives when compared to nonclinical staff—approximately 65% of comments came from clinicians whereas about 35% came from nonclinical staff. Moreover, while all clinicians were active participants in their respective focus group, more than half of nonclinical staff ($n=10$) remained silent throughout the entire focus group session. As shown in Table 2, nonparticipation was evenly distributed across sites and did not readily correlate with practice setting, use of EHRs, or clinicians' gender. Salient themes and subthemes are outlined below according to the four main topics from the discussion guide.

Table 1. Comparison of the focus group sites and non-participating sites.

Characteristics	Focus group Practices (n=5)		Nonparticipating Practices (n=7)	
	Range	Mean	Range	Mean
Providers				
Physicians	1-5	2.8	0-12	3.9
Non-physician clinicians	0-2	1.0	1-2	1.3
Mean number of patients seen per day per practice	30-80	43.6	18-150	57.1
Patient gender, %				
Female	50-60	57.0	55-65	59.2
Patient race/ethnicity, %				
White	50-98	78.2	78-99	91.9
Latino	0-20	6.4	0-7	1.5
Black	0-20	4.3	0-6	1.4
Other	0-10	2.7	0.8-14	5.3
Patient insurance, %				
Medicare	14-48	28.4	1-40	22.8
Medicaid	5-30	15.4	5-50	22.7
Managed care	0-35	22.6	0-25	11.0
Traditional indemnity	12-45	28.0	1-50	21.9
Self-pay ^a	5-8	5.6	6-27	15.4

^aMean difference significant at the .05 level; $t_{10}=2.76$, $P=.02$ (2-tailed independent samples t test, unequal variance).

Table 2. Characteristics of the participating practice settings, EHR use, and focus group participants' professional status and gender.

Practice	Setting	EHR	Composition of participants
A	Suburban; west central Michigan	Yes	2 male physicians 3 female staff (1 participated)
B	Rural; east central Michigan	Yes	1 female physician, 1 male physician 5 female staff (2 participated)
C	Suburban; east central Michigan	No	1 male physician 1 female physician assistant 4 female staff (1 participated)
D	Rural; southern Michigan	No	1 female physician, 1 male physician 3 female staff (2 participated)
E	Rural; Upper Peninsula Michigan	No	1 female physician 3 female staff (2 participated)

Current Colorectal Cancer Screening Approaches

General Approach to Colorectal Cancer Screening

A majority of clinicians reported discussing CRC screening with patients during preventive visits; such visits were described as a natural forum for sharing health information and soliciting patient input. A majority of clinicians reported that they had their own particular methods for remembering to address CRC screening, such as a notation or reminder on the patient's chart

or a more general system based on patient age. However, a moderate number reported not always remembering to bring CRC screening up during the clinical encounter. For example, the clinician in Site E explained: "...it's somewhat hit or miss." All clinicians in the two sites with EHRs (Sites A and B) reported their system provided a computerized reminder that enabled them to be more aware of patients' preventive needs. A clinician in Site A commented: "We have a lot of little chart reminders. Things that are in the chart remind us, oh this person needs a colonoscopy." In the remaining sites, clinicians

described having to review the previous progress notes and/or flow sheets to determine if patients were up to date on preventive services. Clinicians and staff from Site C developed a reminder system that triggered clinicians through the use of a visual cue: they stapled FOBT kits to posters and placed them in examination rooms. Despite this, one clinician noted: "It's kind of hard to keep track of everything...[For [s]ome people it just didn't work. It doesn't matter what you did." Only one site (Site A) reported using a list provided by health insurance companies to identify patients who are due for CRC screening. At this site, office staff contacted the identified patients using letters and telephone calls to inform the patient that it was time for a screening.

Shared Decision Making and Colorectal Cancer Screening

A majority of clinicians described that the primary resource used to facilitate CRC screening discussions was their own interactions with patients during the clinical encounter; a moderate number expressed a need for additional educational tools that could help facilitate more effective discussions, such as brochures and pamphlets (Sites C and D) and video vignettes (Site E).

A moderate number of clinicians reported that when discussing CRC screening with patients, a good portion of the conversation tended to focus on communicating the relative advantages and disadvantages of each screening method. A majority of clinicians, however, revealed they commonly recommended the patient undergo the CRC screening method that the clinicians themselves preferred rather than presenting all options. For example, clinicians at sites A and D primarily recommend colonoscopies, whereas clinicians at sites B and C almost exclusively recommended FOBTs. As indicated by one clinician from site A, "The culture has evolved over the last number of years where colonoscopies was [sic] probably the standard of care." As reported by a majority of clinicians and staff, the principal barriers to patients' access to CRC screening were lack of insurance and concern about costs. A majority of clinicians also described time constraints as a significant barrier. As reported by the clinician from site C, "I don't really want to discuss it. I just want to do it...I don't feel in my office [that] I [could] sit down and have a five or ten minute discussion of the pros and cons of hemocults vs colonoscopies."

Perceptions/Opinions About Colorectal Web

Overall Impression

Clinicians and staff at all sites agreed that Colorectal Web was an informative and educational tool they could easily recommend to their patients; moreover, clinicians from Sites C, D, and E affirmed they would start using it immediately if it were available to patients through the Internet. Clinicians from Site A, however, indicated that a decision aid—Web-based or otherwise—was superfluous because they subscribed to a general belief that colonoscopies are the most appropriate standard for care. While clinicians from Site B described being impressed with the tool, they reported a concern that many of their patients did not have Internet access or the requisite technical skill to complete a Web-based tool.

Facilitators

A majority of clinicians and a moderate number of staff asserted that Colorectal Web is an efficient source of CRC screening information. Because of this, the website was described as having particular utility for those patients who have many questions and want to sift through a lot of information. A small number of clinicians also emphasized that Colorectal Web could be used as a resource for patients to learn more about a procedure even after a preferred screening modality had been identified. This reaction was endorsed even by clinicians from Site A, who believed the Web-based tool could help educate patients about colonoscopies and ease their discomfort about the procedure. In describing communication style with patients about the topic of colonoscopies, one clinician from Site A asserted: "It's usually more a persuasion. Telling them what it's really like and it's not as bad as you think probably and explaining the test and what they have to think about and try to convince them to do it." A moderate number of clinicians described that Colorectal Web could be an especially useful tool for patients concerned about the out-of-pocket expense of screening because it helps users weigh the pros and cons of each screening option through the lens of its monetary cost. A majority of clinicians felt Colorectal Web could help to improve clinical efficiency, as patients' questions about CRC screening could be answered through using the tool prior to the office visit. A typical response was expressed by the clinician in Site E: "Big time saver, I think."

Although a purported benefit of a decision aid is improved shared decision making, none of the clinicians mentioned this as a potential benefit; rather, the decision aid was seen as a way to cut back on the need to discuss CRC screening with the patient. A notable quote was made by the clinician in Site C: "Well, we don't really want to...can I be frank and open? I don't really want to discuss it [ie, screening options]. I just want to order it. Just like I say CBC. This is time to do this."

Barriers

A recurring theme from a majority of clinicians and staff was a concern that many patients may not have regular access to the Internet and therefore would not be able to utilize the Web-based decision aid. The proportion of patients described as having access to the Internet varied by site, with the lowest reported rate being about 5% and the highest about 60%. Moreover, a majority of clinicians argued that relatively few patients were regular users of the Internet, noting that Web-based tools may not necessarily be the preferred method for making health care choices among those aged ≥ 50 years. Relatedly, a majority of clinicians and staff underscored that some older patients do not have the requisite skillset to use a Web-based tool. For example, a clinician in Site B noted:

[many patients have] no comfort with computers, and I can't see more than perhaps 15, 20% of our total patient population even being able to access that. And of that, [we would be lucky] if we had 5 or 7% that would actually do it to the level that you are discussing...[F]or a certain group of patients that would be a wonderful tool. I don't think it would be

for our group of patients primarily because we have a large percentage of low functioning patients.

The majority of clinicians did not have a clear idea of what percentage of their patients were Internet users, and none had actually assessed their patients' Internet usage formally. The general consensus among clinicians was a belief that their older patients (those over age 65) were particularly low utilizers of the Internet. Patients' Internet literacy or interest in using the Internet was also a concern, particularly in regard to the utility of Colorectal Web as an educational tool. As summarized by a clinician in Site C: "You need a killer application. You need to have people [to] have a reason they want to get on the Web. They have to want it before you can get them to use it."

Feasibility of Implementing and Linking Colorectal Web to a Computerized Reminder System

A moderate number of clinicians and staff endorsed the belief that integrating the Web-based decision aid with a computerized reminder system would be an efficient way to manage patients' CRC screening preferences. In addition, they perceived integration to be a natural progression of existing health information technology. However, about an equal number reported concerns that integration might not occur seamlessly given their existing technology and daily workflow. Expressing both excitement about the technology and concern about its integration, a clinician from Site E opined: "From my perspective as a physician I really enjoyed [the clinician reminder system] because it really reminded me at all visits to discuss with people...if they have had it or not had screening. So from my aspect it was awesome, but not everybody shares the same opinion about it as I do because we had a lot of computer issues with it." A clinician from Site A described doubt about the benefit of electronic decision aids, citing a belief that their use was being driven primarily from external pressures rather than clinical utility: "[T]o be honest, I don't know if these tools would be a benefit to us anymore. Because again, it's just a high priority on the insurance companies...I don't know how useful something like this would be."

Anticipated Influences on Practice Workflow and Logistics

Clinicians and staff from each site reported a preference for patients to use Colorectal Web prior to their scheduled office visit. A majority of them believed that it was neither practical nor efficient to have a computer in the waiting area for patients to complete the tool. In addition to expressed concerns about patient confidentiality, concerns about an onsite computer included worry that children might use the computer or that patients would require assistance and thereby distract staff from other duties and responsibilities. One clinician from Site B expressed concern about patients damaging the computer or trying to steal it: "It would be destroyed. Correct. It would be destroyed or it would be stolen....[like] the flowers and all the pictures on the wall." A staff member from Site C was concerned that computers with Web access might be used for inappropriate purposes, thereby requiring constant supervision from staff: "Yeah, it would definitely have to be limited on...access and everything. We wouldn't want people accessing porn sites or anything out in the waiting room."

There was also an expressed concern that patients' use of the tool while in the waiting area may interrupt the clinics' workflow; for example, if patients arrived late or if the clinic was running ahead then patients could be stuck using the tool when it came time to meet with the clinician. One possible solution to this timing problem, as suggested by a small number of participants, would be for patients to access the tool on a tablet computer that could be carried around by the patients throughout the clinic. As an alternative to using Colorectal Web within the clinic, a majority of clinicians and staff endorsed the idea of using mail-based postcard reminders to prompt patients' use of the tool at home and in advance of their schedule appointment. A moderate number of clinicians and staff described already having a system in place for sending patients reminders for appointments for physicals; however, there was no standard for the timing of reminders or for sending reminders that specifically addressed CRC screening.

With the exception of Site A, where no comments on the topic were made, clinicians from each site believed that written materials (eg, information sheets, brochures, informational cards) would be beneficial to help educate patients about CRC and the range of screening options. In fact, a moderate number of focus group participants expressed a desire to have more written materials that could help facilitate discussions about CRC screening, both to save time during the visit and to improve patient's knowledge. While Colorectal Web was lauded for its interactive format and its ability to help patients weigh their own values against the various screening options, written materials were generally regarded as the gold standard for conveying information to patients outside of the context of the clinical encounter. A tri-fold brochure that included a table comparing and contrasting the range of CRC screening options was endorsed by a majority of clinicians and staff as having utility both in and outside of the clinical setting. Brochures were also cited by a small number of clinicians and staff as having benefit due to their perceived cost and ease of use—as stated by one clinician from Site D: "[Pamphlets are] more cost effective and easier, plus the pamphlet...they can still look at when they go home."

When asked about a paper/pencil alternative to Colorectal Web (eg, a CRC preference workbook), both clinicians and staff rejected it as overly cumbersome. They reported a belief that patients would not like to fill out additional paperwork as there are already many forms being completed by patients inside and outside of their appointments. The one exception was for patients who live in rural communities where high-speed Internet access may be limited. For these patients, a workbook-style corollary to the Web-based tool could be given to patients for completion before their next appointment. A small number of clinicians suggested that patients using the workbook should be encouraged to discuss it with their clinician either at the next appointment or through another agreed upon method (eg, phone call).

Discussion

Principal Findings

Our study leveraged a unique opportunity to enroll clinicians and staff from a diverse set of community settings to ascertain how a Web-based and interactive decision aid might impact CRC screening practices and the clinics' daily workflow. With few exceptions, focus group participants generally agreed that promoting patients' use of the decision aid *prior* to the clinical visit would be an effective way to educate and activate patients so they can make informed screening decisions in light of their most salient concerns. While the majority of clinicians endorsed Colorectal Web as a promising tool, enthusiasm was neither universal nor without restrictions. Two commonly cited concerns were patients' limited computer literacy and lack of access to the Internet. This worry was especially salient for those serving a predominantly low-income population. In addition to Internet access, some focus group participants noted concern that the tool might not be sufficiently interesting to motivate patients to use it. While access and interest could be countered, in part, by directing patients to the tool while waiting for their appointment in the clinic, making the tool available to patients during their office visit was largely perceived as unwieldy and time-prohibitive. One of the more salient concerns—especially from office staff—was that patients' use of the Internet would need to be closely monitored (eg, restricting access to inappropriate sites). From this perspective, onsite access to the Web-based tool was perceived as increasing the clinics' workload rather than facilitating shared decision making and optimizing CRC screening. Though there are a number of tools designed to limit users' access to certain Internet content, their use as a possible solution was not raised during the focus group sessions.

While findings from previous research suggest patients' access to high-quality decision aids is accelerating, decision aids continue to be underutilized in community-based primary care settings [6,7]. Commonly cited barriers to decision aid use include time constraints, lack of fit between the aid and patient need, and a poor match between the aid and the demands of the clinical setting [6,7,25,26]. Findings from our study add to the literature by providing a nuanced view of perceived barriers and facilitators, and how an interactive Web-based tool could be integrated into community-based settings. Results show that not all focus group participants believed an electronic, interactive decision aid linked to a computerized reminder system would have enough advantages over traditional paper resources to justify their use in the clinical setting. Interestingly, the sites utilizing EHRs were just as likely to have expressed these concerns as those not using such technology. While potentially reducing concerns related to timing and mobility (eg, patient stuck at a desktop completing the decision aid when it was time for them to see the clinician in the exam room), there was disagreement among focus group participants as to whether tablet devices would be an effective solution. Tablets were described to have their own set of limitations, including cost, maintenance, patients' literacy with the technology, and keeping track of the devices while patients are coming and going throughout the day.

Despite a growing literature suggesting Web-based decision aids may be superior to other decision aid modalities in improving patient knowledge and behavioral outcomes [27-32], the focus group participants in this research were concerned their use could negatively impact their site's day-to-day workflow. This finding complements Schroy et al, who found a majority of surveyed primary care providers were either neutral to or disagreed with the statement that a Web-based decision aid would be easy to implement in their practice [33]. Findings from focus groups also correspond to conclusions reached by Légaré et al, who after reviewing the literature on strategies to improve the use of decision aids by health care professionals could not draw firm recommendations for the most effective dissemination strategy [26]. Rather than a continued focus on the creation of new decision aids *per se*, future research should focus on improving our understanding of how existing decision aids can be integrated into daily practice.

As suggested by others, current policies that shape the nation's health care system will likely need to change before clinicians fully embrace shared decision making and the tools (eg, interactive decision aids, computerized reminder systems) that promote it [6,34-36]. Several candidate policies to be changed include redefining medical necessity so that it better includes the principle of an informed patient; creating economic incentives (and reducing disincentives) for shared decision making; establishing a clear legal standard that facilitates shared decision making and informed patient choice; developing effective systems-based processes that promote decision aid uptake and utilization; and modifying health care accreditation standards to account for the use of tools that promote a patients' ability to make educated, values-based decisions about care when more than one medically reasonable treatment option exists [7,35-40].

Consistent with previous research, a moderate number of clinicians in our study preferred one CRC screening modality over all others [7,38-41]. This finding is troubling given evidence that providing patients with options increases screening follow-through, while a more autocratic recommendation—where one screening modality is strongly favored over another—may act to limit screening follow-through [6,42]. Future studies should seek to elucidate the relationship between clinicians' practice style and patients' screening follow-through by examining patient-clinician encounters directly and assessing how decision aids affect communication, treatment decisions, follow-through, and health outcomes.

Focus group participants from the five community practice sites in this study reported challenges similar to previously published findings about providing opportunistic preventive services: lack of time due to acute or chronic care needs, administrative obstacles, patients' psychosocial limitations (eg, literacy), and clinicians' treatment preferences [42-46]. Findings revealed that clinicians at each site were prone to perceive the provision of opportunistic care as daunting rather than an opening to improve the overall quality of care. The clinicians in sites utilizing EHRs were more open to providing opportunistic preventive care, and although this must be interpreted with caution due to the small sample size, it may suggest that the successful integration of electronic health information

technology such as computerized reminder systems may mediate clinician behavior when the flow of information is relatively seamless. For those sites not actively using EHRs, implementing a new layer of health information technology to communicate patients' screening preferences must be carefully integrated into the sites' existing clinical processes so as to minimize disruptions to productivity and workflow.

Limitations

There are a number of limitations to this study. First, each site was affiliated with the Great Lakes Research Into Practice Network, and all sites had previously participated in a study investigating the implementation of a computerized reminder system. Clinicians and staff at these sites may therefore not represent those less engaged in health services research or those more opposed to the adoption of electronic health information technology. This said, by being early adopters of technology, our sample was likely primed to describe barriers and facilitators to the technology's implementation rather than to the use of Web-based technology itself. Second, the study focused on a limited number of small community practice settings; therefore, findings may not be generalizable to larger practice settings or settings that have a close affiliation with a specific health system. Third, our sample of five sites, 9 clinicians, and 18 staff (of which only 8 staff actively participated) was relatively small. Because the intent of this qualitative study was to solicit rich descriptions informed by the give-and-take dynamic of the focus group, increasing the number of sites was both impractical and cost prohibitive given the study's limited resources. Importantly, because no novel findings were identified by the fifth focus group, thematic saturation was likely achieved. Informed by findings from this research, follow-up studies might consider employing a survey-based methodology to reach a larger and nationally representative sample. Fourth, because of the small sample and to ensure respondents' confidentiality, we did not attempt a more nuanced stratification of responses based on participant demographics. It may be that a persons' background or demographic profile primes or limits ones' readiness to accept new technology or change clinical behavior; for example, it is possible that older physicians, like older patients, may be less comfortable with using new technology when compared to their younger counterparts. Investigating the possible role of background or demographics on ones' readiness/willingness to use new forms of health information technology should be the focus of future research. Fifth, over half of the nonclinical staff failed to actively participate in the focus groups. It may be that some staff were uncomfortable sharing their thoughts in front of clinicians, who in some cases were the staff members' employer. It is also possible that some staff (eg, an office biller) may have been so far removed from the day-to-day clinical milieu that they simply had nothing substantive to add. Focus groups separating clinicians and staff may yield different findings and could be explored in future research. Sixth, the issue of tailoring screening according to the patient's CRC risk (eg, recommending colonoscopy only to those with increased risk vs offering options to those with average risk) was not discussed. Incorporating patients' CRC risk in CRC screening discussion is important, and our current website (now renamed

as ColoDATES and tested in the field in a federally funded study), includes an interactive risk assessment tool [47]. Seventh, the focus groups were conducted in 2006 and 2007 and therefore do not necessarily reflect the increased use of EHRs observed over the past few years. Findings from the 2011 National Ambulatory Medical Care Survey reveal, however, that nearly 40% of United States primary care physicians practice in sites without an EHR, and only 22% practice in sites with fully functional systems [48]. Moreover, the use of Web-based interactive decisions aids linked to a computerized reminder system remains on the cutting edge of electronic health information technology. And last, the five focus group sessions documented clinician and staff member perceptions and not their actual behavior within the clinical setting. It is possible that participants may have under- or overestimated barriers and facilitators based on their personal biases toward electronic health information technology. Likewise, because patients themselves were not included in this research, it is possible that participants may have under- or overestimated patients' barriers to accessing or utilizing Web-based tools. Given previous findings that clinicians may sometimes overestimate their own performance [49,50] and underestimate patients' literacy [51-53] and financial status [54-56], findings should be interpreted with caution.

Conclusions

The clinician and staff participants in this research perceived the interactive and Web-based decision aid as a promising tool for informing patients about the range of CRC screening options. One benefit ascribed to the tool was that it could be utilized by patients outside of the face-to-face clinical encounter. After reviewing the online decision aid, participants agreed that patients would be well informed about the pros and cons of each CRC screening modality, which could help to increase the sophistication of dialogue between patients and clinicians. Moreover, linking the tool to a computerized reminder system was described as a potentially effective way to inform clinicians of patient's screening preference, and the reminder could be used to trigger conversation and promote shared decision making. However, focus group participants also voiced concerns regarding patients' computer and Internet literacy and disruptions to the clinics daily workflow. These concerns—as well as solutions to overcome them—should be the focus of future research.

Web-based CRC screening decision aids and linked computerized reminder systems hold promise for improving patient-clinician communication and subsequent follow-through with screening, but only if the linking fits seamlessly into the clinical setting. Our findings suggest the trend toward adopting electronic health information technology—including the growing mandate to implement and achieve meaningful use of EHRs—must not only focus on improvements to the technology itself, but also integration of the system-related processes that enable the technologies' successful adoption. Close attention to systems and processes has particular importance in small community-based practice settings where resources in time, staff, and money are likely to be limited.

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Conflicts of Interest

Drs Jimbo, Shultz, and Ruffin and Ms Power have no conflicts of interest. Drs Nease and Fetters served as consultants to Cielo MedSolutions, LLC, which licensed Cielo Clinic from the University of Michigan in 2006. Dr Nease and Fetters received royalties through the sale of Cielo Clinic, a derivative of the original ClinfoTracker software, a free-standing computerized registry and reminder system that had been piloted in each of the sites participating in this qualitative study. From March 2011 until October 2012, Dr Nease was an employee of The Advisory Board Company, Inc, which acquired Cielo Clinic in 2011.

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Abbreviations

- CRC:** colorectal cancer
- EHR:** electronic health record
- FOBT:** fecal occult blood test
- PI:** principal investigator

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Original Paper

Puzzling With Online Games (BAM-COG): Reliability, Validity, and Feasibility of an Online Self-Monitor for Cognitive Performance in Aging Adults

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Abstract

Background: Online interventions are aiming increasingly at cognitive outcome measures but so far no easy and fast self-monitors for cognition have been validated or proven reliable and feasible.

Objective: This study examines a new instrument called the Brain Aging Monitor–Cognitive Assessment Battery (BAM-COG) for its alternate forms reliability, face and content validity, and convergent and divergent validity. Also, reference values are provided.

Methods: The BAM-COG consists of four easily accessible, short, yet challenging puzzle games that have been developed to measure working memory (“Conveyer Belt”), visuospatial short-term memory (“Sunshine”), episodic recognition memory (“Viewpoint”), and planning (“Papyrinth”). A total of 641 participants were recruited for this study. Of these, 397 adults, 40 years and older (mean 54.9, SD 9.6), were eligible for analysis. Study participants played all games three times with 14 days in between sets. Face and content validity were based on expert opinion. Alternate forms reliability (AFR) was measured by comparing scores on different versions of the BAM-COG and expressed with an intraclass correlation (ICC: two-way mixed; consistency at 95%). Convergent validity (CV) was provided by comparing BAM-COG scores to gold-standard paper-and-pencil and computer-assisted cognitive assessment. Divergent validity (DV) was measured by comparing BAM-COG scores to the National Adult Reading Test IQ (NART-IQ) estimate. Both CV and DV are expressed as Spearman rho correlation coefficients.

Results: Three out of four games showed adequate results on AFR, CV, and DV measures. The games Conveyer Belt, Sunshine, and Papyrinth have AFR ICCs of .420, .426, and .645 respectively. Also, these games had good to very good CV correlations: rho=.577 ($P=.001$), rho=.669 ($P<.001$), and rho=.400 ($P=.04$), respectively. Last, as expected, DV correlations were low: rho=-.029 ($P=.44$), rho=-.029 ($P=.45$), and rho=-.134 ($P=.28$) respectively. The game Viewpoint provided less desirable results with an AFR ICC of .167, CV rho=.202 ($P=.15$), and DV rho=-.162 ($P=.21$).

Conclusions: This study provides evidence for the use of the BAM-COG test battery as a feasible, reliable, and valid tool to monitor cognitive performance in healthy adults in an online setting. Three out of four games have good psychometric characteristics to measure working memory, visuospatial short-term memory, and planning capacity.

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KEYWORDS

cognitive testing; brain aging; games; validity; reliability; self-monitoring; Internet; eHealth

Introduction

With the rise of the Internet and the introduction of eHealth, the new research area of online health care has evolved rapidly over the last decade [1]. The field of research focusing on public health promotion is no exception [2]. Also, and already for a slightly longer period of time, the gaming industry has established itself as a major global industry [3]. Nowadays, eHealth and “serious gaming” are increasingly intertwined and more researchers are venturing into the realm of (online) game research. In turn, game developers show heightened interest in supporting and helping solve scientific research and societal issues [4]. For example, games are used to assist in stroke rehabilitation [5], in programs aimed at the prevention of youth obesity [6], and in enhancing gait balance in nursing home residents [7].

From a health-behavior change perspective, both eHealth and gaming are of high interest. Widespread Internet access provides the behavior-change researcher with the platform necessary to reach large populations. In Europe and North America, Internet penetration ranges between 63.2-78.6% of the total population [8]. With its massive reach, online gaming has long since shifted from being a typical pastime for younger generations to serving millions of gamers of every age, race, sex, and cultural background [9].

An important drawback of the Internet is that its content has to be fast and entertaining [10,11]. When researchers consider using the Internet as their medium and want to profit from its enormous reach, their interventions and evaluation methods should comply with these characteristics. Therefore, there is a need for quick, easily accessible, and attractive applications and instruments that provide the user with direct feedback [12]. If an intervention fails to do so, it will be difficult to recruit a sufficient number of participants. Also, dropout rates may be high, which will subsequently heavily affect the power of a study [13].

The effects of aging on cognitive functions have been studied increasingly [14,15]. Typically, this has been done by both paper-and-pencil and offline computer-assisted neuropsychological testing [16]. One of the domains within the area of eHealth involves online assessment and monitoring of cognitive (dys)function [17]. Quantifying cognitive performance in tangible measures that are readily interpretable for neuropsychologists and patients alike has gained increasing interest and cognitive training programs like Lumosity have experienced a steep rise in popularity [18]. Now that intervention studies are scaling up in the number of recruited participants, a demand exists for short and easy-to-use validated neuropsychological tests [19]. Traditional person-to-person neuropsychological testing may in this respect often be inefficient from a time and cost perspective [20,21] and certainly does not meet the criteria for successful use in an online environment.

Online cognitive testing has already been proven valid and reliable in children aged 10-12 years [20], as well as adult and older populations ranging from 18-80 years of age [17,22]. We set out to develop an online self-monitor for cognitive

functioning in people aged 40 years and older—the BAM-COG (Brain Aging Monitor-Cognitive Assessment Battery). The BAM-COG consists of four easily accessible, short yet challenging puzzle games that can be completed online, aimed to assess key aspects of cognitive function that are susceptible to aging-related changes, that is, working memory, executive function, and episodic memory. This empirical validation study consisted of two parts. First, we examined the alternate forms reliability and, second, we studied convergent and divergent validity of the BAM-COG. Also, reference values are presented from a sample of 397 adults aged 40-85 years.

To our knowledge, this is the first study to describe, validate, and examine an online self-monitor for cognitive functioning that makes use of visually attractive, easy-to-instruct puzzle games. The BAM-COG was not developed as a diagnostic tool (eg, for the assessment of pathological cognitive aging such as dementia), nor was it designed to predict cognitive decline over time. The aim of the BAM-COG was to enable users to establish their cognitive performance and to monitor their personal cognitive development over time. This is of major importance because it greatly increases the possibilities of online research on cognitive functioning, it increases reach, and it decreases costs both monetary and in time.

The hypotheses for this study are that the BAM-COG games have good alternate forms reliability and that the face and content validity of the four newly developed puzzle games of the BAM-COG transfer into good convergent and divergent validity, compared with standard paper-and-pencil and computer-assisted cognitive assessment.

Methods

Population

We set out to validate the BAM-COG in a cohort of community-dwelling individuals aged 40 years and older. Rationale for the 40-year cut-off point is that from approximately this age onwards normal cognitive aging is firmly evidenced [23]. The only inclusion criterion, apart from age, was that participants had adequate Internet access. Within the given age restrictions, the target population was unrestricted since we searched for a study population representative of the general population. No regional, ethnic background, sex, or language restrictions were applied, although the website description was only available in Dutch. Participants for Part 1 of the study were recruited online through several websites, social media, and blogs. A convenience sample was recruited for Part 2 of the study using flyers in community centers, shopping areas, mid-sized regional organizations, and senior centers. Furthermore, the study received national radio and newspaper attention, which resulted in the recruitment of participants as well.

Study Design

The research website was available to participants for four months. Upon enrollment, we registered sex, age, and education level—the latter ranging from 1-8, where 1 is the lowest value (elementary school) and 8 is the highest value (university level education; see [22] for the Dutch system which is similar to the

ISCED [International Standard Classification of Education] standards from the United Nations [24]). The online games could be completed in the uncontrolled setting of the participants' day-to-day lives [21]. Once participants were logged in, they played the BAM-COG games for the first time. An automated reminder system prompted the participant to visit the website again after 14 and 28 days to perform the second and third round of BAM-COG games.

On their first two visits, participants performed the same BAM-COG games (see Table 1 for more information on the BAM-COG games). In the third round, they performed a different batch of BAM-COG games, thus playing different trials with approximately the same difficulty. To check whether the different batches did not differ with respect to difficulty, we performed alternate forms reliability (AFR) analyses (see Statistical Analyses). In total, there were three different batches of trials. A participant was randomly assigned to any of the six possible sequence groups (1-1-2, 1-1-3, 2-2-1, 2-2-3, 3-3-1, or 3-3-2) by an online random placement script. After completing all three rounds, a participant was awarded a promotional code with a value of €4.99 (US\$6.75) that could be used for a one-month subscription to a puzzle website.

There were two parts in this study. Part 1 involved the data collection for AFR analyses and reference values, which was done exclusively via the Internet. Participants in Part 1 were estimated to need approximately 45 minutes per session to complete the BAM-COG. In total, after three rounds of BAM-COG puzzles within 28 days, participants were estimated to have spent approximately 135 minutes on the BAM-COG. This group will be abbreviated as "Online group" from this point on. Part 2 involved the data collection necessary to calculate the BAM-COG's convergent (CV) and divergent validity (DV). For this procedure, in addition to playing the BAM-COG games online, participants visited the Radboud University Medical Center (RUMC) once (this group will be abbreviated as the "RUMC group"). This group of participants

performed both computerized cognitive tests (subtests from the Cambridge Automated Neuropsychological Test Battery or CANTAB) and paper-and-pencil neuropsychological tests (PnP) (see Table 2 for an overview of the tests and Multimedia Appendix 1 for a more detailed description of the BAM-COG). Specific subtests were related to the individual BAM-COG's cognitive constructs by consultation with experienced neuropsychologists (MAEB, RPCK; see Table 2 for overview of used measures of comparison). Order of the offline testing (CANTAB first vs PnP tasks first) was randomized by flipping a coin. BAM-COG results from participants in Part 2 are also included in the results of Part 1. Duration of the test session was approximately 90 minutes per participant. In addition to the 135 minutes spent on the BAM-COG measurements, participants in Part 2 were estimated to have spent about 225 minutes on the BAM-COG validation study.

For the group of participants visiting the RUMC, two additional inclusion and exclusion criteria were applied. Potential participants were excluded if they had a score ≤ 24 on the Mini-Mental State Examination (MMSE [25]) to make sure none of the participants had any symptoms of neurodegenerative disease [16]. To ensure that participants were capable of working with the CANTAB touch screen and test environment, the session started with performing the CANTAB Motor Screening Task where participants need to touch a flashing "x" stimulus on the screen as quickly and accurately as possible. If participants failed to either comprehend or execute this task, they were excluded from further participation. Since this study design was, in part, focused on gathering reference values, current participants did not receive feedback on their individual scores in comparison to their peers. After completing the three measurements, participants did not have continued access to the games, because the BAM-COG was not designed to be a training instrument, but an assessment instrument. This resembles the manner in which it primarily should be used in further practice.

Table 1. BAM-COG (Brain Aging Monitor–Cognitive Assessment Battery) game details.

BAM-COG game	Cognitive domain	Total levels ^a	Range of scores	Short description
Conveyer Belt	Working memory	7	4-10	This game shows a participant a grocery list on screen. After 1 second, the conveyer belt turns on. Groceries run down the belt and participants need to select only those products that are on their list.
Sunshine	Visuospatial short-term memory	8	3-10	In this game, a sun creates visual patterns in a 5x5 cloud matrix. This visual pattern dissolves and, after it has completely disappeared, participants are asked to reproduce this pattern in the exact same order as it initially appeared on screen.
Viewpoint	Episodic recognition memory	8	1-8	This game presents a 5x5 matrix filled with stimuli (asterisks) to the participant. The participant gets 3 seconds to memorize this presented pattern before it disappears from the screen. After 3 seconds, 3 answer possibilities appear on screen from which the participant is to pick the answer that is an exact match to the previously shown matrix.
Papyrinth	Executive function - planning	5	3-7	This game starts with presenting the participant with a scrambled path. The participants task is to unscramble the path so their pawn can move from start to finish unobstructed. Clearing the route is done by sliding columns and rows in the correct order so that all pieces of road end up connected to each other.

^aExcluding the practice level.

Table 2. BAM-COG^a domains and proposed matching computerized and paper-and-pencil cognitive tests.

BAM-COG game (domain)	CANTAB ^b	Paper and pencil
Conveyer Belt (working memory)	Spatial Working Memory [26]	Letter-Number Sequencing Task from WAIS-III ^c [27]
Sunshine (visuospatial short-term memory)	Spatial Span [26]	Spatial Span subtest from WMS-III ^d [28]
Viewpoint (episodic recognition memory)	Pattern Recognition [26]	Continuous Visual Memory Task [16,29-31]
Papyrinth (planning)	Stockings of Cambridge [26]	Zoo Map Task, part of the BADS ^e [16,32]

^aBAM-COG: Brain Aging Monitor–Cognitive Assessment Battery. For a short description of the BAM-COG games, see [Multimedia Appendix 1](#).

^bCANTAB: Cambridge Automated Neuropsychological Test Battery.

^cWAIS-III: Wechsler Adult Intelligence Scale, third edition.

^dWMS-III: Wechsler Memory Scale, third edition.

^eBADS: Behavioral Assessment of the Dysexecutive Syndrome.

Sample Size Calculation

According to our sample size calculations for CV and DV, we needed 37 participants for Part 2 (alpha error probability <.05, power (1-beta error probability =.8) of our study. Sample size calculation was performed using GPower 3.1 [33].

Instruments

The BAM-COG consists of four puzzle games developed to measure working memory, visuospatial short-term memory, episodic recognition memory, and executive function-planning (see [Table 1](#) for game details). Every game started with brief and clear instructions as to what the participant should expect. In an attempt to maximize comprehension of the instructions,

the written instructions were accompanied by actual game screenshots. After the mandatory instructions, participants performed one practice trial to further familiarize themselves with the game. Following this first practice trial, the actual test commenced. Each level of each game consisted of three trials. To advance to the next level, at least two out of three trials had to be completed successfully. If a participant failed to successfully complete two or three trials, a “game over” screen appeared and the participant was linked back to the main screen where the next game could be selected. For an overview of the games and their instructions, see [Multimedia Appendix 1](#). [Multimedia Appendices 2-5](#) include short videos of the BAM-COG game play. Scores for the Conveyer Belt, Sunshine, and Papyrinth games were the total number of stimuli or moves

that needed to be processed. For the Viewpoint game, the score was the number of levels successfully completed.

Measures of Comparison

Subjects in the RUMC group also participated in tasks from the CANTAB and PnP tasks matched for the BAM-COGs cognitive domains (see Table 2). All these games were carefully selected to mimic the cognitive domains primarily relied on in the BAM-COG games as closely as possible.

Instrument Development

Based on expert opinion from two neuropsychologists, a geriatrician, a public health researcher, and a professional game-design team, the four puzzle games were considered to cover the chosen cognitive constructs of working memory, visuospatial short-term memory, episodic recognition memory, and planning. After this initial assessment, the instrument outline was discussed with a broader group of health care professionals consisting of neuropsychologists, epidemiologists, public health care researchers, and general psychologists. It was agreed that from a content point of view, it would be impossible to cover every cognitive domain that decreases in functionality across the lifespan, when fast and easy access are key criteria. It was decided that choosing three executive functions and one specific memory function, all of which have been established to decline in normal aging and neurodegenerative syndromes [23,34-37], would provide good insight into overall aging patterns.

Statistical Analysis

Alternate forms reliability (AFR) was determined to compare the three batches of BAM-COG games, administered at different time points. Every batch resembles a parallel version of the BAM-COG containing an equal number of levels and trials. Theoretically, these batches do not differ from one another in difficulty. The AFR was determined with an intraclass correlation (ICC: two-way mixed; consistency at 95%) on the results of the second and third round performances of the participants. With respect to interpretation of the ICCs, we needed to take into consideration that the study was executed outside of a clinical laboratory setting where people could be easily distracted, which may affect the test's reliability. Therefore, ICC values between .4 and .6 were considered sufficient to support AFR for the BAM-COG. This is in line with another online validation study [17]. Also, note that no specific cut-off scores for ICCs exist [38].

To further analyze possible systematic differences between measurements, Bland-Altman plots were calculated. In these plots, the differences between two sessions were plotted against their mean. Furthermore, the scores' means and limits of agreement were calculated as the mean of the difference between the two measurements ± 2 SD of these differences. The standard error of measurement and the 95% confidence intervals for the mean difference between the two measurements were also calculated. If the 95% confidence interval does not include zero, this indicates a systematic and undesirable change in the mean [39].

The CV determines whether the cognitive domain supposedly measured by the BAM-COG game is actually assessed, using

validated cognitive tasks as gold standards. In contrast, the DV examines to what extent the BAM-COG correlates with cognitive domains it should not correlate with. By comparing the BAM-COG game scores to a non-related cognitive construct (in this study, IQ scores derived from the Dutch version of the National Adult Reading Test, NART), the distinctive capacities of the BAM-COG are established. Due to non-normal data distribution on BAM-COG outcome measures and small samples, both CV and DV of the BAM-COG are calculated using a one-tailed Spearman's rho correlation coefficient.

For interpretation purposes, the data from the three batches were aggregated into one measure for the calculation of CV and DV. This enables us to judge the task as one entity instead of three separate batches. Single test statistics were generated based on participants' average game scores (for more information on scoring, see Instruments). Reference values are provided for the games to provide some insight into the expected distribution of scores in a normal aging population of people aged 40 years and older. For every analysis, participants with a raw test score of 0 were excluded. This was done as these participants had either viewed the instructions but not started playing or played only one or two trials out of the necessary three to advance to the next level.

This study was deemed exempt from formal ethical evaluation by the local medical ethics committee (region Arnhem-Nijmegen, registration number: 2011/490). All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 20.0. The Bland-Altman plots were performed with GraphPad Prism version 5.03 for Windows.

Feasibility

BAM-COG's feasibility was assessed based on the total number of registrations and dropouts, the percentage of participants who played and completed the first, second, and third rounds, and examination of the score distributions for floor and ceiling effects.

Results

Participants

Through our research website, 641 participants were enrolled in this study of whom 124 (19.3%) were excluded as they did not fulfill the age criterion. Immediately after registering, each participant was asked to perform the BAM-COG test battery for the first time. A total of 76.8% (397/517) participants in this group played at least one game and were therefore eligible for analyses; 78.6% (312/397) of these were women. The mean age was 54.9 (SD 9.6) years and the modus of education level was 6 (range 1-8).

We recruited 56 participants to participate in Part 2 of the study. Of these 56 participants, 41 were willing to register online, with a mean age of 60.8 (SD 8.2) years, of whom 58.5% (24/41) were female with a modus of educational level of 7 (range 1-8). All participants were native Dutch speakers. All were able to successfully complete the CANTAB Motor Screening Task. In total, 21 (51.2%) of the 41 participants completed the CANTAB tasks first as compared to 20 (48.8%) of the 41 participants completing the PnP tasks first.

In [Table 3](#), scores for the MMSE, NART-IQ, and mean BAM-COG scores are presented. Data from the three batches were pooled to get an overall average score on all four games. The RUMC group was significantly older ($t_{395}=3.78$, $P<.001$) and had a higher education level ($\chi^2_7=33.8$, $P<.001$). This resulted in higher overall test scores (except for Viewpoint)

even though these differences only reached statistical significance in Sunshine. Since there was such a large inequality in gender distribution in our sample, we controlled for systematic differences between men and women on the raw BAM-COG scores. Using a Fisher Exact test, we found no significant differences (ranging from $F_{13}=18.68$, $P=.07$ to $F_{19}=21.82$, $P=.19$).

Table 3. Mean (SD) for age, MMSE^a, NART-IQ^b, and BAM-COG^c scores and mode (range) for education for RUMC^d and online group.

	Online group	RUMC group
Age, years, mean (SD)	54.9 (9.6)	60.8 (8.2)
Education, mode (range)	6 (1-8)	7 (1-8)
MMSE, mean (SD)	--	29.4 (1.07)
NART-IQ, mean (SD)	--	123.2 (12.83)
Conveyer Belt score	5.95 (n=217)	6.33 (n=26)
Sunshine score	4.60 (n=236)	5.10 (n=24)
Viewpoint score	3.97 (n=306)	3.90 (n=28)
Papyrinth score	4.64 (n=152)	5.30 (n=21)

^aMMSE: Mini Mental State Examination.

^bNART-IQ: National Adult Reading Test–Intelligence Quotient.

^cBAM-COG: Brain Aging Monitor–Cognitive Assessment Battery.

^dRUMC: Radboud University Medical Center.

Alternate Forms Reliability

[Table 4](#) shows the AFR with their respective 95% confidence intervals for all four BAM-COG games. With the exception of Viewpoint, all games have good (>.4) to very good (>.6) AFR. To further clarify this relationship, [Multimedia Appendix 6](#)

shows the generated Bland-Altman plots. These also show that, with the exception of the Viewpoint game, the error bias does not deviate far from zero. This ascertains the absence of systematic error between the second and third round measurements.

Table 4. Alternate forms reliability (AFR) of BAM-COG^a games in intraclass correlations (ICC^b).

BAM-COG game	AFR	95% CI
Conveyer Belt (n=55)	.420	0.17-0.62
Sunshine (n=78)	.426	0.23-0.59
Viewpoint (n=101)	.167	–0.04 to 0.36
Papyrinth (n=37)	.645	0.41-0.80

^aBAM-COG: Brain Aging Monitor–Cognitive Assessment Battery.

^bAll ICC values >.4 are considered to support sufficient AFR.

Convergent and Divergent Validity

With the exception of Viewpoint, the BAM-COG games have good (>.4) to very good (>.6) CV in comparison to both the CANTAB and PnP tasks (see [Table 5](#)). Conversely, as hypothesized, all games also show good (<.2) DV with an unrelated overall measure of IQ. Please note that a poor AFR for Viewpoint also translates into poor CV and DV values.

To control whether the individual games did not heavily load on the same cognitive domain, we performed Spearman correlation analysis using aggregated game scores. As was expected with a large sample, most correlations are significant. However, the size of the correlations range from very small ($\rho=.143$, $P=.056$), between Conveyer Belt and Viewpoint, up to medium small ($\rho=.406$, $P<.001$), between Sunshine and Papyrinth.

Table 5. Convergent and divergent validity of BAM-COG^a games (Spearman rho's correlation coefficient).

BAM-COG game	Convergent validity ^b		Divergent validity ^c	
	Cognitive test	rho (P value)	Cognitive test	rho (P value)
Conveyer Belt (n=26)				
	WAIS-III ^d Letter Number Sequencing	.577 (.001)	National Adult Reading Test	-.029 (.44)
	Spatial Working Memory	-.577 (.001)		
Sunshine (n=24)				
	WMS-III ^e Spatial Span Task	.669 (<.001)	National Adult Reading Test	-.029 (.45)
	Spatial Span	.620 (.001)		
Viewpoint (n=28)				
	Continuous Visual Memory Test	.202 (.152)	National Adult Reading Test	-.162 (.21)
	Pattern Recognition	-.157 (.212)		
Papyrinth (n=21)				
	BADS ^f Zoo Map	.400 (.036)	National Adult Reading Test	-.134 (.28)
	Stockings of Cambridge	.424 (.028)		

^aBAM-COG: Brain Aging Monitor–Cognitive Assessment Battery.

^bAll convergent validity values of rho≥.4 are considered to support good CV; values of rho≥.6 are considered very good.

^cAll divergent validity values of rho<.2 are considered to support good DV.

^dWAIS-III: Wechsler Adult Intelligence Scale, third edition.

^eWMS-III: Wechsler Memory Scale, third edition.

^fBADS: Behavioral Assessment of the Dysexecutive Syndrome.

Reference Values

We present reference values for all games (Table 6) displaying the total number of times any given score was reached in all three batches.

Table 6. BAM-COG^a reference values.

Score	Conveyer Belt (n=217)		Sunshine (n=236)		Viewpoint (n=306)		Papyrinth (n=152)	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
1	NA ^b	NA	NA	NA	145	27.5	NA	NA
2	NA	NA	NA	NA	57	10.8	NA	NA
3	NA	NA	75	19.7	32	6.1	57	25.3
4	78	24.4	148	38.9	90	17.1	82	36.4
5	100	31.3	79	20.8	70	13.3	27	12.0
6	26	8.1	55	14.5	41	7.8	15	6.7
7	43	13.5	15	3.9	13	2.4	44	19.6
8	58	18.2	6	1.7	79	15	NA	NA
9	12	3.8	2	0.5	NA	NA	NA	NA
10	2	0.7	0	0	NA	NA	NA	NA

^aBAM-COG: Brain Aging Monitor–Cognitive Assessment Battery.

^bNA: Not Applicable, as this score is not a possible outcome for this game.

Feasibility

The number of registrations totaled 641 participants. The BAM-COG received nationwide attention on two national radio shows and in several regional and national newspapers and magazines. Of the 517 eligible participants, only 397 participants played at least one game out of any of the three batches (76.8%).

The Conveyer Belt game was played most at all three assessments (314, 143, and 107 times respectively) and Papyrus was played the least frequently (189, 123, and 87 times respectively). On average, 75.7% of participants played all four games and, from the participants that finished the last game on a previous round, on average 80.7% returned to play the next round.

Only 8 participants quit while in the middle of playing a game. All the other participants continued until the “game over” message appeared and either continued with the next game or decided to quit playing after this message. The 8 participants who dropped out all stopped while playing Papyrus, which is the only game that does not have an integrated time limit.

No real floor or ceiling effects were present in the data. The only possible exception to this may be a slight ceiling effect on Papyrus and Viewpoint (with 19.6%, 44/225 and 15.0%, 79/527 respectively, completing the highest level). Otherwise, the percentages of participants completing the tasks were very low (0.5%, 2/380 and 0.7%, 2/319 respectively).

Discussion

Principal Findings

This article provides substantial support for the use of the BAM-COG game battery as an online self-monitor for cognitive performance. Three out of four games appear to be adequate measures of the related cognitive concepts (working memory, visuospatial short-term memory, and planning). Conveyer Belt, Sunshine, and Papyrus all have good alternate forms reliability and turned out to be feasible for use in aging adults. Furthermore, they all have good to very good convergent and divergent validity and reference values for the games are now available. Since all games were designed to measure some form of cognitive domains, it stands to reason that their correlations are statistically significant. Their size, however, is either considerably smaller or equal to the task correlations with outside gold-standard measurement tools. The game Viewpoint, designed to assess episodic recognition memory, did not have an adequate validity and reliability and is not suitable for inclusion in an online assessment battery. In addition, a strength of our setup are the correlations of the BAM-COG scores with the gold-standard CANTAB and PnP tasks. The fact that the BAM-COG games proved to be solid measures of the intended cognitive domains provides good hope that replication of these results is possible in other samples and the BAM-COG can be put to use for its intended purpose.

Limitations

Even though the current findings are promising with respect to the BAM-COG's applicability, some adjustments can be recommended on the basis of these results. First, we occasionally

received feedback of technical difficulties, in particular with the performance of the Conveyer Belt game. Small-sized stimuli (in this case, groceries such as apples and pears) appeared difficult to click resulting in unintentional missed responses. However, although we cannot fully rule out technical issues on some remote systems, this may have also been due to suboptimal mouse handling by individual participants. This explanation is likely since neither the software developers nor the researchers have been able to replicate this problem on different systems with different operating systems and Internet browsers. Moreover, the problem did not emerge so frequently ($n=19$ out of $n=314$) that it would have severely influenced the outcomes of our analyses. Second, feedback was given that there is a need for additional practice levels. Apparently just one trial to get acquainted with the task was not always enough for all participants to fully comprehend what was requested of them. This may have resulted in a slight underachievement in average scores. In a future release of the BAM-COG battery, this can easily be taken into account. Third, regardless of our follow-up efforts (one additional phone call and one personal reminder email), 15 participants in the RUMC group failed to register online even after they had visited the memory clinic. Reasons for this dropout could have been a sole interest in the neuropsychological screening at the research center, time restrictions, loss of motivation, or the relative ease with which reminder emails and online interventions can be ignored and forgotten. Additionally, the limited amount of personal contact with the researchers and the ease of the registration process may increase attrition [40,41], as well as technical or computer-access problems, physical illness, burden of the program, the static structure, and low adaptation to user preferences [42,43]. This again stresses that high dropout rates are an important issue to consider when setting up Internet-based studies. However, since the characteristics of the group of dropouts did not differ in any way from the other registered participants, we do not feel this has significantly affected the current results.

In the interpretation of these results, we need to take the naturalistic setting in which the games were performed into account. That is, laboratory studies in which results are produced under highly controlled conditions typically result in higher ICCs and correlations. The BAM-COG assessments in this study have all been performed in the participants' home environment without any supervision by the research team. Because the BAM-COG is not designed to be used in a laboratory setting, we feel the present design is a valid approach to examine its feasibility, validity, and reliability. If biased, the performance presented in this study may be an underestimation of the real reliability and validity of the BAM-COGs tasks [38]. Therefore, we feel we can validly conclude that the BAM-COG is an adequate online self-monitor for cognitive performance.

The fact that our population consisted mainly of women (78.6%, 312/397 and 58.5%, 24/41 for Part 1 and Part 2 respectively) somewhat decreases the external validity of this study. However, this type of research and these types of puzzle games have previously been shown to attract more female participants than males [9,17,22]. Also, the notion that not all participants finished (all) the games has consequences for the way ceiling and floor effect results should be interpreted. It remains possible that the

participants not starting or dropping out in level 1 are, in fact, experiencing a floor effect. Finally, it should be mentioned that the RUMC group differed from the online group, as the RUMC group was both older and better educated. This resulted in slightly higher average test scores. Further research in a more balanced sample could strengthen the conclusions drawn and external validity for the BAM-COG battery and validation studies with other cognitive measures should be performed to replicate the present results.

Conclusions

In sum, this study provides evidence for the use of the BAM-COG test battery as a feasible, reliable, and valid tool to monitor cognitive performance in healthy adults in an online setting. Three out of four games were found to have good to very good psychometric characteristics to measure working memory, visuospatial short-term memory, and planning capacity. It should be stressed that the results can by no means be used to either diagnose neurodegenerative disorders or predict cognitive performance. The BAM-COG is suitable for use in practice for online monitoring cognition and stimulating eHealth interventions for healthy brain aging.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Overview of the BAM-COG games.

[[PDF File \(Adobe PDF File\), 2MB - jmir_v15i12e270_app1.pdf](#)]

Multimedia Appendix 2

Short video of BAM-COG’s game play - Conveyer Belt.

[[MP4 File \(MP4 Video\), 3MB - jmir_v15i12e270_app2.mp4](#)]

Multimedia Appendix 3

Short video of BAM-COG’s game play - Sunshine.

[[MP4 File \(MP4 Video\), 3MB - jmir_v15i12e270_app3.mp4](#)]

Multimedia Appendix 4

Short video of BAM-COG’s game play - Viewpoint.

[[MP4 File \(MP4 Video\), 2MB - jmir_v15i12e270_app4.mp4](#)]

Multimedia Appendix 5

Short video of BAM-COG’s game play - Papyrinth.

[[MP4 File \(MP4 Video\), 6MB - jmir_v15i12e270_app5.mp4](#)]

Multimedia Appendix 6

Overview of the Bland-Altman plots for alternate forms reliability.

[[JPG File, 3MB - jmir_v15i12e270_app6.jpg](#)]

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Abbreviations

- AFR:** alternate forms reliability
- BAM-COG:** Brain Aging Monitor – Cognitive Assessment Battery
- CANTAB:** Cambridge Automated Neuropsychological Test Battery
- CV:** convergent validity
- DV:** divergent validity
- ICC:** intraclass correlation
- IQ:** Intelligence Quotient
- ISCED:** International Standard Classification of Education
- MMSE:** Mini Mental State Examination
- NART:** National Adult Reading Test
- RUMC:** Radboud University Medical Center

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Original Paper

Outsourcing Medical Data Analyses: Can Technology Overcome Legal, Privacy, and Confidentiality Issues?

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Abstract

Background: Medical data are gold mines for deriving the knowledge that could change the course of a single patient's life or even the health of the entire population. A data analyst needs to have full access to relevant data, but full access may be denied by privacy and confidentiality of medical data legal regulations, especially when the data analyst is not affiliated with the data owner.

Objective: Our first objective was to analyze the privacy and confidentiality issues and the associated regulations pertaining to medical data, and to identify technologies to properly address these issues. Our second objective was to develop a procedure to protect medical data in such a way that the outsourced analyst would be capable of doing analyses on protected data and the results would be comparable, if not the same, as if they had been done on the original data. Specifically, our hypothesis was there would not be a difference between the outsourced decision trees built on encrypted data and the ones built on original data.

Methods: Using formal definitions, we developed an algorithm to protect medical data for outsourced analyses. The algorithm was applied to publicly available datasets (N=30) from the medical and life sciences fields. The analyses were performed on the original and the protected datasets and the results of the analyses were compared. Bootstrapped paired *t* tests for 2 dependent samples were used to test whether the mean differences in size, number of leaves, and the accuracy of the original and the encrypted decision trees were significantly different.

Results: The decision trees built on encrypted data were virtually the same as those built on original data. Out of 30 datasets, 100% of the trees had identical accuracy. The size of a tree and the number of leaves was different only once (1/30, 3%, $P=.19$).

Conclusions: The proposed algorithm encrypts a file with plain text medical data into an encrypted file with the data protected in such a way that external data analyses are still possible. The results show that the results of analyses on original and on protected data are identical or comparably similar. The approach addresses the privacy and confidentiality issues that arise with medical data and is adherent to strict legal rules in the United States and Europe regarding the processing of the medical data.

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KEYWORDS

confidentiality; patient data privacy; data protection; medical decision making; computer-assisted; data analysis

Introduction

Background

Medical data are gold mines for deriving knowledge. Hiding within those mounds of data is knowledge that could change the life of a single patient, or sometimes change the health of an entire population [1]. Medical doctors—field experts—use the data collected from various sources on a daily basis for treating patients. Many data from examinations and laboratory tests require further analyses, which can be very time consuming and require experts to conduct them. In fact, the amount of data produced by medical electronic equipment is enormous and continues to grow at a very fast rate—the amount of data doubles in approximately 15 months [1-3]. The large volumes of data make human-driven analyses impossible. Machine support and intelligent data analyses are definitely required. Medical experts and other employees of a health care service provider generally do not possess in-house expertise for doing automatic data analyses. There is also a distinction between deriving knowledge from Web pages, blogs, social media systems, etc, and from the closed systems typically present in medical environments. The former is mostly used for branding purposes (advertising, marketing, and content delivery) [4] and the latter to support doctor's decision making. Sometimes information technology (IT)-related resources in a health care system, including hardware and software, may not be adequate or even available for the data analyses aimed at knowledge discovery. The obvious choice is to have a third party conduct the analyses.

Here, privacy and confidentiality issues arise together with legal obligations. Respect for privacy has been a part of the medical profession since ancient times. “Whatever I see or hear in the lives of my patients, whether in connection with my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private...” is the text from an oath attributed to Hippocrates referring to confidentiality [5]. Privacy and confidentiality are very important contemporary issues, especially in the Western world, and are not limited to the medical field.

Privacy has (re)emerged as an important issue since the emergence of social media, as noted by Mark Zuckerberg, the founder of the most-used social network, Facebook [6], and Facebook's chief operation officer, Sheryl Sandberg. They observed that privacy controls were centered at Facebook's core at all times [7,8]. Indeed, privacy needs to be considered seriously from a technological point of view when designing applications and solutions. In Canada, the Ontario Privacy Commissioner, Ann Cavoukian, has developed a Privacy by Design (PbD) framework [9-11] which emphasizes the need to adopt a proactive rather than a reactive compliance approach to the protection of privacy.

The laws of most developed countries impose obligations to respect informational privacy (eg, confidentiality, anonymity, secrecy, and data security), physical privacy (eg, modesty and bodily integrity), associational privacy (eg, intimate sharing of death, illness, and recovery), proprietary privacy (eg, self-ownership and control over personal identifiers, genetic data, and body tissues), and decisional privacy (eg, autonomy

and choice in medical decision making) [12,13]. In this paper, however, we address the first type of privacy: informational privacy.

Informational privacy is usually violated by a data breach, which can result from theft, intentional or accidental unauthorized access to data, acts of revenge by unsatisfied employees, or by the accidental loss of media or devices that bear data.

Despite the regulations in place, the stories of privacy and confidentiality breaches are still frequent. Major hospitals and health-related institutions, most notably in the United States but also elsewhere in the world, have experienced highly publicized data breaches—more than 770 breaches have occurred since 2005 in the United States alone [14]. Anciaux et al [15] observed that traditional electronic health records (EHR) have no security guarantee outside the health care service domain and pervasive health, a new concept based on latest developments, requires implementable principles for privacy and trustworthiness [16]. Van der Linden et al [17] noticed that before the virtual lifelong patient record can become reality, more clarity has to be provided on the legal and computational frameworks that protect confidentiality.

Can technology help and how can it help? First, let us take a closer look at definitions of privacy and confidentiality and how they are reflected in laws and rules.

Privacy and Confidentiality

Daniel Solove [18] has stated: “Privacy is a concept in disarray. Nobody can articulate what it means.” But one must note that privacy and confidentiality do share at least some common grounds among the philosophers and jurists, and many technologies exist that address privacy and confidentiality.

In Ancient Greek civilization, there existed 2 interdependent and sometimes conflicting areas: the public area of politics and political activity, the *polis*, and the private area of the family, the *oikos* [19,20]. These areas were reflected in classic dramas (eg, in Sophocles' *Antigone* and *Oedipus Rex*), and the new order of the polis, despite its weaknesses, reigned supreme at the end of the dramas [21].

More systematic discussion of the concept of privacy began with an article by Samuel Warren and Louis Brandeis titled “The Right to Privacy” [22]. Citing “political, social, and economic changes” and a recognition of “the right to be let alone,” they argued that existing laws afforded a way to protect the privacy of the individual, and they sought to explain the nature and extent of that protection. Focusing in large part on the press and publicity allowed by recent inventions, such as photography and newspapers, but referring to violations in other contexts as well, they emphasized the invasion of privacy brought about by public dissemination of details relating to a person's private life. Warren and Brandeis felt a variety of existing cases could be protected under a more general right to privacy which would protect the extent to which one's thoughts, sentiments, and emotions could be shared with others. They were not attempting to protect the items produced or intellectual property, but rather the peace of mind attained with such protection; they said the right to privacy was based on a principle of “inviolate personality” which was part of a general right of

immunity of the person: “the right to one’s personality” [22]. Thus, Warren and Brandeis laid the legal foundation for a concept of privacy that has come to be known as control over information about oneself [23].

In an attempt to systematize and more clearly describe and define the new right of privacy upheld in tort law, William Prosser [24] wrote in 1960 about 4 different interests in privacy, or privacy rights:

1. Intrusion upon a person’s seclusion or solitude, or into his private affairs;
2. Public disclosure of embarrassing private facts about an individual;
3. Publicity placing one in a false light in the public eye; and
4. Appropriation of one’s likeness for the advantage of another [23].

Prosser noted that the intrusion in the first privacy right had expanded beyond physical intrusion, and pointed out that Warren and Brandeis had been concerned primarily with the second privacy right. Nevertheless, Prosser felt that both real abuses and public demand had led to general acceptance of these 4 types of privacy invasions. Thomas Nagel, one of the America’s top contemporary philosophers, gives a more contemporary (philosophical) discussion of privacy, concealment, publicity, and exposure [25].

More recently, Adam Moore [26], building on the views of Ruth Gavison [27], Anita Allen [28], Sissela Bok [29], and others offered a control-over-access account of privacy. According to Moore, privacy is a cultural- and species-relative right to a level of control over access to bodies or places of information. While defending the view that privacy is relative to species and culture, Moore argues that privacy is objectively valuable: human beings that do not obtain a certain level of control over access will suffer in various ways. Moore claims that privacy, like education, health, and maintaining social relationships, is an essential part of human flourishing or well-being [23].

In a medical context, as viewed by Allen [13], the privacy at issue is very often confidentiality [30], specifically the confidentiality of patient-provider encounters (including the fact that an encounter has taken place), along with the secrecy and security of information memorialized in physical, electronic, and graphic records created as a consequence of these encounters [30]. Confidentiality is defined as restricting information to persons belonging to a set of specifically authorized recipients [13,28,31,32]. Confidentiality can be achieved through either professional silence, leaning on the moral aspect, or through secure data management [33], leaning on technologies and techniques.

The moral significance attached to medical privacy is reflected in data protection and security laws adopted by local and national authorities around the world. The point of these laws is to regulate the collection, quality, storing, sharing, and retention of health data, including the EHR [13].

Medical Data Legal Regulations in the United States and Europe

United States

In the United States, several prominent cases in the 1990s aroused public and legal interest in privacy and confidentiality of medical data. There was no federal law regulating privacy and confidentiality before 1996. One of the key turning points was a breach of Nydia Velasquez’s medical records during her campaign for a House seat. At hearings before the US Senate Subcommittee on Technology and the Law of the Committee on the Judiciary on January 27, 1994, she said:

...I woke up one morning with a phone call from my friend Pete Hamill, a columnist at the New York Post. He told me that the night before, the Post had received an anonymous fax of my records from St. Claire Hospital. The records showed that I had been admitted to the hospital a year ago seeking medical assistance for a suicide attempt. He told me that other newspapers across the city had received the same information, and the New York Post was going to run a front page story the next day. For the press, it was a big story. For me, it was a humiliating experience over which I had no control...When I found out that this information was being published in the newspaper and that I had no power to stop it, I felt violated. I trusted the system and it failed me. What is most distressing is that once medical records leave the doctor’s office, there are no Federal protections to guard against the release of that information. In some States, it is easier to access a person’s medical history than it is to obtain the records of a person’s video rentals... [34]

Many similar stories have urged US legislators to adopt federal regulations implemented under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 [35]. Before the HIPAA, no generally accepted set of security standards or general requirements for protecting health information existed in the health care industry. Under HIPAA, the US Department of Health and Human Services (HHS) has adopted 5 administrative rules, among them the HIPAA Privacy Rule [36] and the HIPAA Security Rule [37], the latter complementing the former. The Privacy Rule deals with all protected health information (PHI) regardless of the form (ie, including paper and electronic formats), and the Security Rule deals specifically with electronic PHI (ePHI).

The HIPAA Privacy Rule, or the *Standards for Privacy of Individually Identifiable Health Information*, is a set of federal standards to establish protection of certain health information. The *Security Standards for the Protection of Electronic Protected Health Information* (the Security Rule) established a national set of security standards for protecting certain health information that is held or transferred in electronic form. The Security Rule operationalizes the protections contained in the Privacy Rule by addressing the technical and nontechnical safeguards that organizations, called *covered entities*, must put in place to secure individuals’ ePHI. [38]. The Security Rule specifies administrative, technical, and physical measures that

must be adopted by covered entities to adequately protect the privacy and confidentiality of ePHI.

Additionally, the HHS issued a set of rules [39] requiring the covered entities to notify individuals when their health information is breached. Furthermore, the covered entity must inform the HHS Secretary and the media when a breach involves more than 500 persons; thus, implementing provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act. The rules also apply to the business associates of the covered entities to notify the covered entity of events that affect privacy and confidentiality of ePHI at or by the business associate.

In the Breach Notification Rule [39], the HHS has specified the encryption and destruction as the technologies and methodologies that render PHI unusable, unreadable, or indecipherable to unauthorized individuals. Entities subject to the HHS and Federal Trade Commission regulations that secure health information as specified by the guidance through encryption or destruction are relieved from having to notify in the event of a breach of such information [39,40].

Europe

In 1995, the European Parliament passed Directive 95/46/EC on the protection of individuals in regard to the processing of personal data and the free movement of such data [41]. Member States in the European Union can, within the limits of the provisions of the Directive, determine more precisely the conditions under which the processing of personal data is lawful. Based on the Directive, the European Parliament and the Council on December 18, 2000, adopted the Regulation (EC) No 45/2001 on the protection of individuals in regard to the processing of personal data by the Community institutions and bodies and the free movement of such data [42].

Interestingly, Article 8 of the Directive 95/46/EC explicitly prohibits the processing of special categories of data, including the processing of data concerning health. However, the prohibition does not apply where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment, or the management of health care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy [41].

Furthermore, Article 17 of the directive prescribes security of processing. The controller of data must implement appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, or unauthorized disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing. Having regard to the state of the art and the cost of their implementation, such measures shall ensure a level of security appropriate to the risks represented by the processing and the nature of the data to be protected. The controller must, when processing is carried out on his behalf, choose a processor providing sufficient guarantees in respect of the technical

security measures and organizational measures governing the processing to be carried out, and must ensure compliance with those measures. Processing by way of a processor must be governed by a contract or legal act binding the processor to the controller, stipulating that (1) the processor shall act only on instructions from the controller, and (2) the obligations regarding the appropriate technical and organizational measures to protect personal data, as defined by the law of the Member State in which the processor is established, shall also be incumbent on the processor. The contract or the legal act between the controller and the processor relating to data protection and the appropriate technical and organizational measures to protect personal data must be in written form [41].

When personal data are processed by automated means, measures shall be taken as appropriate in view of the risks. The measures should ensure that during communication of personal data and during transport of storage media, the data cannot be read, copied, or erased without authorization [42].

Directive 95/46/EC has been unchanged in principle since 1995. At the beginning of 2012, the European Commission proposed a comprehensive reform of the 1995 data protection rules to strengthen online privacy rights and boost Europe's digital economy. Technological progress and globalization have profoundly changed the way the data are collected, accessed, and used. In addition, the 27 EU Member States have implemented the 1995 rules differently, resulting in divergences in enforcement. The proposed law would restrict the way Internet companies can gather, use, and retain the volumes of personal data that their users post online [43]. Among other measures, the use of encryption standards may be required in certain situations (Article 27), and a 24-hour notification rule is proposed: in a case of a personal data breach, the controller must notify, without undue delay and, when feasible, not later than 24 hours after having become aware of it, the personal data breach to the supervisory authority (Article 28). The European regulation, once passed, could serve as a template for other countries as they draft or revise their data protection policies [44], and it is threatening the current business practices of the Internet giants, such as Facebook [45].

Technological Similarities in Protecting Medical Data in the United States and Europe

The main difference between the American and European legislation pertaining to medical data is in the level of detail of how the data should be protected. The HIPAA and the accompanying rules, especially the Privacy and Security Rules, give great detail in how to protect data. In Europe, the detail of the protection is left to the EU Member States who must apply national provisions pursuant to Directive 95/46/EC within 3 years from the adoption of the directive.

However, there is one common point: both systems suggest the use of encryption to protect sensitive data. Although the HIPAA Security Rule does not dictate the use of encryption, it becomes an evident choice when considering the HITECH Breach Notification Rule. Entities covered by the rule are relieved from having to notify the media and others in the event of a breach of encrypted information. The EU Regulation (EC) No 45/2001, based on the Directive 95/46/EC, suggests the use of encryption

when processing data for historical, statistical, or scientific purposes (Article 4) [42]. On the other hand, local laws of EU Member States usually do not dictate the use of encryption, as in case of the Data Protection Act of 1998 in the United Kingdom [46]. The same, for example, is true for the German Federal Act on Protection of Data [47]. It seems that recommendations to use encryption are lowered to the level of various guidance and recommendations [48,49].

Regardless of the legal system and local rules, the use of encryption seems an obvious choice for protecting medical data.

Technology to Increase Confidentiality and Privacy With Outsourced Data Analyses

The fact that the outsourced data analyses poses a potential security threat to data has been well known for decades [50]. To protect sensitive data, several techniques have been developed.

Firstly, the techniques developed for the protection of statistical databases can be used. The goal of these techniques is to disclose the statistical data (eg, sums, counts, averages, minimums, maximums) without exposing sensitive individual records [51]. In these cases, the sensitive individual data values are either generalized or not disclosed. In the data analysis world, we cannot have data that have been generalized or are not available at all.

A typical result of an intelligent data analysis is a set of decision rules. A decision rule is a function which maps an observation to an appropriate action. Such rules are typically found in a medical diagnosis process in which several measurements are observed and an action is taken (eg, a drug is prescribed). For example, a computer-generated decision rule on generalized and not disclosed data would read: if a patient's 2-hour postload plasma glucose level is ≤ 199 mg/dL and the patient's body mass index (BMI) and age are unknown, then diagnosis of diabetes mellitus is negative. However, the American Diabetes Association recommends a postload glucose level ≤ 155 mg/dL with a 75 g glucose load [52]. High values may indicate diabetes and the doctors will not use just a single test result (measurement) to diagnose diabetes mellitus. If a doctor receives nondisclosed data (or a rule created on nondisclosed data) from the computer-assisted decision system, she has no use of it because additional data are needed for the final decision.

Secondly, one can modify the real value of an attribute using a value-class membership technique or value distortion [53] and try to reconstruct the original distribution as close as possible [54]. In the first case, the values are partitioned into a set of disjointed, mutually exclusive classes; for example, the numeric value of 2-hour postload glucose can be divided into 3 separate disjointed classes (c), 0-139 mg/dL, 140-199 mg/dL, and 200-299 mg/L, written as $c_1 = (0..139)$, $c_2 = (140..199)$, and $c_3 = (200..999)$, respectively. The selection of classes needs to be done carefully based on the domain knowledge; otherwise, the approach is useless. In the second case, the values are slightly changed, namely a random value drawn from some distribution is added to the original value. This approach can be used for numeric attributes (only) and for constructing a classifier [53]. Previous research focused on cases in which the data were

distorted, expecting that the data were (deliberately) changed at the entry point into a system. In many cases, the models built were very sensitive to distorted values. For example, a computer-generated decision rule on distorted data may read: if the 2-hour postload plasma glucose level is ≤ 150 mg/dL and the BMI is >35 kg/m² and age is ≤ 35 years, then diabetes mellitus diagnosis is negative, instead of the original if the 2-hour postload plasma glucose level is ≤ 127 mg/dL and BMI >26.4 kg/m² and age is ≤ 28 years, then diabetes mellitus diagnosis is negative. An action based on a wrong decision rule can have serious consequences, especially in cases in which the values are very sensitive to small changes. However, the mentioned works are orthogonal to the work presented in this paper and can be used complementarily, if needed.

Thirdly, the encryption techniques can be implemented so that the data are encrypted on-site before they are sent for analysis. An analyst decrypts the data based on a password that was previously agreed upon and works with the original values. Typically, a data owner stores the data in an Excel or Word file and protects it by using the internal protection methods; alternatively, the data are stored in another format and compressed using WinZip tools, again protecting it with an internal protection method. The files are then transported to the outside world. Such a procedure has many drawbacks. Firstly, the data are not protected once the outsourced external analyst receives the files and deactivates the files' internal protection to access the data. The data are vulnerable to any and all attacks possible once residing on the analyst's computer. Secondly, the password with which the files are protected can easily be broken. A recent study showed that 93% of test files containing sensitive medical data could be recovered within a 24-hour period by using commercially available tools [55]. Interestingly, nothing has changed in the terms of using strong passwords for decades [56,57]. It can be concluded that passwords will continue to be the weakness of computing security.

The Contribution

The aim of the present work is to develop a procedure to protect medical data in such a way that the outsourced analyst is capable of doing analyses on protected data and the results will be comparable, if not the same, as if they had been done on the original data by following the PbD principle. We tested this hypothesis by determining whether there were differences between outsourced decision trees built on encrypted data and the ones built on original data.

Methods

Formal Setting for Encrypting Data for Outsourced Analyses

In our proposed method, we avoided the weaknesses of the previously mentioned approaches. The data values were encrypted in such a way that outsourced data analyses were still possible, but the data remain encrypted and protected. This can be done by using a strong encryption algorithm, such as those approved by National Institute of Standards and Technology (NIST): Triple Data Encryption Algorithm (TDEA) [58],

Advanced Encryption Standard (AES) [59], or Skipjack [60], so that the security should rely only on secrecy of the keys [61].

The formalization of the approach is presented in [Multimedia Appendix 1](#) and is based on the flat file format (in principle, a textual file with data items separated by a comma), which is the usual format for data analytic tools [62].

The Algorithm for Protection of Data for Decision-Making Analyses

We designed an algorithm that encrypts a flat file with plain text data into an encrypted flat file in such a way that external data analyses are still possible. The algorithm is presented in [Multimedia Appendix 2](#).

For clarity of the proposed approach, let us take a closer look at an experiment with real-world examples from the medical and life sciences fields.

Data Collection

For the purpose of demonstrating the usability of the proposed approach, we used all publicly available datasets from the University of California at Irvine (UCI) Machine Learning Repository [63], with the following restriction: the problem task was classification, data type was multivariate, from the life sciences area, and the data were in matrix (table) format. The UCI Machine Learning Repository lists 41 such datasets [64]. We further removed the following 11 datasets: Arcene, Dorothea, and p53 Mutants (the number of attributes >1000, the primary task is feature selection, not classification), both of the Kyoto Encyclopedia of Genes and Genomes (KEGG) datasets and the PubChem Bioassay Database (textual data), Parkinson's (time series data), and the Thyroid Disease family of datasets (the task is from domain theory). Next, we used only original or larger datasets in which several sub-datasets were available (removed Breast Cancer Wisconsin Diagnostic and Prognostic, Soybean-small, SPECT Heart). We ended up experimenting with 30 datasets.

Most of the datasets in Attribute-Relation File Format (ARFF) were taken from the Software Environment for the Advancement of Scholarly Research (SEASR) repository [65], the rest were converted to ARFF from the UCI repository files by the authors. The original ARFF files are included in [Multimedia Appendix 3](#).

Data Processing

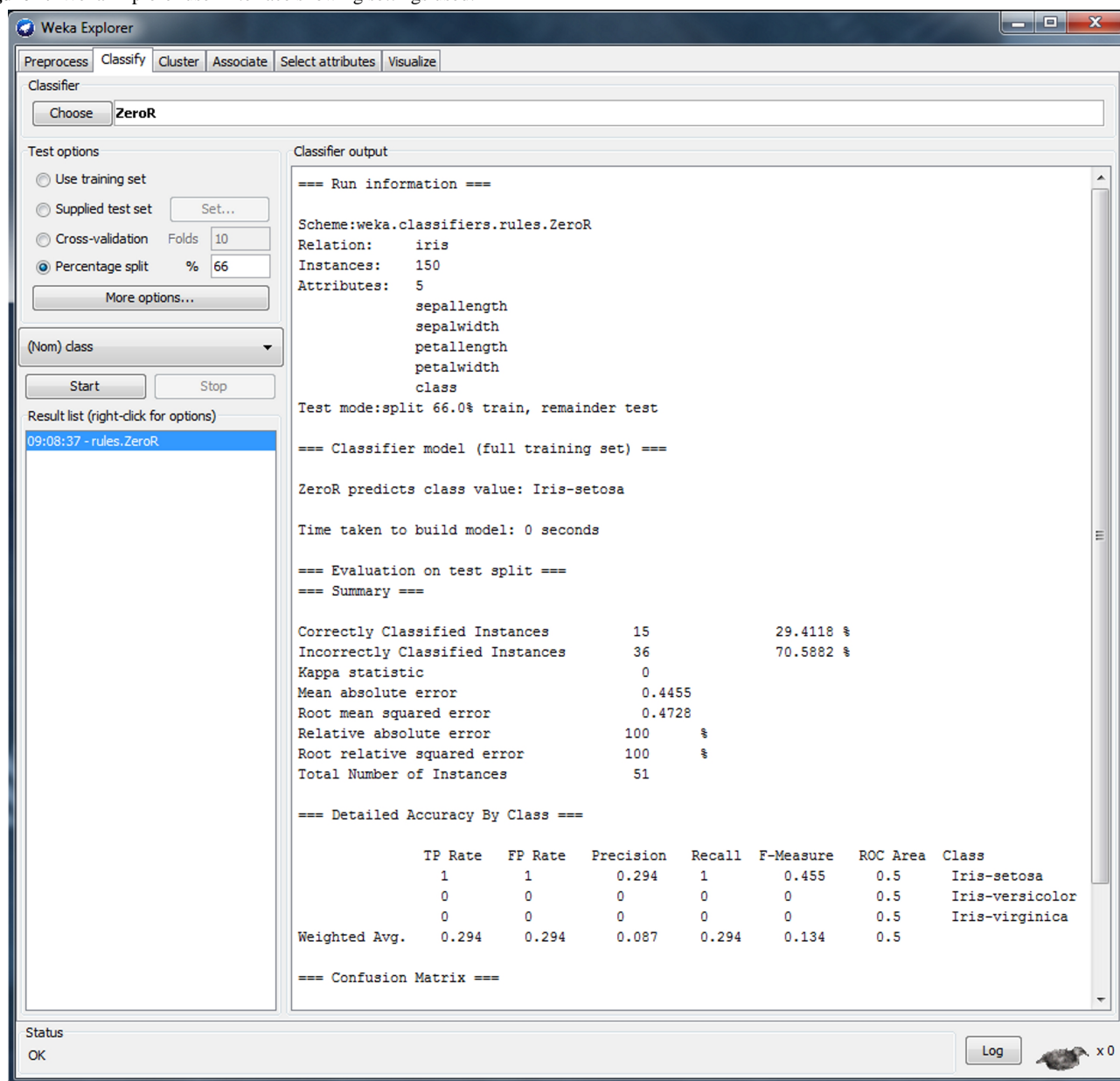
For the analytics tool in this experiment, we chose the J48 decision tree builder with standard built-in settings and initial values, which is freely available from the Waikato Environment for Knowledge Analysis (Weka) project toolkit [62] version 3.6.8. J48 is java-based decision tree builder based on a Quinlan's C4.5 tree induction [66].

First, each original dataset was used to build a decision tree using the J48 decision tree (see [Figure 1](#)). We used 66% of all dataset items for training and the remaining data were used for testing the model; therefore, we ignored any separate training or test set, or any associated cost model.

For each decision tree model, we measured the number of leaves, size of the tree, and the percentage of correctly classified instances (see [Multimedia Appendix 4](#)). The number of leaves defines the total number of decision rules included in a tree. The size of a tree gives the number of nodes (measurements) in a tree: the higher the number of nodes, the more complicated the rules are. The percentage of correctly classified instances (ie, accuracy) measures how many mistakes the computer-generated decision trees make when they are tested on real-world data. Measuring only the accuracy is not enough because many different trees based on different data can have identical accuracy.

Secondly, each data file was protected with the proposed algorithm (see [Multimedia Appendix 5](#)). We implemented a prototype with limited features in JavaScript language (see [Multimedia Appendix 6](#)). The advantage of using JavaScript is that the data are not sent to a server residing elsewhere, but are processed in a browser locally. We used the AES algorithm with 256-bit key on all string-, categorical-, or nominal-type attribute values. For numeric values, we simply multiplied the original values by 2 and added 1, thus hiding the original values. In real life situations, any numeric transformation preserving the desired statistical properties of data can be used [51]. Then, decision trees were built for each protected dataset with the same settings as the original datasets. Finally, the number of leaves, the size of the tree, and the percentage of correctly classified instances were measured again (see [Multimedia Appendix 7](#)).

Figure 1. Weka Explorer user interface showing settings used.



Hypotheses

For the approach to be useful there should be no statistically significant difference between the original and encrypted trees in terms of tree size, number of leaves in a tree, and the accuracy of the tree. Our hypotheses were (1) the mean tree size after encryption would be the same as before encryption, (2) the mean number of leaves after encryption would be the same as before encryption, and (3) the mean accuracy after encryption would be the same before encryption.

Statistical Analysis

The same subject (a decision tree built with a specific dataset) was observed under 2 different conditions. The “before” samples were made of decision trees built on original data, and the “after” samples were made of decision trees built on encrypted

data. Bootstrapped paired *t* tests for 2 dependent samples were used to identify whether significant differences occurred because of encryption of data on 3 independent variables: tree size, number of leaves, and accuracy. We considered differences to be significant at the <.05 level. SPSS version 21 (IBM Corp, Armonk, NY, USA) was used for analysis.

Results

Differences Between Decision Trees Based on Original and Protected Data

First, we tested if the decision trees built on original and protected data were different. Table 1 lists the size of a tree, the number of leaves in a tree, and the percentage of correctly classified items for each dataset when the tree was built on original data and when it was built on the protected data.

Table 1. Results of analyses on original and encrypted data files for tree size, number of leaves, and accuracy.

Database name	Original dataset			Encrypted dataset		
	Tree size ^a , n	Leaves ^b , n	Accuracy ^c , %	Tree size ^a , n	Leaves ^b , n	Accuracy ^d , %
Abalone	2312	1183	21.97	2312	1183	21.97
Acute inflammations	5	3	100.00	5	3	100.00
Arrhythmia	99	50	71.43	99	50	71.43
Audiology (standardized)	54	32	83.12	54	32	83.12
Breast cancer	6	4	68.04	6	4	68.04
Breast cancer Wisconsin (original)	27	14	95.38	27	14	95.38
Breast tissue	29	15	47.22	29	15	47.22
Cardiotocography	19	14	98.34	33	25	98.34
Contraceptive method choice	263	157	55.29	263	157	55.29
Coverttype	29,793	14,897	93.59	29,793	14,897	93.59
Dermatology	41	31	92.74	41	31	92.74
Echocardiogram	9	5	70.37	9	5	70.37
Ecoli	43	22	78.95	43	22	78.95
Haberman's survival	5	3	75.96	5	3	75.96
Hepatitis	21	11	79.25	21	11	79.25
Horse colic	29	18	68.55	29	18	68.55
Iris	9	5	96.08	9	5	96.08
Lung cancer	16	10	63.64	16	10	63.64
Lymphography	34	21	78.00	34	21	78.00
Mammographic mass	15	12	82.26	15	12	82.26
Mushroom	30	25	100.00	30	25	100.00
Pima Indians diabetes	39	20	76.25	39	20	76.25
Post-operative patient	1	1	70.97	1	1	70.97
Primary tumor	88	47	39.13	88	47	39.13
Seeds	15	8	97.18	15	8	97.18
Soybean (large)	93	61	90.52	93	61	90.52
Spectf heart	17	9	66.67	17	9	66.67
Statlog (heart)	45	27	76.09	45	27	76.09
Yeast	369	185	58.81	369	185	58.81
Zoo	17	9	94.12	17	9	94.12

^aNumber of nodes (measurements) in a tree.

^bNumber of decision rules in a tree.

^cPercentage of correctly classified original items with respect to all items (ie, the number of times the tree's rules lead to the right decision).

^dPercentage of correctly classified encrypted items with respect to all items (ie, the number of times the tree's rules lead to the right decision).

The analysis of the results showed that all but 1 of the encrypted decision trees were identical to the original ones on all 3 attributes: tree size, number of leaves, and accuracy. The only difference was with the tree built on the Cardiotocography dataset, in which the size of the tree and the number of leaves were different (tree size: 19 vs 33; leaves: 14 vs 25 for original and encrypted datasets, respectively). The difference is due to

internals of the algorithm building a decision tree: the algorithm decides how to build the decision tree based on the measurement values; when they are the same, the decision how to build is based on the measurement names, which are not preserved with encryption. Because the values are the same, the induced decision trees are different only in the structure and not in the accuracy or the meaning of the rules.

We tested our hypotheses by using bootstrapped paired samples *t* tests, (see [Multimedia Appendix 8](#)). The paired samples results are shown in [Table 2](#).

The unusually high standard deviation indicates the presence of outliers in the data. The outliers are in the Abalone and Covtype data. Outliers tend to increase the estimate of sample variance; thus, decreasing the calculated *t* statistic and lowering the chance of rejecting the null hypothesis. Therefore, we used bootstrapping for the paired samples test, which makes no

assumption about underlying population distributions [67]. The results of the bootstrapped paired samples tests are presented in [Table 3](#).

With a significance of $P=.19$, we cannot reject the hypotheses that the mean difference in tree size and in number of leaves would be the same as before encryption. The before and after samples are the same, so we retain the hypothesis that the mean accuracy after encryption would be the same as before encryption.

Table 2. Paired samples statistics.

Pairs	Mean	SD	SEM
Pair 1, n=30			
Original size	1118.1	5432.1	991.8
Encrypted size	1118.6	5432.0	991.8
Pair 2, n=30			
Original leaves	563.5	2715.7	495.8
Encrypted leaves	563.7	2715.7	495.8
Pair 3, n=30			
Original accuracy	0.763 ^a	0.189	0.034
Encrypted accuracy	0.763 ^a	0.189	0.034

^aThe correlation and *t* test cannot be computed because the standard error of the difference is zero.

Table 3. Bootstrapped paired samples test results.

Pairs	Mean	Bias	SEM	95% CI	<i>P</i>
Pair 1: Original size–encrypted size	–0.5	–0.3	0.4	–2.1, –0.5	.19
Pair 2: Original leaves–encrypted leaves	–0.2	–0.1	0.2	–0.9, –0.2	.19

Usability of Encrypted Decision Trees

Secondly, we tested whether a decision tree built on encrypted data could be of any use to the data owner and how to make use of it. We will demonstrate the approach with the Pima Indian Diabetes Dataset [68,69]. This dataset has 768 instances and 8 attributes (columns or measurements that describe each instance): number of times pregnant (preg); plasma glucose concentration after 2 hours in an oral glucose tolerance test in mg/dL (plas); diastolic blood pressure in mm Hg (pres); triceps skin fold thickness in mm (skin); 2-hour serum insulin in $\mu\text{U}/\text{mL}$ (insu); BMI in kg/m^2 (mass); diabetes pedigree function (pedi); and age in years (age). The final prediction class, actually a rule based on measurements, was tested negative for diabetes (tested_negative) or tested positive for diabetes (tested_positive).

Based on the data, an external analyst (a medical expert) should be able to construct a decision tree that would be able to assist in diagnosing diabetes mellitus for each individual represented

by data values in a record (tuple). The decision tree constructed from the original plain text dataset is depicted in [Figure 2](#). The same tree built on encrypted data is depicted in [Figure 3](#).

The trees are identical, except for the attribute names and values, which are encrypted. For example, if the data owner would like to decrypt the encrypted decision rule (see [Multimedia Appendix 2](#)), which would read “if [encrypted data] ≤ 255 and [encrypted data] > 53.8 and [encrypted data] ≤ 57 then [encrypted answer]”, as seen in lines 1, 3, and 4 from the pruned decision tree, he or she would simply query the lookup table using Structured Query Language (SQL) or any SQL-based graphical tool [70]. The list of queries and the results are shown in [Table 4](#).

Thus, the final decision rule, which was previously encrypted, now reads: IF 2_hr_postload_plasma_glucose ≤ 127 \wedge body_mass_idx > 26.4 \wedge age ≤ 28 THEN tested_negative (if 2-hour postload plasma glucose level is ≤ 127 mg/dL and BMI > 26.4 kg/m^2 and age ≤ 28 years then predict negative diabetes diagnosis).

Figure 2. Decision tree model to assist diagnosing diabetes mellitus built with plain text data from the Pima Indians Diabetes Dataset.

```

Scheme:weka.classifiers.trees.J48 -C 0.25 -M 2
Relation: pima_diabetes
Instances: 768
Attributes: 9
           preg
           plas
           pres
           skin
           insu
           mass
           pedi
           age
           class

Test mode:split 66.0% train, remainder test

=== Classifier model (full training set) ===

J48 pruned tree
-----

plas <= 127
| mass <= 26.4: tested_negative (132.0/3.0)
| mass > 26.4
| | age <= 28: tested_negative (180.0/22.0)
| | age > 28
| | | plas <= 99: tested_negative (55.0/10.0)
| | | plas > 99
| | | | pedi <= 0.561: tested_negative (84.0/34.0)
| | | | pedi > 0.561
| | | | | preg <= 6
| | | | | age <= 30: tested_positive (4.0)
| | | | | age > 30
| | | | | | age <= 34: tested_negative (7.0/1.0)
| | | | | | age > 34
| | | | | | | mass <= 33.1: tested_positive (6.0)
| | | | | | | mass > 33.1: tested_negative (4.0/1.0)
| | | | | | | | preg > 6: tested_positive (13.0)
plas > 127
| mass <= 29.9
| | plas <= 145: tested_negative (41.0/6.0)
| | plas > 145
| | | age <= 25: tested_negative (4.0)
| | | age > 25
| | | | age <= 61
| | | | | mass <= 27.1: tested_positive (12.0/1.0)
| | | | | mass > 27.1
| | | | | | pres <= 82
| | | | | | | pedi <= 0.396: tested_positive (8.0/1.0)
| | | | | | | pedi > 0.396: tested_negative (3.0)
| | | | | | | | pres > 82: tested_negative (4.0)
| | | | | | | | age > 61: tested_negative (4.0)
| mass > 29.9
| | plas <= 157
| | | pres <= 61: tested_positive (15.0/1.0)
| | | pres > 61
| | | | age <= 30: tested_negative (40.0/13.0)
| | | | age > 30: tested_positive (60.0/17.0)
| | | | | plas > 157: tested_positive (92.0/12.0)

Number of Leaves : 20

Size of the tree : 39

Time taken to build model: 0.01 seconds

=== Evaluation on test split ===
=== Summary ===

Correctly Classified Instances          199           76.2452 %
Incorrectly Classified Instances        62           23.7548 %
Kappa statistic                        0.4342
Mean absolute error                    0.3125
Root mean squared error                0.4059
Relative absolute error                 69.2946 %
Root relative squared error            86.7189 %
Total Number of Instances              261

```


Figure 3. Decision tree model to assist in diagnosing diabetes mellitus built with encrypted data.

```

Scheme: weka.classifiers.trees.J48 -C 0.25 -M 2
Relation: U2FsdGVkX1/GxsbGxsbGxrgqCMLcfGvhyEmUHQeGMJG=
Instances: 768
Attributes: 9
U2FsdGVkX1/GxsbGxsbGxvt rbfwab23/zMrMCC1c8co=
U2FsdGVkX1/GxsbGxsbGxqJGWHYKV11/Ghr/VuGPcjE=
U2FsdGVkX1/GxsbGxsbGxoXzVlWdQ43dQspjQXWinfU=
U2FsdGVkX1/GxsbGxsbGxiPQLnvLyNm2q+849Kr02F8=
U2FsdGVkX1/GxsbGxsbGxkxhAq+vRRR1IhgB783XDw=
U2FsdGVkX1/GxsbGxsbGxncCuqWM8tY1K+ndRFEKNw6w=
U2FsdGVkX1/GxsbGxsbGxslJy2av/D222iri8o97xMM=
U2FsdGVkX1/GxsbGxsbGxht0/44acjje28K5W1ldQ24=
class
Test mode: split 66.0% train, remainder test

=== Classifier model (full training set) ===

J48 pruned tree
-----

U2FsdGVkX1/GxsbGxsbGxqJGWHYKV11/Ghr/VuGPcjE= <= 255
|
|   U2FsdGVkX1/GxsbGxsbGxncCuqWM8tY1K+ndRFEKNw6w= <= 53.8: U2FsdGVkX1/GxsbGxsbGxkb6Q6I1Z7BQpR5rsBg40i0= (132.0/3.0)
|   |
|   |   U2FsdGVkX1/GxsbGxsbGxncCuqWM8tY1K+ndRFEKNw6w= > 53.8
|   |   |
|   |   |   U2FsdGVkX1/GxsbGxsbGxht0/44acjje28K5W1ldQ24= <= 57: U2FsdGVkX1/GxsbGxsbGxkb6Q6I1Z7BQpR5rsBg40i0= (180.0/22.0)
|   |   |   |
|   |   |   |   U2FsdGVkX1/GxsbGxsbGxht0/44acjje28K5W1ldQ24= > 57
|   |   |   |   |
|   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxqJGWHYKV11/Ghr/VuGPcjE= <= 199: U2FsdGVkX1/GxsbGxsbGxkb6Q6I1Z7BQpR5rsBg40i0= (55.0/10.0)
|   |   |   |   |   |
|   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxslJy2av/D222iri8o97xMM= <= 2.12: U2FsdGVkX1/GxsbGxsbGxkb6Q6I1Z7BQpR5rsBg40i0= (84.0/34.0)
|   |   |   |   |   |   |
|   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxslJy2av/D222iri8o97xMM= > 2.12
|   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxvt rbfwab23/zMrMCC1c8co= <= 13
|   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxht0/44acjje28K5W1ldQ24= <= 61: U2FsdGVkX1/GxsbGxsbGxmp/63Zm/4QY7G/27AXImc= (4.0)
|   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxht0/44acjje28K5W1ldQ24= > 61
|   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxht0/44acjje28K5W1ldQ24= <= 69: U2FsdGVkX1/GxsbGxsbGxkb6Q6I1Z7BQpR5rsBg40i0= (7.0/1.0)
|   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxht0/44acjje28K5W1ldQ24= > 69
|   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxmp/63Zm/4QY7G/27AXImc= (6.0)
|   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxncCuqWM8tY1K+ndRFEKNw6w= > 67.2: U2FsdGVkX1/GxsbGxsbGxkb6Q6I1Z7BQpR5rsBg40i0= (4.0/1.0)
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxvt rbfwab23/zMrMCC1c8co= > 13: U2FsdGVkX1/GxsbGxsbGxmp/63Zm/4QY7G/27AXImc= (13.0)
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxqJGWHYKV11/Ghr/VuGPcjE= > 255
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxncCuqWM8tY1K+ndRFEKNw6w= <= 60.8
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxqJGWHYKV11/Ghr/VuGPcjE= <= 291: U2FsdGVkX1/GxsbGxsbGxkb6Q6I1Z7BQpR5rsBg40i0= (41.0/6.0)
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxqJGWHYKV11/Ghr/VuGPcjE= > 291
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxht0/44acjje28K5W1ldQ24= <= 51: U2FsdGVkX1/GxsbGxsbGxkb6Q6I1Z7BQpR5rsBg40i0= (4.0)
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxht0/44acjje28K5W1ldQ24= > 51
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxht0/44acjje28K5W1ldQ24= <= 123
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxncCuqWM8tY1K+ndRFEKNw6w= <= 55.2: U2FsdGVkX1/GxsbGxsbGxmp/63Zm/4QY7G/27AXImc= (12.0/1.0)
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxncCuqWM8tY1K+ndRFEKNw6w= > 55.2
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxoXzVlWdQ43dQspjQXWinfU= <= 165
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxslJy2av/D222iri8o97xMM= <= 1.79: U2FsdGVkX1/GxsbGxsbGxmp/63Zm/4QY7G/27AXImc= (8.0/1.0)
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxslJy2av/D222iri8o97xMM= > 1.79: U2FsdGVkX1/GxsbGxsbGxkb6Q6I1Z7BQpR5rsBg40i0= (3.0)
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxoXzVlWdQ43dQspjQXWinfU= > 165: U2FsdGVkX1/GxsbGxsbGxkb6Q6I1Z7BQpR5rsBg40i0= (4.0)
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxht0/44acjje28K5W1ldQ24= > 123: U2FsdGVkX1/GxsbGxsbGxkb6Q6I1Z7BQpR5rsBg40i0= (4.0)
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxncCuqWM8tY1K+ndRFEKNw6w= > 60.8
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxqJGWHYKV11/Ghr/VuGPcjE= <= 315
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxoXzVlWdQ43dQspjQXWinfU= <= 123: U2FsdGVkX1/GxsbGxsbGxmp/63Zm/4QY7G/27AXImc= (15.0/1.0)
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxoXzVlWdQ43dQspjQXWinfU= > 123
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxht0/44acjje28K5W1ldQ24= <= 61: U2FsdGVkX1/GxsbGxsbGxkb6Q6I1Z7BQpR5rsBg40i0= (40.0/13.0)
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxht0/44acjje28K5W1ldQ24= > 61: U2FsdGVkX1/GxsbGxsbGxmp/63Zm/4QY7G/27AXImc= (60.0/17.0)
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   U2FsdGVkX1/GxsbGxsbGxqJGWHYKV11/Ghr/VuGPcjE= > 315: U2FsdGVkX1/GxsbGxsbGxmp/63Zm/4QY7G/27AXImc= (92.0/12.0)

Number of Leaves : 20
Size of the tree : 39

Time taken to build model: 0.01 seconds

=== Evaluation on test split ===
=== Summary ===

Correctly Classified Instances 199 76.2452 %
Incorrectly Classified Instances 62 23.7548 %
Kappa statistic 0.4342
Mean absolute error 0.3125
Root mean squared error 0.4059
Relative absolute error 69.2946 %
Root relative squared error 86.7189 %

Total Number of Instances 261
    
```

Table 4. List of queries for transforming encrypted data to original.

Query	Result
SELECT original_attribute FROM lookup_table WHERE renamed_attribute=" U2FsdGVkX1/Gxs-bGxsbGxqJGWHYKVII/Ghr/VuGPcJE="	2_hr_postload_plasma_glucose
SELECT original_value FROM lookup_table WHERE encrypted_value=255 AND attribute_name="2_hr_postload_plasma_glucose"	127
SELECT original_attribute FROM lookup_table WHERE renamed_attribute=" U2FsdGVkX1/Gxs-bGxsbGxnCuqWM8tY1K+ndRFEKNw6w="	Body mass index
SELECT original_value FROM lookup_table WHERE encrypted_value=53.8 AND attribute_name="Body mass index"	26.4
SELECT original_attribute FROM lookup_table WHERE renamed_attribute=" U2FsdGVkX1/Gxs-bGxsbGxht0/44acjje2SK5W1ldQ24="	Age
SELECT original_value FROM lookup_table WHERE encrypted_value=57 AND attribute_name="Age"	28
SELECT original_value FROM lookup_table WHERE encrypted_value=" U2FsdGVkX1/Gxs-bGxsbGxsbGxkb6Q6ILZ7BQpR5rsBg4Oi0=" AND attribute_name="Class"	Tested_negative

Discussion

Principal Findings

This study evaluated the use of a proposed algorithm on 30 publicly available datasets from the UCI repository. The aim of the study was to assess whether analyses on properly protected and encrypted data are possible without a data analyst having access to the original plain text data, which may not always be available because of internal and external restrictions of health care provider institutions.

The analysis showed that the results of building decision trees on original and protected (encrypted) data using the proposed algorithm are virtually identical. The trees were not significantly different based on the bootstrapped *t* tests ($P=.19$).

A decision tree, built on protected data (and the data themselves), is useless for an adversary because all the data are encrypted. The data owner can query the original source data to transform the encrypted data back to readable plain text.

Use Cases and Limitations

There are 3 scenarios or reasons why one might consider using our solution. First, a lack of knowledge and expertise within the health care institution may prevent data processing for decision-making analyses. Secondly, the available resources may not be adequate to perform the analyses. Thirdly, the adherence to an organization's security policy (eg, based on a need-to-know basis) may not allow for the analyses to be performed on unprotected data. Let us discuss the scenarios in more detail.

The first scenario is when there is a lack of knowledge to do the actual data processing for decision-making purposes and knowledge discovery. In the future, in-house data scientists may be trained so that this becomes less of a practical issue in the business context, but it may remain in the health care environment where the core business is providing health care-related services, not data analyses.

The second scenario is about the lack of computing-related resources that may be available within the health care institution.

Although the proposed solution is demonstrated using open-source tools and datasets, customized third-party tools may be needed, which would involve third-party specialists in decision making. When the reason to outsource is because of insufficient computing resources (eg, computing power or storage capacity), one may consider using cloud computing services. These services still need to address the privacy issues (eg, [71,72]), although it is feasible to scale the proposed approach to use multiprocessor power available in the cloud computing environment [73-75].

The third scenario addresses the restrictions imposed on data processing that might exist within the organization because of internal or external rules and regulations. A restriction about data processing could have been set by an internal security policy [76], such as when a security policy based on a need-to-know rule is enforced (eg, [77-79]). The need-to-know rule specifies that the access to sensitive (medical) data is allowed only to those who need to know these data to perform their jobs. Typically, only medical personnel (doctors, nurses) need to have access to specific records to perform their job. Data analysts do not need the access to the undisclosed and unprotected data to perform their job. Rather, they can perform their duties on encrypted data, as suggested by our approach.

All 3 scenarios indicate that the data owner wants to outsource the ability to process the data without actually giving the processor access to it. This may seem contradictory, but we have shown that our approach is feasible if the data are encrypted. In this case, the data processor does not have (nor does she need) the key to decrypt the data, so she does not have the access to the plain text data. The data are safe even when being processed by a third party, or internally when the security policy requires it to be.

Nevertheless, an important limitation should be highlighted. Namely, the plain text data need to be either in numeric or textual (categorical or strings) form. The approach does not support the data mining or decision making on purely textual data. For these to be supported, further work is needed, including the incorporation of a homomorphic encryption scheme [80].

Nonetheless, most of the existing decision-making tools use numeric or categorical data.

Comparison With Prior Work

The approach developed within our study can be used in conjunction with approaches presented by Adam and Wortman [51], Agrawal and Aggarwal [54], or by Agrawal and Srikant [53]. The approaches developed or presented by these authors aim toward blurring or not disclosing the original data. Their approach would produce slightly different analysis results if the original data were used. Our approach can, nevertheless, be applied after one of the previously developed approaches to fully prevent reconstructing the original data by means of statistical disclosure mechanisms.

The proposed solution follows the 7 principles [81] of the PbD [9-11] framework:

1. Proactive not reactive, preventive not remedial: Data are preventively encrypted so any disclosure has no intermediate consequences.
2. Privacy as the default setting: The maximum degree of privacy is delivered by ensuring that personal data are automatically protected in any given IT system or business practice.
3. Privacy embedded into design: Privacy is embedded into the design and architecture of health care IT systems and business practices.
4. Full functionality-positive-sum, not zero-sum: Accommodate all legitimate interests and objectives in a positive-sum win-win manner, not through a dated, zero-sum approach, where unnecessary trade-offs are made. The pretense of false dichotomies, such as privacy vs security, is avoided demonstrating that it is possible to have both.
5. End-to-end security-full lifecycle protection: By having the encryption embedded into the system before the first element of information is stored, the protection is extended throughout the entire lifecycle of the data involved, including during processing.
6. Visibility and transparency (keep it open): The component parts and operations, as proposed by our approach, remain visible and transparent to users and providers alike.
7. Respect for user privacy (keep it user-centric): By using the approach, the architects and operators are required to keep the interests of the individual uppermost by offering such measures as strong privacy defaults.

Conclusions

Medical data stored in online systems are true goldmines. However, if they are not analyzed, they are useless. The problem of data analyses within health care organizations is that these

organizations' primary focus is providing health care services and they rarely have enough computing and employee resources to do the analyses. The obvious choice is to use external third-party analysis services. However, exporting sensitive medical data to the outside world can be exposed to significant risks and keeping the medical data safe within health care organizations is also an organizational and technological challenge. Being responsible for someone else's potential mistakes can easily tip the decision toward not using external analyses. Because of time constraints, many health care goals, and the tasks or decisions needed to pursue those goals, these are intentionally deferred until a future opportunity [82], if it ever comes.

It was observed that traditional EHRs have no security guarantee outside the health care service domain [15,16]. The technology that can help is available: the proposed algorithm can be considered as an interface between a data owner from the health care service domain on one side and an outside data analyst on the other side. The design of the algorithm is such that the data are protected in a manner that data analyses are still possible, yet not decipherable by a third party at the same time. Thus, the algorithm conforms to the strict regulations regarding the use and processing of medical data, such as the HIPAA rules and the EU's Directive 95/46/EC. Any potential breach that would involve the data protected with the proposed algorithm is exempt from the HITECH Breach Notification Rule.

In our study, we investigated the feasibility of using encryption within the decision-making process. We tested our approach on 30 databases only. As a part of our future work, further studies with different databases and different types of decisions will be performed to confirm this study's results.

The results of our research confirm that data analyses conducted on protected data can be equivalent to those on original unprotected data. This study's results are promising and provide evidence that the method works. However, more study is needed to show that the method works in all cases.

The procedure can be fully automated. The data owner and the data analyst can seamlessly exchange the data and the results. Importantly, the data and the results are safe while in transit and during processing with the data analyst. The data analyst is not required to implement any additional security measures because these were already implemented at the data owner's side. The proposed approach is compatible with all 7 foundational principles of the PbD framework. By following the PbD framework, we can harness large amounts of data to gain valuable insights into the health system and the health of populations to improve clinical outcomes and achieve cost efficiencies without intruding on privacy [83].

Conflicts of Interest

None declared.

Multimedia Appendix 1

Formal description of data-protecting algorithm.

[[PDF File \(Adobe PDF File\), 128KB - jmir_v15i12e283_app1.pdf](#)]

Multimedia Appendix 2

The algorithm for protection of data for decision-making analyses.

[[PDF File \(Adobe PDF File\), 120KB - jmir_v15i12e283_app2.pdf](#)]

Multimedia Appendix 3

Datasets from UCI Repository in original UCI format and/or ARFF format.

[[ZIP File \(Zip Archive\), 9MB - jmir_v15i12e283_app3.zip](#)]

Multimedia Appendix 4

Decision trees built on original data.

[[ZIP File \(Zip Archive\), 230KB - jmir_v15i12e283_app4.zip](#)]

Multimedia Appendix 5

Datasets from UCI Repository in ARFF format, protected with the proposed algorithm.

[[ZIP File \(Zip Archive\), 11MB - jmir_v15i12e283_app5.zip](#)]

Multimedia Appendix 6

The proposed algorithm prototype with limited functionality implemented in JavaScript.

[[ZIP File \(Zip Archive\), 13KB - jmir_v15i12e283_app6.zip](#)]

Multimedia Appendix 7

Decision trees built on protected data.

[[ZIP File \(Zip Archive\), 280KB - jmir_v15i12e283_app7.zip](#)]

Multimedia Appendix 8

SPSS files with result of bootstrapped two dependent samples paired *t* test.

[[ZIP File \(Zip Archive\), 14KB - jmir_v15i12e283_app8.zip](#)]

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Abbreviations

- AES:** Advanced Encryption Standard
- ARFF:** Attribute-Relation File Format
- EHR:** electronic health records

ePHI: electronic protected health information
HHS: US Department of Health and Human Services
HIPAA: Health Insurance Portability and Accountability Act of 1996
HITECH: Health Information Technology for Economic and Clinical Health Act
KEGG: Kyoto Encyclopedia of Genes and Genomes
NIST: National Institute of Standards and Technology
PbD: Privacy by Design
PHI: protected health information
SEASR: Software Environment for the Advancement of Scholarly Research
SQL: Structured Query Language
TDEA: Triple Data Encryption Algorithm
UCI: University of California at Irvine

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Original Paper

Young Men's Views Toward the Barriers and Facilitators of Internet-Based Chlamydia Trachomatis Screening: Qualitative Study

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Abstract

Background: There is a growing number of Internet-based approaches that offer young people screening for sexually transmitted infections.

Objective: This paper explores young men's views towards the barriers and facilitators of implementing an Internet-based screening approach. The study sought to consider ways in which the proposed intervention would reach and engage men across ages and socioeconomic backgrounds.

Methods: This qualitative study included 15 focus groups with 60 heterosexual young men (aged 16-24 years) across central Scotland, drawn across age and socioeconomic backgrounds. Focus groups began by obtaining postcode data to allocate participants to a high/low deprivation category. Focus group discussions involved exploration of men's knowledge of chlamydia, use of technology, and views toward Internet-based screening. Men were shown sample screening invitation letters, test kits, and existing screening websites to facilitate discussions. Transcripts from audio recordings were analyzed with "Framework Analysis".

Results: Men's Internet and technology use was heterogeneous in terms of individual practices, with greater use among older men (aged 20-24 years) than teenagers and some deprivation-related differences in use. We detail three themes related to barriers to successful implementation: acceptability, confidentiality and privacy concerns, and language, style, and content. These themes identify ways Internet-based screening approaches may fail to engage some men, such as by raising anxiety and failing to convey confidentiality. Men wanted screening websites to frame screening as a serious issue, rather than using humorous images and text. Participants were encouraged to reach a consensus within their groups on their broad design and style preferences for a screening website; this led to a set of common preferences that they believed were likely to engage men across age and deprivation groups and lead to greater screening uptake.

Conclusions: The Internet provides opportunities for re-evaluating how we deliver sexual health promotion and engage young men in screening. Interventions using such technology should focus on uptake by age and socioeconomic background. Young people should be engaged as coproducers of intervention materials and websites to ensure messages and content are framed appropriately within a fast-changing environment. Doing so may go some way to addressing the overall lower levels of testing and screening among men compared with women.

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KEYWORDS

qualitative research; adolescent male; socioeconomic status; chlamydia; sexually transmitted diseases; screening; Internet

Introduction

Chlamydia trachomatis is a common bacterial sexually transmitted infection (STI) in the United States, United Kingdom (UK), and other European countries [1-3] and disproportionately affects young people under 25 years of age. Chlamydia has been referred to as a “silent epidemic” or “silent infection” due to its largely asymptomatic course [4,5], which provides young people with no or few visible cues with which to seek health care. Chlamydia can be identified via screening (“members of a defined population, who may not know they are at risk of a disease or its complications, are asked a question or offered a test to identify those who are more likely to be helped than harmed by further tests or treatment”) [6]. Screening can be *opportunistic* (“a health professional offers a screening test to patients attending health care or other defined settings for unrelated reasons; the onus is on the health professional to repeat the test offer at appropriate intervals”) or *proactive* (“population registers are used to invite members of the population at risk for screening at appropriate intervals”) [6]. A screening program is one in which there is systematic and organized provision of regular chlamydia testing to reach a defined population—whether by opportunistic or proactive approach [2]. A survey by the European Centre for Disease Prevention Control (ECDC) in 2008 reported no organized chlamydia screening activity across almost half of the countries surveyed [7]; however, nine countries, including France, Ireland, and the Netherlands, had plans to introduce screening programs in the future. More recently, Low et al (2012) conducted a cross-sectional survey of 33 European countries to assess current and planned chlamydia control activities [8]; they also identified nine countries with plans to introduce a screening program (Bulgaria, Finland, Greece, Luxembourg, Slovenia, Turkey, Norway, France, Netherlands), with Norway being the only country exploring and planning a proactive screening approach. An opportunistic screening program has been operating in England since 2007, but as health is devolved within the United Kingdom this does not extend to Scotland, Wales, or Northern Ireland, which have no program.

A number of studies have explored the feasibility and acceptability of home-based sampling, based on uptake, since the introduction of urine-based testing around 2000 [9]. Collectively, these studies indicate that such screening approaches are acceptable and feasible, across a range of populations, settings, and methods (for example, direct mailing of test kits or requests made online) [10]. Studies of home collection of urogenital specimens for direct mailing to a laboratory for testing have been facilitated via websites such as “I Want The Kit” [11] and have found such a method to be acceptable to men. While many early studies focused on women, more recent work has provided evidence on men’s responses to screening invitations and moved the evidence-base toward a more nuanced understanding of acceptability beyond simple uptake rates. For example, an ongoing trial in the Netherlands examining Internet-based screening assessed acceptability via questionnaires [12] and found nonresponse to the screening offer was not due to a lack of Internet access, but was largely based on perceptions of individual risk.

Technology, such as websites, mobile (cell) phones, and short messaging services (SMS or “texts”), offers exciting opportunities for non-clinical approaches to offer convenient, easy, and confidential services, which fit with what young people report they prefer [13]. Smartphone ownership—phones based on an operating system such as Android, Blackberry, or iOS, with Web access, “apps”, and ability to synchronize email—is increasing, particularly over recent years and among younger people [14]. This increases opportunities to deliver a service straight into young people’s pockets and for interventions to be available when young people demand them. The feasibility and acceptability of different forms of technology in sexual health promotion are being explored, with emerging evidence of increased acceptability and effectiveness [15-19]. Recent service-focused findings demonstrate technology facilitates improvements in partner notification, access to diagnostic tests such as chlamydia screening, appointment keeping, and notification of medical investigations [18,20-25]. The neighboring literature on HIV prevention suggests information and communication technology (ICT) has the capacity for broad diffusion of prevention activities as well as targeting and tailoring of services and messages [21,26]. A particular strength is the ability of ICT to enable a shift toward routine testing, with reduced time burdens and costs [21].

Continued exploration and evaluation of these screening approaches should take account of not just the reach of screening—in terms of overall numbers of people screened as a proportion of those eligible for screening—but also the variation in testing by, for example, age, gender, and class, or combinations in terms of intersectionality. This kind of monitoring will contribute to a greater understanding of inequalities in screening uptake [27]. Currently, men are most often included at the periphery of chlamydia screening approaches and programs, mostly via partner notification. Even efforts to target men alongside women have resulted in more women being screened than men, which results in missed opportunities for men and also missed opportunities for primary prevention for women—as screening men reduces the prevalent reservoir of infection from which women acquire chlamydia [28]. Economic modelling, which explored the options of men being included as primary screening cases or via partner notification, found the former would lead to a faster and greater reduction in overall prevalence [29]. Sheringham et al (2011) explored social variations in the delivery of the National Chlamydia Screening Programme (NCSP) in England to assess whether screening was reaching those in deprived areas of England [30]. They found screening coverage was highest in more socioeconomically deprived areas where chlamydia positivity was also highest. However, Woodhall et al (2012), who also analyzed data from the NCSP in England to describe who was using an Internet-based screening approach, found Internet-based testing was more evenly distributed across areas of high deprivation than either clinic or community-based approaches within the NCSP [31]. It may be that the Internet has driven, or at least in some way facilitated, a greater uptake among young people in deprived areas.

Although somewhat limited, there is growing evidence of what encourages young people to engage with a screening offer in

the first place. Internet-based interventions, such as that by Kang and colleagues [32], suggest the method of contacting young people (eg, email) may have an impact on engaging them. Other work, such as “Sexunzipped”, provides a window into what young people want from a general sexual health website [33]. In the Sexunzipped study, the focus group data with 67 young people aged 16-22 years found a desire for straightforward information, a degree of interactivity with peers online, and to see themselves in images or video material online [33,34]. This study is a good example of involving young people in shaping the design of online sexual health interventions; nevertheless, we have a paucity of data that involves young people themselves as co-producers of interventions and assesses whether this affects the effectiveness of chlamydia screening efforts. It may be challenging to take the time to seek young people’s views and integrate them into intervention designs within a fast-paced environment of shifting technology, but such challenges should be faced if it leads to a highly acceptable sexual health intervention for young people.

The intent of this study was to gather evidence to inform the subsequent design of an Internet-based approach to chlamydia screening targeting young men (aged 16-24 years). To aid the development of our intervention, we aimed to explore the barriers and facilitators to implementing an Internet-based chlamydia screening approach, including the acceptability of such an approach. We sought to explore differences in the views of young men, by sample characteristics including age group (16-19 years and 20-24 years) and deprivation.

Methods

Design and Setting

Participants were selected purposely to include a range of characteristics, including age, level of deprivation in their area of residence, ethnicity, residing in an urban or semi-rural area, and current employment status (unemployed, in school, or employed). We aimed to recruit an even number of groups by age group (split into two groups: 16-19 years and 20-24 years). We also made a deliberate effort to recruit men from areas of high deprivation, using the Scottish Index of Multiple Deprivation (SIMD) to identify areas of high and low deprivation across central Scotland. The SIMD is a measure of relative deprivation, derived from the ranking of small areas (using postcode [zip code] data) as most deprived (1) through to least deprived (5). The Scottish Government website provides an interactive map to identify the SIMD rank of small areas [35]. The 2012 SIMD combines 38 indicators across 7 domains, namely: income, employment, health, education, skills and training, housing, geographic access, and crime; the overall index is a weighted sum of the 7 domain scores. Our purposive

strategy to select young men allowed us to explore within our data whether there were differences in the views of men by their characteristics, in particular by age and deprivation. We sought the postcode (zip code) of each participant at the interview to check they were from the SIMD area we were recruiting within and to enable us to categorize groups as being from areas of high or low deprivation.

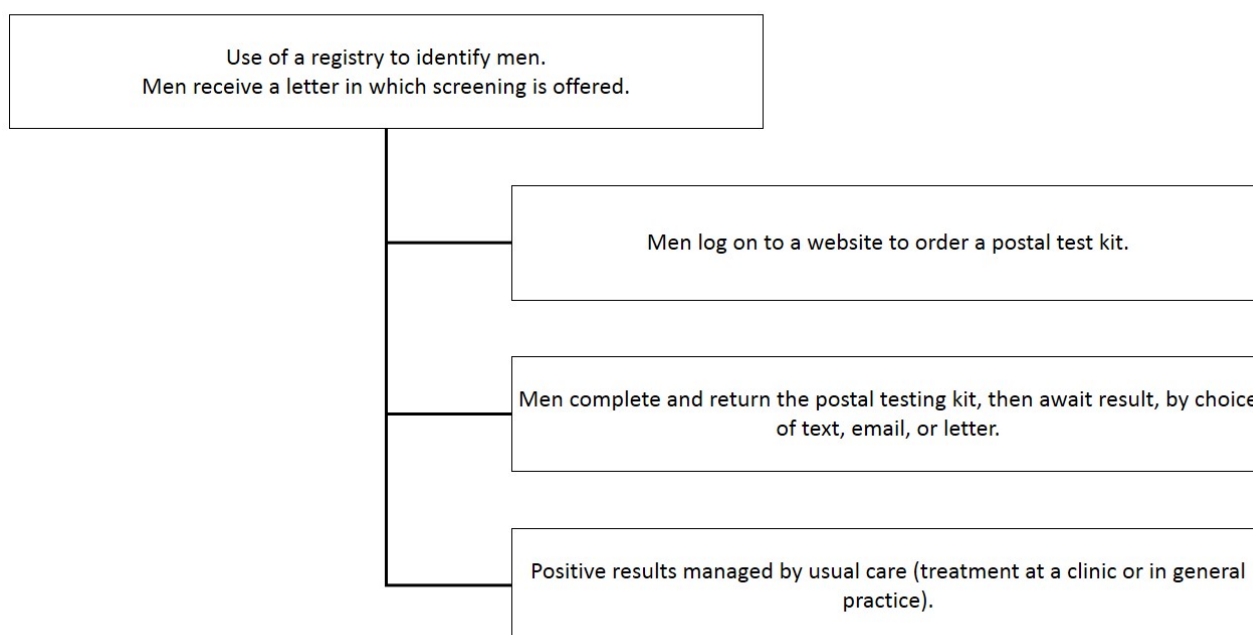
Recruitment

Men were recruited via a range of non-clinical settings, including workplaces, health and fitness settings, community groups, and further education settings (post-high school age but lower than university level). A mixture of purposive and snowball sampling was used to ensure a heterogeneous sample for a range of characteristics: age, socioeconomic background, and ethnicity. Focus groups were homogenous by age group, ethnicity, and deprivation.

Data Collection

Focus groups lasted between 1-2 hours and took place in private spaces made available by our community partners or at the university, with the same facilitator. At the start of each focus group, after consent forms were completed, participants were asked to verbally confirm their postcode. The ensuing focus group discussions focused on knowledge of chlamydia, technology use and attitudes towards smartphones and the Internet, and views on sample screening letters and websites. Focus groups began with participants being asked to describe their knowledge of chlamydia and then technology use, including use of a mobile (cell) phone and the Internet. Participants were invited to reflect on the amount of access they had to, and their use of, such technologies, how private their use was, and their desire for more or less technology use. Insights were then gained from men about their willingness to participate in a proactive screening approach, which made use of the Internet and postal testing kits. To facilitate these discussions, we described the proposed proactive approach to screening as shown in [Figure 1](#).

Young men were first shown three sample screening invitation letters (each were different in order to elicit their style and content preferences) to be sent from GPs (general practitioner), or via a central register, and then a sample postal test kit, before being shown on a laptop existing UK-based websites offering chlamydia screening. Five sites were shown, with each chosen to present a range of styles and content for the men to comment on their preferences (see [Multimedia Appendix 1](#)). A semi-structured topic guide was designed to guide participants through these topic areas in order to build a picture of potential barriers and facilitators to a proactive, Internet-based approach to chlamydia screening.

Figure 1. Process of Internet-based proactive screening provided to the young men.

Data Analysis

Group discussions were audio-recorded and transcribed verbatim and checked. QSR NVivo 10 was used to facilitate analysis. Transcripts were read repeatedly by the researcher and a thematic coding framework was developed as a collaborative effort within the research team (including KL and LM); we then used the “Framework” approach, where data are coded, indexed, and charted systematically, then organized using a matrix or framework [36]. The five key stages of Framework are: familiarization, identifying a thematic framework, indexing, charting, mapping, and interpretation. Framework analysis begins deductively from the study aims and objectives (generating prepositions), but is also inductive (using patterns and associations derived from observations) [37]. Constant comparison was carried out to check for deviant cases as well as similarities, in an iterative process. During analysis, we explored participants’ attributes (eg, age, deprivation), in which we had an a priori interest, against the various themes to rigorously explore emergent patterns in response, particularly by age and deprivation.

Ethics

Ethical approval was obtained from Glasgow Caledonian University School of Health and Life Sciences Ethics Committee. Participants provided written informed consent and permission for the discussion to be audio-recorded and received a £10 (US\$16) payment for their time, in the form of a voucher, which they could spend in a variety of shops.

Illustrative quotes are used throughout indicating the focus group, age, and deprivation category of the respondents.

Results

Participant Characteristics

Fifteen focus groups were conducted with men aged 16-24 years (n=60 individuals), with a minimum of 3 and maximum of 5 participants in the groups. The young men were sociodemographically diverse and most groups consisted of pre-existing friendship or work networks. In only one group did the participants not know each other. Table 1 shows demographic information about the groups. Of the 15 groups, 8 were of men aged 16-19 years and 7 with men aged 20-24 years. Nine groups were of men from deprived areas and 6 from non-deprived areas. Most (11/15) were from urban areas.

Table 1. Focus group participants (groups n=15; individuals n=60).

Focus group	Aged 16-19 years	Aged 20-24 years	White British	BME ^a	Deprived (SIMD ^b 1 or 2)	Non-deprived (SIMD 4 or 5)	Urban	Semi-rural
1	✓		✓		✓			✓
2	✓		✓		✓			✓
3	✓		✓		✓			✓
4	✓		✓		✓			✓
5	✓		✓			✓	✓	
6	✓		✓			✓	✓	
7		✓	✓			✓	✓	
8		✓	✓			✓	✓	
9	✓		✓			✓	✓	
10	✓		✓		✓		✓	
11		✓	✓		✓		✓	
12		✓		✓	✓		✓	
13		✓		✓		✓	✓	
14		✓	✓		✓		✓	
15		✓	✓		✓		✓	
Total	8	7	13	2	9	6	11	4

^aBME: Black and Minority Ethnic

^bSIMD: Scottish Index of Multiple Deprivation

Men's Technology Use

Young men were invited to describe their use of technology, particularly their phone and Internet usage. While most men used the Internet every day, their use was heterogeneous in terms of individual practices using new technologies. All participants used a mobile phone and most phones were Internet-enabled (eg, Blackberry device or iPhone), with only two men having a phone with no Internet function, but with Internet access elsewhere. Most men described "being online" for a few hours each day, including frequent Internet browsing on their phone (checking Facebook, email, sports, and news websites), as well as computer-based game play and browsing to socialize. Some described infrequent Internet usage, whether on a phone or computer, for activities such as checking email and browsing websites. Nevertheless, almost every man reported using Facebook on a daily basis.

While there were some differences in Internet use between groups from areas of high and low deprivation, our comparative analysis revealed the strongest difference in technology-based practices was between the younger and older age groups (16-19 and 20-24 years). Almost every 20-24 year old reported having Internet access on his mobile phone and often used a more technical language during their discussions, mentioning IP addresses, firewalls, torrents (a computer file that contains metadata about files and folders to be distributed), which was something the younger respondents did not mention. This perhaps suggests greater use and familiarity with these technologies, and therefore integration in their lives, among the older men.

I'm doing alright. I've now got ten things in my house connected to the Internet. I've got one more thing, I've got a tablet now...two computers, X-Box, PlayStation, two phones, tablet, PSP [PlayStation Portable], Kindle... [Focus Group 8, 20-24, non-deprived]

We identified three themes related to barriers and facilitators to successful implementation of an Internet-based screening program from the young men's discussions: acceptability of proactive screening, confidentiality and privacy concerns, and language, style, and content.

Acceptability of Proactive Screening

Overall, almost all of the young men considered an Internet-based screening approach to be acceptable and suggested they would use it, if it were offered to them. Participants described feeling inclined to be screened using this approach due to their perceptions of the ease and convenience with which they could be tested. In particular, they could avoid visiting a clinic and/or taking time off from work or education to do so.

The anonymous part of this is just brilliant compared to having to sit [at a clinic]. [Male 1, Focus Group 7, 20-24, non-deprived]

If I had to do it, if I was going to be, see myself round and I needed to get tested, I would choose this option [Internet screening] over going to the GP or the clinic. [Male 3, Focus Group 7, 20-24, non-deprived]

However, these aspects were not valued by all, as a few teenage men in a group drawn from a deprived, semi-rural area thought clinic attendance would provide them with quicker access to a test.

I probably wouldn't even use it [test kit]. I'd probably just get the bus up to [sexual health clinic] and let them give me a check-up. [Male 4, Focus Group 2, 16-19, deprived]

No, I would just go to the clinic. I'd just rather do it than go online and need to wait. Just get it done there. [Male 5, Focus Group 2, 16-19, deprived]

These men spoke of a nearby clinic offering convenience due to its location and their experience of attending gave them familiarity with the service, which they did not have for an online service. Nevertheless, these men spoke favorably of an Internet-based approach for “others”, which means that overall most men found the proposed approach to be acceptable.

Privacy and Confidentiality Concerns

Participants, across almost all groups, described privacy and confidentiality concerns in relation to most aspects of the proposed Internet-based screening approach. Across these discussions, some men merely sought clarification on the confidentiality that would be offered and had no strong concerns about it. For example, some asked for clarification on the process of receiving their result, expressing a desire to choose the method they felt offered the greatest degree of confidentiality. However, others described possible scenarios of anxiety or conflict arising from being sent a screening invitation letter. One young man, who lived with his parents, envisaged conflict arising between him and his parents if a letter were to arrive for him:

If my ma finds it [letter] man, I'll kill her before she kills me. [Male 4]

Right, so is that an issue then, if your parents find out? [Facilitator 1]

If my mum and dad found out, man, they'd kick me out again. [Male 4, Focus Group 1, 16-19, deprived]

Another young man was concerned about his girlfriend assuming the invitation suggested unfaithfulness.

Language, Style, and Content

Participants wanted screening invitation letters and a screening website to have content that is salient, credible, and straightforward. A degree of personalization was favored, particularly for the letters to be clearly addressed to individuals, so that letters would not be misinterpreted as “junk mail” and discarded without reading. The idea of screening “speaking to them” (of being personally relevant) emerged strongly across discussions. Indeed, some of the most excitable, animated, and enthusiastic discussions across the groups occurred when men were shown and allowed to browse five sample chlamydia screening websites on a laptop placed in front of them. Most discussions centered upon men’s design and content preferences; the level of detail almost every man provided about font size, color, images, and text was extremely rich. Participants were encouraged to reach a consensus within their groups on their

broad design and style preferences, which aggregated across the groups included: careful use of imagery to appeal to a broad spectrum of men; no use of “text speak” (eg, RU clear, test 4U); use of an official health organization logo and colors (eg, NHS); minimal use of informal, chatty, humorous language; simple, straightforward text, presented using minimal length paragraphs; and the use of a “hide” button for privacy (enables the Web page to instantly change to the Google search page or minimizes the window).

Some men voiced uncertainty as to whether websites should be “cool” or serious. The following extract from a group discussion illustrates this, with two men attempting to convince a third that chlamydia screening websites should look “serious”:

See, the first one [website], I would not type my details. [Male 2]

It's a graffiti font there. I can't take that seriously. [Male 1]

Is that how bad websites look like, then? [Male 3]

It's not about being bad websites, but serving a purpose. In this case, it's about health, it's not about being cool, which that website aims... [Male 1]

What's wrong with being cool? [Male 3]

I think it doesn't tie in... [Male 1]

So that people have actually...? [Male 3]

Because I think it has to be straight to the point and professional, instead of being cool. [Male 1]

I think if you're actually thinking about saying what it says, that you're concerned and you're worried about it, so you're not...you're more about getting straight to business, not like funky websites [Male 2]

Exactly. If you are worried about this, I think a funky website would be the last thing I would enjoy. So, what you have is chlamydia and they show you pictures of rabbits. [Male 1, Focus Group 12, 20-24, deprived]

It was clear that images and use of color invoked more reaction than the text-based content, except for key headings or “tag lines” such as “RU Clear?”. It appeared that men felt patronized by the use of certain images and “text speak”. Men were keen to feel that there was an “authentic” voice in order to avoid discouraging them from engaging in screening—that authentic voice should be from youths rather than adults clearly masquerading as youth. Some men, particularly older and those from non-deprived areas, described STI testing as an adult issue, which led them to believe that the letters and websites should treat men in an adult fashion. Most thought the whole look and feel should be aimed at men around age 25 years to avoid being patronizing.

Why do they keep putting, like, “R U” and stuff? I actually don't know anyone who texts like that anymore. [Male 2]

Just overly, excessively cheesy [corny, lacking in taste]. [Male 1, Focus Group 5, 16-19, non-deprived]

I would feel quite patronized by that [website 2].
[Male 2]

Yeah, absolutely. [Male 5]

You know, I don't think, like, chlamydia testing should try to make itself cool, really, it's not... [Male 4]

I'd say the "R U clear" thing's a bit unnecessary. It's like, it's different if you're seven years old or something, but I think people our age can pick up so quickly or easily, if people are trying to look or an organization is trying to tap into a youth [sic]. [Male 3, Focus Group 6, 16-19, non-deprived]

However, most participants acknowledged the difficulty in designing a website that would appeal to all men aged 16-24.

Discussion

Principal Findings

In this paper, we analyzed data from 15 focus groups with young men aged 16-24 years ($n=60$) and drew over half the groups from areas of high deprivation. We identified a number of potential barriers and facilitators to Internet-based chlamydia screening, including: the acceptability of Internet-based screening to the target group, men's confidentiality and privacy concerns, and language, style, and content across screening materials, including an invitation letter and a website. Our data illustrate the importance of not only taking time to develop messages that are framed appropriately for the target population, but to engage the target population in the design stage. We found levels of disconnect from technology, such as the Internet, among the younger men and men from deprived areas, which suggests that an Internet-based approach to STI screening (whether chlamydia-focused or broadened to include other STIs) may have the potential to widen inequalities in the absence of available, alternative screening opportunities.

Strengths and Limitations

We presented sample letters and websites to men with a "real-world" screening context, which means they stated preferences and intentions, rather than actual behaviors. Intentions do not always predict behavior, as shown in a study of acceptance of herpes testing in adolescents and young adults [38], where many young people with high intentions of participating did not have a test. Thus, the high level of acceptability among the men in this study would not necessarily translate into high uptake of Internet-based screening. The focus group, by definition and design, allowed participants to be influenced by the group interaction [39]. Nevertheless, it is also a strength of the method for this work because sexual behaviors and attitudes are often related to peer influence and focus groups can therefore illuminate these shared meanings. Other limitations include the use of a female researcher, which may have influenced the performative aspects of the men's participation and thereby influenced the data. *What* men chose to report and to *whom* has been discussed by others, who report differences in men's stories according to the gender, ethnicity, or class of the interviewer [40]. Furthermore, our findings are based on a small number of men from a limited range of localities in Scotland and caution should be taken in any attempt to

generalize from the results. Qualitative research provides rich descriptions of the particular, thus caution is always warranted for any attempt to generalize. We recommend further mixed methods research is carried out in order to enhance this work.

Our study focused on men, which necessarily means we offer no comparative analysis with women's views. Previous work has described men as a hard-to-reach group and found many more women than men providing their views toward the development of a general sexual health website [33]. Our study prioritized men's views and fills an important gap in the current literature. Our deliberate recruitment of men from areas of high deprivation is also a strength of this work, as it has enabled comparison of views by deprivation as well as age group, thereby not treating young men as a homogenous group.

Comparison With Prior Work

Our findings point to the importance of message framing for how men may respond to the provision of a sexual health service, which aligns with recent work in different cultural and policy contexts [33,41-43]. Focus groups with American youth, which included young people in the development of technology-based interventions for sexual health promotion or service delivery, found issues such as the "authenticity of voice" were key to ensuring effective communication with youth [44]. Young people interviewed in a Canadian study by Davis et al (2012) "perceived the youthful messaging style as feigned" and that the level of seriousness absent from the reviewed websites rendered messages as being without value [41]; participants valued websites that had a professional and relatively serious tone. The young people who assisted in the development of the UK-based Sexunzipped website also sought websites they considered trustworthy and mature [33]. In our study, most men dismissed informal, casual styles and content as inappropriate for the seriousness of the issue of chlamydia infection.

Men in our study queried the extent of privacy and confidentiality offered by the screening approach we described, in relation to almost every aspect of the process. Clearly, these issues were of great importance and would be either barriers or facilitators to screening uptake, depending on how they are dealt with by intervention developers and then perceived by men. Apprehensiveness about who will know they sought screening (eg, from letters arriving at their parental home or a test kit arriving in the mail), how people may react to the knowledge they sought screening (eg, girlfriends believing a test suggests unfaithfulness), and how private their results would remain were of great concern to the men in our study. Clearly, their decision to participate in the screening we proposed would be dependent on them feeling confident that they were being offered the most private and confidential approach possible. The issue of privacy is one that has emerged across various contexts, such as with other Scottish youth [13], as well as in England [45], the United States [46,47], and Canada [48].

There are few qualitative studies that seek to obtain the views of youth toward the offer of chlamydia screening and even fewer that focus on the views of young men with which to compare. In our study, men from more deprived areas expressed different views toward technology use and Internet-based chlamydia screening than men from more affluent areas, reporting a lack

of interest in engaging with particular technologies. Younger men and those from lower socioeconomic demographics who participated in Internet-based screening in the Netherlands were better reached with reminders by text message than email [49], although, overall, men participated less than women [25]. In contrast, a randomized controlled trial in Australia of the effects of text and email on young people's sexual health had limited impact on men [50]. However, a text-based approach to sexual health promotion with San Francisco youth reached youth from low income backgrounds [44] and others have found low income minority groups can be reached in large proportions using the Internet [51]. Thus, there is emerging evidence, albeit variable, that these technologies could serve men better than "traditional" settings-based approaches, perhaps due to the way technology can deliver information and services. Our work aligns with the view that young people use technologies "that are dominant in their lives [and are a] fit with their own habitus, which, in turn, links to their social background" [52].

Meaning of the Study

Our findings point to opportunities to refine the design and content of Internet-based sexual health interventions. For example, it is important that young men perceive a screening approach as offering privacy and confidentiality. This means intervention developers should seek the active involvement of men in the design stages, particularly younger men and those from areas of high deprivation—subgroups of men who have to date largely not been reached to the same level as other groups.

Our ability to engage men in this study should direct others to cease simply labelling them as "hard-to-reach". Although there is a paucity of qualitative studies focusing on young men, work does show that men query the relevance of chlamydia screening to them believing it to be a "woman's disease" [45,53], hold lower knowledge about chlamydia than women [54,55], and fear a swab-based test [56,57]. This underscores the importance of engaging various groups of men in the development of interventions to ensure that they, along with women and more affluent youth, shape future interventions. One man in this study, once the focus group ended, reflected: "We have been talking about chlamydia for the last hour, I think that's cool..." [Focus Group 12, 20-24, deprived). Many men may wish to become part of a solution to rising chlamydia rates rather than be labelled as part of the problem.

Conclusions

The findings of this study provide timely and important data on the benefits and challenges of Internet-based STI screening, within a context of no national screening program, poor engagement with men in screening, and challenges in engaging men from deprived areas. Although we have shown that an Internet-based approach has potential and technology is increasingly becoming integral to people's lives, clearly some men engage with it more than others. Technology opens up opportunities for rethinking how we deliver sexual health services to young people, but we should be careful not to widen inequalities; we should consider carefully how to engage various groups of men and ensure we do not promote "one-size-fits-all" screening approaches.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Websites shown to young men during focus group discussions.

[[PPTX File, 2MB - jmir_v15i12e265_app1.pptx](#)]

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Abbreviations

Apps: applications
ECDC: European Centre for Disease Prevention Control
GP: general practitioner
ICT: information and communication technology
NCSP: National Chlamydia Screening Programme
SIMD: Scottish Index of Multiple Deprivation
SMS: short messaging services
STI: sexually transmitted infection

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Original Paper

Aligning Medication Reconciliation and Secure Messaging: Qualitative Study of Primary Care Providers' Perspectives

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Abstract

Background: Virtual (non-face-to-face) medication reconciliation strategies may reduce adverse drug events (ADEs) among vulnerable ambulatory patients. Understanding provider perspectives on the use of technology for medication reconciliation can inform the design of patient-centered solutions to improve ambulatory medication safety.

Objective: The aim of the study was to describe primary care providers' experiences of ambulatory medication reconciliation and secure messaging (secure email between patients and providers), and to elicit perceptions of a virtual medication reconciliation system using secure messaging (SM).

Methods: This was a qualitative study using semi-structured interviews. From January 2012 to May 2012, we conducted structured observations of primary care clinical activities and interviewed 15 primary care providers within a Veterans Affairs Healthcare System in Boston, Massachusetts (USA). We carried out content analysis informed by the grounded theory.

Results: Of the 15 participating providers, 12 were female and 11 saw 10 or fewer patients in a typical workday. Experiences and perceptions elicited from providers during in-depth interviews were organized into 12 overarching themes: 4 themes for experiences with medication reconciliation, 3 themes for perceptions on how to improve ambulatory medication reconciliation, and 5 themes for experiences with SM. Providers generally recognized medication reconciliation as a valuable component of primary care delivery and all agreed that medication reconciliation following hospital discharge is a key priority. Most providers favored delegating the responsibility for medication reconciliation to another member of the staff, such as a nurse or a pharmacist. The 4 themes related to ambulatory medication reconciliation were (1) the approach to complex patients, (2) the effectiveness of medication reconciliation in preventing ADEs, (3) challenges to completing medication reconciliation, and (4) medication reconciliation during transitions of care. Specifically, providers emphasized the importance of medication reconciliation at the post-hospital visit. Providers indicated that assistance from a caregiver (eg, a family member) for medication reconciliation was helpful for complex or elderly patients and that patients' social or cognitive factors often made medication reconciliation challenging. Regarding providers' use of SM, about half reported using SM frequently, but all felt that it improved their clinical workflow and nearly all providers were enthusiastic about a virtual medication reconciliation system, such as one using SM. All providers thought that such a system could reduce ADEs.

Conclusions: Although providers recognize the importance and value of ambulatory medication reconciliation, various factors make it difficult to execute this task effectively, particularly among complex or elderly patients and patients with complicated

social circumstances. Many providers favor enlisting the support of pharmacists or nurses to perform medication reconciliation in the outpatient setting. In general, providers are enthusiastic about the prospect of using secure messaging for medication reconciliation, particularly during transitions of care, and believe a system of virtual medication reconciliation could reduce ADEs.

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KEYWORDS

medication reconciliation; secure messaging; secure email, primary care; provider experiences; health information technology (HIT)

Introduction

Adverse drug events (ADE) are common, costly, and preventable [1-3]. Medication discrepancies, defined as unintentional differences between medication listed in the patient's medical record compared with medication the patient reports taking, are a type of medication error and an important contributor to adverse outcomes [4]. Serious, preventable medication discrepancies are associated with 7000 deaths annually [2]. In 2006, The Joint Commission, an independent organization responsible for accrediting many health care organizations and programs in the United States, designated medication reconciliation as a National Patient Safety Goal [5]. Concurrent with this emphasis on medication safety, there has been a marked increase in the use of patient Web portals and secure messaging (also known as secure email) for patient communication [6]. Innovative organizations are beginning to leverage these tools to improve medication safety and health outcomes [7-10].

Efforts to reduce medication discrepancies using health information technology (HIT) have recently emerged [11,12]. Prior studies using HIT to target medication reconciliation have largely focused on computerized tools for provider-facilitated medication reconciliation during hospitalization [9,13] or in-person medication reconciliation at outpatient clinics [14]. Incorporating HIT in medication reconciliation can reduce potential ADEs and medication discrepancies at the point of hospital discharge [9,15]. ADEs occur at least as frequently in ambulatory care [16], where medically complex patients or those with limited mobility may be at high risk for ADEs because of difficulty accessing primary care services [17].

Strategies for virtual (non-face-to-face) medication reconciliation have the potential to reach patients during vulnerable periods, such as following hospital discharge, when the risk of ADEs is high [5]. Though research has been limited, some studies have found that patients and providers are enthusiastic about exchanging health information via electronic communication [18-21]. In contrast, other studies have suggested less enthusiasm, particularly among providers [22]. The concept of integrating medication reconciliation with secure messaging (ie, secure email between patient and clinical team within a patient Web portal) is appealing, though little literature exists on the topic. One study found that ambulatory patients were satisfied following the use of a Web portal tool for medication management [23]. However, provider perspectives on technology designed to improve medication reconciliation in ambulatory care have received little attention.

In the United States, the Institute of Medicine and the Agency for Healthcare Research and Quality, among others, advocate for restructuring processes of care to emphasize patient-centeredness to improve quality [24,25]. Eliciting primary care providers' experiences of medication reconciliation can help to inform organizations designing patient-centered solutions for improving ambulatory medication safety. Therefore, in preparation for a pilot study of secure messaging (SM) for medication reconciliation [26], we conducted structured observations of current practices of secure messaging and medication reconciliation in the primary care setting and in-depth interviews among primary care providers. Our aim was to characterize providers' experiences with medication reconciliation and SM and to characterize providers' perspectives on a virtual medication reconciliation system, such as one using SM, on ambulatory medication safety.

Methods

Setting, Study Design, and the Study Team

This study was conducted at a single Veterans Affairs (VA) medical center with seven associated outpatient clinic facilities. Approximately 39 providers practice in these facilities. To understand the current status and best practices of outpatient medication reconciliation and the potential role for secure messaging in medication reconciliation, the study was designed in two parts: direct observations of medication reconciliation and secure messaging workflow in the primary care clinics, followed by in-depth interviews with providers.

Providers were recruited for this study from January 18, 2012 to May 30, 2012. To be eligible, providers practiced ambulatory primary care and had at least one year of clinical experience at the VA. A nurse informaticist (TM) assisted the study team in identifying the two clinic sites most active in the use of secure messaging. A list of eligible providers at these sites was generated and randomly scrambled in their order; several additional providers were randomly added to this list so that providers from the largest clinic site (and third most active in secure messaging) were represented. Providers were then contacted sequentially via email regarding their willingness to participate in an interview. In this process, only one provider declined. Interviews were conducted until theoretical saturation was reached; a total of 15 providers participated.

The inter-professional study team included two physicians (LH and SRS), two research assistants (JC and TM), a pharmacist (AP), a project coordinator (MS), and a systems engineer

(CA). The VA Boston Institutional Review Board approved this study.

Direct Observations of Secure Messaging Use

To confirm that providers were already engaging in medication management via SM and to better understand the team-based approach to SM triage in primary care, we conducted observations of how primary care staff and providers managed SM at the two largest clinics within the VA Boston Healthcare System. Four individuals on the study team (TM, AP, MS, and CA) led the observations of staff members (providers, nurses, and pharmacists) within two primary care clinics. To minimize observers' bias, LH and CA created an observation protocol to guide each observer to report on the role and purpose of the staff member replying to the SM, as well as detailing SM workflow and actions taken to process each SM (see [Multimedia Appendix 1](#)). On the day prior to the observation, we contacted clinic staff members via telephone or email to explain the intended process of observation. We obtained in-person verbal consent from staff members on the day of observation. Each clinic site was observed once for 2-3 hours by two members of the study team, during which time each observer took field notes while staff members viewed and handled the SM in their inbox at the time. Specifically, we observed how staff members managed secure messages in their inbox, noting how the staff members routed messages to other members of the clinical team, how they referenced other information to respond to patients' inquiries (eg, medication list or schedule of upcoming visits, both of which are found electronically in a location separate from the secure messaging portal), and how they responded by reply message or by telephone to the patients' requests.

In-Depth Interviews With Primary Care Providers

To characterize medication reconciliation practices, we conducted in-depth interviews with 15 eligible primary care providers. An interviewer (LH) obtained informed consent and conducted the interviews using a semi-structured interview guide that we developed (see [Multimedia Appendix 2](#)). The interview questions consisted of both closed-ended and open-ended questions (eg, "Are adverse drug events a significant cause of morbidity/mortality for your patients?" and "What does medication reconciliation mean to you?"). Probing questions were added to the script and improvised during the interview to enrich providers' responses. Each interview lasted approximately 40 minutes. Interviews were structured around three main domains of interest: (1) clinician perspectives on medication reconciliation and adverse drug events, (2) practice of medication reconciliation in the ambulatory setting, and (3) use of, and potential for, secure messaging in medication reconciliation.

Providers were encouraged to make additional open-ended comments about their experiences. A total of 14 interviews were audio recorded; for one interview, the clinician's responses were transcribed verbatim by hand per request. All recorded interviews were transcribed (JC, TM, and MS) for subsequent coding and analysis.

Data Coding and Analysis

A co-investigator (CA) compiled handwritten notes from roughly 3 hours of direct observations based on the protocol ([Multimedia Appendix 3](#)). We incorporated findings from the structured observations of primary care practices in our analyses of the interview content.

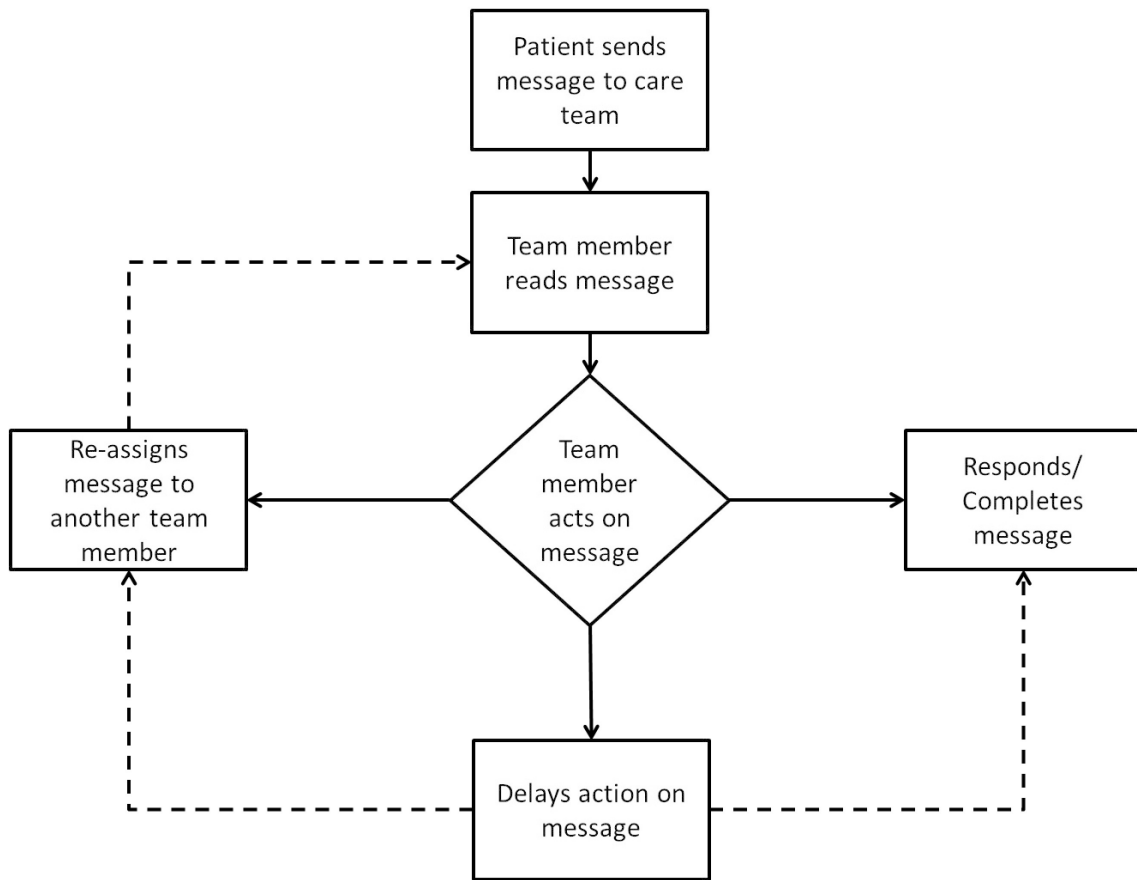
Over ten hours of formal interviews produced 254 pages (double-spaced) of transcription. All transcripts were de-identified prior to coding. We conducted a content analysis informed by grounded theory, with the goal of developing a theoretical framework for using secure messaging for medication reconciliation [27,28]. The initial coding scheme was developed by a team (LH, JC, and SRS) from a sample of three of the interview transcripts: LH and JC independently reviewed these transcripts, annotating important themes, and then met with SRS to review the themes and generate a coding scheme. The newly defined coding scheme was then applied to the remaining transcripts (JC and TM) with regular team meetings to discuss discrepancies and to refine the coding scheme. Discrepancies were resolved by consensus. All coded transcripts were reviewed to ensure that the quotes selected were relevant and accurate to the established coding scheme (LH and TM). We used NVivo 8 for coding and analysis of the interview data [29].

Results

Observations of Secure Messaging in Primary Care

Our objectives were to ascertain which members of the clinical team were viewing secure messages from patients, how messages were forwarded among staff members, and the workflow for resolving the requests or issues raised in the patient's message. We also wanted to confirm that SM was being used to address issues related to medication management—a topic we hoped providers could address in detail during the in-depth interview. In observations of SM use within primary care, we observed that the first member of the clinical team to view each of the 42 observed patient-initiated SM were divided between 5 primary care providers (physicians or nurse practitioners), 4 licensed practicing nurses, 3 registered nurses, and 2 pharmacists. Among 42 SM managed by staff members during our structured observations, the most common subjects of patients' secure messages related to medication management (20 messages) and general medical issues (7 messages). Among the 42 messages observed, the individual initially retrieving the message most commonly responded or completed the message immediately (27 messages) and less commonly reassigned the message to a more appropriate person (9 messages). In a minority of cases, there was a delay of more than two business days before responding to the patient's message (6 messages). The observed workflow, illustrated in [Figure 1](#), provided a foundation for creating relevant in-depth interview questions. Appreciating the team-based structure of SM triage and confirming that medication management was already being conducted were common experiences upon which providers could further elaborate during the interview.

Figure 1. Observations of secure messaging workflow in primary care. This diagram depicts the observed sequence of events by the clinical team in response to retrieving an SM (42 SM were observed in total).



In-Depth Interviews With Primary Care Providers: Baseline Characteristics

We interviewed 15 eligible primary care providers about their medication reconciliation practices and perspectives on the use of secure messaging. Twelve of the providers interviewed were female and 10 worked at the largest primary care clinic within the local VA system. Eleven providers saw 10 or fewer patients in a typical workday. All providers reported having staff to assist with patient-care responsibilities and all providers deferred to a hospitalist for inpatient care of their patients. Providers consistently reported that medication reconciliation, based on their own definition, was performed less than 25% of the time

prior to a patient encounter. Only one provider noted that her practice tracked adverse events. All but one provider recognized that the Computerized Patient Record System (CPRS), the VA’s electronic health record, included computerized decision support to improve medication safety. Comparing providers interviewed for our study with the demographics of other providers working at these same three clinic sites, providers in our study were more likely to be a physician, female, and practice at the two clinic sites closest to VA Boston’s hospital; study participants reflected the larger population of providers in this setting in terms of deferring to an inpatient physician for care of inpatients (Table 1).

Table 1. Characteristics of providers participating in an interview, compared to providers within the VA Boston Healthcare System.

Characteristics	Study Participants, n (%)	All VA Boston Primary Care, n (%)	P value ^a
Providers			
MD	13 (87)	31 (79)	.45
Nurse Practitioner or Physician Assistant	2 (13)	8 (21)	
Gender			
Female	12 (80)	25 (64)	.17
Male	3 (20)	14 (36)	
Clinic Site^b			
Jamaica Plain	9 (60)	15 (38.5)	.002
West Roxbury	6 (40)	9 (23)	
Brockton	1 (7)	15 (38.5)	
Has staff to assist with patient-care			
Yes	15 (100)	- ^c	-
No	0	-	
Attending physician of record when patients are admitted^d			
Yes	0	0	-
No	14 (93)	31 (100)	
% of patients who had medication reconciliation performed prior to office visit			
0-24% ^e	15 (100)	-	-
25+%	0	-	
Uses decision making or support tools to prevent adverse drug events			
Yes	14 (93)	-	-
No	1 (7)	-	

^aP values calculated via Fisher's Exact Test.

^bDoes not sum to 15 due to 2 physicians with clinics at 2 sites.

^c“-“ denotes an absence of a system-wide standard practice.

^dNumbers may not sum to 15 due to non-response.

^ePhysicians who reported “few”, “rare”, “not usually”, “very few”.

Provider-Reported Experiences and Perspectives in Outpatient Medication Reconciliation

Four overarching themes characterized providers' experiences and perspectives with medication reconciliation in the primary care clinic (summarized in Table 2). First, providers shared the belief that good quality medication reconciliation could improve outcomes. Second, providers felt that achieving quality

medication reconciliation among medically complex patients was often challenging. Third, providers identified systems-level obstacles that prevented high-quality medication reconciliation. Last, providers described opportunities they believed could improve medication reconciliation after hospital discharge. Each theme is examined further, using providers' quotes to illustrate subthemes.

Table 2. Summary of themes on provider-reported experiences and perspectives in outpatient medication reconciliation.**Theme 1: When done right, medication reconciliation can be effective**

Medication reconciliation has the potential to improve medication safety

No standard approach to quality medication reconciliation

Theme 2: Perceived patient-level challenges to effective medication reconciliation

Patients often lack understanding of their medications

Home environment of patients often chaotic

Informed caregivers are valuable in assisting with medication reconciliation in complex patients

Theme 3: Perceived system-level obstacles preventing high-quality medication reconciliation

Limited time and staff support for medication reconciliation

Lack of subspecialist involvement in managing medications they prescribe

EHR^a often complicates medication reconciliation

Theme 4: Perceived opportunity for improving medication reconciliation after hospital discharge

Medication reconciliation is already a key priority during the post-hospital follow-up visit

Leveraging EHR capabilities for medication management

Team-based collaborative care for improving medication reconciliation

^aEHR: electronic health record

When Done Right, Medication Reconciliation Can Be Effective**Overview**

Most providers believed that performing in-depth, quality medication reconciliation could have the potential to decrease ADEs and improve medication safety in general, though many providers acknowledged the lack of a standard approach to medication reconciliation.

Medication Reconciliation has the Potential to Improve Medication Safety

Providers emphasized the importance of performing medication reconciliation in order to recognize side effects of medications and their interactions, even when medications are taken as prescribed:

I think [the effectiveness of medication reconciliation] is huge...because the side effects of various meds in poly-pharmacy are frequently...more deleterious for the patients than the illnesses the medications were prescribed for. [Provider 3]

I think what people do for medication reconciliation is so variable...if you really do it as a process, it would be highly effective. Some adverse drug events [are] just the risk of [taking] medicines, [it] is never going to be zero, but when done right, [medication reconciliation can be] highly effective. [Provider 5]

No Standard Approach to Quality Medication Reconciliation

Limited formal training in conducting medication reconciliation was commonly cited and many providers had not adopted a standard approach for in-person medication reconciliation:

Honestly, I, once in a while, might read an article about it, in a journal, but most of my education just comes through the discussion we have in our primary care meetings. [Provider 9]

Perceived Patient-Level Challenges to Effective Medication Reconciliation**Overview**

Providers shared concerns regarding experiences where patients lacked skills in medication management. This issue was magnified by disorganized home environments and particularly challenging for medically complex patients, where providers reinforced the value of a caregiver to corroborate the medication list.

Patients Often Lack Understanding of Their Medications

Providers suspected that a significant proportion of their patient population both lacked understanding of their medications and did not take their medications as prescribed:

It's probably 50/50 [of patients accurately taking their medications]. I do see a lot of young women who are [taking] just a few medicines and are very knowledgeable...And then I have a handful where, sometimes it takes multiple visits and even this morning, calling a visiting nurse and really trying to figure out who's putting the pills in the box, and what exactly is going in there. [Provider 5]

I mean, I think I'm a very good clinician, but I bet it's probably only 30 or 40% [of patients accurately taking their medications]. It's probably not very good. [Provider 15]

I think that what is useful sometimes is when they actually bring their bottles in with them. But then again sometimes the bottles can be expired, they can

be from other physicians who prescribed them, and if they aren't sure what they are taking even with the bottles, then it can be even more challenging. [Provider 9]

Home Environment of Patients Often Chaotic

Many providers suspected or were aware of poor medication organization at home and cited this as being a major barrier to accurate in-person medication reconciliation:

And an example recently is someone finally went into the home of [a patient] only because their diabetes wasn't under good control and the person agreed to a home visit. And this guy is functioning and working, they found pill bottles old, new, mixed up in every room of the home. No one had any idea that it was going to be that chaotic. [Provider 12]

I have patients who I don't know the full list of what they have at home, but they will tell me I have some [medications]...but won't throw them away. Then it's really impossible to do medication reconciliation because I can't even begin to understand what they have at home. [Provider 5]

Informed Caregivers are Valuable in Assisting With Medication Reconciliation in Complex Patients

Providers frequently described that medication reconciliation among medically complex patients, such as those with multiple chronic conditions or dementia was challenging. Presence of a caregiver or someone who had knowledge of the patient's medication administration in this situation was felt to be very helpful in achieving accurate medication reconciliation.

It helps if there's a caregiver or someone in the family who comes with them...sometimes you can't complete medication reconciliation with the veteran themselves in that situation, so you have to rely on caregivers. [Provider 1]

So I usually try to always have them bring the pill bottles. Then I always try to get collateral information. Usually they're in an assisted living or in a setting where other people are also involved. I try always to contact who else is involved in the administration of the medications, to really understand how they are taking it. [Provider 5]

Perceived System-Level Obstacles Preventing High-Quality Medication Reconciliation

Overview

For many providers, issues relating to organizational structure or clinic workflow frequently impeded their ability to perform effective medication reconciliation. Providers repeatedly expressed frustration in managing medications prescribed by specialists or non-VA providers and many felt that the EHR medication reconciliation more difficult to accomplish than expected.

Limited Time and Staff Support for Medication Reconciliation

The majority of providers felt that the time provided in a routine primary care appointment was often insufficient for detailed medication reconciliation. Providers recognized that executing medication reconciliation could be especially time-intensive among cognitively impaired patients. Many providers acknowledged a lack of support staff to assist with medication reconciliation, primarily taking on this task alone:

A pharmacist doing [medication reconciliation] in-person with the patient and the family when they are around at the time of discharge takes an hour per patient to do med rec. So how they expect, in a 30-minute follow up visit with a complicated patient, that this is going to get done...and the estimates from the nursing staff is 40% of the discharged patients are cognitively impaired. [Provider 8]

It depends on the number of medications, of course. And it depends on the detail in which we are doing medication reconciliation. A very cognitively impaired person, who's living independently, is going to take a lot more time, because we are going to look in the bottles and potentially do some pill counts to check. [Provider 13]

My nurse or LPN hands me a list with the veteran's printed medications on them and I would say one out of ten times there are checkmarks on this document indicating some kind of [medication] discrepancy, but would I call this medication reconciliation? No. [Provider 14]

Lack of Non-VA or Subspecialist Provider Involvement in Managing Medications They Prescribe

A commonly cited experience among providers was the responsibility for managing medications prescribed by subspecialist physicians adding to the challenge of accurate medication reconciliation in primary care:

I think a lot ends up falling on primary care...we're often called upon to reconcile things that we're not necessarily managing. So it has to be something that the whole medical center buys into so that we can get the help of subspecialists...we might not be able to resolve the discrepancies ourselves. [Provider 1]

I think that what is useful sometimes is when they actually bring their bottles in with them. But then again sometimes the bottles can be expired, they can be from other physicians who prescribed them, and if they aren't sure what they are taking even with the bottles, then it can be even more challenging. [Provider 9]

EHR Often Complicates Medication Reconciliation

Providers reported difficulty clearly displaying reconciled medications in the EHR. This issue was often magnified among patients being seen in subspecialist clinics or care outside of the VA:

It bothers me that specialty clinics don't change the med list in [the EHR]. If they do add a new medicine to [the EHR], it automatically spits out a new refill, which may not be what the veteran needs at that moment. So, the specialist often does nothing, which makes it difficult for me to figure out what the actual dose or medicine they are taking is. I wish specialists could just update the medications in CPRS without it automatically generating a refill. [Provider 14]

And then we have people who literally are here to save \$5 a month on their simvastatin and it's a completely different situation... they are really coming in for medication reconciliation, updating our medical records, making sure they have recent labs so we can safely give them the cheaper medicines. It's almost like a pharmacy transaction and less of a medical visit, which is why so many VA [physicians] hate [medication reconciliation]. It just doesn't feel that good. [Provider 2]

Perceived Opportunity for Improving Medication Reconciliation After Hospital Discharge

Overview

A number of providers described potential solutions for improving medication safety during a vulnerable transition period, such as following hospital discharge. Providers commonly suggested technology-based solutions involving the EHR and also believed that training support staff to assist with medication reconciliation could improve the process.

Medication Reconciliation is a Key Priority During the Post-Hospital Follow-Up Visit

There was agreement among all providers that medication reconciliation was a priority when seeing a patient in follow-up of a hospital visit:

Medication reconciliation is usually the first priority. Oftentimes, things have been changed in the hospital reflecting things that were going on there, when it's better just to have people on their pre-hospital medication regimen. I think that medication reconciliation is...probably the first priority. [Provider 11]

Leveraging EHR Capabilities for Medication Management

Providers imagined a variety of approaches to improve medication reconciliation, many involving streamlining the EHR to identify errors and interactions:

The other part of that is that I think there can be electronic surveillance of medications or a mechanism to identify those patients who aren't refilling. That's probably a pretty good clue if they haven't refilled in 6 months...I think that is something that is within our grasp as well. [Provider 13]

I personally think the more you can do on the online automated system the better. For example, if you prescribe someone a potentially dangerous medication [and]...there is no follow up within a certain amount of time, you should not be able to discharge patient. [Provider 4]

Team-Based Collaborative Care for Improving Medication Reconciliation

A majority of providers envisioned a scenario where a pharmacist or clinical staff member performed detailed medication reconciliation prior to the provider's visit. This could minimize the time necessary for medication reconciliation by the provider, freeing up time to discuss clinical issues:

In an ideal world, it would be awesome if, when the patient comes in, or that time when they are sitting in the waiting room, there was a pharmacist or someone who could do that medication reconciliation process in a way so that when they do make it into the exam room, I know the list already...that would be in an ideal, perfect world, to already have that done, before I even see them. [Provider 5]

I don't think it is the physician's responsibility to do the whole extensive med rec, I think it's very time consuming and you will never get to the other clinical issues and that is really what you are trained to do. So I envision nurses and clinical pharmacists really can do this better. [Provider 12]

I would love [for pharmacists] to review the prescriptions with the patient after the visit. If there was...a real problem patient... If I could say to them, look I'm really having a problem with this patient. He brought all his medications in but he's also in congestive heart failure or he's worse or whatever problem I might need to deal with that day, could you go over his meds with him? [Provider 15]

I think for certain patients, it would be helpful to have a system where they did bring in their pills and maybe reviewed them with a nurse ahead of time and then the nurse kind of made note of where the discrepancies are and brought that to me and then I could further work on where the discrepancies are. [Provider 1]

Providers' Experiences Regarding Secure Messaging

We identified 3 main themes with respect to providers' SM use (summarized in [Table 3](#)): (1) the use of SM improved workflow, (2) the existence of patient and provider-level barriers to use of SM, and (3) providers believed in the potential of using SM to improve medication reconciliation in ambulatory primary care. Each theme is described in detail, with selected quotes exemplifying each theme.

Table 3. Summary of themes on providers' experiences regarding secure messaging.**Theme 1: Improved work flow**

Avoids "phone tag"

Increases workflow efficiency

Theme 2: Obstacles to more frequent use of secure messaging

Technical difficulties accessing secure messaging

The process of enrollment and use of SM can be complicated for patients

Theme 3: Integrating medication reconciliation and secure messaging

Secure messages as potential tool to assist with reconciling medicines in the outpatient setting

Potential to decrease adverse drug events

Improved Work Flow**Overview**

Providers who used SM agreed that many patient questions and requests were streamlined and addressed by the most appropriate member of the team.

Avoiding "Phone Tag"

The direct patient contact via SM reduced time spent in "phone tag" (ie, leaving messages for the patient to call back) and providers reported feeling like communication was easier and often more descriptive.

The electronic communication is wonderful. It avoids the whole issue of phone tag. It avoids the whole issue of someone having to give their message to another person, which often distorts the meaning of the request. The asynchronous communication makes all communication easier. [Provider 2]

You can get patients' answers to questions in a more timely fashion than playing phone tag, so it can be a little bit more. You can have a back-and-forth conversation and get work done and document the work that you're doing. [Provider 1]

Increases Workflow Efficiency

The team-based model of SM triage means that providers never saw many of the messages that patients addressed to them, as team members were able to answer and fulfill requests by SM with minimal or no provider input, something providers appreciated.

Patients typically will communicate with me first to let me know that they need something. My team screens all the incoming secure messages and they only give it to me if it's a medication renewal. They screen all the messages so I don't have to deal with certain things that don't need my involvement. [Provider 15]

I think it can also get to the point of it much more succinctly. Not to be antisocial, but you don't have to deal with the niceties of 'How are you feeling today?' They write you with whatever is the concern and you respond to it. [Provider 10]

It's helpful because it's taken away the clutter from the call center in my inbox and all the things I don't need to deal with like appointments and physical therapy consults are taken care of. [Provider 14]

Obstacles to More Frequent Use of Secure Messaging**Overview**

Providers expressed frustration with their inability to easily access SM and also identified the multi-step process for SM registration and less technically savvy elderly patients as potential challenges to widespread patient adoption of SM.

Technical Difficulties Accessing Secure Messaging

A commonly cited complaint among providers was the need for a separate log-in to the SM service and slow network speeds:

It's a very difficult system to use. It's often...not working and it's not easy to get into...If I need to use secure messaging...I have to look [the patient] up and wait and wait for the delay...I know they are planning to interface it better with our Outlook in the future. [Provider 7]

I think the speed of our network is horrible and so that, yet another password, yet another log-in. My computer takes 20 minutes to boot in the morning, we've timed it...I have to check my emails and check my secure messages, yet another administrative burden. And my value should be in talking to patients, seeing patients, or personally writing papers and developing... [Provider 13]

The Process of Enrollment and Use of SM Can Be Complicated for Patients

Providers commonly noted that a lengthy opt-in process, the requirement for in-person authentication, as well as limited technical literacy of many elderly patients as barriers to increased SM use among patients:

You have to remember our patient population isn't a high-tech patient population. I think [using SM for the elderly] would be relatively ineffective. [Provider 13]

it looks like we have a lot of patients who got authenticated, but haven't opted in...I think the opt-in process is not clear to patients. It shouldn't be so

hard to check a box accepting terms and conditions. A lot of the people who have been opted in are younger, tech-savvy veterans. If this were user friendly, they would be able to do it. They shouldn't need a lot of coaching. [Provider 2]

Integrating Medication Reconciliation and Secure Messaging

Overview

Providers were uniformly enthusiastic about the potential for SM to improve medication reconciliation in primary care, particularly in the post-hospital discharge period and in clinics without the help of a clinical pharmacist.

Secure Messaging: Potential Tool to Assist With Reconciling Medicines in the Outpatient Setting

Having acknowledged the vulnerability to complications during transition periods such as post-hospital discharge (see above), providers reported that SM could also play a role during such a time:

I think [SM] would be helpful...there are a lot of problems with med rec through the transition. [Provider 12]

Providers also expressed the potential of SM to fill the void in clinics not assigned a clinical pharmacist to assist with medication management:

[Using SM for medication reconciliation] would solve the problem of not having an available pharmacist. It's just a huge disparity in access to services that other clinics should have the full-time pharmacist and we should have nothing. [Provider 2]

Potential to Decrease Adverse Drug Events

All providers believed that SM had the potential to reduce ADEs. Proactive and frequent medication reconciliation was among providers' most common reasons to believe that medication reconciliation by SM could reduce ADEs:

Oh, I think [using secure messaging for medication reconciliation] would make [ADE] go way down, because you would be more proactive about finding the problems, instead of waiting until the adverse event happened and then discovering the problem. [Provider 4]

Using [secure messaging for medication reconciliation] engages the patient a little bit more. And I feel like the more the patient is aware of their medicines and the potential for adverse drug events and can identify things sooner on their own, that's always great. The more knowledgeable they are [of] their medicines and having the interface with the computer would help that. I think it would decrease adverse drug events. [Provider 5]

Discussion

Principal Findings

In this study across multiple ambulatory clinics within a large VA health care system, we conducted direct observations of medication reconciliation and secure messaging workflow in primary care and interviewed primary care providers about their experiences with medication reconciliation. Our findings confirm providers' perception that medication reconciliation has the potential to improve medication safety. Providers highlighted a number of patient-level obstacles hindering high-quality medication reconciliation, emphasizing the difficulty in achieving accurate medication reconciliation among complex or elderly patients. Providers identified limited time and support for medication reconciliation as key barriers. While the majority of providers felt that the task of medication reconciliation was the responsibility of the primary care provider, almost all providers favored shifting this often time-intensive task to support staff or pharmacists and suggested that the process could be optimized by being conducted prior to the visit, either virtually or in person.

With respect to secure messaging, providers commonly expressed positive experiences and reported that its use in primary care improved workflow, largely via team-based message triage, but felt that making it easier for patients to sign up for and use SM could foster more frequent provider use and increase patient adoption. We found that providers were optimistic about the potential use of SM for medication reconciliation, primarily seeing such a system as an opportunity to decrease ADEs.

Traditionally, medication reconciliation has been recognized as the responsibility of the prescriber, usually a physician. Our finding that most providers would choose to relinquish this role to pharmacists or share the responsibility with clinical support staff is noteworthy and supports prior literature demonstrating provider support for the role of pharmacists in medication reconciliation [13,30]. This perspective may reflect the increasing pressures in primary care, including a workforce shortage resulting in increasing patient care demands [31], pay-for-performance programs [32], as well as high levels of physician burnout [33]. Future research should focus on providers' definitions of medication reconciliation and their perception of their role and the role of other team members in executing it.

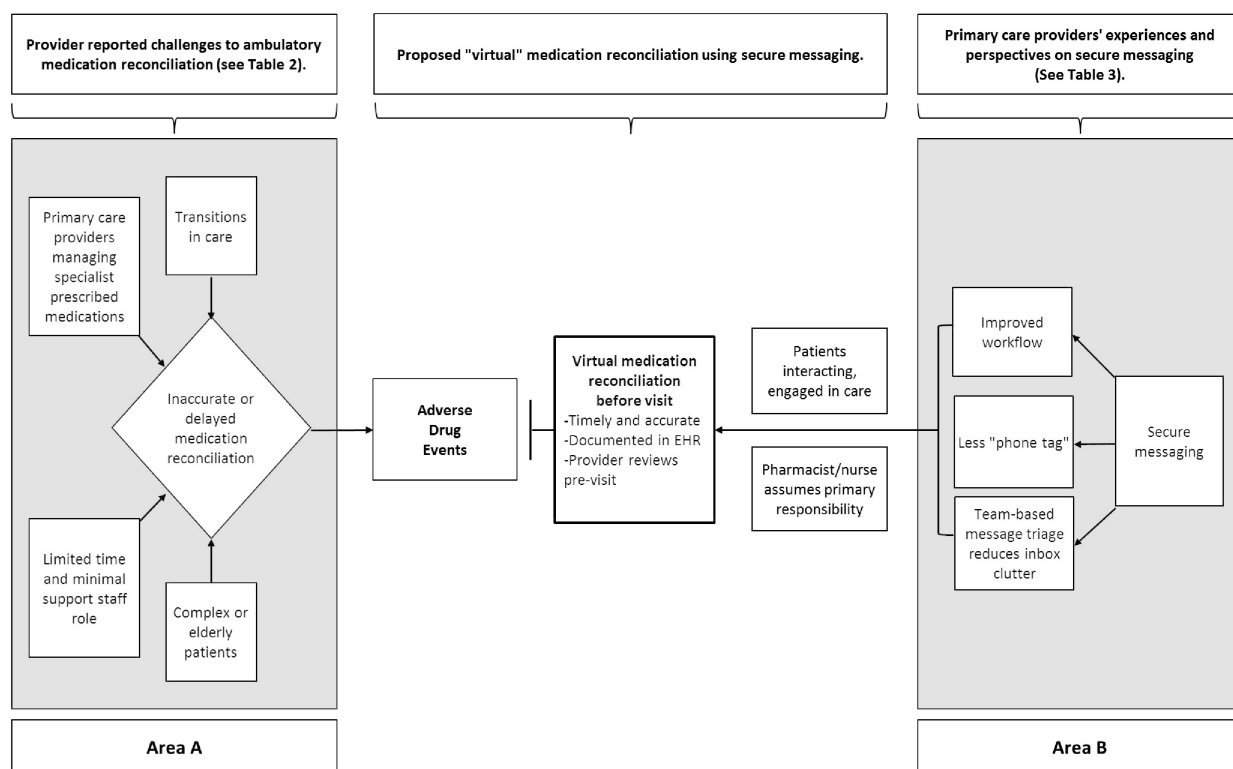
Our findings underscore the ongoing challenge of effective medication reconciliation in primary care, particularly for medically complex patients and during transitions in care. Our study suggests that a tool designed to facilitate virtual (non-face-to-face) medication reconciliation via SM would likely benefit providers in primary care (Figure 2).

There is little literature describing effective or novel medication reconciliation practices in primary care [34]. One recent study demonstrated provider interest in a patient self-service kiosk linked to the EHR for medication reconciliation [35], while other studies have shown that existing SM users within the VA system have lower rates of health care utilization [36]. Surveys

have consistently found high patient interest and satisfaction ratings when given the option to communicate with providers via SM [37-39]. At a time when large health care organizations are investing in patient portals and Web-based health

management [8,40], our study contributes the perspectives of primary care providers to the existing literature that, to date, has focused on patients' willingness and organizational-level readiness to embrace Web portals and SM to manage care.

Figure 2. Conceptual model of the challenges to ambulatory medication reconciliation and the possible role of virtual medication reconciliation. Area A shows challenges to medication reconciliation and Area B reflects providers' perspectives on secure messaging and medication reconciliation. The central area between A and B proposes the possibility of virtual medication reconciliation from home following hospitalization.



Limitations

There were several limitations of our study. First, interviews were conducted among a small number of individuals (mainly female physicians) at three clinics within a single institution, possibly limiting generalizability. Future research should examine perspectives from other members of the clinical team. One of the interviews was transcribed by the interviewer instead of being recorded (given the wishes of the interviewee), potentially impacting the data collected. However, this interview was conducted over a longer time frame in order to mitigate possible inaccuracies and to transcribe complete quotes. Second, because these interviews were conducted ahead of a pilot study recruiting patients to use a medication reconciliation tool within secure messaging, it is possible that some providers were alerted to this intervention by patients participating in focus groups, priming their perceptions of SM use for medication reconciliation prior to the interview. Future research should examine providers' perspectives in the proactive use of SM for a range of topics in primary care. Last, all providers were part of a large, integrated national health care system with a common

EHR, established patient portal, and computerized provider order entry linked to pharmacy dispensing software, resulting in potentially distinctive provider perspectives on medication reconciliation and SM compared to providers practicing in clinics or private offices without such integration, and thus limiting generalizability.

Conclusions

With the pursuit of medication reconciliation as a National Patient Safety Goal [5,30,41-43], novel approaches to accurate medication reconciliation will be vitally important to improving medication safety and systems of care within primary care. Our study found that primary care providers, on the frontlines of patient safety and chronic illness management, recognize the importance of complete and accurate medication reconciliation. Providers favor having their professional colleagues, such as nurses and pharmacists, assume primary responsibility for medication reconciliation and express enthusiasm about aligning and shaping SM for the purposes of medication reconciliation. At a time of organizational readiness for patient-led online health management [8,40], future studies should focus on the

design and implementation of SM or other Web-based tools for medication reconciliation.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Secure messaging observations protocol.

[[PDF File \(Adobe PDF File\), 29KB - jmir_v15i12e264_app1.pdf](#)]

Multimedia Appendix 2

Interview script.

[[PDF File \(Adobe PDF File\), 20KB - jmir_v15i12e264_app2.pdf](#)]

Multimedia Appendix 3

Coding scheme.

[[PDF File \(Adobe PDF File\), 5KB - jmir_v15i12e264_app3.pdf](#)]

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Abbreviations

ADE: adverse drug event

CPRS: Computerized Patient Record System

EHR: electronic health record

HIT: health information technology

SM: secure messaging

VA: Veterans Affairs

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Original Paper

The Sexunzipped Trial: Young People's Views of Participating in an Online Randomized Controlled Trial

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Abstract

Background: Incidence of sexually transmitted infections (STIs) among young people in the United Kingdom is increasing. The Internet can be a suitable medium for delivery of sexual health information and sexual health promotion, given its high usage among young people, its potential for creating a sense of anonymity, and ease of access. Online randomized controlled trials (RCTs) are increasingly being used to evaluate online interventions, but while there are many advantages to online methodologies, they can be associated with a number of problems, including poor engagement with online interventions, poor trial retention, and concerns about the validity of data collected through self-report online. We conducted an online feasibility trial that tested the effects of the Sexunzipped website for sexual health compared to an information-only website. This study reports on a qualitative evaluation of the trial procedures, describing participants' experiences and views of the Sexunzipped online trial including methods of recruitment, incentives, methods of contact, and sexual health outcome measurement.

Objective: Our goal was to determine participants' views of the acceptability and validity of the online trial methodology used in the pilot RCT of the Sexunzipped intervention.

Methods: We used three qualitative data sources to assess the acceptability and validity of the online pilot RCT methodology: (1) individual interviews with 22 participants from the pilot RCT, (2) 133 emails received by the trial coordinator from trial participants, and (3) 217 free-text comments from the baseline and follow-up questionnaires. Interviews were audio-recorded and transcribed verbatim. An iterative, thematic analysis of all three data sources was conducted to identify common themes related to the acceptability and feasibility of the online trial methodology.

Results: Interview participants found the trial design, including online recruitment via Facebook, online registration, email communication with the researchers, and online completion of sexual health questionnaires to be highly acceptable and preferable to traditional methods. Incentives might assist in recruiting those who would not otherwise participate. Participants generally enjoyed taking part in sexual health research online and found the questionnaire itself thought-provoking. Completing the sexual health questionnaires online encouraged honesty in responding that might not be achieved with other methods. The majority of interview participants also thought that receiving and returning a urine sample for chlamydia testing via post was acceptable.

Conclusions: These findings provide strong support for the use of online research methods for sexual health research, emphasizing the importance of careful planning and execution of all trial procedures including recruitment, respondent validation, trial related communication, and methods to maximize follow-up. Our findings suggest that sexual health outcome measurement might encourage reflection on current behavior, sometimes leading to behavior change.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 55651027; <http://www.controlled-trials.com/isrctn/pf/55651027> (Archived by WebCite at <http://www.webcitation.org/6LbkxdPKf>).

KEYWORDS

Internet; randomized controlled trials; qualitative research; outcome assessment (health care); sexual health; chlamydia trachomatis

Introduction

The incidence of sexually transmitted infections (STIs) among young people in the United Kingdom is increasing, despite an overall decrease [1]. More effective interventions aimed at reducing the incidence of STIs in young people are therefore clearly needed.

The Internet is a suitable medium for the delivery of sexual health information and other sexual health promotion tools, given its high usage among young people and its potential anonymity and ease of access. Computer-based interventions for sexual health promotion can have an impact on sexual health outcomes including knowledge, safer sex, self-efficacy, intention, condom use, and partner numbers [2-4], although stronger evidence is needed to be certain of these effects and to understand how interventions may work.

Online trials are increasingly being used to evaluate online interventions [5]. Conducting trials online has a number of advantages when compared with more traditional trial methods [5,6], including the ability to recruit large numbers of participants over the Internet in a relatively short period of time [7,8] and at lower cost [5,7], recruitment of groups not usually recruited using other methods [6,9], instantaneous data collection [5,6], reduced burden on participants [10], and increased participant anonymity [8], which may be particularly important when providing sensitive information about sexual health [11].

While there are many advantages to using online methodologies for conducting randomized controlled trials (RCTs), online trials can be associated with a number of problems, including poor engagement with online interventions [12], poor trial retention [5,9,13], and concerns about the validity of data collected through online self-reporting [8]. As online trials and online data collection become increasingly common, it is important to determine the best ways of addressing these kinds of problems and to further knowledge about the best ways of conducting research online.

We conducted an online feasibility trial that tested the effects of the Sexunzipped website for sexual health compared to an information-only website. The trial was designed to test the best methods of recruitment, retention, contact with participants, and sexual health outcome measurement [14]. This study reports on a qualitative evaluation of the research procedures [15], reporting trial participants' experiences and views of the Sexunzipped online trial.

The aim of this qualitative study was to determine the acceptability and validity of the online trial methodology used in the pilot RCT of the Sexunzipped intervention. More specifically, our purpose was to determine young people's views on participating in an online RCT, receiving and returning a urine testing kit for genital chlamydia via post, and the importance of receiving incentives for participation. The results of this study will inform the design of a full RCT of the Sexunzipped sexual health online intervention, but also provide useful information for other researchers designing online trials.

Methods

Overview

The Sexunzipped intervention site is an interactive, tailored sexual health website for young people [16]. It was designed according to principles of behavior change theory [17] and was developed in collaboration with young people [18]. The website aimed to provide young people with the tools to make informed decisions about their sexual health, encouraging both safer sex behaviors and greater satisfaction with relationships and sexual choices. The site provided information under the broad categories of "relationships", "safer sex", and "sexual pleasure".

The Randomized Controlled Trial Design

The design of the RCT of the Sexunzipped website is described in [Textbox 1](#) (see also [Multimedia Appendices 1](#) and [2](#)). Quantitative outcomes of this pilot trial are reported in the companion paper [14].

Textbox 1. Summary of the Sexunzipped online pilot RCT.*The study*

We conducted an online randomized RCT to test the hypothesis that the Sexunzipped theory-based, interactive online intervention would be more effective in promoting sexual health in young people than an information-only comparator website. Ethical permission for the study was granted by the University College London Ethical Committee (ref: 1023/002).

The websites

The primary difference between the “intervention” and the “control” website was the presence of interactive content on the intervention website. The control site presented simple factual information only, while the intervention site encouraged active engagement and self-reflection through quizzes and decision-making activities that were absent from the control site.

Recruitment

We invited young people aged 16-20 years living in the United Kingdom to participate in the study by placing advertisements on sexual health websites, the social networking site Facebook, on UK school and college notice boards, and by distributing flyers outside three sexual health clinics and one school for students over 16 in London, UK. We also emailed study participants to ask them to invite friends to participate.

Online enrollment and consent

Young people enrolled via the Sexunzipped website, which offered a £10 incentive for participation. Once they provided consent online, participants created a username and password and were directed to a baseline demographic and sexual health questionnaire.

Participants

In total, 2036 participants provided consent to participate in the trial, recruited from all four countries of the United Kingdom and Northern Ireland. After removal of duplicate or invalid registrations, 2006 people participated in the online trial (age range 16-21 years, median age 19; females=62.81%, 1260/2006; males=36.59%, 734/2006; transgender and “other”=0.60%, 12/2006). For a detailed discussion of the methods used for removal of duplicate and invalid registrations, see the companion paper [14].

Baseline and follow-up questionnaires

Demographic information including email address and postal address was collected online at baseline. Participants also completed the Sexunzipped Sexual Health Questionnaire, which measured knowledge, self-efficacy, intention, and behaviors relating to safer sex and communication, sexual and relationship problems, and satisfaction ([Multimedia Appendix 1](#)). Participants were contacted by email at 3 months and invited to click on a hyperlink to complete the follow-up sexual health questionnaire, which was identical ([Multimedia Appendix 2](#): email wording). The overall response rate for submission of the follow-up questionnaire was 71.78% (1440/2006).

Randomization

After completing the baseline questionnaire, 1034 participants were randomized to the intervention and 972 to the comparator website. All were given unlimited access to their allocated website during the course of the study. Approximately three-quarters of participants (1520/2006) accessed their allocated website at least once.

Postal chlamydia tests

Half of the participants (n=1030) were randomized to receive by mail a urine pot to test for genital chlamydia at 3 months. Participants returned the urine sample using a pre-paid return envelope. Nonresponders received one repeat postal kit. Participants could choose to receive the test results by text, phone, or mail. The return rate for the chlamydia sample pots was 44.85% (462/1030).

Incentives

In a substudy to increase retention, 902 participants were randomized after recruitment but before follow-up to receive a £10 (438/902) or a £20 (464/902) incentive for completion of either the follow-up questionnaire (417/902) or completion of the follow-up questionnaire plus return of the chlamydia test (485/902). The greater incentive boosted completion rates by 6-10%.

Qualitative Study Design

We used three qualitative data sources to assess the acceptability and validity of the online pilot RCT methodology: (1) individual interviews with 22 participants from the pilot RCT, (2) emails received by the trial coordinator from trial participants, and (3) free-text comments on the online baseline and follow-up questionnaires.

Data Source 1: Interviews**Recruitment**

The last question at the end of the 3-month follow-up questionnaire asked trial participants whether they would be interested in participating in an interview regarding their participation in the Sexunzipped online trial. Of the 1205 trial

participants who responded to this question, 583/1205 (48.38%) said they did not want to participate in an interview, 167/1205 (13.36%) stated they would like to participate, and 455/1205 (37.76%) said they would like more information before deciding. The postal codes of those participants who stated they would like to participate or would like more information were analyzed to identify the locations of clusters of potential interview participants. Five geographical clusters were identified (described below), and those trial participants who indicated interest and who were residing in these areas were emailed to invite them to participate in an interview. With the exception of one interview (conducted by JB), interviews were conducted by researchers who had not been involved in the development of the Sexunzipped site or in the administration of the online trial (AN and CS). Participants were made aware of this.

Interviews were conducted in five locations across the United Kingdom to help achieve a maximum variation sample and to help increase transferability of findings. The five cities were chosen because there were clusters of participants in each [14] (generally related to the presence of one or more large universities) and because they represent vast differences in level of deprivation and affluence, population, ethnic mix, and geographical profile. Glasgow is the largest city in Scotland (population approximately 600,000 in 2011) [19] but also has one of the highest unemployment rates in the United Kingdom. Liverpool (population approximately 455,400 in 2011) [20] is one of the largest cities in England but has the highest level of deprivation of any English city. Bristol (population approximately 440,000 in 2012) [21] is in England's Southwest and is England's eighth largest city; it has a large population of 20-29 year-olds, probably owing to its large tertiary student population. Southampton (population approximately 236,900) [22] is a relatively small English city located on the southern coast of England. Compared with other cities in the United Kingdom, unemployment in 2012 was relatively low. Manchester (population approximately 503,100) [23] is one of England's largest cities, but rated 4th on the index of multiple deprivation in 2010. London (population approximately 8,173,900) [22] is England's capital city and had the highest level of disposable income of any UK city in 2010.

We aimed to gain a maximum variation sample of the trial participants in terms of age, gender, allocation to the intervention or control site, and allocation to receive a chlamydia test in order to gain feedback from a diverse range of participants. As the recruitment process proceeded, we undertook more purposive sampling by specifically targeting particular groups who were underrepresented in the interviews, such as males, participants who had received the chlamydia test, and younger trial participants, until distribution of these characteristics of interview participants better reflected those of the pilot RCT sample. We continued to recruit participants for the interviews until data saturation, in other words, until there were no new themes emerging regarding participants' experiences of the online trial methodology.

Interview Procedures

All participants were interviewed face to face. The interview content included questions regarding the acceptability and feasibility of the online trial methodology (reported here), as well as participants' opinions on the website itself (not reported in this paper). The latter required participants to engage with the Sexunzipped website, with the interviewer directly observing. The researchers therefore chose to conduct interviews face to face, rather than via online means such as Skype or an online chat facility.

Interviewers used a topic guide for the semistructured interviews, which reflected our research agenda and also allowed scope for participants to expand on topics and themes as they chose. Interviewers also encouraged participants to raise other issues regarding the trial that had not been prompted but they thought important to discuss. The topic guide covered participants' experiences of being in the online trial and of receiving a postal chlamydia-testing kit.

Written consent was gained from all participants to record the interview and for the use of anonymous quotations. All interviews were audio-recorded and sent to a professional transcriber for verbatim transcription. Interviewers' field notes were also used in conjunction with the transcripts in the interview analysis.

Interview Setting

The interviews were conducted in a variety of settings including in a seminar room at a sexual health center, in university offices, in a seminar room at a community center, and in a commercially rented office. Participants were interviewed alone, apart from 2 participants (close friends) who requested to be interviewed together.

Analysis of Interview Data

All interview transcripts were coded and analyzed using a thematic analysis technique and using Atlas.ti software (Version 6) for data management. Three researchers coded one of the manuscripts and compared coding decisions to finalize the coding schema to be used. The rest of the analyses were undertaken by one of the researchers who had conducted a number of the interviews (AN). Transcripts were initially coded as being responses to a particular question and subsequently free-coded by theme. Thematic coding occurred iteratively, with themes emerging throughout the analysis. Once all transcripts had been coded in this way, codes were grouped and common themes identified. Emergent themes were discussed with other researchers at intervals throughout the coding process, with clear themes emerging early in the analysis process.

Data Sources 2 and 3: Participant Emails and Questionnaire Free-Text Comments

Data Collection and Procedures

Throughout the course of the trial, the trial coordinator saved all emails received from participants that asked questions or provided comments about the trial. These emails were sorted into folders based on their content. Those that concerned questions or comments on trial participation or trial procedures were used as a dataset for this qualitative study. The trial coordinator was sent 133 emails from trial participants in relation to the trial methodology.

On both the baseline and follow-up RCT outcome questionnaires (filled in online), participants were provided with a space to add any free-text comments. At the end of the study, the researcher extracted these comments from the questionnaires and used these as a dataset for qualitative thematic analysis; 180 free-text comments were made on baseline questionnaires (out of 2006 submitted questionnaires) and 109 on the 3-month follow up questionnaire (out of 1440).

Data Analysis

AN analyzed the content of participant emails and the questionnaire free-text comments. This was done by initially identifying those emails and comments related to the trial methodology and then using an iterative, thematic analysis approach to identify common themes across the emails and the questionnaire free-text comments. This was done manually.

The results of the analysis of the free-text comments and emails were considered in combination with those of the interviews. These data tended to further illustrate themes that had arisen in the interviews.

Results

Overview

These results represent findings from all three data sources described in the Methods section. Results are presented thematically, rather than by data type, but the data type is specified in each section.

Interview Participants

Interviews were conducted with 22 participants aged 16-20 years who had participated in the online pilot RCT of the

Sexunzipped website. Demographic characteristics of these participants are outlined in [Table 1](#). The median age of interview participants at the time of trial registration was 19 years (range 16-20). The median age and distribution of gender reflect that of the pilot RCT sample (see [Textbox 1](#) and the companion paper [14] for further details of the demographics of the pilot RCT participants). More than two-thirds of participants (77%, 17/22) were white British, also similar to the pilot RCT sample (84.20%, 1679/1994). Almost all participants were either currently participating in, or had just completed, either high school or a university degree. They were predominantly undergraduate students. An equal number of participants were interviewed from the intervention and control conditions and similar numbers of participants were interviewed from the chlamydia-test and no chlamydia-test groups.

Table 1. Interview participant demographic characteristics (N=22).

Characteristics	n (%)
Gender	
Female	15 (68)
Male	7 (32)
Ethnicity	
White British	17 (77)
Black Caribbean	1 (5)
Mixed cultural background	1 (5)
South American	1 (5)
White other	1 (5)
White Irish	1 (5)
Location	
London	10 (45)
Liverpool	4 (18)
Bristol	3 (14)
Manchester	2 (9)
Southampton	2 (9)
Glasgow	1 (5)
Website allocation	
Intervention	11 (50)
Control	11 (50)
Chlamydia test	
Sent postal sample pot	10 (45)
No sample pot	12 (55)

Participating in Online Research

Reasons for Participating

Almost all of the interview participants stated that they were recruited to the RCT through an advertisement on Facebook (overall, 84.0%, 1685/2006 of the pilot RCT participants were recruited via Facebook) [14]. The most common reasons for wanting to participate were to help the researchers because they

understood it is difficult to find participants or because they liked to help other people in general, and to gain the voucher offered as an incentive. Some participants who felt they were from “minority” sexualities (identifying themselves as gay, bisexual, polyamorous, and/or as having a transgender sexual partner) stated they wanted to represent their sexualities in the research:

As a gay man...I feel it's important to get a fair representation, so I felt like my opinion was important. [Participant 1278, male, 20 years]

A number of participants expressed an interest in sexual health as their primary motivator for participation. Other participants described participating simply because they like to take part in studies: "I just generally say 'yes' to these things" [Participant 427, female, 18 years]. Some interviewees stated that they participated because they were psychology or sociology students, encouraged to participate in research to learn about research methods and processes, or because they thought it would be fun or interesting to "take part in a sex survey" [Participant 494, male, 16 years].

When asked directly if they would have participated without the offer of incentives, the majority of participants said that they would have because they had other motives for participation. However, those who participated in the trial purely for the incentive seemed to differ from those who participated for other reasons in that they tended to be studying topics unrelated to health or social welfare and they also tended not to have participated in much research in the past.

Participants' Understanding of the Purpose of the Research

Despite having indicated they had read the information sheet that provided a clear overview of the trial purpose and procedures and having provided written consent to participate in the trial, the interview participants most commonly thought (incorrectly) that the purpose of the research was to gain data on the sexual health of young people, to test the sexual health knowledge of young people, or to measure attitudes to sex. Only one person thought, correctly, that the research was conducted to determine whether the Sexunzipped website would promote sexual health behavior change, and one further person was partially correct in thinking that the study would help to create a better website.

Who Was Running the Research and Is That Important?

When asked whether they knew who was running the Sexunzipped research project, about half of the interview participants correctly said it was University College London (UCL). An almost equal number, however, did not know who was responsible; 2 participants knew it was a university, but were not sure which one.

About a third of interview participants said that it did not matter to them who was running the research, while another third said that they knew UCL was a well-regarded university and that was important to their decision to participate. A number of participants thought it was important that it was a university running the research, but it did not matter which one. Two participants said it was only important that the research was not being run by a commercial company:

I think if it had been a corporate company doing it, I think I would still have done it, but I kind of would have approached it with a different attitude, I guess, if I thought they were trying to sell something. [Participant 595, female, 19]

Experience of Completing the Research Online

No participants reported negative experiences of participating in the research. All participants reported either a positive experience or a "fine" or neutral experience. All participants said that they would participate again.

No interview participant reported any negative attitudes to contact via email. On the contrary, they frequently expressed a preference for email over mail or phone, citing the convenience and time-saving aspects of email, as well as the feeling of anonymity. Participants also raised no objections to the specific content of the emails.

In regard to the questionnaires being presented online, interview participants again expressed their appreciation of the electronic format. Specific comments articulated the ease of completing the questionnaires at any time the participants had an Internet connection (on a laptop, university library, at home) and of being able to press a button and have their responses submitted without any further effort. Participants were clearly comfortable with online communication and data collection.

Attitudes Toward the Sexual Health Questionnaire

Despite the considerable length of the online questionnaires and the inclusion of detailed personal questions about participants' sexuality and sexual behaviors, both trial and interview participants were generally positive about the questionnaires. Comments provided by the pilot RCT participants directly on the sexual health questionnaires suggest that they were highly engaged with the questionnaires. About a third of comments provided on the baseline questionnaire and more than two-thirds on the follow-up questionnaire expressed positive views about the questionnaire. The most common positive comments related to participants finding the content and range of the questions interesting, that the questions challenged participants' thinking about sex and sexual health, and the inclusivity of the response options. Positive comments about the online format being easy to use were also relatively common.

Less positive, though constructive, comments commonly made suggestions for additional response options to questions, particularly "middle of the road" options such as "maybe" or "not sure" and for additional clarification of questions or terms used within questions, such as what actually constitutes "sex".

A relatively large number of comments provided additional details to the multiple-choice responses in the questionnaire, suggesting a desire from participants for their answers to be understood in context. For example, explaining a "Not applicable" response by stating "I have only had sex with my recent husband". Participants also seemed concerned that researchers not judge them negatively, frequently providing comments in defense of their responses: "I feel like I may come off as someone who doesn't care about STIs and such. This isn't true. Yes I have multiple partners, but every 6 weeks we all go to the sexual health clinic together".

Being Asked About Sex and Relationships

Interview participants were asked if they minded being asked about sex and relationships on the Sexunzipped online questionnaire. Only one person expressed any concern about

this, and her concerns related to questions regarding confidence to discuss sex in relationships. While some interview participants simply thought the questions were “no big deal”, some found the questions to be really “fun and interesting” and liked the directness of the questions. A number of interview participants said that participation in a sexual health study implied being asked these sorts of questions:

When you signed up, you...realized what you were going to be asked, so there was nothing shocking.
[Participant 985, male, 18 years]

Others said that, while they might have felt confronted or somewhat shocked by some of the questions, they appreciated those questions:

If I was shocked by anything I was...glad to see it because...we should talk about everything, and not be scared to talk about these things. [Participant 1278, male, 20 years]

Honesty in Responding and the Importance of the Questionnaire Responses

All interview participants said they responded honestly to the questionnaire, and all but one participant stated that they believed that the responses they provided on the questionnaires were important to the research. A number of interview participants referred to the sense of anonymity afforded them by completing the questionnaire online and stated that they would not have felt so comfortable in responding honestly if they had needed to hand their completed questionnaires to a person, or to complete their responses with others present:

...because it was online and no one was asking you anything to your face, it was sort of easy just to answer as honestly as you could. So, I think that was good...I think if someone had been asking me that face to face, I don't think I would have been as honest!
[Participant 1072, female, 19 years]

Once again, those interview participants who saw their sexuality as somewhat “unusual” or in the minority expressed that being honest allowed them to be represented in the research. Some interview participants simply thought that lying would be pointless or would require more effort than just telling the truth.

Several interview participants referred to aspects of the questions themselves that facilitated honest answers. For example, because the questions always provided a response option that allowed them to provide an honest response (ie, not forced into an “approximate” response through the forced-choice options). Furthermore, some interview participants also referred to the wording of the questions in facilitating honest responding:

even things like...‘how many times in the last 3 months have you had sex without a condom?’...The amount of times we are told in school...that that is strictly forbidden... the fact that they ask it in such a comfortable and normal way...it's just easier to be honest that way. [Participant 1519, male, 19 years]

Did Completing the Questionnaire Change Sexual Health Behaviors?

Interview participants were asked whether completing the sexual well-being questionnaire had made them think differently about their sexual health and whether they had changed any behavior relating to their sexual health as a result. The majority of interview participants stated that in order to answer the questionnaire honestly, they had reflected on their own behavior and that some particular questions had made them think very carefully about some aspects of their sexual well-being. Comments made by the pilot RCT participants on the online questionnaires also illustrated that the questions had changed their thinking about sexual health, including comments such as “challenged my thinking”, “made me think more”, and “Made me think more about my sex life and that I need to take more care and be protected more often”.

A number of the interview participants had given particular thought as to whether they were comfortable talking to their partner about sex. Some reported thinking more about contraception and their attitudes towards different types of sexual practices (eg, oral sex, anal sex, masturbation, use of sex toys). Other interview participants said that they had given particular thought to control in relationships, past relationships in general, sexual health services available, sex and alcohol, sexuality, pressure to have sex and regret after sex:

I'd had, like, an experience in the past where I'd kind of felt a bit more pressured into it...it (the questionnaire) did make me think... should I be more aware of that in the future and maybe I can do something to prevent that feeling or that situation
[Participant 1278, male, 20 years]

When asked if they had acted differently as a result of completing the questionnaire, about two-thirds of interview participants said they had not. Most frequently, this was because they felt that no changes needed to be made, either because they were already “careful”, were in a long-term monogamous relationship, or not currently sexually active. Only one participant felt that he needed to make changes but had not. Those interview participants who said they had changed their behavior consequent to completing the questionnaire (about a third) had changed behavior relating to using contraception, being more careful about using contraception for sex while drinking alcohol, standing up to pressure to have sex, not having “casual sex” they might regret, or being screened for STIs.

Postal Tests for Genital Chlamydia

Approximately half of the overall pilot RCT participants received a test in the post for genital chlamydia. All interview participants were asked how they felt about having to provide their address as part of the research and whether they understood why their address was needed. Those who received the test were asked how they felt about it, and those who had not received the test were asked if they would have minded receiving the test via the post.

Only one interview participant stated that she did not like having to provide her address. This was because she was concerned her parents would find out about her participation in the study.

While the majority of interview participants did not mind providing their address, a number said that was because they lived with friends or at a college, but they would be more concerned if they lived with their parents. This concern was also exemplified in several emails sent to the research coordinator from pilot RCT participants asking if post relating to the Sexunzipped study (the urine test package, voucher, or postal questionnaires) would display a Sexunzipped logo on the package as the trial participants were concerned that their parents would learn of their participation in the study.

A number of interview participants also specified that they did not mind providing their address because they trusted UCL as a legitimate organization or because they understood the need for the address:

But I did understand that it might actually have something to do with the research, so I didn't really mind... I mean, I've given my postal address for worse things, like for adverts and things, when I'd just learned about the Internet... And also you guys were a legitimate research body. So I wasn't scared, you know, oh, maybe they're going to sell my postal address, or they will try and steal my identity.
[Participant 489, male, 20 years]

Of the interview participants asked to state why they thought the research team needed their address, approximately half believed it was to receive the postal chlamydia test, a few thought it was to receive the shopping vouchers received as incentives, two thought it would be used to collect data about participants' location, and the remainder were uncertain why they needed to provide an address (but provided it anyway).

More than two-thirds of interview participants either did not mind or would not have minded receiving the chlamydia test in the post. Many of the interview participants had completed genital chlamydia urine tests prior to participating in the study and found the testing "pretty standard". Participants had sometimes received testing kits via post from the National Health Service or had picked them up from family doctors, sexual health clinics or nightclub bathrooms, or received kits at university:

I've received them loads of times from the NHS
[Participant 1072, female, 19 years]
I'd have been fine doing it, because we did them at...we had the people come round our uni quite recently anyway to do chlamydia tests and we got like a free T-shirt if we did and stuff like that. [Participant 427, female, 19 years]

A number of interview participants obtained chlamydia tests regularly anyway: "I'd just cross 'Chlamydia test' off my checklist" [Participant 1101, female, 18 years]. Two participants thought that receiving a test was not appropriate: "It's kind of intrusive...[you] should go to your local clinic" [Participant 734, female, 19 years].

Several emails sent to the research coordinator from the pilot RCT participants specified concerns or questions regarding return of the urine sample. Some trial participants had recently completed a chlamydia test and asked if they therefore needed

to be tested again. One participant had never had sex and wanted to know if he should return the sample anyway. Another participant wanted further explanation as to what the urine sample would be used for before making the decision about whether to return it.

Incentives for Participation

Of the 22 participants interviewed, most had received one £10 voucher, one had received the £20 voucher, and the remainder had received the £10 total in two £5 increments, with the exception of one participant who had not yet received any vouchers and one who could not recall the amount he had received.

The majority of participants thought the £10 they received was an adequate incentive, while the participant who received £20 thought that amount was too much for what she had been required to do as part of the research. While participants were glad to receive such an incentive, the majority of them also stated that they would have participated anyway with no incentive.

Discussion

Principal Findings

This evaluation of young people's views of the methodology used in an online pilot RCT demonstrates that the online methodology used was highly acceptable to this group and is in fact preferred to "traditional" face-to-face or postal methods for sexual health research. Recruitment online via Facebook proved to be effective for the age group 18-20 years, and this recruitment method was highly acceptable to participants. However, we could not recruit young people aged 16-17 years via Facebook since Facebook prohibits advertisements with reference to sex or sexual health to those under 18 years old.

Participants' main motivations for participation were a desire to aid the research, to gain the incentive, and an interest in the area of sexual health. Despite the incentive being identified as a common motivator for participation, the majority of interviewees stated that they would have participated without it. This is consistent with previous research that suggests that altruistic motivations for participation in research are common, such as wanting to contribute to scientific knowledge, particularly if the risk and burden of participation is low [24]. Interview participants said that having to complete the sexual health questionnaires was not particularly burdensome, and on the contrary, could be fun, interesting, and thought provoking.

It is important to note that almost all of the interview participants were university students with an interest in research and studying health- or welfare-related degrees. Incentives may have been important for attracting participants without specific interests in the research process: interviewees who rated the incentives as most important to participation were studying in a non-health-related field and had not participated in prior research.

Contact by email was highly acceptable, and also postal contact, as long as the sexual health content was not obvious to anyone other than the recipient. We did not collect telephone numbers,

but this may have boosted retention beyond the maximal 77.2%, 166/215 (achieved with a £20 incentive) [14]. Bull et al maximized trial retention by using a series of incentives and by contacting participants in several different ways (via email, post, and telephone) [9].

The young people interviewed thought it important that studies of the sexual health of young people are conducted and wanted to help by providing valid data. Many comments on the sexual health questionnaires also expressed positive reactions to the broad range of questions asked and indicated strong engagement with the questionnaire, suggesting that they were keen to provide accurate responses to the questions.

The information participants were asked to provide was of a highly sensitive nature (eg, types of sexual activity, number of sexual partners, history of sexually transmitted infections), but interview participants were comfortable with providing this information anonymously online. All participants said they provided completely honest answers to the questions, but they might not have done so if they had to hand in a written questionnaire or if asked for that information by a person (face to face or by phone). This finding is consistent with that of Copas et al [11] who concluded that use of Computer Assisted Self Interview technology compared with pen and paper completion improved data accuracy for a survey of sexual attitudes and lifestyle in a British population. This suggests that information collected online is likely to be at least as valid as information collected offline.

A majority of interview participants said they were more willing to participate in the research because it was university-run. For many participants, their confidence was enhanced by the knowledge that the research was being conducted by a reputable university and not by a commercial company. Beyond this, the details of the research were not important to them, with few participants understanding the purpose of the study and only half being able to name the university responsible, despite these details being clearly provided in all recruitment materials.

Participants expressed a preference for online registration processes, communications with researchers via email, and completion of the questionnaires online, seeing these as convenient in terms of being able to participate at a time and place of their choosing and in affording them a maximum sense of anonymity. The online environment was also valued by participants in an online trial of an alcohol harm reduction website (Down Your Drink) [10].

All participants had reflected on their own sexual health behavior to complete the questionnaires, and for about a third of participants interviewed, this had resulted in their changing their sexual health behavior. This illustrates the high likelihood of reactivity to assessment, which is essential to consider when baseline data are collected prior to an intervention [25]. It is well known that assessment of alcohol consumption alone can significantly reduce alcohol consumption [26], and further work is needed to determine the likely level of effect of reactivity of assessment in a sexual health context. Collecting only a minimal number of sexual health outcomes at baseline (to allow the examination of baseline differences between groups), with full

outcome measurement at follow-up, would help to minimize measurement effects.

The majority of our interview participants thought that receiving and returning a urine sample for chlamydia testing was acceptable. However, the maximal return rate of the tests in the online trial was relatively low (47.4%, 118/249) [14]. Interview responses and email queries suggest that, in a number of cases, participants might not have returned their tests because they did not need the result, either because they were not sexually active or because they had a recent test. The companion paper [14] provides further data and discussion on this issue. A small number of interview participants thought that receiving the chlamydia test by post was too intrusive. In such cases, it might be useful to offer an alternative method of testing, such as attending a sexual health clinic.

Limitations

The 22 interview participants, while being a diverse sample in terms of sexual preference (including gay, straight, bisexual, polyamorous, and with transgender sexual partners), allocation to intervention or comparator, geographical location, and gender, were not representative of participants in the Sexunzipped trial. They were in the upper end of the age range of the target audience, were mostly undertaking university studies, and the majority either had a specific interest in sexual health and/or in being part of research studies. This group therefore represents participants who are highly educated and motivated to participate in sexual health research, and their opinions may therefore differ from those from the broader RCT pilot sample. Furthermore, by recruiting interview participants via the follow-up questionnaire, we could not include participants who had registered for the study but dropped out. We were therefore unable to determine if aspects of the methodology were unacceptable to participants who dropped out of the study. Greater attempts to follow up with those who drop out of online studies would provide more complete information regarding aspects of these studies that may lead to attrition from online research.

Future Directions

Recommendations for the conduct of online randomized controlled trials and online sexual health research can be found in [Multimedia Appendix 3](#). These recommendations were derived from this qualitative evaluation and from the linked quantitative evaluation of the Sexunzipped trial procedures reported in the companion paper [14].

Conclusions

This study contributes an increased understanding of common problems and concerns related to the conduct of online sexual health research through analysis of the views of young people who participated in the Sexunzipped trial (expressed in in-depth interviews, free-text comments on an online questionnaire, and in trial-related emails).

The online recruitment of young people through Facebook was highly acceptable to the interview participants. Similarly, online trial methodology such as online registration, email reminders and communication with the researchers via email, and

completion of questionnaires online were preferred above more traditional methods. The findings of this study also suggest that online data collection for sensitive information such as sexual health data may assist in gaining valid and complete data in comparison to offline methods. Our findings suggest that sexual health outcome measurement may in itself prompt reflection or behavior change, so it is important to consider potential measurement reactivity in the design of an RCT. The provision of incentives for participation in sexual health research online

may help to access harder-to-reach groups who may not normally participate.

Notwithstanding the limitations of self-selection into this study, these findings provide support for the use of online research methods for sexual health research, emphasizing the importance of careful planning and execution of all trial procedures including recruitment, respondent validation, trial-related communication, and methods to maximize follow-up.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Sexunzipped sexual health questionnaire.

[[PDF File \(Adobe PDF File\), 287KB - jmir_v15i12e276_app1.pdf](#)]

Multimedia Appendix 2

Sexunzipped online trial - example email content.

[[PDF File \(Adobe PDF File\), 269KB - jmir_v15i12e276_app2.pdf](#)]

Multimedia Appendix 3

Recommendations for the conduct of online randomized controlled trials and online sexual health research.

[[PDF File \(Adobe PDF File\), 39KB - jmir_v15i12e276_app3.pdf](#)]

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Abbreviations

RCT: randomized controlled trial
STI: sexually transmitted infection
UCL: University College London

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Original Paper

Initial Design of Culturally Informed Behavioral Intervention Technologies: Developing an mHealth Intervention for Young Sexual Minority Men With Generalized Anxiety Disorder and Major Depression

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Abstract

Background: To our knowledge, there is no well-articulated process for the design of culturally informed behavioral intervention technologies.

Objective: This paper describes the early stages of such a process, illustrated by the methodology for the ongoing development of a behavioral intervention technology targeting generalized anxiety disorder and major depression among young sexual minority men.

Methods: We integrated instructional design for Internet behavioral intervention technologies with greater detail on information sources that can identify user needs in understudied populations, as well as advances in the understanding of technology-specific behavioral intervention technology dimensions that may need to be culturally tailored.

Results: General psychological theory describing how to effect change in the clinical target is first integrated with theory describing potentially malleable factors that help explain the clinical problem within the population. Additional information sources are then used to (1) evaluate the theory, (2) identify population-specific factors that may affect users' ability to relate to and benefit from the behavioral intervention technology, and (3) establish specific skills, attitudes, knowledge, etc, required to change malleable factors posited in the theory. User needs result from synthesis of this information. Product requirements are then generated through application of the user needs to specific behavioral intervention technology dimensions (eg, technology platform). We provide examples of considerations relevant to each stage of this process and how they were applied.

Conclusions: This process can guide the initial design of other culturally informed behavioral intervention technologies. This first attempt to create a systematic design process can spur development of guidelines for design of behavioral intervention technologies aimed to reduce health disparities.

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KEYWORDS

mobile health; eHealth; cultural competency; minority health; male homosexuality; male adolescents; young adult; anxiety; depression

Introduction

Behavioral intervention technologies are patient-facing information and communication technologies (eg, websites, virtual reality, text messages) designed to improve physical and mental health by targeting behaviors and cognitions [1]. Although behavioral intervention technologies may have the potential to improve access to behavioral health care for underserved populations, we know of no well-articulated process for culturally informed behavioral intervention technology design. We describe the early stages of such a process, using the methodology that is currently being used for the initial design of a behavioral intervention technology targeting generalized anxiety disorder (GAD) and major depressive disorder (MDD) in young sexual minority men.

At the outset, we decided this intervention would be technology-based due to barriers to traditional care. Although barriers to mental health services affect youth in general [2], sexual minority youth face additional barriers such as reluctance to disclose to providers their sexual orientation and related issues [3,4]. Further, many psychologists are not trained to meet their needs [5]. Many young sexual minority men (22%) are uninsured, and 12% indicate they have nowhere to present for health care or information [6].

Methods

As there were no validated psychological intervention models for anxiety or depression in sexual minority youth [7], we

required a systematic design approach. The instructional design (ID) process for Internet behavioral intervention technologies [8] informed our thinking regarding identification of the users and usage contexts, and establishment of learning needs and goals. However, the ID process for Internet behavioral intervention technologies did not detail sources of information that can help to understand the users. Such information is particularly critical when the target population is understudied, and we addressed this in our process. We also endeavored to more broadly establish user needs, which include learning needs but also address other population-specific needs.

Thus, our behavioral intervention technology design process outlines sources of information to better understand the user and their cultural context. This information is used to generate user needs, which are then translated into product requirements. Requirements are organized using advances in the understanding of behavioral intervention technologies dimensions (ie, technology platform, functionality, content, and user interface) that may require cultural tailoring [9].

This paper focuses on the question of how to arrive at an initial conception of a behavioral intervention technology. While evaluation of the perceived usefulness, usability, and feasibility should occur throughout the design process [8], evaluation methods are beyond the scope of this paper. We suggest readers consult user-centered design [10] to choose evaluative methodologies for each phase of their design process. Each step of our initial design process is displayed in Figure 1, and an example is described in Table 1.

Figure 1. Process for the initial design of a behavioral intervention technology targeting generalized anxiety disorder and major depression among male sexual minority youth (rectangle=internal processes; trapezoid=process resulting in the input of information).

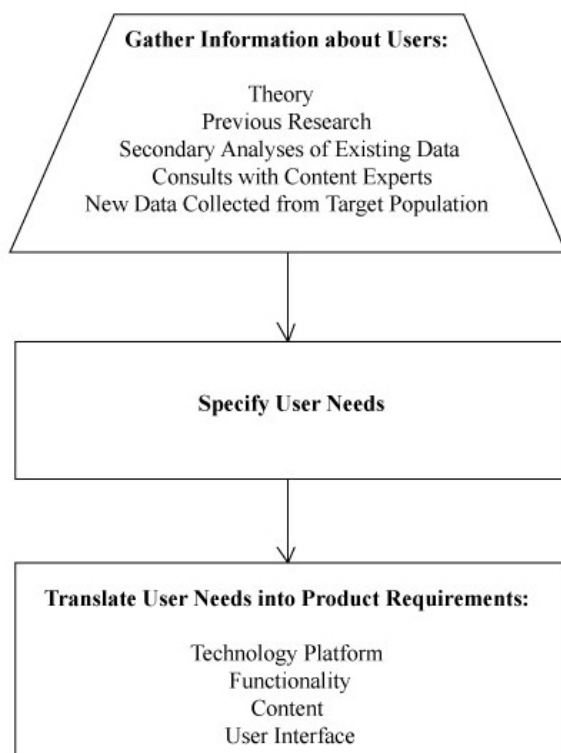


Table 1. Example of how a piece of information gathered about the users is used to specify a user need, which is then translated into a product requirement.

Information gathered about the users	User need	Product requirement
Minority sexual orientation is a relatively concealable, stigmatized characteristic that can pose safety risks if revealed to others.	Private access to the intervention.	A study-provided mobile phone will offer private access to the intervention, which will also be password-protected.

Results

Step 1: Gather Information About Users

Overview

We first defined characteristics of our users: (1) males who are attracted to other males, (2) aged 17-20, and (3) experiencing GAD and/or MDD. Although sexual orientation refers to multiple facets of sexuality including attraction, behavior, and identity (eg, self-identification as “gay”, etc), there is some evidence that attraction, unlike behavior and identity, is considered by adolescents to be critical in terms of defining one’s sexual orientation [11]. Thus, attraction to other males was the only defining characteristic in terms of the target population’s sexual orientation.

We next gathered information regarding ways that each of the defining user characteristics may influence behavioral intervention technology design, preferring any available information relating to their intersection. Our objectives were to establish (1) user needs relating to the “gap” between optimal behaviors, thoughts, and feelings versus current behaviors, thoughts, and feelings in this population, (2) knowledge, skills, attitudes, etc, needed to enable users to close this gap [8], and (3) user needs regarding behavioral intervention technology feasibility and acceptability.

We will now describe types of information that can be gathered to help answer these questions. We suggest first selecting theory, as theory helps establish the other types of required information. We next recommend consulting previous research to evaluate the evidence supporting the theory and identify user characteristics that could influence the way users relate to and engage with behavioral intervention technologies. A review of other previous research may also be necessary depending on the theory, and we will describe an example.

Other sources of information can augment theory and research findings. Consultation with content experts can be a rich source of clinical data throughout the information gathering and subsequent stages of this design process. In addition, secondary analysis of existing data and collection of new data from users are being employed to fill in gaps of the research literature.

Theory

ID for Internet behavioral intervention technologies suggests using theory to guide understanding of user needs; in our case, we required general theory describing how to bring about affective change [8]. We also needed to expand the conceptualization of theory to include population-specific theory. As young sexual minority men are at increased risk for anxiety and depressive symptoms [12,13], we required theory

elucidating potentially malleable factors that explain this disparity.

General Theory of Affective Change

Internet interventions based on principles of cognitive behavioral therapy (CBT) for anxiety, depression, and stress have demonstrated efficacy when supported by brief provider contact [14]. Literature is growing that supports cognitive behavioral Internet interventions for adolescents with depressive and anxiety disorders [15]. Thus, the cognitive behavioral model was used as a framework for affective change. Due to high depression and anxiety comorbidity, shared mechanisms have been identified and used to create unified CBT protocols for adults and youth [16,17]. Unified cognitive behavioral theory describes putative maladaptive thoughts and behaviors common to individuals with depression and anxiety (ie, overestimation of the probability and consequences of negative outcomes, avoidant emotion regulation strategies) and thoughts and behaviors that are optimal in promoting affective change (ie, realistic cognitive appraisals and adaptive emotion regulation strategies) [16]. Thus, unified cognitive behavioral theory has outlined the differences, or “gaps”, between existing versus optimal thoughts and behaviors, as well as skills that can be taught to help users close these gaps. The cognitive behavioral model also has implications for the contexts in which users should interact with the intervention, as it requires that patients apply their learning during problematic situations encountered in daily life.

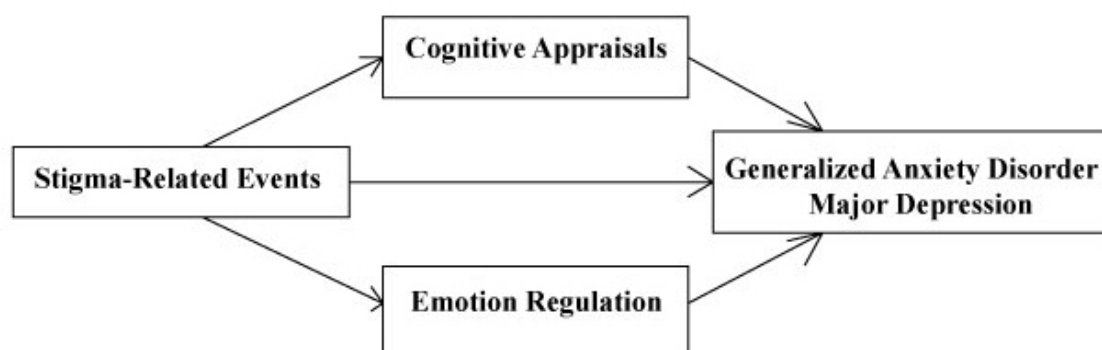
Theory of Mental Health Disparities Among the Users

Overview

Ample evidence supports the minority stress model, which implicates stressors generated by stigmatizing social contexts (eg, discrimination, victimization) in mental health disparities among sexual minority people [3,18,19]. Unlike some other stigmatized identities, sexual orientation may be concealable, and such concealment is also conceptualized as a form of minority stress [18]. However, disclosure of sexual orientation can also be a source of minority stress, as disclosure can place youth at risk for victimization [20,21].

The psychological mediation framework [22] extended the minority stress model by proposing pathways between stigmatizing events and mental health. Many of these pathways (eg, appraisals of social support, rumination) are malleable according to unified CBT protocols, as they involve maladaptive cognitive appraisals and emotion regulation. Thus, we integrated unified CBT with the most clearly compatible aspects of the psychological mediation framework (see Figure 2) to derive a population-specific model of affective change to guide the behavioral intervention technology design.

Figure 2. The population-specific theory of affective change used to guide the design of a behavioral intervention technology targeting generalized anxiety disorder and major depression among male sexual minority youth.



Previous Research

We searched previous literature for evidence regarding the population-specific model of affective change. Prospective and experimental evidence suggests that emotion dysregulation does mediate the relationship between stigma-related events and psychological distress [22]. Regarding cognitive appraisals in our population-specific model of affective change, discrimination, victimization, and concealment may negatively influence cognitive appraisals of social support and thus increase depression and anxiety [22,23]. In partial support of this idea, lower perceived social support has been found to predict depression among gay youth [24]. The evidence for the population-specific model of affective change was limited, however, as most research with sexual minority people is cross-sectional [25], obscuring the ways minority stress processes interrupt healthy development [26]. Also, as very large samples are required to recruit representative sexual minority samples, convenience samples are often used that overrepresent white individuals and those who identify as gay [27,28].

As cognitive behavioral principles are designed for use in distressing situations, we also used previous research to identify contexts in which our users would likely encounter minority stress. Unlike many other stigmatized characteristics, families are unlikely to share the youth's sexual orientation and may be hostile toward it [29]. Sexual minority youth are also more likely than heterosexual youth to be victimized at school and skip school due to safety concerns [3]. Adolescent males attracted to both males and females report lower academic achievement than their male heterosexual peers [30], and this may be due to hostile school climates [31]. Young sexual minority men can also lose friendships over their sexual orientation [32]. Thus, sexual minority youth can experience stigma-related events in the context of family, school, and friendships, all of which are key domains in the lives of many young people.

Previous research regarding acceptability and feasibility considerations was then examined. One of the first steps to developing a culturally inclusive design was gaining better understanding of how users may conceptualize their sexual identity. Little work has been done to develop design requirements for sexual minority people, so we began with examining the language young men use to describe their sexual orientation. In contrast to labels such as "gay" or "bisexual",

many adolescents appear to better understand their sexual orientation in terms of the sex(es) to whom they are sexually attracted [33]; indeed, some youth reject sexual orientation labels entirely [34]. For others, a wide variety of terms are used (eg, "pansexual").

Finally, we sought research on the implications of user characteristics that are not related to sexual orientation for behavioral intervention technology feasibility and acceptability. First, a key developmental task of adolescence for both sexual minority and majority youth is to increase autonomy [3,35]. Second, metacognitive skills can be impaired by depression [36]. Third, due to mood-congruent recall [37], it may be difficult for users to remember how to implement new skills when they feel depressed or anxious.

Secondary Analyses of Existing Data

When designing behavioral intervention technologies for an understudied population, researchers may expect limitations in the literature regarding evidence for their model of population-specific change. Consequently, we are conducting a secondary analysis of data from an ongoing longitudinal cohort study of 451 racially diverse sexual minority men aged 16-20 (first reported by Mustanski et al [38]), recruited in Chicago using a sampling method that facilitated enrollment of young men unaffiliated with the gay and bisexual community. Respondent driven sampling [39] was used and modified to allow a higher percentage of initial recruits (ie, "seeds"), who were located through community outreach, school organizations, flyers posted in community locations frequented by LGB youth, and geosocial network applications (ie, Grindr and Jack'd). The seeds were then compensated for recruiting up to 3 other young sexual minority men into the study. New recruits, in turn, could also earn monetary incentives by recruiting up to 3 of their peers into the study.

Participants were given measures of minority stress, cognitive appraisals, and anxiety/depressive symptoms every 6 months. Ongoing, unpublished analyses are thus far highlighting the importance of appraisals of family support in predicting anxiety/depressive symptoms 6 months later. Although the inclusionary definition of sexual orientation differed in this longitudinal study from our defined target population, the analyses provided some support for the pathway between cognitive appraisals and anxiety/depression in our population-specific model of affective change. Had there been

published trials of behavioral interventions for anxiety or depression with this population, we would have also requested to analyze such data to ascertain whether our model of affective change mapped onto mechanisms of action.

Consultation With Content Experts

To work toward culturally informed implementation of evidence-based principles, content experts should review the researchers' understanding of gathered information. We have begun discussions with mental health professionals at a community organization serving sexual minority youth regarding our population-specific model of affective change, preliminary results of our secondary analysis, and their implications for intervention strategy. Further, the research team includes a psychologist and a physician with expertise on the health of male sexual minority youth, an adolescent psychologist with expertise in CBT for anxiety and depression, an expert in behavioral intervention technology development (DCM), and a software engineer. This team only begins to speak to the need to define "content experts" broadly, due to the multidisciplinary nature of behavioral intervention technology design.

New Data Collected From the Target Population

Information gathered thus far suggests the tentative learning goals are to increase perceived family support or help youth source positive social support from other individuals, and foster adaptive emotion regulation strategies. However, as young sexual minority men are understudied, the knowledge, skills, behaviors, and attitudes needed to meet these learning goals are unclear. A few qualitative studies have been conducted with samples that were not characterized on the basis of mental health, indicating sexual minority youth use a variety of strategies and resources to cope with minority stress (eg, [40]). However, it is difficult to evaluate the adaptive potential of these strategies without specifically examining youth who experience minority stressors without becoming distressed.

Accordingly, we have designed qualitative interviews to conduct with a subset of young sexual minority men participating in the aforementioned longitudinal study; we are inviting participants who have repeatedly (ie, at their two most recent assessments) evidenced nonclinical anxiety and depression symptom scores, despite repeatedly experiencing discrimination, to participate in the qualitative interviews. By understanding adaptation among youth who are resilient to minority stress, we will begin to understand how, specifically, male sexual minority youth can remain emotionally regulated and protect their perceptions of family support in the face of minority stress.

Step 2: Specify User Needs

Due to the potentially concealable nature of sexual orientation, and the fact that its disclosure could result in discrimination or victimization, the paramount user need is private access to the behavioral intervention technology.

As stated previously, the behavioral intervention technology also needs to help youth improve appraisals of family support, or build or strengthen other social supports, and replace maladaptive with adaptive emotion regulation strategies. Subsumed user needs (eg, the skills, knowledge, and attitudes

required to fulfill these broader learning needs) remain unknown, as we have not yet conducted the qualitative interviews regarding resilience to minority stress. Resources are often too limited to gather all desired information sources prior to applying for funding. Other researchers may also find it necessary to partially specify user needs and translate them into product requirements to create a thoughtful proposal and seek such funding. We thus conceptualize the information gathering phase as continuing to occur during the other phases of our process, enabling refinement of user needs and product requirements as new information becomes available.

The behavioral intervention technology must address minority stress driving higher rates of anxiety and depressive symptoms among the target population, and this is more likely if therapies actively engage youth in these stigmatizing social contexts [41]. As sexual minority youth may face stigma in their family, school, and social life, and CBT relies on use of new behaviors and ways of thinking during distressing situations, users need the ability to access the behavioral intervention technology during as much as of their daily life as possible. Users who report distress also need prompts to remind and guide them to use cognitive behavioral skills in the moment.

Due to educational disruptions or depression, some users may need the behavioral intervention technology to accommodate lower levels of literacy and metacognitive skills, respectively. Given their developmental stage, users also need the behavioral intervention technology to convey respect and support for their growing need for autonomy. Finally, the language of the behavioral intervention technology needs to be compatible with users' understanding of their sexual orientation.

Step 3: Translate User Needs Into Product Requirements

Overview

Within this phase, we have subsumed the recently published model of specific features of patient-facing behavioral intervention technologies that require cultural consideration, which comprise (1) technology platform, (2) functionality, (3) content, and (4) user interface [9]. We now describe several examples of how user needs inform each of these four areas.

Technology Platform

A mobile phone platform meets the need for ubiquitous technology resulting from the varying contexts in which minority stress takes place and the corresponding need for application of cognitive behavioral skills in the face of minority stress. Also, a purely Web-based intervention may not meet the user need for private access to the behavioral intervention technology. Youth may not have a point of access to the Web that is not monitored by others. Thus, for the duration of the intervention, users will be provided with a mobile phone to allow private access to the behavioral intervention technology. The behavioral intervention technology will also be password-protected to protect the youth's data if the phone is lost or stolen.

Functionality

The extent and nature of interactivity, amount of user control, sequencing of information, and rate of delivery [42] should be selected based on user needs [8]. To reduce the metacognitive skill required, we are using short, scaffolded didactic information and frequent interactive experiences with corrective feedback [42]. Accordingly, each day the application will provide users with either a small chunk of information or a brief, interactive skills practice with clear linkage to previous material. Further, the mobile phone application will prompt users several times daily to report on their mood. The behavioral intervention technology will guide users reporting distress through tools that will scaffold them in enacting behaviors that are adaptive given their current discrete emotion(s) and intensity. For example, youth reporting moderate guilt will be routed to tools that target guilt by restructuring maladaptive cognitive appraisals, such as by focusing on how to learn from a mistake. In contrast, youth experiencing intense guilt would first be walked through distress tolerance exercises [43,44], such as focusing on the sensations of one's feet touching the ground. Another example of feedback is that the phone application will offer visualization tools to show users how their emotions relate to their behaviors and contexts. For example, youth can see a graph showing their average level of sadness in each location in which they have reported their mood.

The intervention "functionality" also includes human coaching, which is commonly used to increase adherence to Internet behavioral intervention technologies [45]. As mentioned, the behavioral intervention technology depends on feedback [42], and there are some tasks (eg, completing a thought record) that may be too complex for the mobile phone application to provide meaningful feedback. The behavioral intervention technology will enable coaches to view users' work, such that coaches can provide feedback for more complex tasks. In keeping with the goal for the behavioral intervention technology to foster frequent but short interactive experiences, coaching contacts will include a brief telephone call (5-10 minutes) and email each week. A coaching protocol ("TeleCoach") [46] based in part on motivational interviewing [47] will be used to maintain engagement in treatment despite avoidance behaviors that may arise due to anxiety and depressive symptoms. Coaches will be clinicians with expertise in motivational interviewing.

Content

The need for autonomy among youth indicates that a collaborative, empowering tone is appropriate for the content. For example, the intervention will first involve personal goal-setting that will be used to frame the other intervention components. Also, the behavioral intervention technology content around loss of family support will stress the youth's emerging independence and ability to obtain social support from other sources (eg, the idea of building a "family of choice" [3]).

Consistent with the many domains in which sexual minority youth can encounter minority stress, the content will also address minority stress occurring in a variety of contexts. Skills such as cognitive restructuring, problem solving, and finding alternatives to avoidant emotion regulation strategies are taught in part through the use of examples. Such examples include a

young man encountering bullying at school, a youth who has lost a good friend after he disclosed his sexual orientation, and a young man trying to problem solve regarding how and when to disclose his sexual orientation to his parents. Examples will be enhanced by incorporation of young sexual minority men's narratives collected during the qualitative interviews regarding resilience to minority stress.

User Interface

Users will be able to obtain the same information from audio voiceovers, illustrations, and videos as contained in the text, to accommodate possible educational disruptions due to school victimization [8]. The terminology used to describe sexual orientation will also be inclusive (eg, "attracted to men" versus "gay" or "bisexual"). When discussing sexual identification, a spectrum of possible sexual orientation labels will be acknowledged.

Discussion

Principal Results

Design of behavioral intervention technologies for underserved populations can be guided by general psychological theory describing how to effect change in the clinical target, integrated with theory describing potentially malleable factors that help explain incidence of the clinical problem among the population. Previous research, analysis of existing data, consultation with content experts from multiple disciplines, and collection of new data can then be used to (1) evaluate the guiding theory, (2) identify group-specific factors that are not learning needs, but may affect users' ability to relate to and benefit from the behavioral intervention technology, and (3) establish specific skills, attitudes, knowledge, and behaviors required to change malleable factors posited in the theory. User needs result from synthesis of this information. Generation of product requirements is then guided by application of the user needs to choice of technology platform, functionality, content, and user interface.

Limitations

Future work should extend this process model by articulating methods to evaluate each of its stages, as well as incorporating cultural intersectionality, the idea that multiple identities (eg, Latino, bisexual, male) are not additive and cannot be fully understood in isolation [48].

Conclusions

This early design process is readily understandable to clinical scientists and thus can be translated to serve interventionists targeting other populations or clinical targets, as well as those interested in creating a model for the entire design process of culturally informed behavioral intervention technologies. The process of gathering information and defining user needs is also applicable to the development of interventions that do not involve technology. The model could also assist clinicians in culturally tailoring their interventions for patients from underserved populations, as well as to spur further discussions of guidelines and standards in the development of behavioral intervention technologies aimed to reduce health disparities.

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Conflicts of Interest

None declared.

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Abbreviations**CBT:** cognitive behavioral therapy**GAD:** generalized anxiety disorder**ID:** instructional design**MDD:** major depressive disorder

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Original Paper

Development and Initial Evaluation of an Internet-Based Support System for Face-to-Face Cognitive Behavior Therapy: A Proof of Concept Study

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Abstract

Background: Evidence-based psychological treatments, such as cognitive behavior therapy (CBT), have been found to be effective in treating several anxiety and mood disorders. Nevertheless, issues regarding adherence are common, such as poor patient compliance on homework assignments and therapists' drifting from strictly evidence-based CBT. The development of Internet-delivered CBT (ICBT) has been intensive in the past decade and results show that guided ICBT can be as effective as face-to-face CBT but also indicate a need to integrate the two forms of CBT delivery.

Objective: In this study, we developed and tested a new treatment format in which ICBT and face-to-face therapy were blended. We designed a support system accessible via the Internet (using a computer or an Apple iPad) for patients and therapists delivering CBT face-to-face. The support system included basic CBT components and a library of interventions gathered from existing ICBT manuals.

Methods: The study involved 15 patients with mild to moderate anxiety or depression (or both). Eight therapists conducted the treatments. All participants were interviewed after the nine-week intervention. Further, patients provided self-reports on clinical measures pre- and post-trial, as well as at a 12-month follow-up.

Results: A reduction was found in symptom scores across all measures. The reliable change index ranged from 60% to 87% for depression and anxiety. Large effect sizes (Cohen's *d*) ranging from 1.62 (CI 95% 0.59-2.66) to 2.43 (CI 95% 1.12-3.74) were found. There were no missing data and no treatment dropouts. In addition, the results had been maintained at the 12-month follow-up. Qualitative interviews revealed that the users perceived the support system as beneficial.

Conclusions: The results suggest that modern information technology can effectively blend with face-to-face treatments and be used to facilitate communication and structure in therapy, thus reducing therapist drift.

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KEYWORDS

cognitive behavior therapy; Internet; anxiety; depression; Apple iPad

Introduction

The lifetime prevalence of mood and anxiety disorders is high, ranging from 20.8% to 28.8% [1], and these disorders are associated with significantly reduced quality of life in sufferers [2]. According to the World Health Organization (WHO), by the year 2030 depression is expected to be the largest contributor to disease burden [3]. Thus, there is a need for cost-effective and accessible treatments. Evidence-based treatments exist and both pharmacotherapy and psychological treatments (mainly cognitive behavior therapy; CBT) have established evidence bases [4]. However, access to CBT, often the preferred treatment option [5], is limited; thus, a gap remains between demand for treatment and actual provision [6]. Moreover, evidence-based psychological treatments do not help all patients and issues regarding adherence to therapy are common [7]. Dropout from treatment, poor engagement, and incomplete adherence to homework assignments are all issues that can reduce the treatment's effectiveness [8]. Further, therapist drift from evidence-based CBT (toward supportive therapy) has been highlighted as a potential obstacle to effective CBT [9]. Hence, ways to optimize the delivery of CBT, improve response rates, and increase the treatment's availability represent important goals for the field.

Research on Internet-delivered cognitive behavior therapy (ICBT) has been intensive in the past decade and studies indicate that clinician-guided ICBT can be as effective as face-to-face CBT for some diagnoses [10,11]. ICBT has been developed for several mood and anxiety disorders [12,13] and has also been implemented in regular clinical psychiatric settings [14]. Several clear advantages can be noted when comparing ICBT with traditional, face-to-face CBT [15]. Obviously, less time is needed when the treatment is delivered via the Internet [16]; hence, more patients can be reached at a lower cost. In addition, the rationale and content of ICBT adhere to treatment manuals closely and, even though there is a role for the therapist in guided ICBT [17], this treatment format is probably less susceptible to therapist drift. On the other hand, some problems with ICBT should be noted. Therapies with minimal support may lead to increased dropout rates (particularly in unguided ICBT) [18], and some patients probably need more support than ICBT provides in order to adhere to the therapy [19]. Face-to-face meetings with patients have the advantage of providing additional clinically relevant information that can be used for diagnostic purposes and individual case management. Moreover, when patients need support in order to understand therapeutic techniques, face-to-face contact is beneficial (as a treatment technique can be illustrated directly during the session).

Based on our research experience examining both treatment-delivery methods—face-to-face and via the Internet—we sought to merge the two to create a blended treatment format. Previous studies have combined computerized manuals with face-to-face treatment [20,21], used technological adjuncts in therapy [22], or used the Internet after treatment completion to help prevent relapse [23,24]. To our knowledge, this is the first study to merge ICBT and face-to-face CBT in a system used by both the therapist and the patient. Accordingly,

we constructed a Web platform accessible via personal computer and Apple iPad and blended ICBT with traditional face-to-face CBT. This case series pilot study aimed to explore clinical outcomes on measures of anxiety, depression, and quality of life when Internet-delivered support was provided to patients and their therapists. In addition, we also examined user experiences and the ways that the support system was used and perceived. We hypothesized that the support system would contribute positively to adherence and that outcomes would align with those achieved in face-to-face CBT. This study was designed as a proof-of-concept study, generating ideas for further research.

Methods

Procedure

The local ethics committee approved the study (ID: 2011/456-31). Fifteen participants fulfilling all inclusion criteria were notified via email of their acceptance and gave written informed consent prior to treatment. The treatment duration was between eight and nine weeks. In combination with the last session, a qualitative interview was conducted with the patient. On this occasion, each patient was also directed to a website where he or she was to fill out self-report questionnaires representing the clinical outcome measures. At post-treatment, seven therapists participated in a focus group discussing user experiences. One individual interview was conducted with another therapist. In addition, long-term follow-up clinical data were obtained at a 12-month follow-up with each patient.

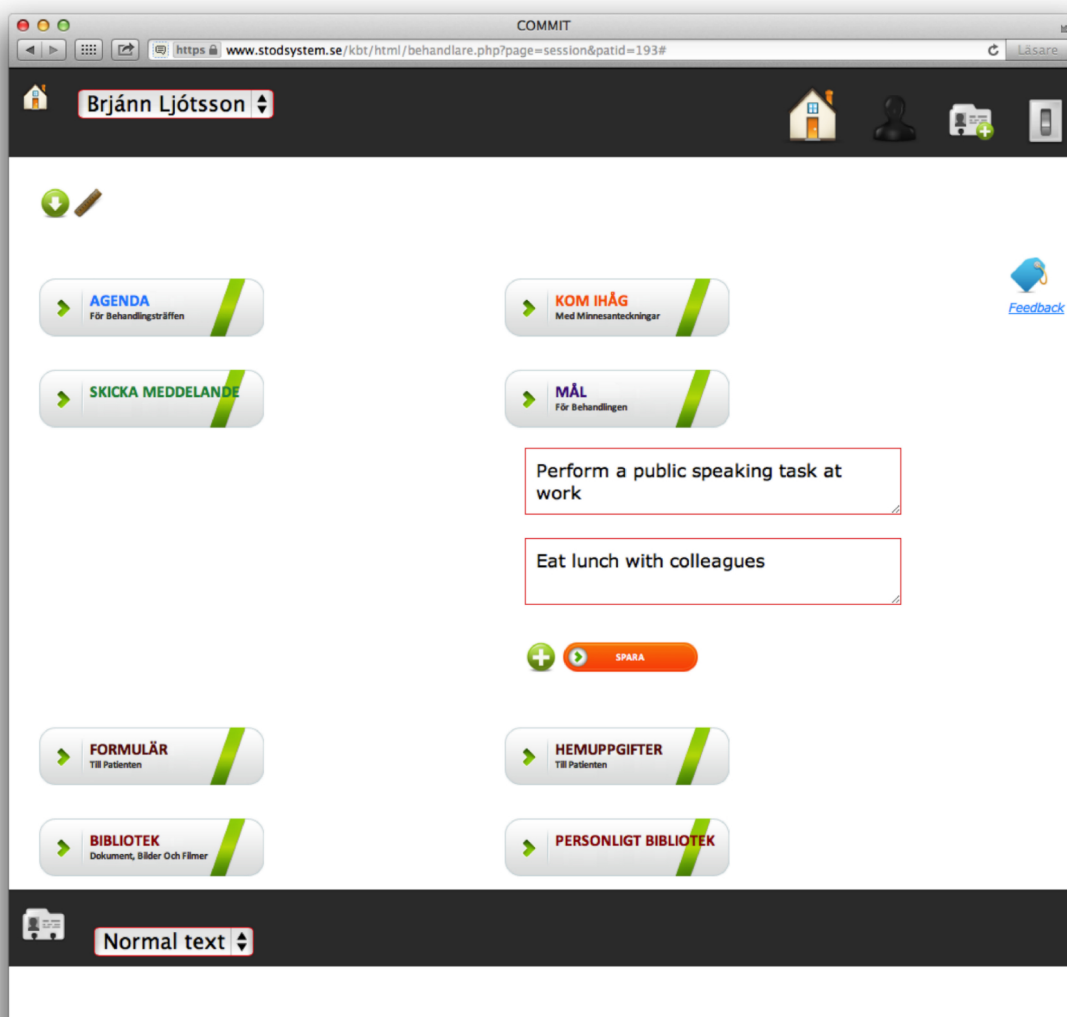
The Support System

The platform (support system) utilized in the study was conceived and designed by the first and the last authors, KM and GA. A programmer wrote the code and used the open-source code language PHP and MySQL to construct the platform, which was accessible via personal computer or Apple iPad through an encrypted secure sockets layer (SSL) connection to the Internet. The support system was not developed as a mobile phone application. Users were assigned personal log-in IDs via email and an additional temporary password was sent via SMS (short message service) at each attempt to log on (this feature was implemented in order to increase the level of security). The platform was to be used at home and in the clinical setting where treatment was provided. The platform was set up so that the user would receive part of the information that would have been provided in a face-to-face treatment session—in other words, there were no computerized treatment components and the main part of the system consisted of material that in a face-to-face session would have been presented on printed paper or verbally (eg, goal setting). The therapists and patients did not access the same content in the platform; therapists controlled which support resources and information patients had access to. The platform contained some basic components of CBT, such as scheduling visits, keeping an agenda, and setting goals. The platform also included a library with both text and media resources used in psychoeducation and as homework assignments. These resources were compiled primarily from prior studies on ICBT for anxiety [25] and depression [26]; they were presented not as discrete treatments but rather as part of the face-to-face treatment (ie,

as handouts). Use of text material in face-to-face treatment has been found to be common among CBT practitioners [27] and we regarded this procedure as aligning with standard CBT. The digital library contained supplemental information on CBT, such as behavioral activation, activity scheduling, exposure therapy, common cognitive biases, and maintenance via safety behaviors. We also provided some audio files, such as relaxation instructions. In addition, the platform included common questionnaires and forms used in homework assignments, such as guides to creating a fear hierarchy and keeping daily thought records and sleep diaries.

In addition, the users could communicate via an internal message system and the therapists could communicate via mobile phone SMS. However, communication between users was essentially made within the support system. Users could also create memos about topics they wished to remember or discuss in therapy and they were able to upload and share personal files. The Web platform was built to give support to both therapists and patients in the delivery of face-to-face CBT. For further details, see [Figure 1](#) and [Multimedia Appendix 1](#).

Figure 1. Screenshot of the Internet-based support system.



Recruitment

The study involved 23 participants in total: 15 patients and 8 therapists. Patients were recruited mainly via local media advertising and information distributed on a university campus. Participants declared their interest via a research project website and provided informed consent. Therapists were recruited separately via email.

Participants

The patients' mean age was 43 years old (SD 15) and ages ranged from 22 to 70 years. A majority of participating patients

(60%, 9/15) were currently university students or previously had been. [Table 1](#) presents the demographic characteristics and [Table 2](#) the distribution of psychiatric diagnoses. Of the eight therapists who were involved in the study, seven had recently received basic psychotherapy training as part of the final year of their five-year clinical psychology program. One therapist was in his first year of clinical practice as a psychologist. The mean time of experience in CBT under supervision was 14 months (range 4-26 months). All the therapists volunteered and did not receive any compensation.

A total of 26 patients were interviewed via telephone using the structured diagnostic psychiatric interview for Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) and International Classification of Diseases (ICD-10): Mini-International Neuropsychiatric Interview (MINI [28]). Two psychology students in their final term conducted the clinical interviews. Both students had experience with diagnostic interviews and basic training in CBT. After the interviews, participants were instructed to fill out self-reports measuring anxiety, depression, quality of life, and alcohol consumption via a secured and encrypted website.

The following participant inclusion criteria were applied in the study: (1) over 18 years of age, (2) no history of ongoing suicidal attempts or current tendency toward self-harm, (3) no current alcohol or drug addiction, (4) no current contact with a physician

administering pharmacotherapy that required monitoring, (5) if the patient was on pharmacotherapy, the dose had been stable for at least one month before the study began and the participant agreed to keep the dosage unchanged during the study or inform the therapist if a change was needed, (6) not receiving other concurrent psychological treatment, (7) not diagnosed with severe major depression disorder according to MADRS-S (Montgomery Åsberg Depression Rating Scale – self-report) (cut-off at >30 points), (8) reported <4 on MADRS-S item 9 (about suicidal ideations), (9) not suffering from a severe psychiatric condition that could interfere with the treatment (eg, bipolar disorder or schizophrenia, as reported in the clinical interview), and (10) access to the Internet via a computer. A senior researcher (licensed psychologist and psychotherapist) reviewed participants to determine their eligibility for inclusion.

Table 1. Demographic characteristics (N=15).

Characteristic	Mean (SD) or n (%)
Age, mean (SD)	43.0 (15)
Gender, female, n (%)	10 (67)
Educational level, n (%)	
Completed university	7 (47)
Completed vocational training	4 (27)
Current university	2 (13)
Completed high school	2 (13)
Employment status, n (%)	
Working	9 (60)
Student	4 (27)
Retired	2 (13)
Current pharmacotherapy, n (%)	
SNRI ^a	4 (27)
SSRI ^b	2 (13)
Sedatives	2 (13)
Previous experience of therapy, n (%)	
CBT ^c	4 (27)
Unspecified therapy	3 (20)
Single CBT interventions	2 (13)
Counseling	2 (13)
Computer experience, n (%)	
Good	13 (87)
Limited	2 (13)

^aSNRI: serotonin and norepinephrine reuptake inhibitors

^bSSRI: selective serotonin reuptake inhibitors

^cCBT: cognitive behavior therapy

Table 2. The distribution of diagnoses according to the MINI psychiatric interviews (N=15).

Diagnosis	Frequency, n (%)
Major depressive episode	6 (40)
Social anxiety disorder	5 (33)
Generalized anxiety disorder	4 (27)
Agoraphobia	3 (20)
Panic disorder	2 (13)
Comorbidity (participants fulfilling two or more diagnostic criteria)	5 (33)

Cognitive Behavior Therapy

The individualized CBT was delivered during a period of eight to nine weeks. The treatments were based on generic CBT components, such as case conceptualization, behavior analysis, agenda setting, goal setting, psychoeducation, and homework assignments. Therapists received clinical group supervision from a licensed clinical psychologist during four scheduled appointments during the trial. In addition, on four occasions the therapists and the research project manager met and discussed experiences and feedback regarding technical issues. Each therapist and patient pair individually decided how to use the platform during the treatment—for instance, during therapy sessions and in additional contact between sessions.

Clinical Measures

We used the Beck Anxiety Inventory (BAI) [29] and the Generalized Anxiety Disorder Screener-7 (GAD-7) [30] to measure anxiety. The Montgomery Åsberg Depression Rating Scale-self-rating version (MADRS-S) [31] and the Patient Health Questionnaire-9 (PHQ-9) [32] were used to measure symptoms of depression. In addition, the Quality of Life Inventory (QOLI) [33] was administered. All clinical measures have established good psychometric properties when administered via the Internet [34,35]. We also used the Alcohol Use Disorder Identifications Test (AUDIT) [36] for screening purposes but not as an outcome measure.

Statistical Analysis

Data were analyzed with SPSS version 21. All the statistical analyses were intent-to-treat and statistical significance was set at $P < .05$. Differences between pre- and post-treatment measures and pre-treatment and long-term follow-up measures of depression, anxiety, and quality of life were examined using

paired sample *t* tests. Within-group effect sizes were calculated based on the pooled standard deviation, expressed as Cohen's *d*.

We used a reliable change index (RC) in accordance with Jacobson and Truax [37] to determine the proportion of participants who showed treatment improvements from pre- to post-treatment and from pre-treatment to long-term follow-up. As suggested by Lambert and Ogles [38], we used internal consistency as a measure of reliability. The following values were used in the calculation of RC: Cronbach alpha=.92 for BAI, GAD-7, and PHQ-9 [29,30,39]; Cronbach alpha=.87 for MADRS-S [40]; and Cronbach alpha=.83 for QOLI [33].

Qualitative Analysis

This part of the study was based on content analysis in order to analyze the data [41]. Individual interviews and the focus group were recorded and transcribed. All interviews were recorded using a portable digital recorder. The purpose of the interviews was to identify user experiences of the platform used in the treatment. Meaningful units from the text based on the research question were coded and organized into categories. Sentences that reflected opinions, such as adjectives and words that expressed an emotive experience were selected. Meaningful units and user experiences were sorted as positive, negative, and neutral. Topics that were mentioned frequently and explicitly became the basis for the categorization. Each patient interview (n=15) was merged and overarching themes were created (see Table 3). Overarching themes were formulated in an ongoing discussion between two researchers, facilitating the development of supplementary views and critical perspectives. The same procedure of qualitative analysis was applied in analyzing both the focus group discussions and the individual therapists' comments.

Table 3. Overarching themes identified in the qualitative interviews with patients and therapists.

Connotation	Feedback
Patient interviews	
– ^a	Computer skills influenced the work with the support system
+ ^b	Facilitating treatment outside the therapy room
+	Memory support and learning
+	Positive experiences of the treatment
+	Positive implications for homework assignments
+	Potential to gain an overview of the treatment process
+	Promoted a sense of autonomy and responsibility
+	Supported maintenance after therapy
+	The library—an individualized supplement
+	The use of the support system during and between sessions
+/ ^c –	The iPad was not seen as an obstacle
+/ ^c –	Working with digital material—helpful or unnecessary
Therapist interviews	
–	For patients with less computer experience, ICBT hampered the work
+	Increased therapist skills by providing overview of the therapy process
+	Positive experience of communication between sessions
+	Positive experiences using the support system
+	The library—an important support
+	The support system promoted additional structure in the therapy
+	The use of the support system during and between sessions
+/ ^c –	Heterogeneity in amount of time engaging in treatment
+/ ^c –	Pros and cons of the support system as a substitute to the face-to-face sessions
+/ ^c –	Pros and cons of using the support system in face-to-face sessions
+/ ^c –	The support system affected the therapists' workload

^a –, negative feedback

^b +, positive feedback

^c +/–, positive and negative feedback

Results

Clinical Outcome Measures

This study had no missing data and no treatment dropouts. Statistically significant main effects were obtained for all clinical outcome measures, pre- to post-treatment, $t_{14}=4.25$ to 7.25 , all P 's<.001, and pre- to long-term follow-up, $t_{14}=3.53$ to 6.20 , all P 's<.05 (see also [Table 4](#) and [Figures 2-4](#)). Moreover, comparing mean values post-treatment to long-term follow-up

were nonsignificant: $t_{14}=0.73$ to 1.55 , all P 's>.142. Large within-group effect sizes (Cohen's d) were observed on all clinical outcome measures, with pre- to post-effect sizes ranging from 1.26-2.43 and long-term follow-up between 1.08-1.94 ([Table 4](#)). Reliable change as defined by Jacobson and Truax [34] was observed in a majority of the patients, ranging from 60% to 87% on depression and anxiety measures and from 53% to 80% at long-term follow-up ([Table 4](#)). Reliable change on quality of life was 40% at post-treatment and 60% at 12-month follow-up.

Table 4. Mean, SD, effect size, and reliable change index at pre-treatment, post-treatment, and at long-term follow-up to treatment.

	Pre-treatment (n=15)	Post-treatment (n=15)	Long-term follow-up ^a (n=15)
BAI^b			
Mean (SD)	18.07 (7.7)	7.67 (4.2)	9.60 (7.8)
Effect size (CI 95%)	—	1.67 (0.6-2.74)	1.09 (0.39-1.79)
Reliable change, n (%)	—	11 (73)	9 (60)
GAD-7^c			
Mean (SD)	11.93 (5.9)	4.07 (1.7)	6.00 (4.9)
Effect size (CI 95%)	—	1.80 (0.64-2.97)	1.08 (0.32-1.84)
Reliable change, n (%)	—	9 (60)	8 (53)
MADRS-S^c			
Mean (SD)	21.20 (4.1)	9.07 (5.7)	10.27 (6.7)
Effect size (CI 95%)	—	2.43 (1.12-3.74)	1.94 (0.9-2.98)
Reliable change, n (%)	—	13 (87)	12 (80)
PHQ-9^d			
Mean (SD)	12.13 (6.0)	4.46 (2.7)	5.33 (4.2)
Effect size (CI 95%)	—	1.62 (0.59-2.66)	1.31 (0.32-2.31)
Reliable change, n (%)	—	11 (73)	10 (67)
QOLI^e			
Mean (SD)	-0.13 (1.6)	1.60 (0.9)	1.98 (1.6)
Effect size (CI 95%)	—	1.26 (0.49-2.02)	1.29 (0.41-2.18)
Reliable change, n (%)	—	6 (40)	9 (60)

^aEffect size and the reliable change index were calculated based on pre-treatment data versus long-term follow-up data.

^bBAI: Beck Anxiety Inventory.

^cGAD-7: Generalized Anxiety Disorder questionnaire (7-item version).

^dMADRS-S: Montgomery Åsberg Depression Rating Scale (self-report version).

^ePHQ-9: Patient Health Questionnaire (9-item version).

^fQOLI: Quality of Life Inventory.

Figure 2. Histograms showing clinical measures of anxiety. Mean values at pre-treatment, post-treatment, and at 12-month follow-up. Error bars represent the standard deviation.

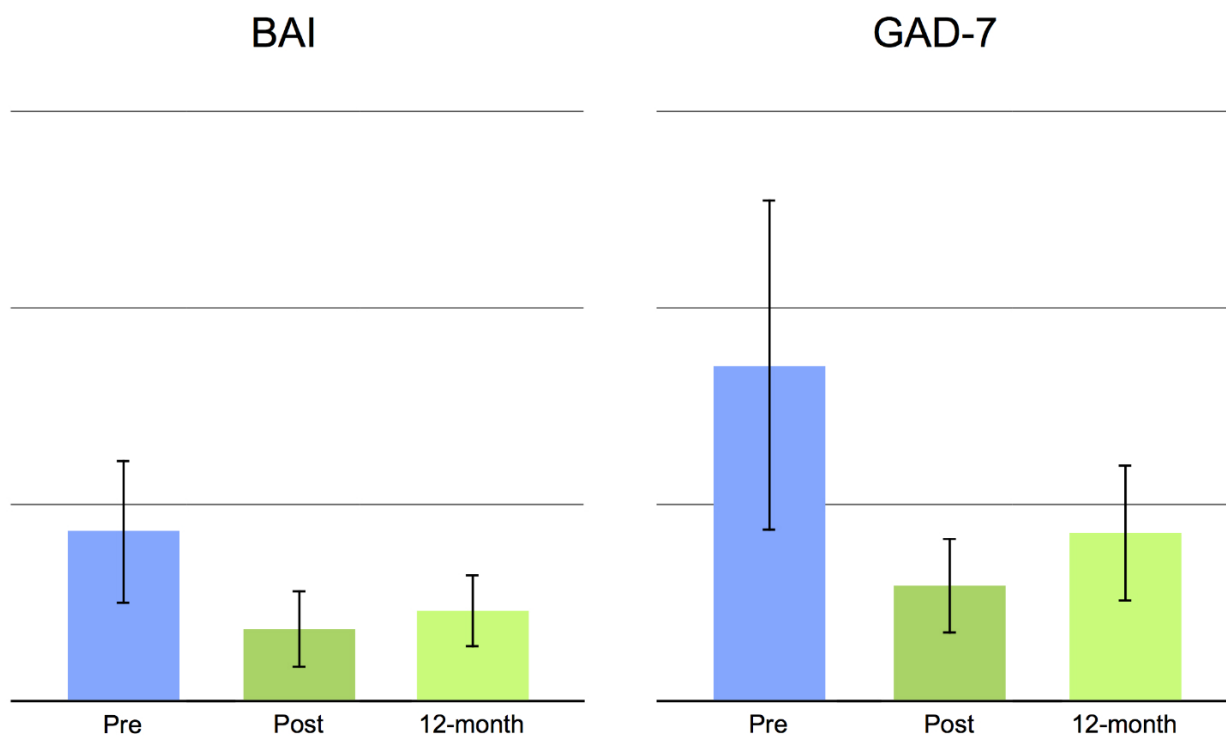


Figure 3. Histograms showing clinical measures of depression. Mean values at pre-treatment, post-treatment, and at 12-month follow-up. Error bars represent the standard deviation.

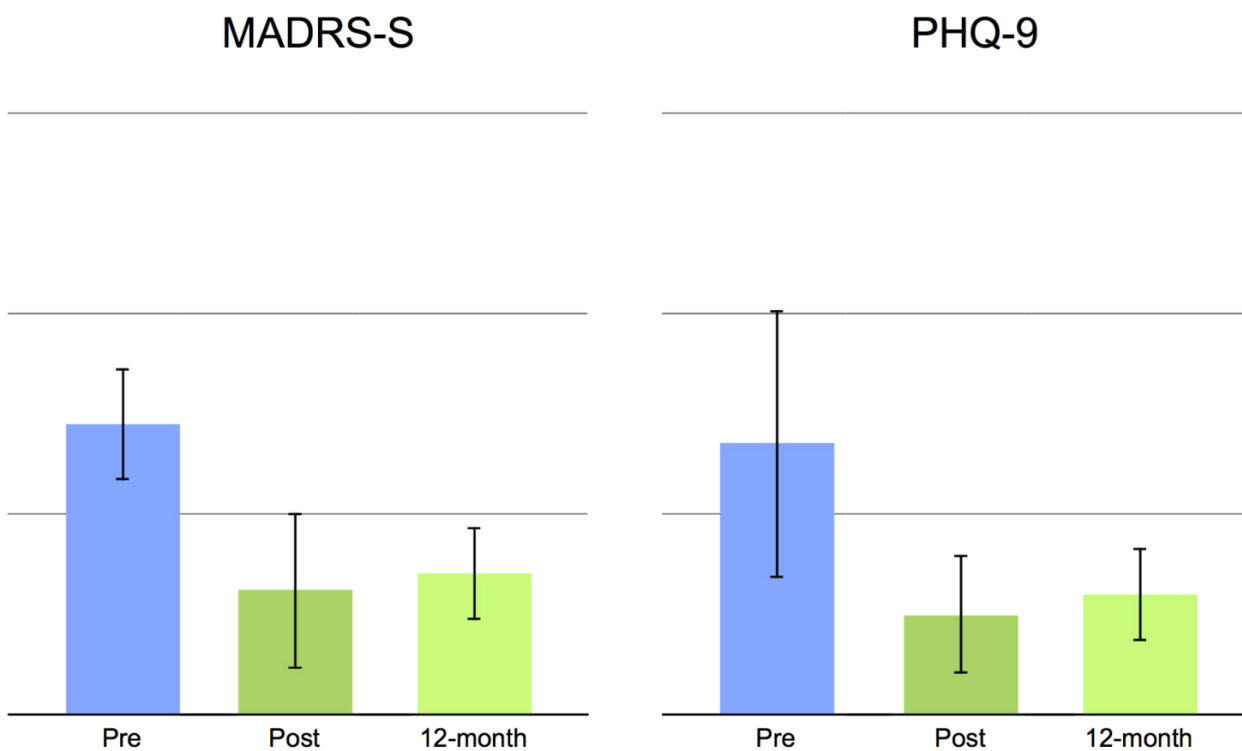
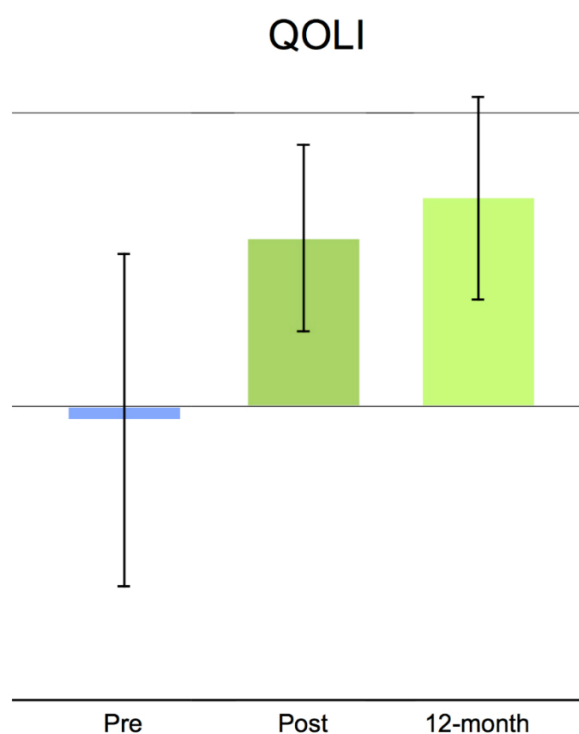


Figure 4. Histogram showing clinical measures on quality of life. Mean values at pre-treatment, post-treatment, and at 12-month follow-up. Error bars represent the standard deviation.



Patients' User Experiences

The patients reported that they had used the various featured components of the support system. A majority said that the platform was easy to use; however, two patients with less computer experience had used the platform only sporadically. No patient regarded the iPad as a disturbing feature of the therapy. Thirteen patients reported that they had carried out all or almost all their homework assignments; two patients reported that they had carried out more than half their assignments. The availability of assignments on the Internet was described as easy, convenient, and modern, and patients indicated that it prevented avoidance of feared situations (eg, in exposure therapy tasks). About half the patients appreciated having online feedback between face-to-face sessions. One patient had more frequent contact with the therapist during a period of challenging homework assignments. Some also found the process of writing about their problems to be helpful. Most of the patients expressed largely positive opinions about sharing information and homework over the Internet. One-third of the patients also reported that they spent additional time reading other information on the Internet related to the therapy. The content in the library was perceived as a supplement to the treatment, promoting theoretical understanding and enhanced knowledge. Several patients highlighted the use of the platform as a memory aid. One patient described the educational advantages of obtaining information through several media, such as speech, writing, and images. Another reported advantage of the Internet-based platform was the patients' ability to return to previous assignments and reflect on their experience of change, which was perceived as motivating. A few patients indicated that the treatment contributed to increased participation and responsibility for their treatment and that both the therapist and

patient collaboratively created the homework assignments with the help of the support system.

The treatment was said to facilitate the generalization of treatment to the patients' everyday lives. Several patients perceived the treatment duration as longer and more extensive than they had expected a nine-week intervention to be. About one-third of the patients expressed ambivalence when it came to continued work on their own. One patient also suggested developing this concept so that it could be used after treatment in order to maintain treatment gains.

Therapists' User Experiences

The self-reported estimation of time spent with each therapy and week ranged between 15 and 180 minutes (mean 77, SD 57). Seven therapists (87.5%, 7/8) estimated that they spent less or as much time in these treatments, compared to treatments without the platform. The therapists accessed the platform on average seven times per patient per week. However, this number also includes the pre-treatment phase, during which the therapists were introduced to the support system. The therapists confirmed that they had used all the components of the platform. Internal messages and correspondence via SMS were frequently used. Messages contained clarifications and reformulations of homework assignments, providing support, encouragement, and answers to patients' questions. Correspondence via the platform was also used to remind patients about assignments. This resulted in the use of the platform when therapy sessions were cancelled. The therapists were able to help the patients relatively rapidly instead of waiting until the next appointment. This may have contributed to the therapy's continuity, allowing therapists to prepare the face-to-face sessions based on the results of a patient's weekly assignments. One therapist also highlighted that the platform made it possible to focus more on the relational

aspects of treatment during sessions. A majority of the therapists highlighted these possibilities as major benefits. Using the platform also contributed to structure in therapy. The structure was obtained when both therapist and patient could agree on and set an agenda, goals, and the central focus of homework assignments. The library was considered a source of knowledge and therapy-skill enhancement; it supported therapists in choosing among interventions and was helpful when therapists presented the treatment rationale. However, this easy access also led therapists to rely more on the content of the library material and to seek fewer other sources for help and supervision. The iPad was used to take notes, to draw, and to take pictures and videos during therapy sessions that could later be shared via the platform. Using the iPad during face-to-face sessions could potentially be clumsy and problematic, creating a barrier between therapist and patient, in particular if the therapist's technical experience was limited. But using the iPad to take pictures of drawings on the wallboard was highlighted as beneficial. The patients' level of computer experience was mentioned as important by the therapists, even if technology was not seen as a problem for a particular patient.

Discussion

Principal Findings

The aim of this study was to investigate the combination of face-to-face CBT and an Internet-based support system. Overall, the therapies led to improvements on clinical measures and the platform was perceived as helpful. Clinical outcome data showed significant main effects and reliable changes on all measures and these results had been maintained at 12-month follow-up. The findings on the whole align with previous findings regarding computerized support in combination with face-to-face CBT [42]. The patients' user experiences show that the platform and the iPad were regarded as beneficial. Several patients stated that they gained more from the treatment than they had originally expected to during the nine-week period. However, this might also be explained by the therapists' level of involvement and may not directly relate to the availability of the platform. Obviously, some therapists were involved in the research process, but all the therapists had limited clinical experience and therefore it is reasonable to assume that the support system benefitted the delivery of the therapy. Indeed, this is a research question on its own, given that online therapist education is only in its infancy [43,44] and that direct support for novice therapists via the Internet is even less well researched. We also hypothesize that this support system might be a useful instrument for supervising therapists. If psychotherapy supervision focuses on enhancing interpersonal therapist skills, the support system, which emphasizes the importance of formulation and homework assignments, can serve as a complement in supervision.

Therapists found several major benefits to delivering treatment in this format—for instance, improved between-session communication and ease of sharing treatment-related information. These inputs highlight some important implications and advantages over traditional face-to-face treatments.

Replacing missed sessions with Internet-delivered interventions adds continuity and the treatment thus becomes less vulnerable to factors such as physical health and logistical problems, such as travel distance. Further, this may have implications for structuring treatment, for it demonstrates the importance of the therapists being keen to set the agenda and it shows that homework assignments must be formulated clearly to provide clear, educative information. This study had no missing data, nor any dropouts from treatment. Hence, it is plausible that communication via the Internet between therapy sessions mitigates dropout rates. Further, our results suggest that Internet-based treatment delivery might decrease tendencies toward therapist drift [9] and might increase adherence to CBT treatment manuals.

Limitations

Among the limitations of the present study is that the sample size was low, thus reducing statistical power. We did not include a wait list or an active control group and therefore had no control for time and repeated testing, which limits the generalizability of the findings. Also, the study design does not allow us to explore different factors that explain the outcome of the study. It is possible that certain features in the system, ie, stand-alone SMS communication between therapy sessions, could achieve similar clinical outcome results.

It is noteworthy that two therapists in the study were also involved in the research process and evaluation of the system. Even if our procedure is more biased than if independent researchers had conducted the interviews, the qualitative method, content analysis, provided us with the possibility of reviewing the comments and views of the participants.

The therapists in this study had relatively little experience delivering CBT and the included patients were recruited via media advertisement. Therefore, this method might not be equally applicable in a representative clinical setting. Moreover, some possible obstacles to the support platform emerged in this study. Limited computer experience is likely to make this treatment delivery format less efficient in some situations; indeed, not all the patients found the platform very easy to use. However, only two participants reported having limited computer experience and we did not include any additional evaluative questions. This implies that future studies should address the issue of computer experience in greater detail.

Conclusions

In sum, this study indicates that Internet-based support can be used without compromising the effects of CBT and that it in fact provides a vehicle for communication and for the structure of the therapy. This may be important for new therapists in training, but it is also potentially valuable to experienced therapists, who can have a tendency to drift away from the treatment manuals. Future studies should investigate the relative merits of adding a support system to face-to-face therapy and whether doing so facilitates retention and long-term learning. Studies are also needed to investigate the use of Internet-delivered support in more regular clinical settings with practicing CBT therapists.

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GA conceived the idea for the project, contributed to the manuscript, and received funding support for the project (professor's contract). KM contributed by designing the platform, managing the project, and contributing to the manuscript. MD participated as a clinical supervisor. ESR and EG contributed as therapists, conducted the pre- and post-treatment clinical interviews, and made major contributions to the manuscript. We would like to thank the therapists who volunteered to take part in the study: Daniel Goine, Frida Gustafsson, Nils Johansson, Peter Molander, Pontus Jonsson, and Sahar Gaveli. Finally, we gratefully acknowledge the work of our technician and programmer, Fredrik Nordell.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshots from the therapist's view of the platform. When the patient enters the support system, the view shows only information that is relevant to him or her. The therapist controls the visibility of this content.

[PDF File (Adobe PDF File), 1MB - [jmir_v15i12e280_app1.pdf](#)]

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Abbreviations

AUDIT: Alcohol Use Disorder Identifications Test

BAI: Beck Anxiety Inventory

CBT: cognitive behavior therapy

DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, 4th Edition

GAD-7: Generalized Anxiety Disorder—seven item version

ICBT: Internet-based cognitive behavior therapy

ICD-10: International Statistical Classification of Diseases and Related Health Problems, version 10

MADRS-S: Montgomery Åsberg Depression Rating Scale—self-report version

MySQL: My Structured Query Language

PHP: hypertext preprocessor

PHQ-9: Patient Health Questionnaire—nine-item version

QOLI: Quality of Life Inventory

RC: reliable change index

RCT: randomized controlled trial

SMS: short message service

SNRI: serotonin and norepinephrine reuptake inhibitors

SSL: secure sockets layer

SSRI: selective serotonin reuptake inhibitors

WHO: World Health Organization

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Letter to the Editor

Transparency of Health-Apps for Trust and Decision Making

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KEYWORDS

smartphone; technology; education; medicine; app; health care; Android; iPhone; BlackBerry; Windows Phone; mobile phone; standards

Smart devices such as smartphones and tablet PCs have become an integral part of everyday life as well as for professional applications. This is also true for medicine [1]. To enhance patient safety for medical apps or health apps that are to be used successfully in today's medical settings, a good information policy should always be part of the marketing strategy. Patients and doctors that are well informed about the benefits, limits, and risks of an app are in a better position to give more reasoning to their decisions whether they want to use it in a medical context or not.

To address the current shortcomings concerning the way information about apps is provided to potential users of apps, Lewis, in a recent letter to JMIR, proposed a set of standard criteria [2] analogous to those published by the Health on the Net foundation [3] to be used for assessing the utility of medical apps based on a systematic self-certification model. He suggested using a central platform for this purpose, for example, the United Kingdom National Health Service App Store, to allow registered developers of mobile medical apps to highlight the fact that they conform to these criteria. This would probably also give developers and distributors of such apps an advantage over their competitors.

While this certainly is a promising approach, I would like to add a few points. For one, in an international setting with users coming from various (and in many cases non-professional) backgrounds, it may be difficult to lead them to a separate platform that is not the standard app distribution platform that

users are accustomed to. This is especially the case for casual users who probably tend to use information that is readily available on the app stores or to simply read what other users have to say about an app.

In my opinion, the users themselves should not be disregarded in the overall process since they play an important role by applying the information they have at hand to the product they are interested in and evaluating whether it meets their needs. In contrast to other medical products (eg, for clinical use), where many professional users are confronted with already chosen products that have been labeled as appropriate by experts, many professionals or laypersons have to decide on the appropriateness of the medical app themselves. Therefore, especially for apps, ensuring patient safety also has to include the identification of the right product, in this case an app, that matches the desired setting and indication. Every piece of information covering the necessary aspects helps decision makers and/or end users in professional settings as well as for private use to determine whether an app can be trusted and safe. Thus, to ensure high impact, it would probably make sense to provide users with the appropriate information at places where they expect it (ie, directly in an app's description on the respective app store and/or on the manufacturer's homepage and/or marketing material). This should be done following a standardized structure that includes criteria with a clear rationale (Table 1), for example, in the form of a clearly structured app synopsis (Table 2) [4]. A basis for this was proposed in [5],

which also included the aspects mentioned in [2] with more detail.

There are already a number of existing initiatives and projects that use almost identical criteria to those suggested by Lewis, for example, the “Apps Peer-Review” by the Journal of Medical Internet Research (JMIR) launched in 2013 [6]. The JMIR mHealth disclosure form [7] also covers many of the concerns mentioned in the proposed app synopsis. Mostly, these projects reach this goal by installing certification and/or (third party) review processes and publishing the corresponding evaluation results using specific channels (eg, their own webpage or scientific journals). The app synopsis could be seen as a “first level” approach according to criteria already specified by previous projects dealing with quality assurance for Web-based information sources [8], though its focus is slightly different. At first, it could serve to provide all interested parties with sufficient information that, in addition to providing customers with basic information about an app, can then also be used as a starting point for building tests (eg, to identify the appropriate reviewers and testing methods, independent of the business model or revenue strategy that is employed by each respective

initiative). The current market players come from different backgrounds and thus also have different interests in mind. In Germany, for example, there are some initiatives focusing mainly on a single disease while others target health apps in general. Also, their funding strategies differ significantly, ranging from privately funded initiatives or publicly financed institutions to companies that are being paid on a case-by-case basis.

If manufacturers were to publish the necessary information following this app synopsis, both they as well as the users would clearly benefit. Users would receive a complete and easily comprehensible set of information that would support them in their decision making process while manufacturers would be able to follow the simple structure of the synopsis to compile the necessary information without expending too much effort since they only have to compile information that should already be available to them. Although this is not equivalent to an officially sanctioned certification process, information published according to the synopsis could nevertheless serve as a reference if there are any disputes between both sides.

Table 1. Criteria for assessing health apps and medical apps.

Criteria	Content	Rationale
Imprint	Information about the manufacturer/distributor and associates	To get in touch, to identify conflicts of interest (influence) of the sponsor and all associated parties
	Metadata of the app	To get basic information about the actuality of the app
Rationale	Description of the app’s intended purpose(s), targeted user(s), the dedicated setting of the app, its categorization as a medical / non-medical app	To understand the idea behind the app, its categorization on a professional level and its ideal deployment setting and field of application
Functionality	Description on the functionalities and features of the app and the restrictions and limits	To understand the underlying functions to achieve the app’s purpose(s) and its limits and risks to estimate whether the app is safe for usage
	Details about what measures have been taken to assure good usability of the app	To be informed about methods that were employed during the development cycle regarding the app’s usability for specific target groups
Validity and reliability	Description and reliability of information sources the app is based on	To assess whether the content and its authors are reliable and whether the functionality base on reliable and valid information sources
	Description of quality assurance methods	To estimate the level of quality in the production process of the app
Data requisitioning & management	Description of the amount and types of data that are being collected and processed	To be able to determine whether the app’s data collection & processing are adequate to fulfil the stated purpose
Data protection & privacy	Information about the manufacturer’s adherence to data protection and privacy laws and regulations and the involved jurisdictions	To find out whether the manufacturer provides a privacy statement and data protection policy that is well adapted to the app’s purpose
Data transmission & storage	Description of all measures taken to protect data entrusted to the app	To assess whether data transmission & storage is protected adequately

Table 2. Detailed description of items of the App-Synopsis for health apps and medical apps.

Item Category	Checklist Item	Sub Items	
1. Imprint	1.1 Meta Data	1. Operating system	
		2. Version number	
		3. Web link (project pages and link to the app store)	
	1.2 Developer/Distributor	4. Category: Commercial project, non-commercial project, other	
		5. Category: public access via an app store, only available to a restricted number of users/experts (in-house), other (please specify)	
		1. Information about the manufacturer/developer	
1.3 Sponsoring/Advertising	1.1 Name, address, webpage, contact person(s), email address, phone and fax number		
	2. Information about the distributor		
	2.1 Name, address, webpage, contact person(s), email address, phone and fax number		
2. Rationale	1. Information about the funding used for developing the app		
	1.1 Category: sponsoring, advertisements, other		
	2.1 Category	1. Category: medical product or not, if yes: which class; has the app been certified voluntarily (by whom?), uncertified app	
	2.2 User group	For each user group: 1. Specific disease/condition (or as an alternative/addition: which health care professions are targeted, etc) 2. Gender, age (range), other descriptive items	
	2.3 Setting	1. Clinical, outpatient setting, at home, other 2. Short description of a typical “use case”	
3. Functionality	2.4 Purpose	1. Short description of the purpose of the app 2. Category: information, reference work, educational resources, documentation, diagnostics, therapy, prevention, research, other 3. Basic description of what the app is to be used for including specific information for the user group(s)	
	3.1 Functions and Features	For each available function/feature: 1. Function (designation) 1.1 Example 1.2 Source(s) 1.3 Category: scientifically accepted, up-to-date content and reflects the current state of science and technology, evidence level if applicable	
		3.2 Restrictions and Limits	1. Restrictions and limits of the app 1.1 Specific description of the app’s restrictions and limits 1.2 Description of potential or existing risks for the user group(s) 1.3 Measures that have been implemented to avoid risks for the user group(s) 2. Already known undesirable effects 2.1 Detailed description of undesirable effects, if any
			3.3 Usability
	4. Validity and reliability		4.1 Content

Item Category	Checklist Item	Sub Items
		2. Information about source(s)/reference(s) for all content and algorithms integrated into the app 2.1 Specific information about the source(s) 2.2 Evidence level of the source(s) 3. Studies that have been performed concerning the app 3.1 Type of the study, references/literature, other evidence 4. Additional material about the app (test reports, etc) 4.1 Type of additional material, reference links, ...
	4.2 Quality assurance	1. Information about quality assurance measures that were used during development
5. Data requisitioning & management	5.1 Data handling	1. Data processing 1.1 Information about data collection mechanisms integrated into the app 2. Data protection & privacy 2.1 Voluntariness of participating in any data collection 3. Data transmission & storage 3.1 Purpose of the data collection 3.2 Who profits from the collected data 3.3 What kind of and how much data are being collected, at what times (including time intervals where applicable)? In which country is the data being stored? This is especially important considering the differences between data privacy laws and regulations in different countries. 3.4 Which methods are being used for storing and evaluating the data? 3.5 Specifics about user's rights to obtain information about any data that are stored about him; in addition, there must be means to revoke an already given permission to store data. For this purpose, a contact address must be specified. 3.6 It must also be possible to delete data that have already been stored and the user must be informed about the timespan that is needed until the data are really deleted. 3.7 Encryption methods and level used for protecting the user's data during transmission, storage and evaluation. It should also be specified whether it is possible to connect a specific user to the stored data or whether the data are being stored anonymously or pseudonymized. 3.8 An indication about whether it is possible to prevent data collection and/or transmission and if yes, how this is possible.

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Conflicts of Interest

None declared.

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