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Contents

Guest Editorial

Original Papers

Short Paper

Reviews

Tutorial

Corrigenda and Addenda

Guest Editorial

Intelligent Glasses, Watches and Vests…Oh My! Rethinking the Meaning of "Harm" in the Age of Wearable Technologies

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Abstract

The widespread release and adoption of wearable devices will likely accelerate the "hybrid era", already initiated by mobile digital devices, with progressively deeper levels of human-technology co-evolution and increasing blurring of our boundaries with machines. Questions about the potentially harmful nature of information and communication technologies have been asked before, since the introduction of the telephone, the Web, and more recently, mobile phones. Our capacity to answer them now is limited by outdated conceptual approaches to harm, mostly derived from drug evaluation; and by the slow and static nature of traditional research tools. In this article, we propose a re-conceptualizing of the meaning of "harm", which builds on a global effort focused on health, adding flexibility and richness within a context that acknowledges the physical, mental, and social domains in which it can occur.

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KEYWORDS

harm; digital telecommunication technology; wearable computing; Internet; conceptualization

Introduction

In April of 2013, Google announced the Explorer Program, which gave a small group of people the opportunity to use and test the first commercially available wearable computer that enables users to control all of the features of high-end mobile phones and additional augmented reality features using voice commands in natural language [1]. Anticipating a massive public launch of this product in 2014, other players accelerated their efforts to release or sell their own smart glasses, watches, clothes and even wigs. Together with a growing number of commercially available health and fitness monitors, these disruptive technologies promise to accelerate our move into a "hybrid age" [2].

At a time when at least 50% of the population of the world have access to at least one mobile phone [3] and with the number of mobile phone subscriptions expected to exceed the number of humans by the end of 2014, it is essential to ensure that any harm associated with the use of these powerful new devices is anticipated, quickly detected and prevented, or mitigated as much, and as soon as possible.

Questions such as; "Could this be addictive? [4]", "Could it hurt our children's brains? [5]", "Would this be making us dumb? [6]", "Could this ruin our relationships? [7]", or "Could this turn us into puppets? [8]", have been asked before about the technologies that have preceded wearable technologies, from the web to mobile phones. Answering these questions now is urgent as wearable technologies promise to be with us and on us most of the time with the ability to capture information from

us, our surroundings, constantly, broadcasting it to others, every instant of our lives.

Any attempt to assess the potentially harmful effects of wearable computers, however, will face two gaping holes in our defensive methodological armor. One of the holes is practical, as our traditional research designs, particularly those belonging to the quantitative realm, are unable to match the speed with which digital technologies are spreading and the dynamic ways in which they are affecting all aspects of our lives [9]. This was evident during the evaluation of the risk of cancer associated with mobile phones, as the validity of the data generated by sophisticated observational studies was threatened by the rapid changes in the technology itself and the way in which patterns of use were evolving during the study period [10]. Now, it would be nearly impossible to design prospective meaningful experiments on the risk of cancer, or any other major potential harmful effects of mobile phones because of the difficulties to find appropriate control groups.

The second hole is conceptual. Even if we had tools with the capacity to match the speed and protean nature of wearable technologies, we will soon realize that our notions of harm are outdated. Criteria that were created when most of the exposures were physical or time-limited, and driven by the need to assess the safety of drugs or invasive therapeutic interventions, can no longer keep up with our need to assess and monitor potentially harmful effects in "real-enough-time".

Our vocabulary of harm is also very limited when it comes to the richness of the digital world. Words such as "addiction", "problematic", "pathological" use, and "disorder" have been used to describe individuals, usually youth, who use the Internet or mobile technology at levels that appear excessive to clinicians [11]. This path, which reflects the medicalization of society that characterized the 20th century, carries the risk of labeling as mental disorders behaviors that may represent "a new normal" [12]. The widely criticized Diagnostic and Statistical Manual of Mental Disorders version 5 (or DSM-5) is of little help, as it only proposes criteria to diagnose "Internet gaming disorder" [13]. This tactic also offers little value because it presupposes the habit-forming properties of the relevant entity. A Medline search of the literature completed in November 2014 does not add much either, as the use of "harm" in combination with terms associated with digital telecommunication technologies failed to identify relevant conceptual frameworks.

This dearth of useful approaches of harm associated with the anticipated wave of wearable devices underscores the urgency with which it is necessary to hold a serious conversation involving clinicians, researchers, policy-makers and the general public. We need to ensure that these technologies can do more good than harm before we step into an era in which ubiquitous computing could not only amplify our human abilities, but also usher in a new way of life [14].

Given that wearable devices have not yet been introduced massively, we still have a cleaner context from which we could draw lessons that might give us new insights in relation to other mobile technologies. This process, unavoidably, must start with a better understanding of the meaning of harm in this new context, while building on the knowledge we have gathered in medicine until now.

Building on Efforts to Reconceptualize "Health"

Overview

In December 2008, Alex Jadad and Laura O'Grady issued a call for a global conversation about the meaning of health [15] initiated via a British Medical Journal (BMJ) blog, which grew to include a large number of comments from readers, many of which self-identified as health professionals [16]. As a result of this call to action, the Health Council of the Netherlands hosted a two-day conference attended by a multidisciplinary group of experts to continue the conversation. Guided by a review of the literature, the discussion culminated in a proposed conceptualization of health as the "ability to adapt and to self-manage" in response to physical, mental, or social challenges [17]. As harm is often conceptualized as detracting from health, we might want to build on this work and propose the conceptualization of harm as "any reduction in one's ability to adapt or to self-manage", as a result of the use of wearable computers. We could then use this as the foundation for a much wider discussion about harm, not only as it applies to mobile digital telecommunication technologies, but to information and communication technologies in general.

By conceptualizing rather than by trying to define "harm", as it was the case with "health", it may be possible to operationalize the term. As it is a dynamic construct, the conceptualization of harm might also add flexibility and richness by being placed within a context that acknowledges the physical, mental, and social domains in which it can occur. Such conceptualization might also enable the incorporation of elements of harm that have been extensively studied in relation to drugs or invasive therapeutic interventions, such as its severity, duration, reversibility, as well as frequency. The following examples attempt to illustrate this.

Physical Harm

Physical harm corresponds to any physiological or structural dysfunction that could be verified through a biological or medical lens. The main source of concern in this case is the exposure to the electromagnetic waves that all wearable devices emit in the radiofrequency range. Unlike the well-documented effects of ionizing radiation found in X-rays, it has been suggested that the emission of non-ionized radiation by wireless devices could cause genetic and structural cell damage leading to cancer, reproductive defects, neurological degeneration, or immunological disorders [18]. Research to estimate these risks would require studies taking into account that, unlike mobile phones, wearable devices are designed to communicate wirelessly all the time, with much lower levels of radiation emission.

Psychological Harm

This dimension refers to the lived experience of the users of wearable technologies. Therefore, it encompasses all of the negative emotions, moods, and behaviors that reduce a person's

ability to perform activities of daily living. Examples of potential psychological harm associated with wearable devices include stress in response to a constant barrage of messages requiring immediate attention, or anxiety and confusion from contradictory physiological measures generated by body monitors. Research to understand and describe this type of harm would require a phenomenological approach [19].

Social Harm

Social harm relates to negative effects of digital telecommunication technologies on communities or groups. This dimension is best understood through a normativist perspective [20], as it is concerned with the norms of goodness and badness in a human collective. Wearable devices, for instance, have the potential to increase harm resulting from privacy violations, cyber-bullying, and abusive handling of personal data by surveillance agencies [21]. These cannot be studied using a medical approach or a phenomenological methodology, because they belong to the cultural, political, and economic realms. Rather, they demand the participation of researchers from the humanities and social sciences.

What Next?

By conceptualizing rather than by trying to define "harm", as it is proposed here, it would be possible to operationalize the term as a dynamic construct, with the flexibility and richness needed to acknowledge the physical, mental, and social domains in which it can occur. The proposed conceptualization would also enable the incorporation of elements of harm that have been extensively studied in relation to drugs or invasive therapeutic interventions, such as its severity, duration, reversibility, as well as frequency.

This effort should be taken many steps further. We invite readers to join a global conversation to express their views about our proposal, and to consider supporting the kind of collaborative and iterative processes that are needed to spark and share ideas, which may lead to a better understanding of the potential harm associated with wearable devices.

All it would take to contribute to the conversation. On Twitter, those interested could engage in the conversation by using the hashtag #rethinkingharm and citing the link to this article (which will make the comment appear as tweetation next to this article), or visit the Facebook page, "Rethinking the meaning of harm in the age of wearable technologies." We also welcome submissions of letters to the editor as well as full articles which propose fresh insights in this area to the "Wearable Devices" section of JMIR mHealth and uHealth.

During the year following the publication of this guest editorial, we will review all of the contributions made by readers to the conversation, using the principles of qualitative content analysis. The meanings of sections of data will be noted using codes that will be developed inductively. Those with similar codes will be grouped into the physical, mental, and social domains of the conceptualization, whenever possible, while those that do not fit will form subcategories, which will be combined to form new categories. All of the responses that lead to an important addition to the conceptualization will be acknowledged. We hope that this call to action will yield many new insights into how we could protect ourselves, and future generations, as we move forward into a new era of human interconnectedness.

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Conflicts of Interest

None declared.

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Abbreviations

BMJ: British Medical Journal
DSM-5: Diagnostic and Statistical Manual of Mental Disorders version 5

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Original Paper

Validation of a Portable Device for Mapping Motor and Gait Disturbances in Parkinson's Disease

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Abstract

Background: Patients with severe idiopathic Parkinson's disease experience motor fluctuations, which are often difficult to control. Accurate mapping of such motor fluctuations could help improve patients' treatment.

Objective: The objective of the study was to focus on developing and validating an automatic detector of motor fluctuations. The device is small, wearable, and detects the motor phase while the patients walk in their daily activities.

Methods: Algorithms for detection of motor fluctuations were developed on the basis of experimental data from 20 patients who were asked to wear the detector while performing different daily life activities, both in controlled (laboratory) and noncontrolled environments. Patients with motor fluctuations completed the experimental protocol twice: (1) once in the ON, and (2) once in the OFF phase. The validity of the algorithms was tested on 15 different patients who were asked to wear the detector for several hours while performing daily activities in their habitual environments. In order to assess the validity of detector measurements, the results of the algorithms were compared with data collected by trained observers who were accompanying the patients all the time.

Results: The motor fluctuation detector showed a mean sensitivity of 0.96 (median 1; interquartile range, IQR, 0.93-1) and specificity of 0.94 (median 0.96; IQR, 0.90-1).

Conclusions: ON/OFF motor fluctuations in Parkinson's patients can be detected with a single sensor, which can be worn in everyday life.

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KEYWORDS

accelerometer; kinematic sensor; motor fluctuations

Introduction

The ON/OFF Phase Detection

Patients with idiopathic Parkinson's disease (PD) report fluctuations between an ON-phase—where symptoms are under control—and an often suddenly starting OFF-phase, where many symptoms reappear and their gait turns abnormally slow.

Collecting precise information on the temporal course of OFF episodes (onset and duration) is essential for adjusting a therapy schedule aimed at preventing motor fluctuations in PD patients (ON/OFF changes). The time-in-OFF is the main parameter used to evaluate the effectiveness of a pharmacological intervention and compare the action of different active principles in clinical trials [1].

Currently, the most common method of collecting such information consists in asking the patients to keep an ON/OFF diary. However, this method is rather time consuming for the patient and has a number of limitations, including recall bias and reduced compliance, which make it unsuitable for medium and long term monitoring in clinical practice [2].

Therefore, portable electronic detectors, which could reliably and automatically record patient's motor fluctuations would be welcome. Patients could wear such devices in their daily life activities, provided that devices were small and autonomous enough. Furthermore, the use of such devices would open the possibility of automatic or semiautomatic real-time control of drug infusion rates in currently available drug-pumps (apomorphine or duodopa pumps). Thus, it would be possible to increase the dose when the beginning of an OFF-phase is detected and to reduce it again by the beginning of a new ON-phase.

Up to the moment, experiments with inertial sensors (mainly accelerometers and gyroscopes) have been conducted with the aim of producing a detector capable of determining whether a patient is in ON or OFF [3-6]. Such experiments, however, were carried out in controlled settings (laboratory), where the patients were asked to perform specific maneuvers (eg, sections of the Unified Parkinson's Disease Rating Scale) while wearing the sensors (generally, several sensors located on different parts of the body). In most of these experiments, OFF periods were artificially induced by prolonged withdrawal of the patients' habitual medication. The so induced OFF periods are usually deeper and more clearly defined than OFF periods naturally occurring to patients on their habitual medication. Therefore, the suitability of algorithms validated under controlled conditions to detect natural spontaneous OFF-periods in real life situations (medicated patients in their natural environment) cannot be assured.

The Present Study

The present study was designed as proof of concept for evaluating the feasibility of reliably detecting motor fluctuations in patients performing daily life activities in their habitual environment. The tested device consisted of a unique component attached to the patient's waist, which was easily portable in real-life conditions. In this article, we report the validity of data corresponding to measurements taken by the tested device.

Methods

Design

Algorithms for processing the signals produced by a portable inertial sensor (triaxial accelerometer) designed to detect motor fluctuations (ON/OFF) in Parkinson patients were developed and validated. The study was conducted in two parts. In the first part, an inertial signal database was created with data recorded from 20 patients who were asked to wear the sensor device attached to their waist (Figure 1 shows this device). The algorithms to detect different motor phases were developed using this database. In the second part, the algorithms were validated with data from a new sample of 15 patients (who did not take part in the first part) who were asked to wear the same device.

Figure 1. Portable inertial sensor and the neoprene belt where the sensor was inserted.

Participants and Settings

This study was carried out during 2008 and 2009, with patients between 55 and 75 years of age, living in the Barcelona area, who had been diagnosed to have idiopathic PD according to the criteria of the Brain Bank, London [7]. Only patients with moderate-severe PD and motor fluctuations were included in the second part of the study (while patients with milder forms of the disease, who did not have motor fluctuations, had been allowed to participate in the first part).

Volunteer patients were recruited by convenience sampling among members of local Parkinson patients associations

(Associació Catalana per al Parkinson) and patients visiting the Neurology Department of the Consorci Sanitari del Maresme (Barcelona), the Teknon Medical Center (Barcelona), and the University Hospital of Bellvitge (Barcelona).

Participants finally included in the study were 64 years old on average; 27 (77%, 27/35) of them were men and 8 (23%, 8/35) were women. The median number of years of progression of the disease was 9.5 (interquartile range, IQR, 2-18) and the median Hoehn and Yahr score was 3 (IQR 1-4).

The first part of the study was conducted in the facilities of the Universitat Politècnica de Catalunya and two regional hospitals: (1) Consorci Sanitari del Garraf, and (2) Consorci Sanitari del Maresme, all of them located in Barcelona (Spain). The second part was conducted at the patients' homes.

The Ethical Committee of the Consorci Sanitari del Maresme approved the protocol of the study. All participants signed an informed consent form before their inclusion in the study.

Procedure for Data Collection

A unique research team (a physician, two nursing assistants, and three engineers) specifically trained in the procedures of the study and the administration of the involved questionnaires collected the data.

In the first part of the study (20 patients), data were collected and used to create processing algorithms for detection of ON/OFF motor fluctuations. A first group of 10 patients participated in an experiment under controlled conditions; they were asked to walk 5 meters straight (3 times) while wearing the inertial sensor device attached to the waist (left side). Patients who presented motor fluctuations repeated this experiment both in ON and OFF. The remaining 10 patients participated in another experiment under controlled and uncontrolled conditions. They were asked to complete a movement circuit in the laboratory (controlled conditions), which included walking straight, walking up and down stairs, walking up and down inclined planes, making turns, taking different positions such as sitting, standing up or lying down, walking while carrying a glass of water, walking while carrying a heavy object, and other more complex activities, such as setting the table for a meal. After the circuit, they were asked to take a 15-minute walk outdoors (uncontrolled conditions). Patients who presented motor fluctuations went through this protocol both in ON and OFF. In this first part of the study, reducing patients' dopaminergic medication, when necessary, could induce the OFF status.

In the second part of the study, the processing algorithms developed with data from the first part were validated on 15 new patients. These patients were asked to wear the sensor device during 3 to 5 hours while performing their habitual activities in an environment that was familiar to them (home, neighborhood, or habitually visited places). During this validation phase, the OFF status was not induced by modifying patients' medication schedules; OFF data were collected during naturally occurring OFF episodes. With the aim of increasing the probability of recording at least one naturally occurring OFF episode during the monitoring hours, on the day of the experiment, patients were appointed at the time they typically experienced OFF status.

Measurement Instruments and Control Variables

The sensor used to record inertial signals is a prototype of an inertial measurement unit developed at the Universitat Politècnica de Catalunya, which includes triaxial sensors to record acceleration in their space frame [8]. The triaxial sensor of lineal acceleration (LIS3LV02DQ, STMicroelectronics) can be used to measure acceleration magnitudes up to ±6 G (1 G=9.81 m/s^2), with 2.404 mg sensitivity and 2% maximum nonlinearity on the full scale range. The inertial device is "wearable" and equipped with data processing and wireless information transfer capacities and rechargeable batteries. The sensor sampling frequency was 200 Hz. Signals obtained were downsampled to 40 Hz, since this last frequency is enough to obtain 99% of the acceleration power during walking [9].

Video recording was the gold standard used to identify patients' movements, positions, and ON-/OFF-episodes in experiments under controlled conditions (laboratory) in the first part of the study. Physicians experienced in movement disorders reviewed videos. Additionally, patients were asked to confirm the occurrence of ON-/OFF-episodes. No discrepancies were found between patients' self-reported motor status and expert diagnosis based on video review.

The gold standard used in experimental procedures conducted under uncontrolled conditions (on the street, at home, etc), both in the first and the second parts of the study, was an observer trained in motor symptoms recognition, who accompanied the patient all the time and recorded the occurrence of ON-/OFF-episodes. Patients were asked to confirm the occurrence of every observed ON-/OFF-episode before recording it. For intermediate status between OFF and ON reported by the patients, the term "intermediate" was used. In case patient and observer disagreed about the motor status, the period was labeled "undefined". Data were recorded in real-time using a personal digital assistant (ultra mobile personal computer) with software developed by researchers from the Universitat Politècnica de Catalunya. The software required the researcher to update the patient's motor status every 30 minutes. The researchers in charge of gold standard reading were blind to the results of the algorithms.

After the experimental sessions, patients were administered a specific questionnaire of usability; they were asked about the comfort of wearing the sensor (Likert scale, 1 to 5), possible movement hindrance (yes, no, or slight), preferred location of sensor (waist, legs, or feet), and willingness to wear it daily (open answer). Additionally, by using structured questionnaires, control variables and descriptive data were collected. Such additional data were: (1) sex, (2) age, (3) Hoehn and Yahr stage, (4) year of diagnosis, (5) time of evolution of the disease (in years), and (6) complete list of medicines.

Signal Processing and Analysis Methods

Overview

Inertial data recorded by accelerometers during the first part of the study were used to develop soft-computing techniques aimed

at identifying the ON/OFF status. The developed algorithms are described in this section.

The method used to characterize the ON/OFF status has been published elsewhere [10]. The method is based on analyzing patients' motion fluency while walking and consists of four phases.

Phase 1

The first phase is focused on detecting walking periods. The accelerometer signal was represented as the summation of the three axis of spectral power in the [0.1, 3] Hz and [0.1, 10] Hz ranges, contained in 3.2 second windows (128 samples at 40 Hz). These two features were selected among frequency ranges $[b_1, b_2]$ that satisfied $b_1, b_2 \varepsilon \{0.1, 0.2, \ldots, 19.8, 19.9, 20\}$, $b_2 > b_1$ by means of a ReliefF feature selection algorithm [11]. Both features were used as input for a support vector machine (SVM) [12] whose output was used to classify every window as "walking" or "not walking". The SVM used a radial basis function kernel, and its parameters C and γ were set through a stratified 10-fold cross-validation process applied to data from first part of the study.

Phase 2

The second characterization phase was focused on detecting patients' strides. The principles described by Zijlstra and Hof [13]—based on the behavior of inertial measurements recorded from the L3 vertebra during gait—were adapted to the location of the sensor in this study. These principles are focused on detection of relative extrema in the forward acceleration signal that are known to correspond to the initial contact event of the gait cycle. Since fragments corresponding to gait initiation and termination were considered irrelevant to detection of "walking" or "not walking", the first and last window of each detected period were left out of the stride detection analysis.

Phase 3

In the third ON/OFF characterization phase, the strides detected during the second phase were evaluated through the spectral power in the [0.1, 10] Hz range. This frequency range was found to maximize ON/OFF discrimination as measured through the area under the receiver operating characteristic curve, in the above-mentioned frequency ranges $[b_1, b_2]$. The resulting measurement was a representation of a stride, which was proportional to the patient's motion fluency, the higher the value, the deeper the ON status [14].

Phase 4

In the last phase, all fluency values that represented the strides of a same gait episode were averaged (disregarding the two initial and two final strides). The averaged value was compared with a threshold (unique to every patient) to determine the patient's motor status at that moment. If the averaged measurement was higher than the threshold, the motor status was considered to be ON. Conversely, if the averaged measurement was equal or lower than the threshold, the motor status was considered to be OFF. The threshold was adapted to every individual patient by using 20% of the data available from the patient.

Statistical Analysis

To assess the validity of the algorithms developed in the first part of the study, they were applied to the inertial signals recorded during the second part. The outcomes of the algorithms were compared with reference standards. Thus, data from participants in the first part—used to create the algorithms—were not used in the validation process.

To assess the validity of the ON/OFF detection algorithm, its results (continuous numerical variable) had to be classified into "ON" or "OFF" categories after establishing a splitting ON/OFF threshold. As described in the above section Signal Processing and Analysis Methods, the value of such threshold is specific for every Parkinson patient and has to be individually established. Thus, although the algorithm was developed in the first part of the study, individual thresholds were established for patients who participated in the validation phase (second part).

To establish the ON/OFF splitting threshold for patients in the second part of the study, measurements describing a patient's strides were split into two datasets, one of these datasets was used to fix the threshold, while the other dataset was used to assess the validity of the algorithm against that threshold. The first dataset was a randomly selected 20% of measurements consecutively recorded both in ON and OFF. The remaining data were included into the second dataset. All the validity values reported in this article correspond to the analysis of the second dataset. To minimize the effects of arbitrary selection of the data used to establish individual thresholds, the random splitting process was repeated 30 times.

ON/OFF splitting was established through a SVM with a linear kernel. Since the data to be classified were scalar, the splitting hyperplane found during the training process with the first dataset was a scalar value from which the threshold took its value. Therefore, when enough data were available (at least 10 patterns for every class), 10-fold cross validation (CV) was used; otherwise, 2-fold (minimum) CV was used. SVM with linear kernel was used to follow the maximum margin principle that ensures a good generalization since the Vapnik-Chervonenkis dimension was maximized [12].

The sensitivity, specificity, and positive and negative predictive values corresponding to the ON/OFF detection algorithms were calculated. The ON/OFF algorithm was studied by applying it, on the one hand, to all the detected walking segments and, on the other hand, to segments containing 10 or more strides.

There were five minutes of signal, before the start and after the termination of a motor phase, that were excluded from the analysis as they were considered to be in the margin of synchronization error with the gold standard (a time margin was allowed for the patient and the observer to notice and report a change in motor status). Signal segments corresponding to undefined or signal segments lacking comparison standard because of technical errors or artifacts were disregarded. Motor phases defined as intermediate between ON and OFF were also disregarded, since a gold standard for such phenomena is not available (in current clinical practice, ON/OFF is dichotomous concept).

The validity of the algorithms was studied for individual patients and the results were averaged.

Results

A total of 46.9 hours of inertial sensor signals were recorded, which corresponded to the motion records of the 15 subjects who participated in the validation phase (a mean of 3.1 hours per patient, range 1.4-5.5 hours). The ON/OFF detection algorithm applied to these data yielded valid 1562 results, 1196 of them corresponded to ON (863 of them derived from walking segments of 10 or more strides), 366 corresponded to OFF (267 derived from walking segments of 10 or more strides), and 276 corresponded to intermediate between ON and OFF. The detection algorithm produced an output every 1.09 minutes on average (SD 4.25 minutes; maximum time without producing an output, 70 minutes) for a walking segment. However, when only segments with 10 or more strides were considered, the detection algorithm made a decision every 3.9 minutes on average (SD 10 minutes; maximum time without producing an output, 136 minutes).

For four patients participating in the second part of the study, the recorded motor data (ON/OFF) were not enough to apply the validation method. For the remaining 11 patients, the mean validity values for the ON/OFF detector were, sensitivity 0.91 (median 1; IQR 0.85-1), specificity 0.90 (median 0.92; IQR 0.81-0.92), positive predictive value 0.80 (median 0.80; IQR 0.70-0.95), and negative predictive value 0.94 (median 1; IQR 0.89-1). When only walking segments of 10 or more strides were considered (there were 10 patients with a complete dataset), the mean validity values were, sensitivity 0.96 (median 1; IQR, 0.93-1), specificity 0.94 (median 0.96; IQR 0.90-1), positive predictive value 0.90 (median 0.92; IQR 0.80-1), and negative predictive value 0.98 (median 1; IQR 0.97-1).

Table 1 shows the sensitivity, specificity, and positive and negative predictive values for the ON/OFF detection algorithm. The time the participants spend in the different motor phases (ON/OFF) and the number of walking bouts analyzed is also shown in Tables 1 and 2.

Figure 2 shows as an example the results produced by the ON detection algorithms, together with the corresponding motor state (ON/OFF) gold standard for patient number 3. This figure shows the intermittent detection of the ON-OFF phase provided by the sensor (the outcome of the algorithm is a continuous numerical variable), the motor state reported by the participant and verified by an observer (ON/OFF or an intermediate phase), and the threshold found that allows distinguishing both motor states.

All of the participants rated the comfort of wearing the sensor 4 (good) or 5 (very good). None of them reported the sensor to hinder or restrict their activity, and only one patient would refuse wearing it daily. Only one participant preferred the sensor to be located on the leg.

Table 1. Algorithm applied to walking segments of any length.

Patient	H&Y[a]	# Segments OFF	# Segments ON	Minutes OFF	Minutes ON	Specificity % (SD)	Sensitivity % (SD)	PPV %[b](SD)	NPV %[c](SD)
1	3	86	15	22	122	97 (4)	100 (0)	99 (1)	100 (0)
2	4	23	118	107	161	92 (12)	100 (0)	81 (27)	100 (0)
3	3	5	25	7	213	-	-	-	-
4	3	21	37	26	125	83 (13)	89 (23)	80 (15)	95 (9)
5	2.5	18	97	18	276	99 (1)	100 (0)	95 (3)	100 (0)
6	3	14	120	7	159	94 (4)	100 (0)	70 (2)	100 (0)
7	2.5	25	42	5	159	96 (3)	100 (0)	94 (5)	100 (0)
8	2	15	121	3	138	90 (4)	100 (0)	59 (17)	100 (0)
9	2	5	205	3	327	-	-	-	-
10	4	38	44	11	13	80 (27)	56 (23)	76 (31)	70 (14)
11	1.5	0	50	0	191	-	-	-	-
12	2.5	17	162	22	260	81 (16)	85 (20)	48 (30)	99 (2)
13	3	40	13	41	179	100 (0)	90 (5)	100 (0)	77 (11)
14	2.5	0	60	2	73	-	-	-	-
15	3	59	87	37	107	77 (11)	80 (32)	71 (10)	89 (15)

[a]H&Y=Hoehn and Yahr scale

[b]PPV = positive predictive value

[c]NPV = negative predictive value

Figure 2. Upper figure shows sensor's measurements along time for patient 2. Threshold found to separate motor states is also depicted. Lower figure presents the corresponding gold standard, which is the reported motor status according to patient-2 diary. hh:mm = hour and minutes.

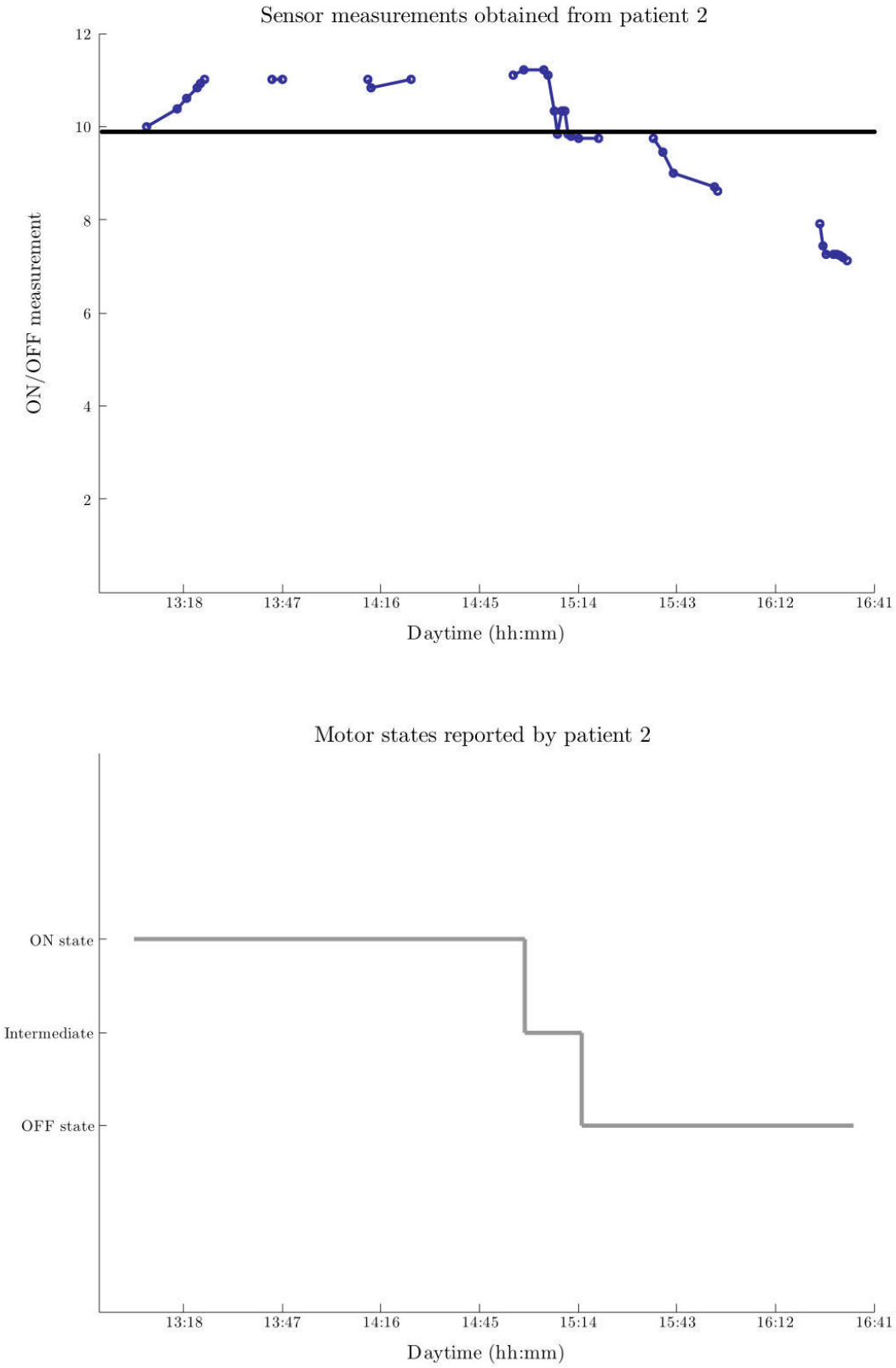

Table 2. Algorithm applied to walking segments of 10 or more strides.

Patient	H&Y[a]	# Segments OFF	# Segments ON	Minutes OFF	Minutes ON	Specificity % (SD)	Sensitivity % (SD)	PPV %[b](SD)	NPV %[c](SD)
1	3	74	14	22	122	95 (5)	100 (0)	99 (1)	100 (0)
2	4	10	84	107	161	94 (3)	100 (0)	68 (15)	100 (0)
3	3	5	5	7	213	-	-	-	-
4	3	8	21	26	125	88 (9)	96 (7)	78 (15)	99 (3)
5	2.5	9	91	18	276	100 (0)	100 (0)	100 (0)	100 (0)
6	3	9	88	7	159	100 (0)	100 (0)	100 (0)	100 (0)
7	2.5	25	41	5	159	96 (0)	100 (0)	94 (4)	100 (0)
8	2	12	114	3	138	97 (4)	100 (0)	81 (21)	100 (0)
9	2	0	160	3	327	-	-	-	-
10	4	28	30	11	13	83 (26)	82 (11)	87 (17)	86 (8)
11	1.5	0	5	0	191	-	-	-	-
12	2.5	5	85	22	260	-	-	-	-
13	3	29	10	41	179	100 (0)	100 (0)	100 (0)	100 (0)
14	2.5	0	45	2	73	-	-	-	-
15	3	53	70	37	107	90 (8)	83 (24)	89 (7)	91 (13)

[a]H&Y=Hoehn and Yahr scale

[b]PPV = positive predictive value

[c]NPV = negative predictive value

Discussion

Principal Results

In the present study, an algorithm was validated to detect motor fluctuations in patients with idiopathic PD, on the basis of inertial signals produced by a sensor attached to the patient's waist. The high mean specificity and sensitivity values found for walking segments with 10 or more strides indicate good validity for this ON/OFF detection algorithm.

Results from patient 10 showed low sensitivity (0.56) when any walking segment was considered. However, sensitivity reached 0.82 for the longest segments. Similarly, the positive predictive value (PPV) for patient 15 was 0.48 when all the walking segments were considered, but reached 0.82 for the longest ones. Thus, the analysis of data from both patients required disregarding short walks since, in the first case, ON segments could be confused with OFF segments and, in the second case, false positives could arise. Regarding patient 12, PPV was 0.48 due to a low number of OFF segments (8), and a similar number of false OFF positives. However, specificity and sensitivity values—less dependent on the sample size—were much higher (>0.8).

Other researchers attempted to identify the patient's motor status. However, up to our knowledge, all of them used algorithms validated in the laboratory setting [3-6], although in some studies patients performed natural or spontaneous activities [3,6]. Keijers et al [3] validated a neural network-based algorithm in a controlled environment with specificity and sensitivity values slightly higher than ours (~0.96). These higher values could be due to the fact that they used the same data set both in the training and the evaluation of the neural network. These authors, however, disregarded long gait episodes, which can actually be analyzed with our algorithm. It could thus be speculated that both algorithms could be complementary. Hoff et al [6] also reported validation results of motor fluctuations during natural activities. However, their specificity and sensitivity values were lower than ours, and those of Keijsers et al [3]. Patel et al [4] reported highly accurate results of monitoring motor fluctuations with accelerometers placed on 8 different parts of the body, in patients performing specific motor tasks. However, although such an approach is useful to estimate the severity of the symptoms, it is not suitable for monitoring the motor status during daily life activities. Additionally, unlike systems used by other researchers [3-6], our system consisted of only one device attached to the waist, which made it easily portable and comfortable.

The relevance of automatic detection of the motor status resides in providing accurate information for physicians to adjust medication schedules, and the possibility of real-time modifications of drug infusion rates, for example, in apomorphine or duodopa pumps. Thus, the infusion rate or bolus administration could be automatically increased upon detection of an OFF phase. The possibility of mapping a subject's motor activity, and objectively determining the time spent in ON or OFF, may additionally promote the use of such detectors in clinical trials for a more reliable determination of subjects' responses to experimental medication.

Limitations

A limitation of our motor status (ON/OFF) detection algorithm derives from the fact that it is based on the analysis of patients' movements while walking. Thus, the algorithm is unable to detect status changes when the patient is at rest. This may lead to the occurrence of long periods without motor information, which is especially critical since patients in OFF tend to stay still. In our opinion, further studies are required to detect OFF periods when patients are at rest (one of the objectives of the ongoing REMPARK project) [14]. However, since patients, even in moderate or advanced phases of the disease, walk more than 40 times per day [15,16], a system like ours, could still produce enough frequent detections. Although not continuous, detection of the motor status with our system could provide very useful information for a better clinical monitoring, since the ON/OFF periods usually last for 1 to 3 hours [17]. At present, no detection system at all is available to neurologists, and they have to rely on patients' or caretakers' reports to figure out the motor fluctuations. Certainly, a system that allows monitoring the motor status, even in an intermittent way, would be seen as a big step forward. Finally, it is worth mentioning that in our study the few OFF data recorded for some participants were more related to the short time they spent in OFF than to a lack of activity when they were in OFF.

The fact that the threshold has to be fixed for every individual patient requires an extra visit to calibrate the sensor. However, it is a simple procedure that in clinical practice would require the patient to take two short walks, one in OFF and one in ON. As the disease progresses, recalibration of the sensor may be necessary.

In technologically complex studies that require the use of technological research prototypes, the sample size is often small, a fact that undoubtedly poses limitations to generalization of results. We postulate that conducting further studies to evaluate the validity of the algorithm with larger samples and longer monitoring times is worth the effort.

Conclusion

In conclusion, our results support the use of portable devices, easily accepted by patients with idiopathic PD for monitoring motor fluctuations in their habitual environment. The use of such devices would open the way to enhanced control of pharmacological therapy and to interactions with other electronic devices, such as drug infusion pumps.

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Conflicts of Interest

None declared.

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Abbreviations

CV: cross validation
IQR: interquartile range
PD: Parkinson’s disease
PPV: positive predictive value
SVM: support vector machine

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Original Paper

Knowledge, Attitudes, and Practices Regarding Avian Influenza A (H7N9) Among Mobile Phone Users: A Survey in Zhejiang Province, China

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Abstract

Background: Understanding people's knowledge, attitudes, and practices (KAP) regarding a new infectious disease is crucial to the prevention and control of it. Human infection with avian influenza A (H7N9) was first identified on March 31, 2013 in China. Out of the total number of 134 cases confirmed from March to September 2013 in China, Zhejiang Province saw the greatest number (46 cases).

Objective: This study employed a mobile Internet survey to assess KAP regarding H7N9 among mobile phone users in Zhejiang Province. This study intended to examine KAP by region and the association between sociodemographic variables and KAP.

Methods: An anonymous questionnaire was designed by Zhejiang Provincial Center for Disease Control and Prevention (CDC). A cross-sectional survey was executed through a mobile Internet application platform of China Unicom in 5 regions in Zhejiang Province. Stratified and clustered sampling methods were applied and mobile phone users were invited to participate in the study voluntarily.

Results: A total of 9582 eligible mobile phone users participated in the survey with a response rate of 1.92% (9582/5,000,000). A total of 9105 valid responses (95.02%) were included for statistical analysis. Generally, more than three-quarters of the participants had some basic knowledge of H7N9 and held the attitude recommended by the Zhejiang CDC toward eating cooked poultry (77.55%, 7061/9105) and visiting a hospital at the occurrence of symptoms (78.51%, 7148/9105). Approximately half of the participants worried about contracting H7N9, and took preventive practices recommended by the Zhejiang CDC. But only 14.29% (1301/9105) of participants kept eating cooked poultry as usual. Although worry about H7N9 infection did not differ by region, Hangzhou saw the largest proportion of participants with knowledge of H7N9, which was probably because Hangzhou had the greatest number of H7N9 cases. KAP varied by some sociodemographic variables. Female participants were more likely to know about symptoms of H7N9 (OR 1.32, 95% CI 1.08-1.61), to worry about contracting it (OR 1.15, 95% CI 1.04-1.27), and to report their lives being influenced by it (OR 1.27, 95% CI 1.15-1.41). They were also more likely to take the recommended precautions. Male participants and younger participants were less likely to comply with advocated protective practices.

Conclusions: The results suggest that health education should be customized depending on sociodemographic variables to achieve more effective behavioral outcomes.

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KEYWORDS

influenza A virus, subtype H7N9; knowledge; attitude; surveillance

Introduction

On March 31, 2013, the Chinese government announced 3 cases of human infection with the avian influenza A (H7N9) virus in 2 provinces [1]. From March to September 2013, a total of 134 cases were identified in 12 provinces with Zhejiang Province seeing the largest number 46 cases, including 11 deaths [2]. The number of confirmed cases in Hangzhou, the capital city of Zhejiang Province, was the largest [2]. Most H7N9 patients had reported recent exposure to live poultry [1]. Clinical symptoms at the onset of the illness include a high fever (≥38°C) and a cough. As the disease progressed, patients could develop dyspnea or severe progressive pneumonia, and could rapidly develop acute respiratory distress syndrome [2-4].

Given China's high population density, prevention and control of new infectious diseases is particularly challenging. There was limited knowledge available about H7N9 when it struck, which raised many public health concerns globally [5]. To prevent and control H7N9, the Zhejiang Province Government implemented a series of interventions, including increasing the emergency response level and closing live poultry markets. During the outbreak of H7N9, the Zhejiang Provincial Center for Disease Control and Prevention (CDC) used different means to conduct health education to encourage the public to take preventive behaviors. For example, the Zhejiang CDC published a booklet titled "Common Respiratory Infectious Diseases Booklet." The printed booklets were given away in communities and the electronic version was uploaded to the Zhejiang CDC's website for downloading. The Zhejiang CDC made full use of major media outlets, such as *Zhejiang Daily* and *Zhejiang Television*, and they also set up a 24-hour hotline. In addition, the Zhejiang CDC used 2 accounts, named China Health Education and Zhejiang Health Education, on Sina Weibo, a Twitter-like Chinese microblog, to disseminate information about behaviors to prevent respiratory communicable diseases.

Inaccurate information and negative attitudes toward emerging communicable diseases may lead to unnecessary concerns, rumors, social chaos, and even excessive panic, which might aggravate the epidemic [6]. Quick-spreading rumors of the outbreak of H7N9 were found in most provinces in China. Previous experience with severe acute respiratory syndrome (SARS) has demonstrated the importance of monitoring public perception of epidemic control, which may affect the public's compliance to advocated precautionary behaviors. Elucidation of factors that may affect precautionary behaviors, such as knowledge and risk perception of the disease, may also help to prevent the spread of infection. Previous studies have demonstrated the positive correlation between perceived infectiousness and the willingness to adhere to recommended behaviors that prevent and control infection [7,8]. Therefore, it is important to assess the public's knowledge, attitudes, and practices (KAP) regarding H7N9 [9]. Specifically, this study evaluated KAP among mobile phone users in Zhejiang Province. Findings of the current study can provide information about the effectiveness of the Zhejiang CDC's health education efforts as well as how to design evidence-based interventions to reduce the risks of contracting H7N9 among the public.

Examining KAP in traditional ways, such as paper-and-pencil questionnaires, involves a great amount of human and material resources and can also take a long time. Considering that increasingly more people used mobile phones to access the Internet, we conducted a mobile Internet survey. According to the China Internet Network Information Center [10], Zhejiang Province had 65.22 million mobile phone users in January 2013, of which 4.81 million were mobile Internet users [11].

Methods

Overview

Zhejiang Provincial CDC designed and conducted the cross-sectional and closed survey among mobile phone users in Zhejiang Province regarding H7N9 during the outbreak of this new avian influenza. We described the survey and reported results according to "Checklist for Reporting Results of Internet E-Surveys (CHERRIES)" [12].

Study Site

We performed this study in 5 regions in Zhejiang Province; 4 regions—Hangzhou, Jiaxing, Huzhou, and Shaoxing—reported cases of H7N9 and 1 region—Ningbo—did not.

Participants

China United Network Communications Group Co, Ltd (China Unicom) has a modern communications network characterized by nationwide coverage and global reach. China Unicom is one of China's largest mobile phone carriers. Participation was voluntary without any financial incentive. Participants' personal information was kept confidential and stored at China Unicom. A total of 500,000 users from the 5 examined regions in the database of China Unicom were selected. According to the registered information, mobile phone users of at least 15 years of age were sampled. Mobile phone users whose mobile phones were switched off were not studied. Participants who did not fully complete the questionnaire were excluded. In addition, after a further check of users' information, participants whose phone number did not associate with registered information and participants who used the wireless network card phone numbers were also excluded.

Procedure

Stratified and clustered sampling methods were employed to select the mobile phone numbers. Then a brief message was sent to the selected mobile phone users inviting them to participate in the study voluntarily. The message contained the link to an online questionnaire. The message also contained information about the investigator, the purpose of the study, and the need for a response within 24 hours. The major advantage of an Internet-based investigation is the ability to quickly recruit a large number of participants with lower cost.

Survey Questionnaire

The online questionnaire, designed by the Zhejiang CDC, listed 16 questions on 1 page. The first 2 questions were about knowledge of H7N9: 1 addressing its symptoms and the other addressing its transmission routes. The next 4 questions were about participants' attitudes toward H7N9. Two focused on

worry and concern, and 2 on the attitude advocated by the Zhejiang CDC. Specifically, participants answered whether they worried about contracting H7N9 and the extent to which their daily lives had been influenced by H7N9. Regarding the attitude recommended by the Zhejiang CDC, participants stated whether they believed it was safe to eat cooked poultry and what they would do if they had a fever and/or a cough. Then participants answered questions about their adoption of 2 preventive practices recommended by the Zhejiang CDC, which were avoiding crowds and increasing the frequency of hand washing. Finally, participants answered sociodemographic questions about age, gender, occupation, and education. The questionnaire was executed through a mobile Internet application platform of China Unicom from April 25 to May 2, 2013. A total of 500,000 messages were sent. The study was approved by the Ethics Committee of Zhejiang Provincial CDC.

Data Analysis

Data were analyzed using SPSS version 13.0 statistical software (SPSS, Inc, Chicago, IL, USA). Chi-square tests were used to explore if sociodemographic variables were related to KAP regarding H7N9 among mobile phone users in 5 regions of Zhejiang Province. We conducted both univariate and multivariate logistic regression analyses to investigate the associations between sociodemographic variables and KAP variables. The univariate analyses revealed the unadjusted effect of a sociodemographic variable without controlling for other sociodemographic variables. The multivariate analyses revealed the adjusted effect of a sociodemographic variable after holding other sociodemographic variables constant. Forward-selection technique was employed for model selection. We dummy-coded categorical variables. For questions about knowledge of symptoms of H7N9, knowledge of its transmission routes, attitude toward eating cooked poultry, and practice of avoiding crowds, answers of “yes” were coded into the high-KAP category indicating high levels of KAP; answers of “no” and “unclear” were coded into the low-KAP category indicating low levels of KAP. For questions about how one’s daily life had been influenced by H7N9, answers of “highly influenced” and “moderately influenced” were coded into 1 category and answers of “not influenced” were coded into the other category. For the question about recent consumption of cooked poultry, answers indicating consumption as usual were coded into 1 category and answers indicating decreased or no consumption were coded into another category. For the question about frequency of hand washing, answers indicating increased frequency were coded into the high-KAP category and answers indicating unchanged frequency or unclearness were coded into the low-KAP category. For the question about visiting a hospital with occurrence of symptoms, answers of visiting a hospital were coded into the high-KAP category whereas answers of self-treatment and no treatment were coded into the low-KAP category. A probability (*P*) value of less than .05 was considered statistically significant.

Results

Sociodemographic Characteristics

A total of 9582 eligible mobile phone users participated in the survey with the response rate of 1.92% (9582/500,000). With the exclusion of responses with missing data or/and logically erroneous data, 9105 of 9582 valid responses (95.02%) were included for statistical analysis. The total sample was 77.00% (7011/9105) male and 23.00% (2094/9105) female. The largest proportion (55.33%, 5038/9105) of participants were aged between 25 and 34 years. Participants involved in the poultry industry accounted for 10.94% (996/9105) of the sample. The majority (61.87%, 5633/9105) of participants had secondary education. Table 1 presents the sociodemographic characteristics of participants in the 5 regions.

Table 1. Cross-tabulation of sociodemographic characteristics of participants by region.

Variables	Region, n (%)					Total, n (%) (N=9105)
	Hangzhou (n=3270)	Huzhou (n=758)	Jiaxing (n=1813)	Shaoxing (n=1261)	Ningbo (n=2003)	
Gender						
Male	2479 (75.81)	565 (74.54)	1443 (79.59)	972 (77.08)	1552 (77.48)	7011 (77.00)
Female	791 (24.19)	193 (25.46)	370 (20.41)	289 (22.92)	451 (22.52)	2094 (23.00)
Age (years)						
15-24	328 (10.03)	121 (15.96)	327 (18.03)	203 (16.10)	329 (16.42)	1308 (14.37)
25-34	1901 (58.13)	379 (50.00)	1007 (55.54)	665 (52.74)	1086 (54.22)	5038 (55.33)
35-44	740 (22.63)	164 (21.64)	343 (18.92)	263 (20.86)	408 (20.37)	1918 (21.07)
45-54	210 (6.42)	66 (8.71)	85 (4.69)	86 (6.82)	122 (6.09)	569 (6.25)
≥55	91 (2.78)	28 (3.69)	51 (2.81)	44 (3.48)	58 (2.90)	272 (2.99)
Occupation						
Related to poultry industry	297 (9.08)	88 (11.61)	220 (12.13)	150 (11.90)	241 (12.03)	996 (10.94)
Not related to poultry industry	2973 (90.92)	670 (88.39)	1593 (87.87)	1111 (88.10)	1762 (87.97)	8109 (89.06)
Education						
Primary or less (≤6 years)	75 (2.29)	38 (5.01)	70 (3.86)	57 (4.52)	78 (3.89)	318 (3.49)
Secondary (6-12 years)	1629 (49.82)	513 (67.68)	1333 (73.52)	823 (65.27)	1335 (66.65)	5633 (61.87)
Postsecondary (>12 years)	1566 (47.89)	207 (27.31)	410 (22.62)	381 (30.21)	590 (29.46)	3154 (34.64)

Knowledge Regarding H7N9

As seen in Table 2, 8379 of 9105 participants (92.03%) had some knowledge of the symptoms of H7N9 and 6816 (74.86%) had some knowledge of its transmission routes. Knowledge of H7N9 differed by region, with Hangzhou having the largest share of participants who had some knowledge about the symptoms (χ^2_8=63.0, P<.001) and transmission routes of H7N9 (χ^2_8=53.9, P<.001). The distribution of rates of knowledge about its symptoms and transmission routes in the 5 regions are displayed in Figures 1 and 2.

Table 2. Cross-tabulation of knowledge, attitudes, and practices regarding avian influenza A (H7N9) by region.

Variables	Region, n (%)					Total, n (%) (N=9105)	χ^2_8	*P*
	Hangzhou (n=3270)	Huzhou (n=758)	Jiaxing (n=1813)	Shaoxing (n=1261)	Ningbo (n=2003)			
1. Knowledge								
Symptoms of H7N9 include fever and cough							63.0	<.001
Yes	3099 (94.77)	693 (91.42)	1626 (89.69)	1127 (89.37)	1834 (91.56)	8379 (92.03)		
No	40 (1.22)	11 (1.45)	38 (2.10)	23 (1.82)	38 (1.90)	150 (1.65)		
Unclear	131 (4.01)	54 (7.12)	149 (8.22)	111 (8.80)	131 (6.54)	576 (6.33)		
Intimate contact with sick poultry can transmit H7N9							53.9	<.001
Yes	2585 (79.05)	547 (72.16)	1288 (71.04)	919 (72.88)	1477 (73.74)	6816 (74.86)		
No	364 (11.13)	110 (14.51)	264 (14.56)	169 (13.40)	258 (12.88)	1165 (12.80)		
Unclear	321 (9.82)	101 (13.32)	261 (14.40)	173 (13.72)	268 (13.38)	1124 (12.34)		
2. Attitudes								
It is safe to eat cooked poultry							39.6	<.001
Yes	2615 (79.97)	559 (73.75)	1359 (74.96)	957 (75.89)	1571 (78.43)	7061 (77.55)		
No	285 (8.72)	83 (10.95)	238 (12.13)	151 (11.97)	204 (10.18)	961 (10.55)		
Unclear	370 (11.31)	116 (15.30)	216 (11.91)	153 (12.13)	228 (11.38)	1083 (11.89)		
I am worried about contracting H7N9							13.1	.11
Yes	1679 (51.35)	410 (54.09)	1008 (55.60)	668 (52.97)	1049 (52.37)	4814 (52.87)		
No	1351 (41.31)	303 (39.97)	704 (38.83)	502 (39.81)	822 (41.04)	3682 (40.44)		
Unclear	240 (7.34)	45 (5.94)	101 (5.57)	91 (7.22)	132 (6.59)	609 (6.69)		
My daily life has been influenced by H7N9							28.5	<.001
Highly influenced	306 (9.36)	95 (12.53)	218 (12.02)	161 (12.77)	205 (10.23)	985 (10.82)		
Moderately influenced	1696 (51.87)	401(52.90)	902(49.75)	619 (49.09)	966 (48.23)	4584 (50.35)		
Not influenced	1268 (38.78)	262 (34.56)	693 (38.22)	481 (38.14)	832 (41.54)	3536 (38.83)		
If I have a fever and/or a cough, I will							10.2	.25
Treat myself with medication	607 (18.56)	119 (15.70)	344 (18.97)	252 (19.98)	396 (19.77)	1718 (18.87)		
Visit a hospital	2585 (79.05)	619 (81.66)	1416 (78.10)	970 (76.92)	1558 (77.78)	7148 (78.51)		
Not go for any treatment	78 (2.39)	20 (2.64)	53 (2.92)	39 (3.09)	49 (2.45)	239 (2.62)		
3. Practices								
Avoidance of crowds							11.9	.16
Yes	1713 (52.39)	433 (57.12)	948 (52.29)	638 (52.59)	1063 (53.07)	4795 (52.66)		
No	1487 (45.47)	311 (41.03)	816 (45.01)	596 (47.26)	887 (44.28)	4097 (45.00)		
Unclear	70 (2.14)	14 (1.85)	49 (2.70)	27(2.14)	53 (2.65)	213 (2.34)		
Frequent hand washing							22.4	.004
Frequency increased	1560 (47.71)	387 (51.06)	876 (48.32)	596 (47.26)	872 (43.53)	4291 (47.13)		
Frequency unchanged	1681 (51.41)	358 (47.23)	920 (50.74)	648 (51.39)	1109 (55.37)	4716 (51.80)		
Unclear	29 (0.89)	13 (1.72)	17(0.94)	17 (1.35)	22 (1.10)	98 (1.08)		
Recent consumption of cooked poultry							37.4	<.001

Variables	Region, n (%)					Total, n (%) (N=9105)	χ^2_8	*P*
	Hangzhou (n=3270)	Huzhou (n=758)	Jiaxing (n=1813)	Shaoxing (n=1261)	Ningbo (n=2003)			
Consumption as usual	455 (13.91)	73 (9.63)	263 (14.50)	170 (13.48)	340 (16.97)	1301 (14.29)		
Decreased consumption	1164 (35.60)	264 (34.83)	651 (35.91)	458 (36.32)	753 (37.59)	3290 (36.13)		
No consumption	1651 (50.49)	421 (55.54)	899 (49.59)	633 (50.20)	910 (45.43)	4514 (49.58)		

Figure 1. Rates of knowledge about symptoms in 5 regions.

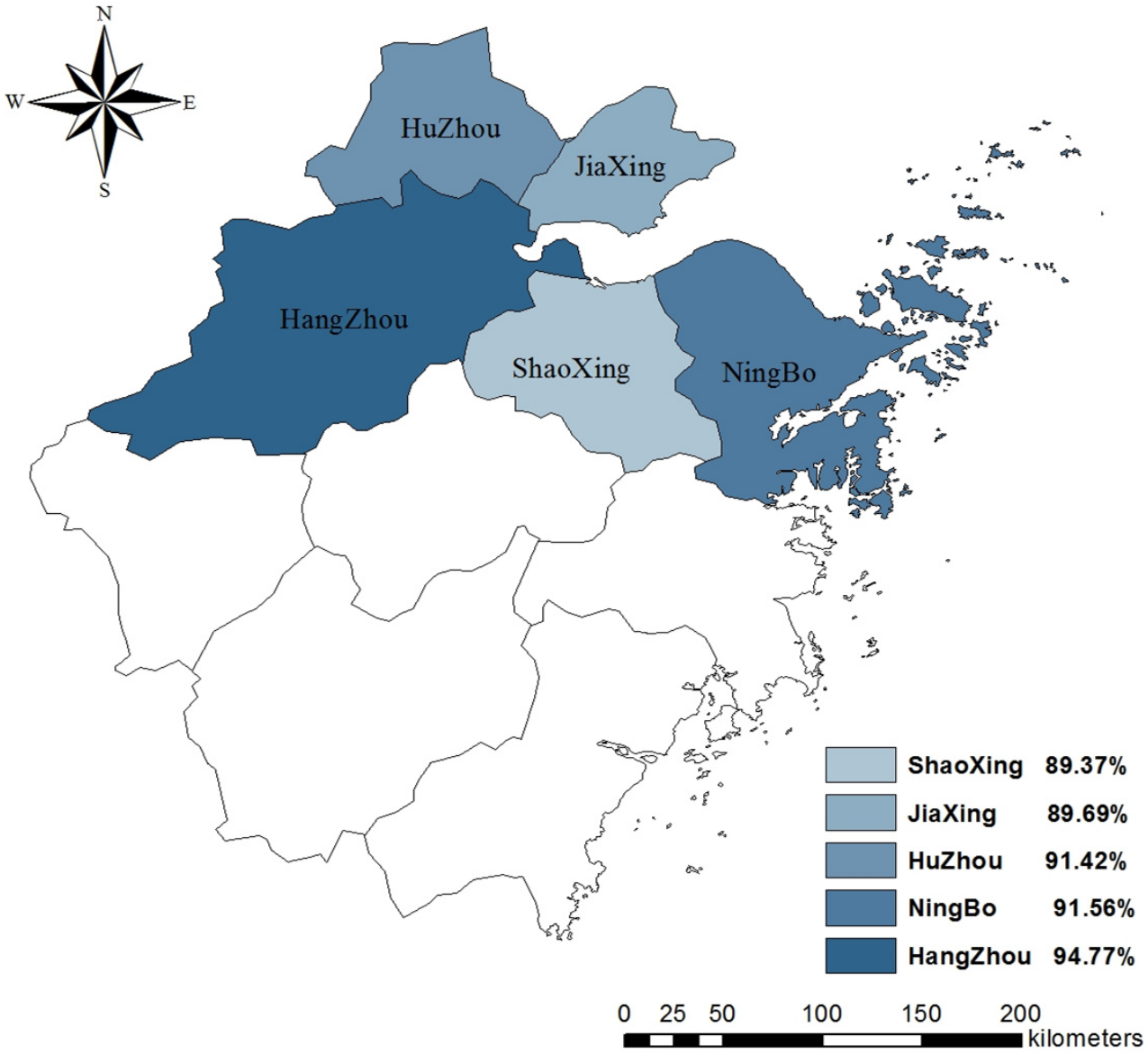
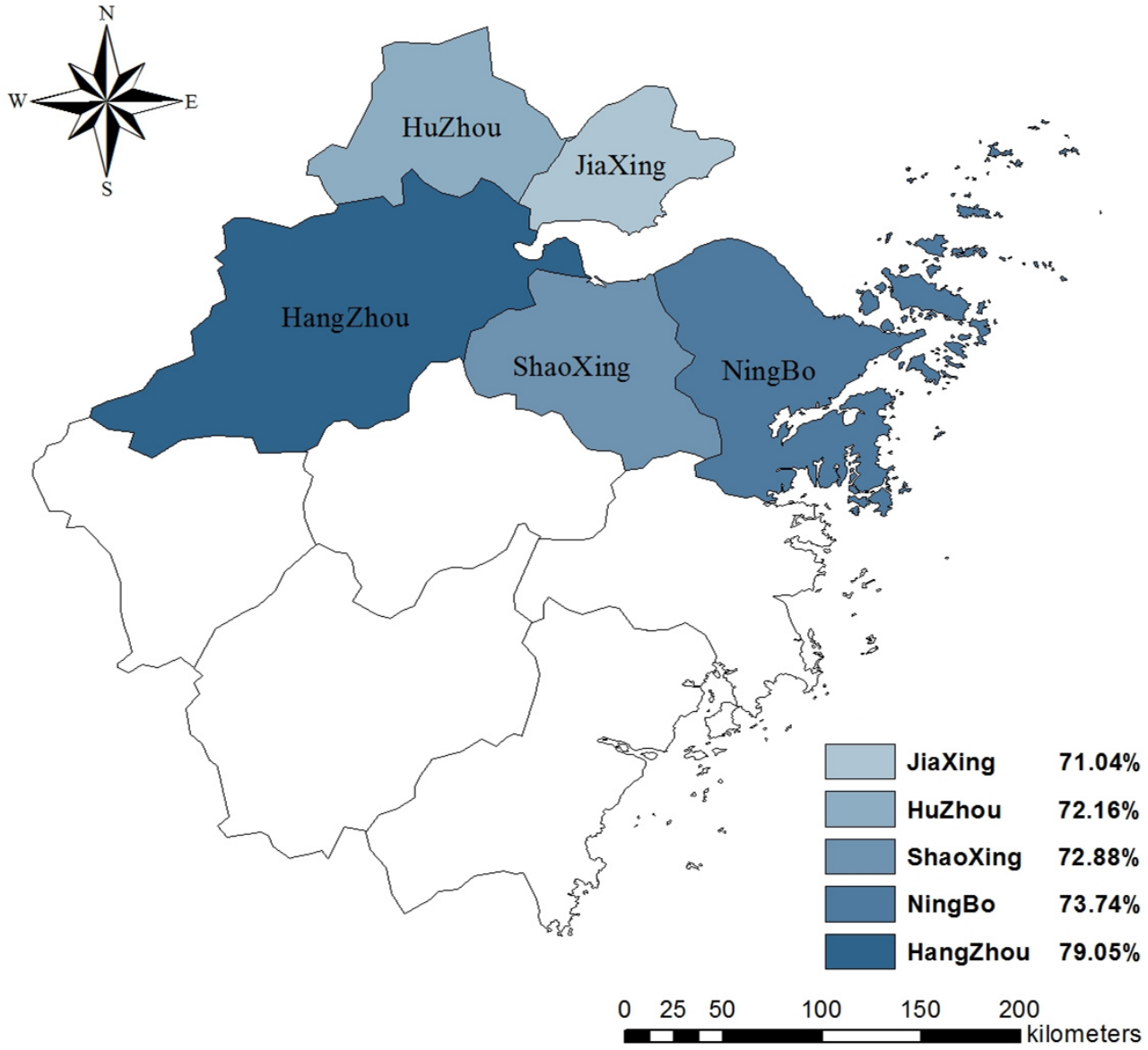


Figure 2. Rates of knowledge about transmission routes of H7N9 in 5 regions.



Attitudes Regarding H7N9

As seen in Table 2, 4814 (52.87%) participants were worried about contracting H7N9 and 8496 (61.17%) participants felt their daily lives had been affected. More than three-quarters of the participants held the attitude recommended by the Zhejiang CDC. Specifically, 7061 (77.55%) participants believed eating cooked poultry was safe and 7148 (78.51%) participants would visit a hospital if they had a fever and/or a cough. Among 4 attitude items, 2 differed by region. Attitude toward the safety of eating cooked poultry differed by region (χ^2_8=39.6, P<.001) with Hangzhou having the highest proportion of participants who thought it was safe. The attitude toward the influence of H7N9 on daily life also differed by region (χ^2_8=28.5, P<.001), with Huzhou having the highest share of participants who thought their daily lives had been affected. The distribution of rates of worrisome attitude in 5 regions are displayed in Figures 3-6.

Figure 3. Proportion of participants who believed it was safe to eat poultry in 5 regions.

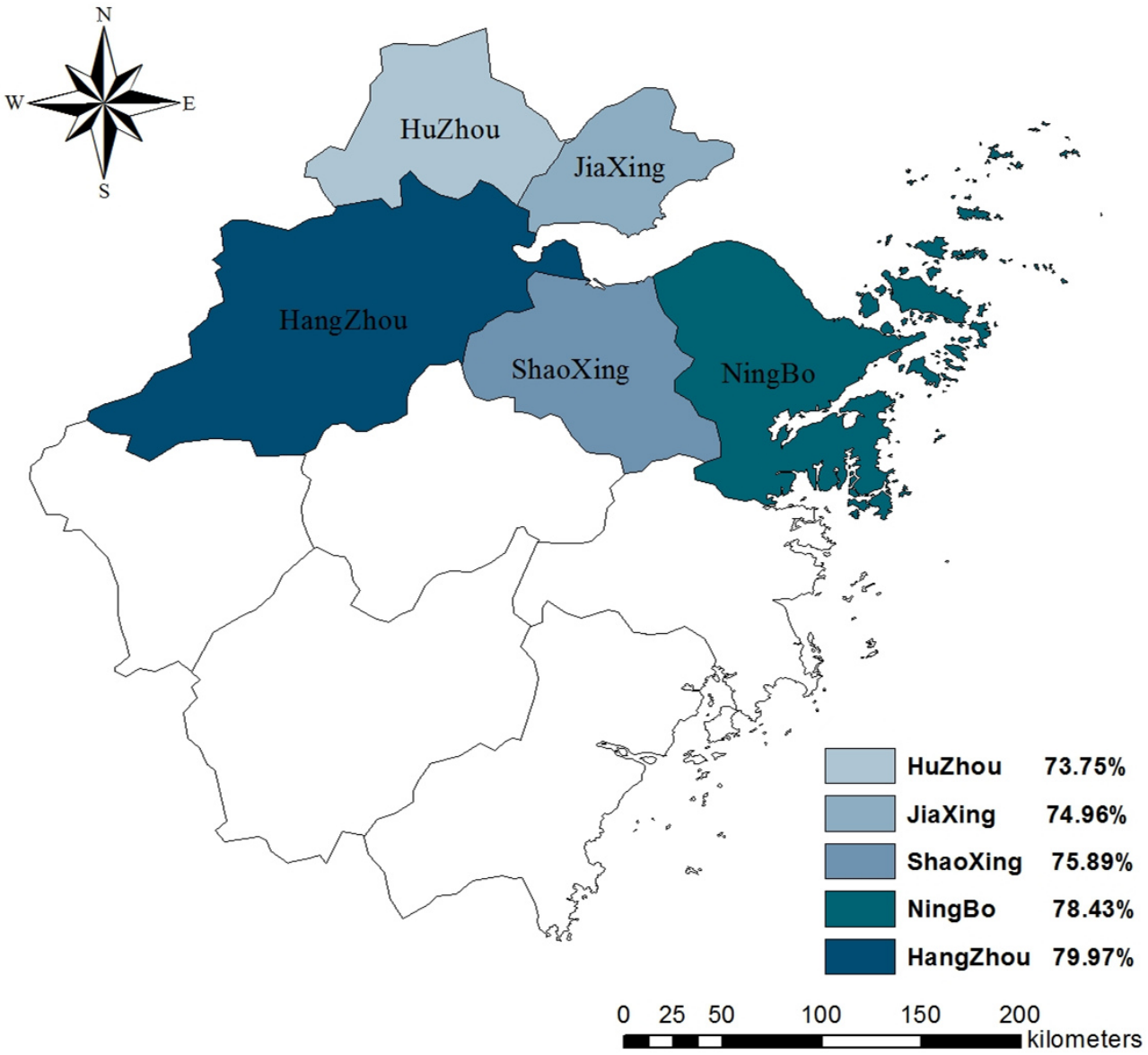


Figure 4. Proportion of participants who were worried about contracting H7N9 in 5 regions.

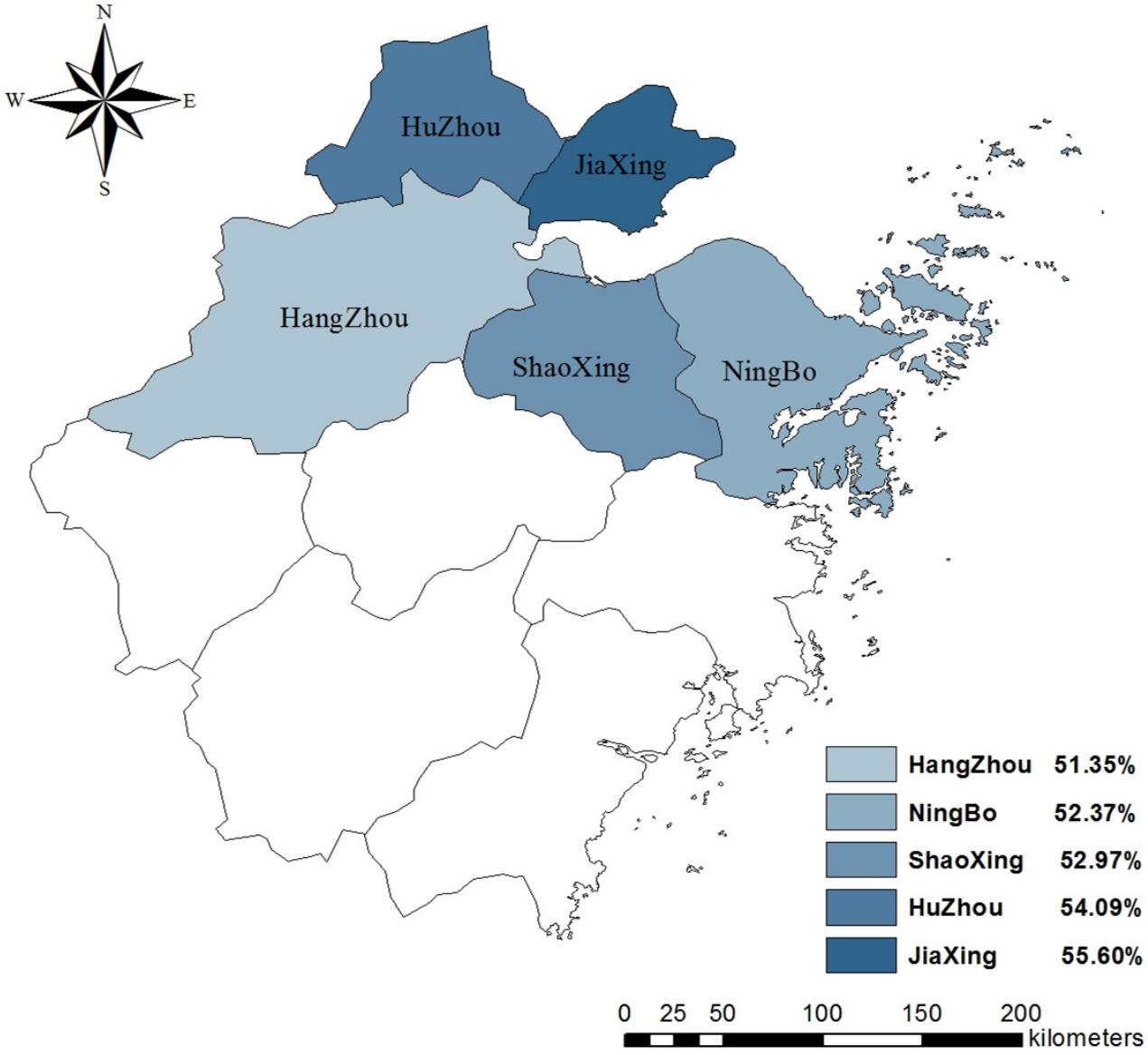


Figure 5. Proportion of participants who thought their daily lives had been influenced by H7N9 in 5 regions.

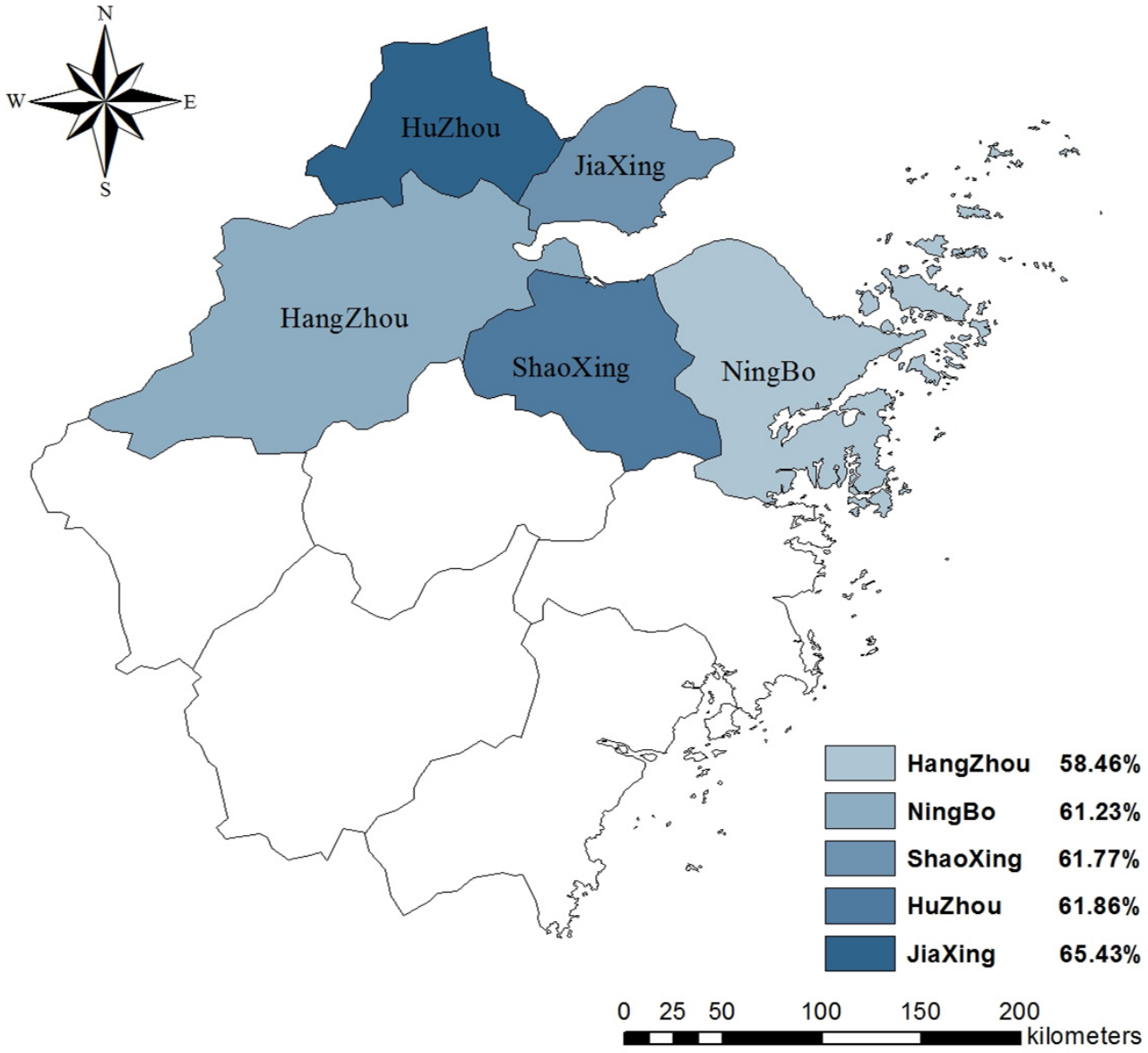
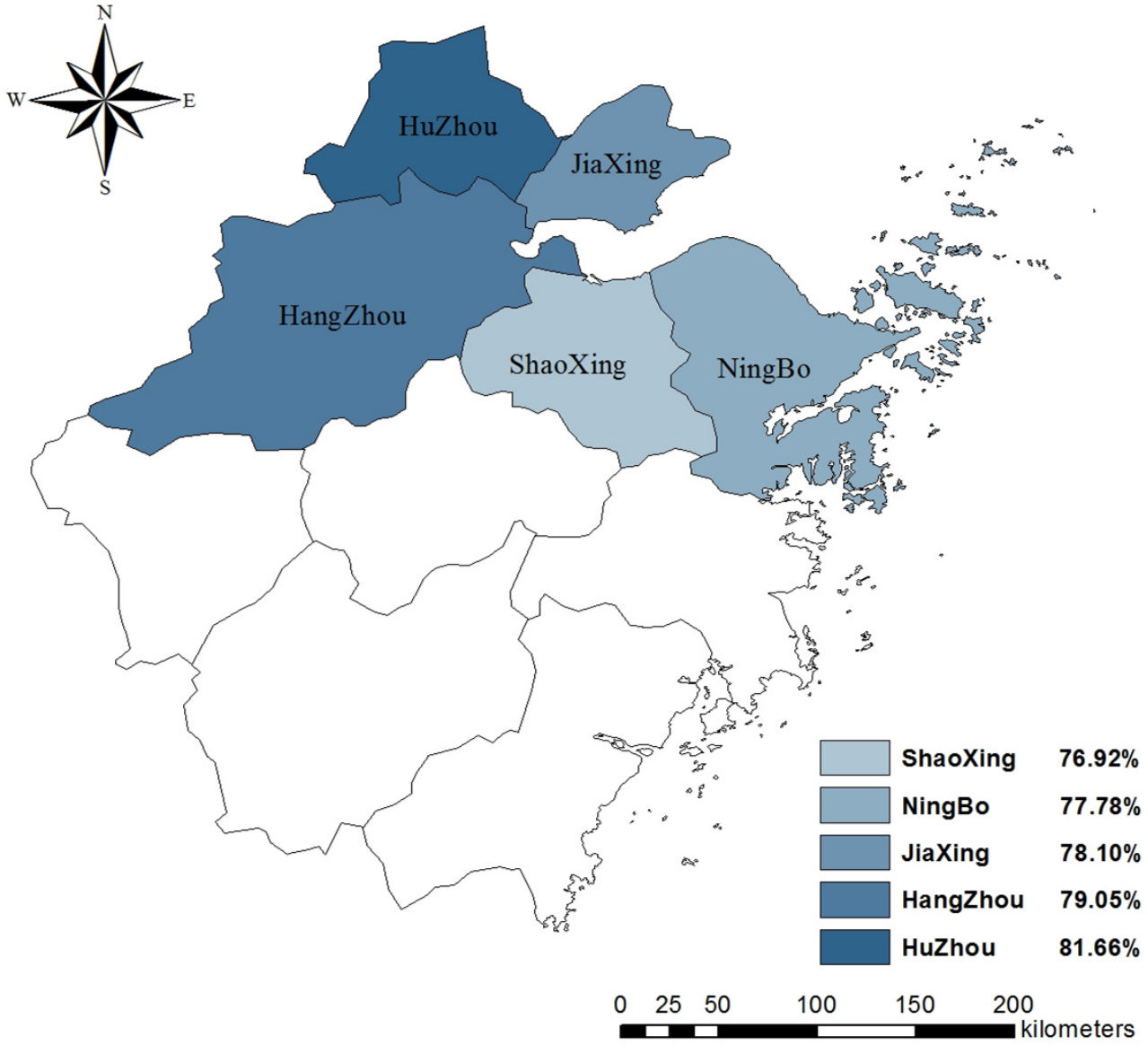


Figure 6. Proportion of participants who would visit a hospital if a fever and/or a cough occurred in 5 regions.



Practices Regarding H7N9

As seen in Table 2, among the 3 practices recommended by the Zhejiang CDC, frequency of hand washing differed by region, with the largest share of participants from Huzhou and the smallest share of participants from Ningbo reporting increased frequency in hand washing (χ^2_8=22.4, P=.004). The frequency of recent consumption of cooked poultry also differed by region (χ^2_8=37.4, P<.001), with the smallest proportion of participants from Huzhou still consuming cooked poultry as usual. The distribution of rates of the 3 practices in 5 regions is displayed in Figures 7-9.

Figure 7. Proportion of participants who avoided crowding areas in 5 regions.

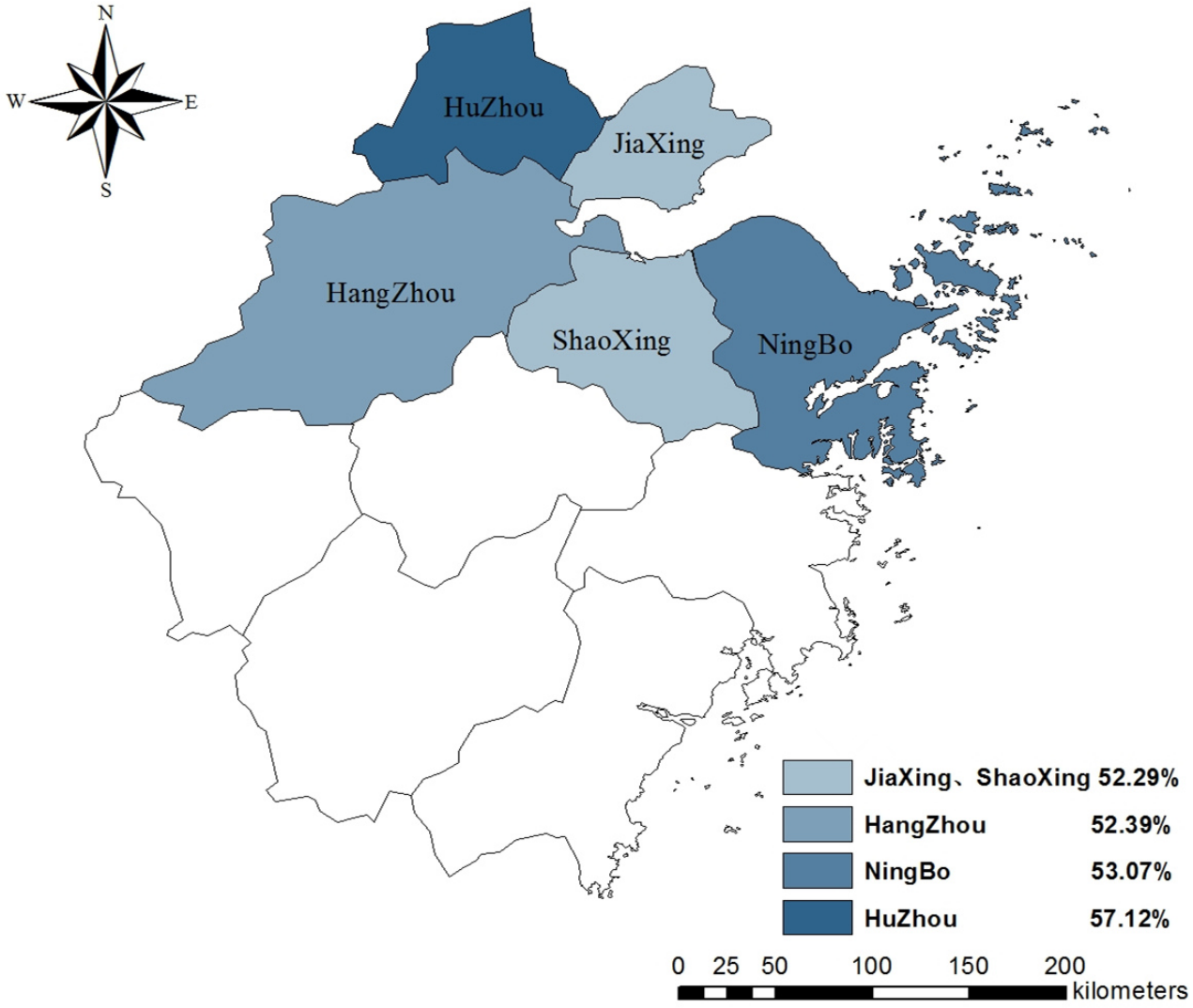


Figure 8. Proportion of participants who increased frequency of hand washing in 5 regions.

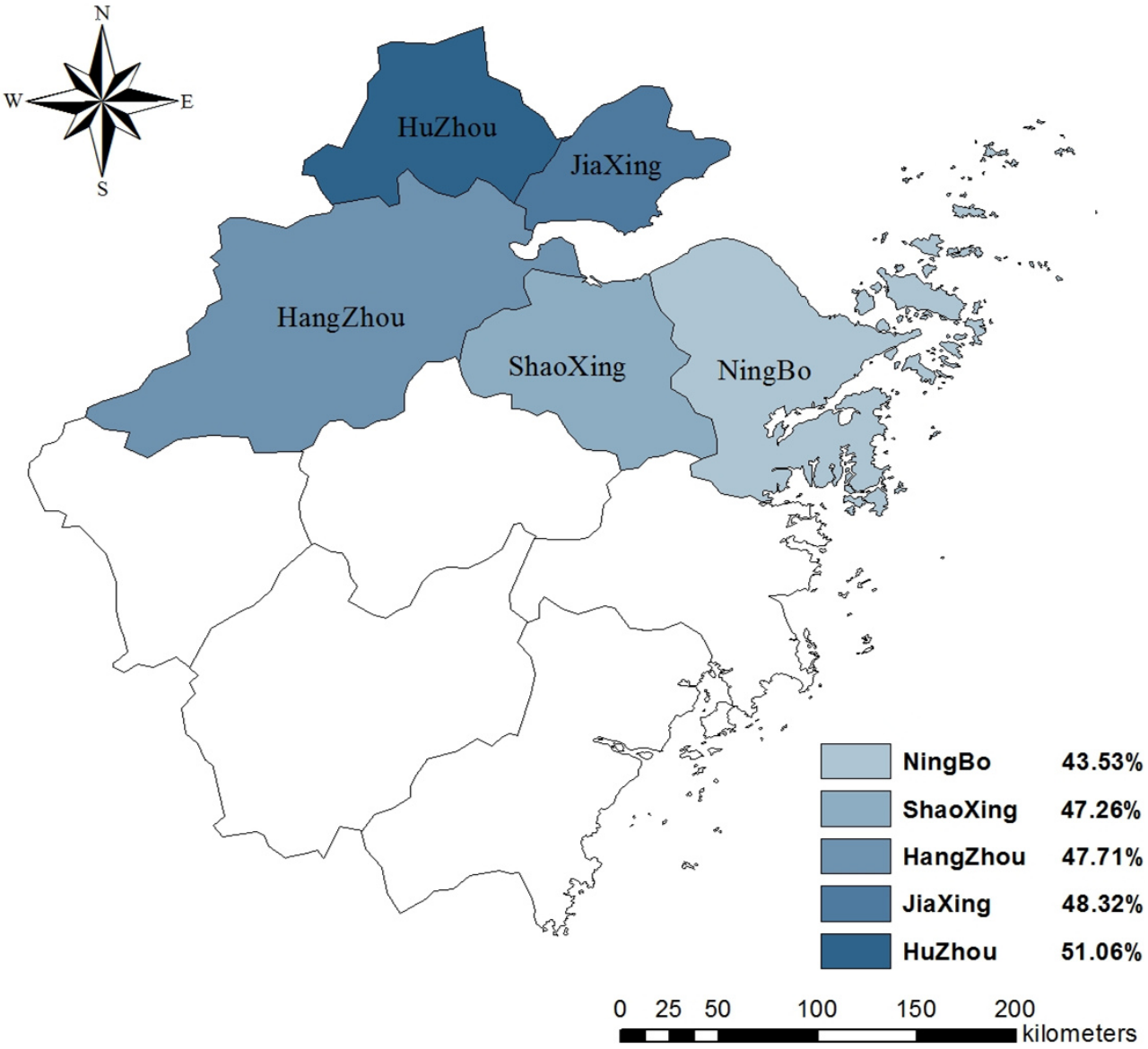
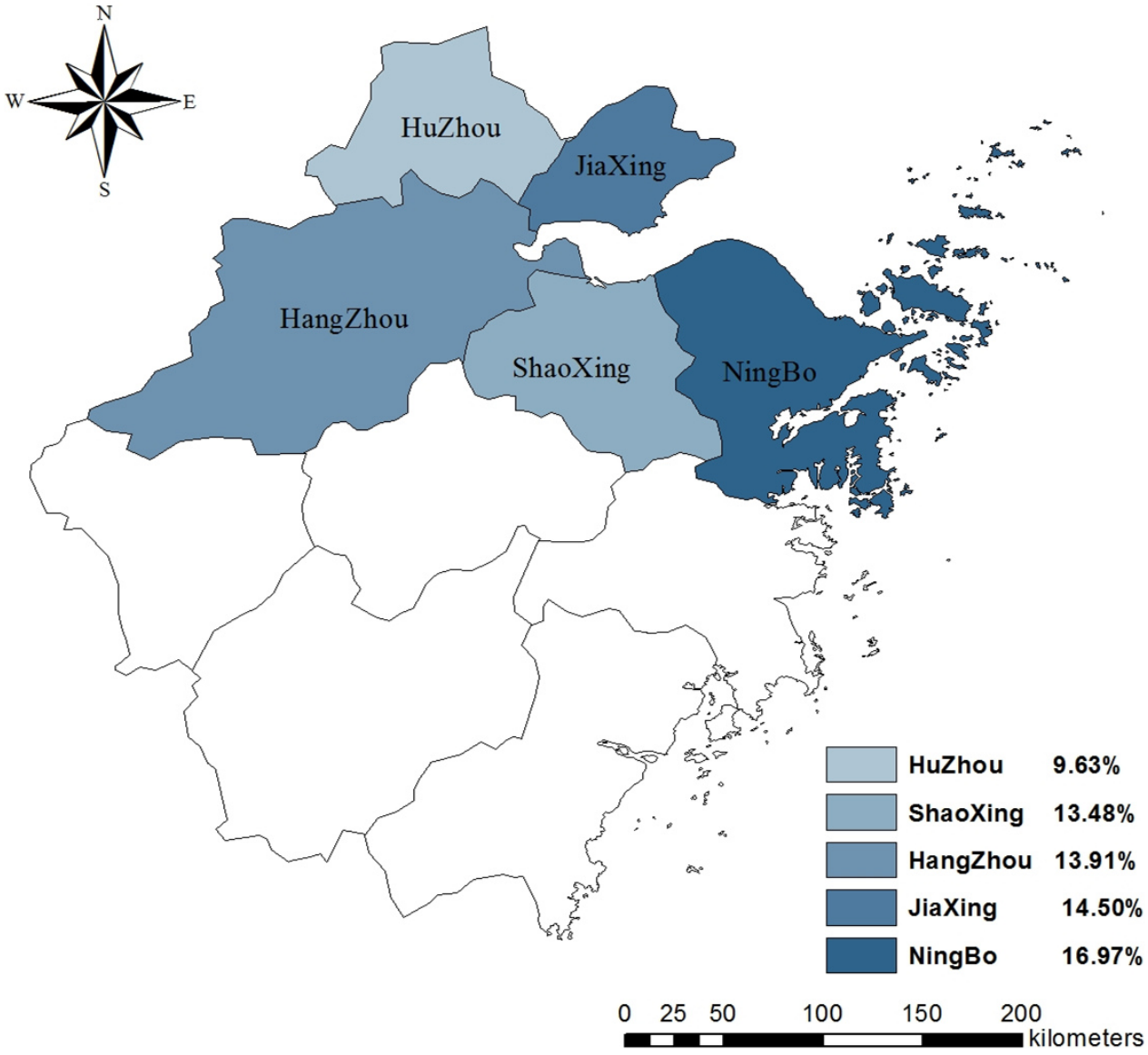


Figure 9. Proportion of participants decreasing or stopping eating cooked poultry in 5 regions.



Association Between Sociodemographic Variables and Knowledge, Attitudes, and Practices

Univariate and multivariate logistic regression analyses were conducted to investigate the association between sociodemographic variables and KAP variables. As seen in Table 3, after controlling for other sociodemographic variables, gender, age, and education were associated with knowledge about symptoms of H7N9. Age and education were associated with knowledge about transmission routes of H7N9 respectively. Female participants (OR 1.32, 95% CI 1.08-1.61) had higher odds of knowing symptoms of H7N9 than male participants. Participants aged 15-24 years had the lowest odds of knowing symptoms of H7N9 or its transmission routes as compared with other age groups. The odds of knowing symptoms of H7N9 (OR 5.05, 95% CI 3.41-7.48) and its transmission routes (OR 1.80, 95% CI 1.39-2.33) were significantly higher among participants with postsecondary or more education than those with primary or less education.

Table 3. Unadjusted and adjusted[a] odds ratios (OR) and 95% confidence intervals (95% CI) of knowledge about H7N9 by sociodemographic variables.

Predictors	Knowledge about H7N9							
	Symptoms of H7N9 include fever and cough				Intimate contact with sick poultry can transmit H7N9			
	OR (95% CI)	*P*	AOR (95% CI)	*P*	OR (95% CI)	*P*	AOR (95% CI)	*P*
Gender								
Male (reference)	1		1		1		NA	
Female	1.40 (1.15, 1.71)	.001	1.32 (1.08, 1.61)	.01	1.03 (0.92, 1.15)	.67		
Age (years)								
15-24 (reference)	1		1		1		1	
25-34	1.54 (1.28, 1.87)	<.001	1.26 (1.04, 1.53)	.02	1.55 (1.36, 1.76)	<.001	1.38 (1.21, 1.58)	<.001
35-44	2.61 (2.01, 3.38)	<.001	2.22 (1.71, 2.88)	<.001	2.08 (1.77, 2.44)	<.001	1.89 (1.61, 2.22)	<.001
45-54	2.77 (1.83, 4.19)	<.001	2.77 (1.83, 4.21)	<.001	2.30 (1.81, 2.92)	<.001	2.25 (1.77, 2.86)	<.001
≥55	6.36 (2.78, 4.51)	<.001	7.82 (3.38, 18.06)	<.001	1.68 (1.24, 2.27)	.001	1.72 (1.26, 2.34)	.001
Occupation								
Related to poultry industry (reference)	1		NA		1		NA	
Not related to poultry industry	1.20 (0.95, 1.51)	.12			1.18 (1.02, 1.37)	.03		
Education								
Primary or less (≤6 years) (reference)	1		1		1		1	
Secondary (6-12 years)	1.32 (0.94, 1.85)	.11	1.78 (1.25, 2.54)	.001	1.04 (0.81, 1.33)	.78	1.04 (0.81, 1.33)	.78
Postsecondary (>12 years)	3.87 (2.66, 5.65)	<.001	5.05 (3.41, 7.48)	<.001	1.80 (1.39, 2.44)	<.001	1.80 (1.39, 2.33)	<.001

[a] Multivariate logistic regression, adjusting for the other factors shown in the table; AOR=adjusted odds ratio.

Table 4 shows the associations between sociodemographic variables and attitude variables. After controlling for other sociodemographic variables, gender was associated with 3 of 4 attitude items. Female participants were more likely to worry about H7N9 infection (OR 1.15, 95% CI 1.04-1.27), to feel that their daily lives had been affected (OR 1.27, 95% CI 1.15-1.41), and to go to a hospital if a fever and/or a cough occurred (OR 1.25, 95% CI 1.01-1.41). Male and female participants did not differ in their attitude toward safety of eating cooked poultry though. The attitudinal effect of age varied by attitude item; for example, participants aged 15-24 years had the lowest odds of believing that it was safe to eat cooked poultry as compared with other age groups. They did not differ from those aged 25-34 years or those aged 55 years and older in the odds of worrying about H7N9 infection. In comparison, participants aged 45-54 years and 35-44 years had lower odds of worrying about H7N9. Participants aged 15-24 years were not different from those aged 25-34 years in the odds of visiting a hospital at the occurrence of a fever and/or a cough. Participants aged 35-44 years (OR 1.69, 95% CI 1.42-2.01), 45-54 years (OR 1.60, 95% CI 1.24-2.06), and 55 years and older (OR 1.91, 95% CI 1.34-2.73) were more likely to visit a hospital than participants aged 15-24 years. Compared to participants whose occupation was related to the poultry industry, others had lower odds of worrying about H7N9 infection (OR 0.78, 95% CI 0.68-0.90) and to feel that their daily life had been affected (OR 0.45, 95% CI 0.38-0.52). Odds of believing in the safety of eating cooked poultry increased by education level. Compared to participants with primary or less education, participants with postsecondary or more education had approximately 3 times the odds (OR 2.81, 95% CI 2.18-3.63) of believing that eating cooked poultry was safe. Meanwhile, they were less likely to worry about H7N9 infection (OR 0.69, 95% CI 0.54-0.88).

Table 4. Unadjusted and adjusted[a] odds ratios (OR) and 95% confidence intervals (95% CI) of attitude toward H7N9 by sociodemographic variables.

Predictors	Attitude about H7N9															
	It is safe to eat cooked poultry				I am worried about contracting H7N9				My daily life has been influenced by H7N9				If I have a fever and/or cough, I will visit a hospital			
	OR (95% CI)	*P*	AOR (95% CI)	*P*	OR (95% CI)	*P*	AOR (95% CI)	*P*	OR (95% CI)	*P*	AOR (95% CI)	*P*	OR (95% CI)	*P*	AOR (95% CI)	*P*
Gender																
Male (reference)	1				1		1		1		1		1		1	
Female	0.96 (0.85, 1.08)	.48			1.11 (1.00, 1.22)	.047	1.15 (1.04, 1.27)	.007	1.22 (1.10, 1.35)	<.001	1.27 (1.15, 1.41)	<.001	1.22 (1.08, 1.38)	.002	1.25 (1.10, 1.41)	<.001
Age (years)																
15-24 (reference)	1		1		1		1		1		1		1		1	
25-34	1.38 (1.21, 1.58)	<.001	1.17 (1.02, 1.35)	.03	0.94 (0.83, 1.07)	.35	1.01 (0.90, 1.15)	.82	1.07 (0.95, 1.21)	.27	1.11 (0.98, 1.25)	.12	1.08 (0.94, 1.25)	.27	1.08 (0.94, 1.24)	.29
35-44	1.89 (1.60, 2.23)	<.001	1.65 (1.39, 1.95)	<.001	0.81 (0.70, 0.93)	.004	0.86 (0.75, 1.00)	.04	1.14 (0.98, 1.31)	.08	1.15 (1.00, 1.33)	.06	1.68 (1.41, 2.00)	<.001	1.69 (1.42, 2.01)	<.001
45-54	2.43 (1.87, 3.15)	<.001	2.40 (1.84, 3.12)	<.001	0.64 (0.53, 0.79)	<.001	0.65 (0.53, 0.79)	<.001	1.01 (0.83, 1.24)	.90	0.98 (0.80, 1.20)	.84	1.59 (1.24, 2.04)	<.001	1.60 (1.24, 2.06)	<.001
≥55	1.91 (1.37, 2.66)	<.001	2.14 (1.52, 3.02)	<.001	1.05 (0.81, 1.37)	.72	0.93 (0.70, 1.22)	.59	2.12 (1.57, 2.85)	<.001	1.49 (1.09, 2.03)	.01	1.86 (1.31, 2.67)	.001	1.91 (1.34, 2.73)	<.001
Occupation																
Related to poultry industry (reference)	1				1		1		1		1		1			
Not related to poultry industry	1.14 (0.98, 1.33)	.10			0.76 (0.66, 0.87)	<.001	0.78 (0.68, 0.90)	<.001	0.44 (0.38, 0.52)	<.001	0.45 (0.38, 0.52)	<.001	0.86 (0.73, 1.01)	.07		
Education																
Primary or less (≤6 years) (reference)	1		1		1		1		1							
Secondary (6-12 years)	1.29 (1.01, 1.64)	.04	1.53 (1.19, 1.98)	.001	0.89 (0.70, 1.11)	.30	0.91 (0.72, 1.16)	.46	0.64 (0.50, 0.82)	<.001			1.15 (0.88, 1.49)	.31		
Postsecondary (>12 years)	2.81 (2.18, 3.63)	<.001	2.81 (2.18, 3.63)	<.001	0.67 (0.53, 0.85)	.001	0.69 (0.54, 0.88)	.003	0.64 (0.50, 0.83)	.001			1.22 (0.93, 1.60)	.14		

[a] Multivariate logistic regression, adjusting for the other factors shown in the table; AOR=adjusted odds ratio.

Table 5 shows the associations between sociodemographic variables and practice variables. After controlling for other sociodemographic variables, gender was associated with the 3 preventive practices recommended by the Zhejiang CDC. Female participants had higher odds to implement the practices than males (avoidance of crowds: OR 1.38, 95% CI 1.25-1.52; frequent hand washing: OR 1.24, 95% CI 1.12-1.36; decreasing consumption of cooked poultry: OR 2.19, 95% CI 1.85-2.60). The odds of using the advocated practices generally increased by age, with participants aged 55 years and older more likely and participants aged 15-24 years least likely to adopt advocated practices. Occupation was only associated with the frequency of hand washing, with participants not involved in the poultry industry being less likely to increase hand washing (OR 0.65, 95% CI 0.56-0.75).

Table 5. Unadjusted and adjusted[a] odds ratios (OR) and 95% confidence intervals (95% CI) of practices regarding H7N9 by sociodemographic variables.

Predictors	Practices about H7N9											
	Avoidance of crowds				Frequent hand washing				Decreased or no consumption of cooked poultry			
	OR (95% CI)	*P*	AOR (95% CI)	*P*	OR (95% CI)	*P*	AOR (95% CI)	*P*	OR (95% CI)	*P*	AOR (95% CI)	*P*
Gender												
Male (reference)	1		1		1		1		1		1	
Female	1.34 (1.22, 1.48)	<.001	1.38 (1.25, 1.52)	<.001	1.18 (1.07, 1.30)	.001	1.24 (1.12, 1.36)	<.001	2.18 (1.84, 2.58)	<.001	2.19 (1.85, 2.60)	<.001
Age (years)												
15-24 (reference)	1		1		1		1		1		1	
25-34	1.12 (1.00, 1.27)	.06	1.23 (1.00, 1.27)	.06	0.99 (0.88, 1.12)	.87	1.02 (0.90, 1.15)	.77	1.33 (1.13, 1.56)	.001	1.30 (1.11, 1.53)	.001
35-44	1.43 (1.24, 1.65)	<.001	1.44 (1.25, 1.66)	<.001	1.03 (0.90, 1.19)	.64	1.06 (0.92, 1.22)	.44	1.73 (1.42, 2.10)	<.001	1.74 (1.43, 2.12)	<.001
45-54	1.70 (1.39, 2.01)	<.001	1.70 (1.39, 2.08)	<.001	1.31 (1.07, 1.59)	.01	1.31 (1.07, 1.59)	.01	1.87 (1.39, 2.51)	<.001	1.94 (1.44, 2.62)	<.001
≥55	1.76 (1.34, 2.29)	<.001	1.67 (1.27, 2.20)	<.001	1.79 (1.37, 2.34)	<.001	1.57 (1.19, 2.08)	.002	1.71 (1.15, 2.54)	.01	2.06 (1.37, 3.10)	.001
Occupation												
Related to poultry industry (reference)	1		1		1		1		1		1	
Not related to poultry industry	0.81 (0.71, 0.92)	.001	0.84 (0.73, 0.97)	.02	0.62 (0.55, 0.71)	<.001	0.65 (0.56, 0.75)	<.001	1.22 (1.02, 1.46)	.03	1.24 (1.03, 1.49)	.03
Education												
Primary or less (≤6 years) (reference)	1		NA		1		NA		1		NA	
Secondary (6-12 years)	0.89 (0.71, 1.11)	.30			0.99 (0.79, 1.24)	.91			1.18 (0.87, 1.61)	.28		
Postsecondary (>12 years)	0.91 (0.72, 1.14)	.41			0.88 (0.70, 1.11)	.28			1.18 (0.86, 1.61)	.31		

[a] Multivariate logistic regression, adjusting for the other factors shown in the table; AOR=adjusted odds ratio.

Discussion

Principal Results

Control and prevention of a new infectious disease need public participation. In order to respond appropriately to the outbreak of an infectious disease, such as H7N9, people need to have basic knowledge about its symptoms and transmission routes. Our study showed that mobile Internet users in Zhejiang Province knew more about the symptoms of H7N9 than about its transmission routes. This showed that people lacked knowledge of how this new communicable disease was transmitted. The finding suggests that in the outbreak of a new infectious disease, the government as well as medical institutions should carry out public health education not only about its symptoms but also about its transmission routes.

In Zhejiang Province, there has been a great demand for live poultry, such as live chickens and ducks, among the general population. After the emergence of H7N9, the provincial government took preventive strategies, such as closing live poultry markets and conducting public health education.

Meanwhile, more than half of the participants indicated that they worried about contracting H7N9 and that their daily lives had been influenced by H7N9. This may be derived from the increasing amount of media coverage of the epidemic and mortality, lack of knowledge about its transmission routes, and closings of live poultry markets.

The literature has shown that hand hygiene can reduce the spread of respiratory disease efficiently [13]. Our study revealed that approximately half of the participants washed their hands more frequently. The tendency to adopt precautionary behaviors to prevent disease infection was seen in previous studies of other types of influenza viruses, such as H1N1 [14-16].

Knowledge of H7N9 differed by region, with Hangzhou having the largest share of participants who knew the symptoms and transmission routes of H7N9. In terms of attitude, Hangzhou also saw the highest proportion of participants who believed it was safe to eat cooked poultry. This may be related to the fact that Hangzhou saw the greatest number of H7N9 cases [2].

In comparison, worry about contracting H7N9 did not differ by region. There was also no difference in region regarding avoidance of crowds and frequency of hand washing. The consumption of cooked poultry differed by region, with Huzhou seeing the largest share of participants decreasing or stopping eating cooked poultry.

Previous studies revealed that demographic factors, such as age, and gender, increased pandemic knowledge, and higher risk perception induced people to adopt preventive practices [17]. Our data indicated that sociodemographic variables were significantly associated with KAP. For example, female participants were more likely to know about symptoms of H7N9, to worry about it, and to report their lives being influenced by it. They were also more likely to take the recommended precautionary practices, such as avoiding crowds and washing hands more frequently, to prevent H7N9 infection. The findings were consistent with the literature, which indicated greater likelihood for females than males to perceive higher levels of risk of contracting contagious diseases [18,19], and to take precautionary measures to prevent getting such diseases [20]. The findings implied a plausible relationship between knowledge and the adoption of preventive practices, as suggested in the literature [21,22], among females. Therefore, enhancing knowledge about a new infectious disease can be an effective strategy to encourage the adoption of preventive measures. The findings also implied a plausible association between risk perception and the adoption of preventive practices among females. This may also apply to participants with occupations related to poultry industry. Specifically, participants with occupations related to the poultry industry were more likely to worry about contracting H7N9 and to report their lives being influenced by H7N9. They were also more likely to take precautionary practices. These results suggest the behavioral effect of risk perception. However, increased worry and concern did not seem to elicit behavioral change among young people or among participants with less education. Young participants aged 15-24 years were more likely to worry about contracting H7N9, but were less likely to comply with advocated protective measures. Education affected attitude toward H7N9; participants with primary education or lower tended to worry about contracting H7N9 and feel that their lives were being affected. But education did not alter the likelihood of taking preventive practices.

In sum, male participants and younger participants were less likely to comply with advocated protective practices, which may imply high risks of contracting H7N9. The difference was that male participants worried less, but young participants worried more about contracting H7N9. The findings suggest the need for more effective materials to promote advocated preventive practices for the high-risk groups and young male individuals, in particular. In addition, the government also needs to develop strategies to encourage the public to change the habit of killing live poultry or purchasing chilled poultry products. To summarize, the content and the form of health education should be designed in accordance with the sociodemographics of the target population to increase accessibility and efficiency.

Limitations

This study has some limitations. First, the study is limited by the volunteer sample of mobile Internet users from 5 regions of Zhejiang Province. Those who cared more about public health may have participated in the study. Thus, the results may not be generalizable to other residents who were not mobile Internet users. Second, the possibility of social desirability bias as a result of the self-reported survey design may exist, which may have led to bias in reported KAP levels. Finally, this was an exploratory study designed as a quick method to understand levels of KAP about H7N9 among mobile Internet users. Considering people may not want to respond to a long questionnaire, we kept the questionnaire short. This may have increased the response rate, but limited the depth of the questions.

Conclusions

Our study provides valuable insights into KAP related to H7N9 among mobile Internet users in 5 regions of Zhejiang Province. There were some regional differences in KAP. Hangzhou, the region that saw the greatest number of H7N9 infections, saw the largest proportion of participants with basic knowledge of H7N9. The associations between sociodemographic variables and KAP suggest that government agencies and medical institutions need to enhance public health education for potentially high-risk groups, such as males, younger people, and people with occupations related to the poultry industry, in order to encourage them to take preventive behaviors. Meanwhile, more education about the disease and, in particular, its transmission routes should be conducted among those with less education.

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Conflicts of Interest

None declared.

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Abbreviations

AOR: adjusted odds ratio
H7N9: avian influenza A
KAP: knowledge, attitudes, and practices
SARS: severe acute respiratory syndrome

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Original Paper

Application of Mobile Technology for Improving Expanded Program on Immunization Among Highland Minority and Stateless Populations in Northern Thailand Border

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Abstract

Background: Studies of undervaccinated children of minority/stateless populations have highlighted significant barriers at individual, community, and state levels. These include geography-related difficulties, poverty, and social norms/beliefs.

Objective: The objective of this study was to assess project outcomes regarding immunization coverage, as well as maternal attitudes and practices toward immunization.

Methods: The "StatelessVac" project was conducted in Thailand-Myanmar-Laos border areas using cell phone-based mechanisms to increase immunization coverage by incorporating phone-to-phone information sharing for both identification and prevention. With limitation of the study among vulnerable populations in low-resource settings, the pre/post assessments without comparison group were conducted. Immunization coverage was collected from routine monthly reports while behavior-change outcomes were from repeat surveys.

Results: This study revealed potential benefits of the initiative for case identification; immunization coverage showed an improved trend. Prevention strategies were successfully integrated into the routine health care workflows of immunization activities at point-of-care. A behavior-change-communication package contributes significantly in raising both concern and awareness in relation to child care.

Conclusions: The mobile technology has proven to be an effective mechanism in improving a children's immunization program among these hard-to-reach populations. Part of the intervention has now been revised for use at health centers across the country.

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KEYWORDS

expanded program on immunization; EPI; hill tribes; stateless; behavioral change communication; mobile technology

Introduction

Thailand Population Statistics

The figures for minority and stateless populations, besides the population of 64 million with citizen identification in Thailand, vary between different reports, depending on the definition of the populations of interest [1]. In 2011, estimates were as high as 3.5 million non-Thai nationals living in the country [2]. Some minority groups, particularly those living in border areas, are difficult to count due to their illegal, migration, and cross-border status. It has been reported that about 30%-60% of indigenous and immigrant highlanders, so-called “hilltribes”, do not possess Thai citizenship. In a highland survey conducted in 1999, about 43% of the nearly 874,000 hilltribe population in Thailand were not recognized as Thai nationals [2,3]. In the United Nations Educational, Scientific, and Cultural Organization’s largest official household survey (Highland Peoples Survey, 2006), 37% of 63,724 hilltribe people residing in 192 border villages did not have Thai citizenship, whereas in the second survey (2010), no new estimate of unregistered hilltribes was addressed [3,4]. In Thailand (2011), there are 9761 government primary health units (PHUs), so-called Subdistrict Health Promotion Hospitals, located at each district throughout the country. Each PHU provides basic health care services and health promotion activities [5]. While the majority of stateless people face difficulties acquiring the “right to health”, including access to basic health care services [6,7], highland minority and stateless individuals along Thailand’s borders do enjoy some access to treatment and care mostly free of charge, should they wish to make the journey to the basic governmental health care facilities provided [8]. However, few nongovernmental organizations work in areas to assist these people attaining Thai citizenship to ensure their basic human rights [9].

Geographically, hilltribe settlements in Thailand are scattered over 20 western and northern border provinces of the country; however, about 90% of them reside in nine upper northern provinces. The highest proportion of the hilltribe population lived in the Chiang Rai Province, Chiang Mai Province, Mae Hong Son Province, Tak Province, and Nan Province. According to the 1995 survey, there are six major distinctive ethnic groups, each of which can be identified by distinctive costumes and languages including: Karen, Hmong, Lahu, Akha, Mein or Yao, and Lisu [10]. According to the report, there was at minimum one primary school in about half of the highland villages providing basic formal education. However, many of the older generation and new stateless migrants/cross-border hilltribe people hardly speak or understand the Thai language, but rather know a few "survival" words [10-14]. Despite most registered minority groups in Thailand having been granted Thai nationality, problems surrounding their children’s health endure, mostly due to inequalities of socioeconomic status [15]. Some stateless children are born in shelters, scattered in remote mountain regions, and never visit health facilities for treatment or care.

The Expanded Programme on Immunisation

Thailand has adopted the Expanded Programme on Immunisation (EPI) as a national policy since 1976 [1,16,17]. Over the course of the 5 year immunization program for each child, there are 6 vaccines offered at the hospitals and PHUs across the country, including Bacillus Calmette-Guérin (BCG) vaccine for tuberculosis, HepB vaccine for hepatitis B, DTP vaccine for diphtheria-tetanus-pertussis, OPV for polio, MMR vaccine for measles-mumps-rubella, and JE vaccine for Japanese encephalitis [1]. A national survey in 2005-2006 reported that 83.3% of Thai children age 12-23 months received all 8 recommended vaccinations, while 1.3% had received none [18]. An unpublished provincial Health Office report in Thailand’s northernmost province, Chiang-Rai, showed the common health problems of highland children included pneumonia and diarrhea; incidences of measles and tetanus, and at least 3 outbreaks of diphtheria in the most remote areas, were reported in 2008-2010.

A review of the literature on the epidemiology of undervaccinated children in resource-limited settings [19-27] revealed barriers at individual, community, and state levels. These include geographic difficulties (eg, living in remote areas and too far from health care facilities), time constraints (due to parents’ work obligations/conditions during vaccination periods), the social norms and cultural structures of the community itself, and the lack of legal documents. At the global level, even though child immunization-coverage trends are positive, there remains a need to develop new mechanisms to increase immunization rates among hard-to-reach populations [28]. The use of mobile technology has been shown to improve vaccination coverage, especially among high-risk, low-income minorities [29,30]. A module integrating cell phones into routine health care systems to improve antenatal care (ANC), as well as EPI services, has already shown positive vaccination outcomes for those underserved populations in Thailand’s border areas [31].

The “StatelessVac” project was developed and implemented in Thailand-Myanmar-Laos border areas in the Chiang-Rai Province, using cell phone-based solutions with the specific purpose to provide an effective mechanism for achieving EPI coverage targets among ethnic hilltribe and stateless populations. Strategies included two system functionalities for phone-to-phone information sharing, for “identification” and “prevention”. “Identification” refers to valid case registration on the EPI scheme for ethnic-minority and stateless children; “prevention” is proper case management so as to receive fundamental immunizations, plus behavior-change communication measures in relation to seeking out and gaining access to health care services. The main objective of this study was to assess project outcomes regarding EPI coverage, and maternal attitudes and practices toward the immunization of their children.

Methods

Project Settings

The areas for project implementation consisted of all villages under the responsibility of three governmental PHUs, covering Thai citizens and both registered and unregistered highland populations. Each village was populated with a mix of 6 main highland minorities: Karen, Hmong, Mein, Akha, Lahu, and Lisu, with one immigrant minority population of Yunnan

Chinese. The distances from each village to its responsible PHU ranged from 1 to 17 kilometers, with a median of 7 kilometers. Figure 1 shows examples of the different study locations.

It should be noted that in Thailand, the Ministry of Public Health has established and maintained 68 provincial hospitals, 759 district hospitals, and 28 referral (regional) hospitals, while providing 9761 primary health care services at the PHUs [5,32]. The PHUs are functioning at subdistrict level across the country. There are generally 3-5 health care staff working at each PHU, providing integrated health care that includes prevention, promotion, curative, and rehabilitation services. While health care personnel at each PHU may work with the nearby district and/or provincial hospital in terms of referral of serious cases beyond their functionalities, they mainly work with village health volunteers (VHVs). Each VHV is responsible for about 8-15 households, and home-visit activities concerning maternal and child health care is one of their monthly routine tasks. In this study, however, only 33 active VHVs, selected from 163 in the project implementation villages, were equipped with customized tools to improve immunization coverage. With the availability of the equipment to be tested, and each VHV's workload was taken into account, other VHVs continued to work on their routine health-promoting activities with each of their households, while the 33 VHVs undertook EPI-promoting activities at their households. The other 130 VHVs were informed of these EPI activities and had no objections.

Figure 1. The StatelessVac project initiatives. (a) Project locations on highland; (b) picture and pronunciation for case identification; and (c) behavior change communication at health center and during routine home visit before schedule date.

Mobile-Technology Initiatives

In response to the call for proposal "Create Low-Cost Cell Phone-Based Solutions for Improved Uptake and Coverage of Childhood Vaccinations" by the Grand Challenges Explorations Round 7, the StatelessVac project was developed [33,34]. In order to improve vaccine delivery, particularly among underserved populations in developing countries, the challenges for which solutions were to overcome include: (1) correctly identifying an individual infant/child, and (2) connecting vaccine availability with target populations. Solutions for the challenges of infant/child identification were requested to find ways to positively record and examine the immunization history, but in many settings names and addresses are not consistently used or difficult to record even in paper-based systems, while printed identification cards can get lost or be impossible to implement. Moreover, robust biometric data for infant/child are usually difficult to validate. Another challenge was to find solutions for vaccinations that need to serve across the extended geographical area, which usually involves difficulties in travelling to receive health care services, while ensuring that the child's family has accurate information on where and when vaccinations are to be offered. It is suggested that such an approach would consequently increase the overall vaccine coverage. The StatelessVac project was thus proposed to offer innovative approaches to address the aforementioned challenges. The challenges were also asked for "off the beaten track" and daring in premise; that was the reason for proposing to launch the initiatives among the hard to reach populations.

Mobile technology, particularly the use of smartphone systems, has already been employed as a vehicle for global health care innovation, in terms of facilitating behavior change and improving health care. The benefits of such innovations include: improved access to and quality of care, patient management, and health outcomes among underserved populations [35]. The four-pillar approach for building an effective response to statelessness, including: activities related to identification, prevention, reduction, and protection [8], can be adapted successfully by using such technology. In the StatelessVac project, two approaches were initiated: (1) case identification, and (2) disease prevention. The data/information transmission and utilization between appointed VHVs residing in each highland village and the local lowland health care center personnel responsible for area coverage was utilized. The use of tablets as part of a phone-to-phone information-sharing strategy is feasible when a telephone signal is available; other system functionalities can be performed offline. Specific information, which is shared on tablets given to the VHVs, and the standardized databases used by health care personnel at each PHU, are adapted from those recorded routine activities of original data sharing carried out on paper-based systems, when VHVs performed monthly home visits. Personal and familial information was treated confidentially within the system's applications.

Some novel ideas for case identification include transmitting "picture" and "pronunciation" data using the phone-to-phone system from remote highland areas to lowland PHUs. Specific issues of complexity concerning the registration procedure include noncitizenship, lack of birth certificate, inconsistency of name, and unspecified residential location. Due to changes of a baby's appearance throughout the 5 year immunization program, the picture of baby was used as a biometric data. With parental permission, pictures of each infant and its mother, taken via tablet prior to each vaccination visit, were securely transmitted to authorized health care personnel at the responsible PHU. Each hilltribe has its own dialect; most have spoken, but not written languages [10-14]. Variations in pronunciation raise even more complex issues, most hilltribe names demonstrate no connection between each speech sound, print representation, or word meaning, when listeners attempt to spell and transcribe them into the Thai language. Many newborns are given, and registered onto, the health care database with Thai names, yet many caregivers do not remember or even recognize when their infant is called out using their Thai name. This has long been a problematic public-health issue, in terms of both case registration and management, and drug and health product distribution for hilltribe communities and migrants. There are numerous and repetitive misidentified cases, with misspellings and mispronunciations of names throughout the official health care database, in both the paper- and electronic-based systems. Despite using pronunciation data for modeling of word recognition, in this project, the simple transmission of pronunciation data (baby's name in the ethnic language spoken by its mother) was programed for use as a confirmation biometric. This was used specifically for case recognition, to correctly identify each baby due for immunization at the health care facility on the EPI schedule.

The case-identification strategy was developed and incorporated into tablet functionality. On a VHV's tablet, after a baby was registered on the responsible PHU's database, EPI scheduling was flagged monthly as due and/or overdue immunization(s) for each VHV's routine home visit. Replacing monthly case management on papers between VHVs and PHU staff, the vaccination history of the infant/child was updated on each VHV's tablet. Monthly information about EPI schedule, plus additional picture and pronunciation of each child's name, was routinely transmitted and synchronized between VHV and responsible PHU's tablet. On the set vaccination dates at the PHU each month, health care personnel employed pictures and pronunciation data obtained from the VHV's tablets, by presenting the child's picture on a television screen and calling out the child's name in the ethnic language from the PHU's tablet. Figure 1 shows how picture and pronunciation data were used for case identification at health care facilities on vaccination day.

Behavior change communication (BCC) and advocacy in the community is another preventive measure that was developed. Based on the United Nations Children's Fund (UNICEF)'s guideline for communication strategy for a development program [36], the effective communication relies on the synergistic use of three strategic components including: (1) advocacy, (2) social mobilization, and (3) BCC. In the StatelessVac project, the advocacy was planned for informing and motivating leadership among health care personnel at PHUs, and VHVs to create a supportive environment to achieve a higher vaccine coverage goal using cell phone-based initiatives. Even though social mobilization was not considered as a critical part of this initiative, it was already in place under the structure of health care services of the country. The PHUs and VHVs have been actively engaging and supporting people in their responsible networking areas, performing routine home visits and promoting health care services. The BCC strategy has adopted the interpersonal approach, for example, using face-to-face communication between VHV and mother during each home visit, as well as health education presentations at the health care facility on each scheduled vaccination day. EPI-related information loaded onto VHV tablets in selectable hilltribe languages were used for recruitment of new and unregistered cases, to raise awareness and concerns about child health, as well as community advocacy about the importance of child immunization. The development of BCC content and format was based on inputs gained from EPI experts at universities and at the Ministry of Public Health, together with local experts on different hilltribe cultures. BCC scripts were translated and back-translated into multi-languages, then pretested in the villages before the final version gained approval. The BCC package currently includes 11 different animations about immunization: 10 against specific diseases, and 1 on pre and postimmunization (focus on false beliefs and culturally/locally based concepts). These animations appear in 9 languages, including 7 targeted tribal languages (Karen, Hmong, Mein, Akha, Lahu, Lisu, and Yunnan Chinese), plus 2 more languages (Thai and English) for public use. Using the case identification module, each VHV knows what vaccine(s) are due for a particular child that month; the VHV can thus show BCC animation(s) about disease-specific immunizations

in the selectable ethnic language of the child's mother. For community advocacy, BCC was presented at each PHU in random scripts and languages on vaccination day. Figure 1 shows examples of BCC activities during these home visits and at the health care facilities.

Project Indicators and Assessment

Expected project outcomes were changes in EPI coverage, and BCC determinants over time. EPI monthly coverage data, by child age and by different type of vaccine, were collected from quarterly reports from the three PHUs to the Ministry of Public Health, submitted from January 2011 to February 2012, and from March 2012 to March 2013, before and after project implementation. BCC outcomes are based on repeat surveys from the same respondents in relation to maternal knowledge, attitudes, and practices (KAP) toward EPI vaccination. As part of the formative project evaluation, surveys were collected at months 6 and 12 after BCC was first launched. The KAP survey content was based on messages delivered via the BCC package. With due consideration of limited literacy among minorities in remote settings, the KAP questionnaire was constructed with minimum critical issues and simplicity of format. The KAP survey composes of 6 items on knowledge, 5 items on attitude, and 6 items on practice. The survey items were developed by consensus among three content experts on immunization and one on hilltribes in the study area. The survey items were piloted and revised in the nearby villages of the study areas and with different ethnics groups participating in this study. The surveys were conducted using individual interview methods by trained, designated VHVs. The VHV interviewer either spoke Thai or translated the items according to the precoded script. The analysis of the data was simply descriptive statistics.

Ethical Considerations

Access to EPI management systems and databases is strictly controlled, and only permitted for authorized health care personnel and village health volunteers in charge of case management. Information sharing on tablets as part of the phone-to-phone mechanism maintains all crucial features of data integrity and confidentiality, mirroring the routine paper-based processes at the local health care clinics, and during routine site/home visits.

Mothers and/or children who visited the health care clinics signed no written informed consent or assent form, or when meeting with health care personnel during site/home visits; all activities were routine work performed as part of standard health care practices. Data extracted for analysis were all secondary data and summary statistics, and were not identification (ID)-linked. The authors were granted permission to use extracted data for analysis from the authorized person at the Chiang-Rai Provincial Health Office. The study protocol was reviewed and approved by the Ethics Committee, Faculty of Tropical Medicine, Mahidol University.

Results

Expanded Program on Immunization Coverage

During the study period, a total of 3649 highland children age < 6 years were registered in the three PHUs. Immunizations for tuberculosis (BCG) and hepatitis B (HepB) have been reported at 100%, according to the records that all children were immunized at the hospital at birth. Vaccine coverage for children age 1 year showed a slight improvement after project implementation. Overall immunizations for OPV and DTP increased from 91.7% (483/527) to 94.4% (408/432), while measles increased from 89.2% (470/527) to 89.6% (387/432) (Figure 2 shows this). Fluctuations in monthly coverage suggested a slightly higher trend after tablet applications started to be used in the project areas; the minimum-maximum range for monthly immunizations of OPV-DTP changed from 81% (26/32)-98% (47/48) to 86% (30/35)-100% (36/36), and for measles vaccine 73% (33/45)-97% (31/32) to 83% (30/36)-97% (32/33) (Figure 3 shows this).

Among children age 2 years, overall coverage for OPV-DTP increased from 86.3% (391/453) to 86.6% (362/418), while JE increased from 83.9% (380/453) to 87.6% (366/418). However, the minimum-maximum range for monthly immunizations of OPV-DTP changed from 77% (24/31)-94% (31/33) to 60% (12/20)-96% (24/25), and for JE it was 67% (24/36)-93% (27/29) to 68% (21/31)-98% (43/44). Due to a change in the JE vaccine schedule for children age 3 years during the project implementation period, the overall coverage for JE decreased from 80.6% (348/432) to 75.4% (310/411), while the minimum-maximum range changed from 71% (20/28)-91% (20/22) to 68% (21/31)-88% (29/33). Among children age 4 years, the overall coverage for OPV and DTP increased from 73.2% (372/508) to 78.0% (348/446), and the minimum-maximum range for monthly immunizations changed from 54% (13/24)-87% (27/31) to 58% (21/36)-89% (17/19).

Figure 2. Overall immunization coverage before and after project implementation. (BCG= Bacillus Calmette-Guérin vaccine, DTP= diphtheria-tetanus-pertussis vaccine, JE= Japanese encephalitis vaccine, HepB= Hepatitis B vaccine, and OPV= oral polio vaccine).

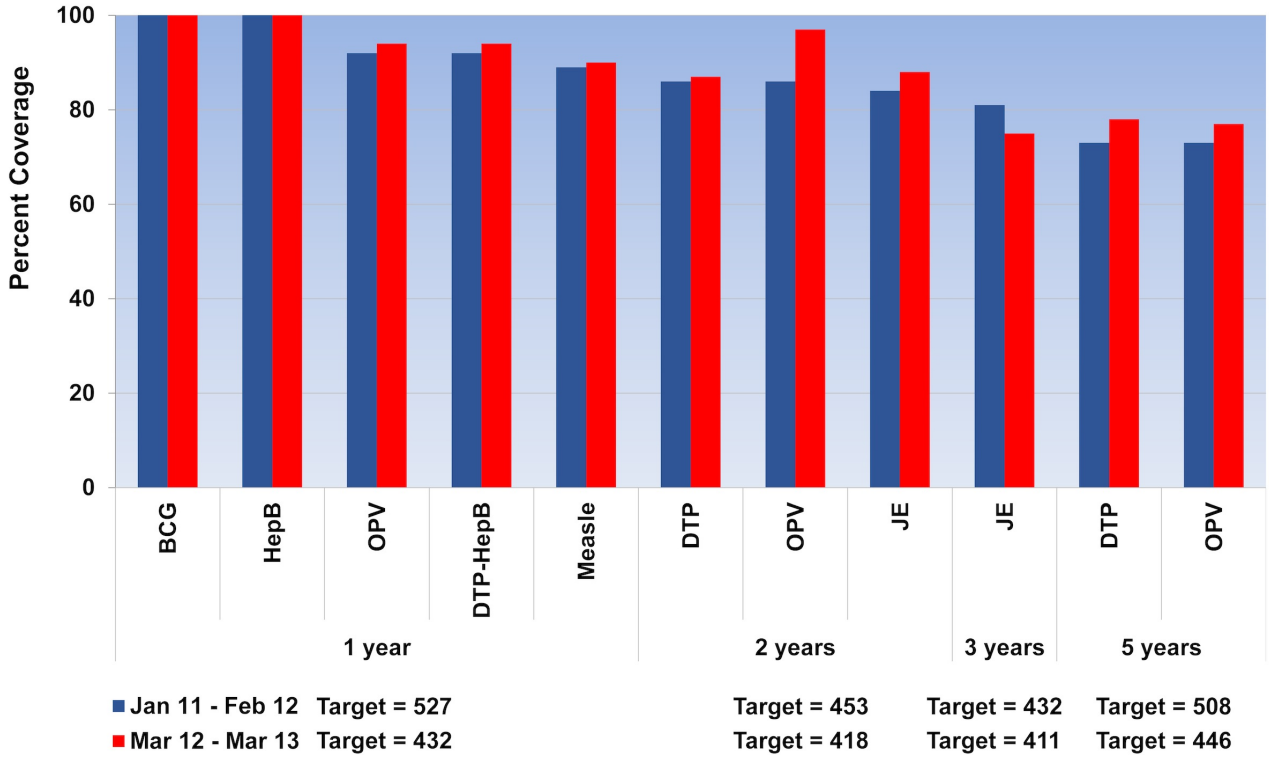
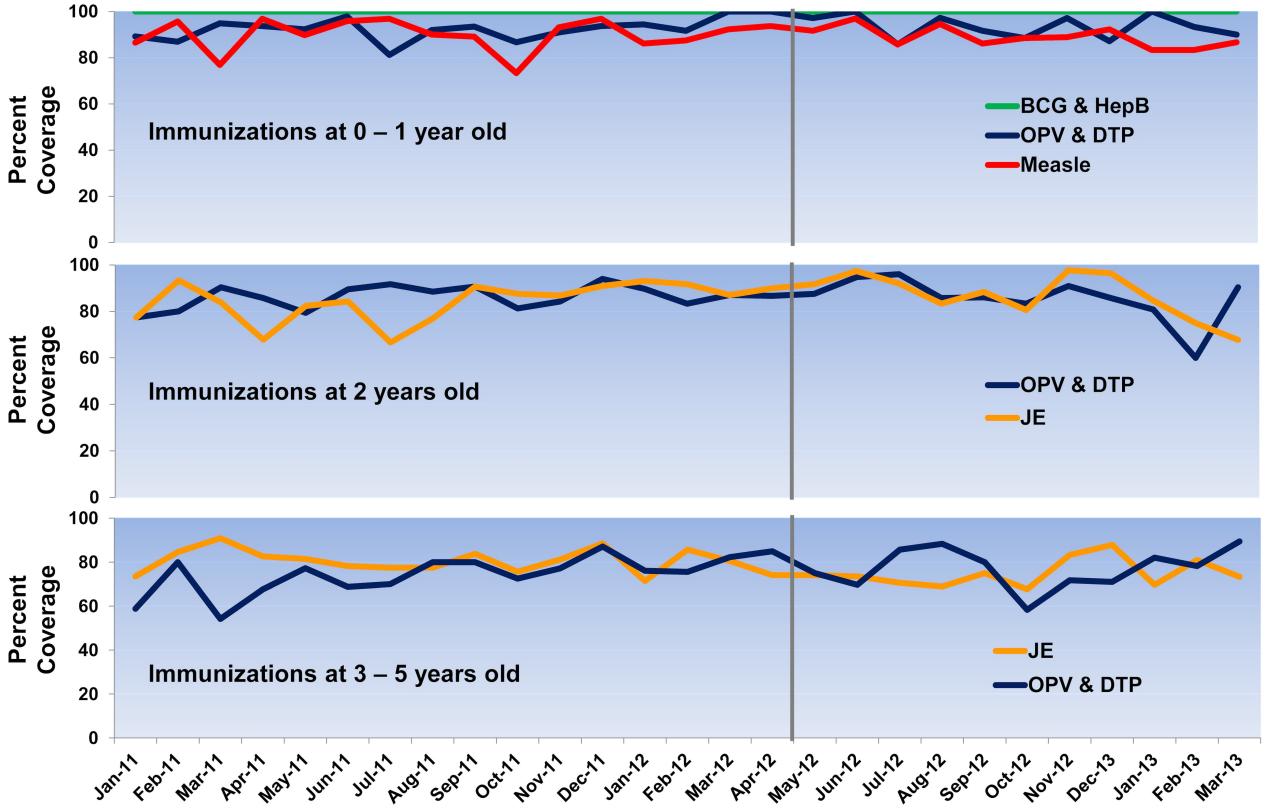


Figure 3. Monthly immunization rates by children ages. (BCG= Bacillus Calmette-Guérin vaccine, DTP= diphtheria-tetanus-pertussis vaccine, JE= Japanese encephalitis vaccine, HepB= Hepatitis B vaccine, and OPV= oral polio vaccine).



Behavior Change Communication Determinants

Repeat KAP surveys were carried out among the 7 highland minority groups, and composed of: 32.5% (104/320) Akha, 25.3% (81/320) Lahu, 15.6% (50/320) Hmong, 11.3% (36/320) Mein, and other groups (Table 1); about 77.2% (247/320) held a Thai ID card; 12.5% (40/320) a special hilltribe status card; and 7.5% (24/320) possessed no official card at all. All

respondents were mothers, with an average age of 30.3 (SD 7.9) years. Approximately 55.3% (177/320) and 40.9% (131/320) had 1-2 and 3-5 children, respectively; 58.8% (188/320) and 31.3% (100/320) had 1 and 2 children age < 6 years, respectively.

Knowledge scores, measured at months 6 and 12 after the BCC was launched, appeared to increase, but without statistical significance. The percentages of those who scored > 50% correct about a particular disease changed from 82.2% (263/320) to 88.8% (284/320) (Table 2). Regarding maternal attitudes toward immunization, about 80.9% (259/320) at month 6, and 84.4% (270/320) at month 12, displayed a highly positive attitude level (ie, a minimum 4 of 5 items ranked positively). Some with moderate attitude levels at month 6 shifted to higher positive levels. Regarding practices about preparation and having their children immunized at health facilities, most mothers changed their behaviors. At month 6, about 28.1% (90/320) of mothers reported using appropriate practices (ie, at least 5 of 6 items ranked as “always”/“never”, depending on the positive/negative items). At month 12, these practices increased significantly, to 44.1% (141/320).

Table 1. Characteristics of respondents in repeated KAP survey.

Characteristics	n	Percentage (N=320)
Ethnic groups		
Akha	104	32.5
Lahu	81	25.3
Lisu	7	2.2
Karen	1	0.3
Hmong	50	15.6
Mien	36	11.3
Other	36	11.3
Missing	5	1.5
Age groups		
≤ 20 years	24	7.5
21-30 years	148	46.3
31-40 years	106	33.1
≥ 41	42	13.1
Identification holders		
Thai ID card	247	77.2
Hilltribe status card	40	12.5
Other cards	3	0.9
Stateless status	24	7.5
Missing	6	1.9
Number of live children		
1-2	177	55.3
3-5	131	40.9
≥ 6	9	2.8
Missing	3	1.0
Number of children < 6 years		
1	188	58.8
2	100	31.3
3	11	3.4
Missing	21	6.5

Table 2. KAP of mothers at months 6 and 12 after implementation of behavior change communication package.

KAP survey	Month 6 (N=320)		Month 12 (N=320)		*P* value
	n	percentage	n	percentage	
Knowledge (6 items)					
≥ 80% (5-6 score)	17	5.3	12	3.8	.134
≥ 50% (3-4 score)	246	76.9	272	85.0	
< 50% (1-2 score)	50	15.6	30	9.3	
None (0 score)	1	0.3	0	0.0	
Missing	6	1.9	6	1.9	
Positive attitude (5 items)					
≥ 80% (4-5 items)	259	80.9	270	84.4	.004
≥ 50% (3 items)	40	12.6	17	5.3	
< 50% (1-2 items)	19	5.9	24	7.5	
Missing	2	0.6	9	2.8	
Proper practice (6 items)					
≥ 80% (5-6 items)	90	28.1	141	44.1	< .001
≥ 50% (3-4 items)	195	61.0	138	43.1	
< 50% (1-2 items)	35	10.9	23	7.2	
Missing	0	0.0	18	5.6	

Discussion

Technical Challenges Met

The technical challenge of applying information sharing between tablets of VHVs and health care personnel staff in remote areas was manageable. The telephone signals in the highland project implementation villages varied, but all data could be transmitted when a telephone signal was available, while other routine activities and data collection during each home visit were conducted offline. This proved that the innovation could be useful in hard-to-reach populations. Other research also suggests this kind of innovation can yield timely information for improving case management, delivering much higher quality, validity, and reliability [35,37]. In a similar study using smartphones to promote maternal and child health, mobile technologies were reported as an effective platform via provision of 6 core functionalities: (1) informing stakeholders, (2) training health providers, (3) enabling more accurate and precise self-monitoring, (4) delivering prompt reminders/supportive messages, (5) supporting effective service delivery over time, and (6) alerting care providers to specific cases [38]. In terms of the monitoring assessment carried out during the course of the project, the tablet application appears to have been well accepted by health care providers (ie, PHU personnel and VHVs) and by highland people in the villages. However, it should be noted that there was no formal assessment on acceptance of the technology conducted in this study; the acceptance was simply based on unstructured interviews with all health care providers in the study areas and with some random villagers during project monitoring of VHVs' home visit activities. At the start of project implementation, however, there were minor changes in the information sharing process, and customization of application displays corresponding with the needs of VHVs and mothers.

In 2011, Thai nationwide statistics indicated that vaccine coverage rates were > 90%: 99% for BCG, DTP, and OPV; and 98% for measles and HepB [39]. But as found in this study, the rates were slightly lower for highland minority and stateless populations. In this study, slight improvement on vaccine coverage rates was shown; this could be partially explained by the study having intensified awareness in the community area. Such improvement was also observed during the first initiative to use cell phones for boosting ANC/EPI activities among migrants on the western border of Thailand [31]. In the report on updates of evidence-based strategies for children's health and well-being [40] regarding the effectiveness of both patient-oriented intervention (including client reminder/recall system and education) and system-oriented intervention (including home visiting and case management), the findings of several studies over the decade revealed that client reminder/recall interventions could increase immunization rates by 5% to 20%, and clients who received home visits had significantly higher completed immunization rates. Overall coverage of different vaccines in this study showed increment in the range of 1% to 5%. The increasing rates appear to confirm the notation on stability in coverage once vaccination rates increase above a certain threshold, such that the increase in either developed or developing countries tends to taper off after 85% [41,42]. It was suggested, however, that good performance in immunization strategies for health care practices should be measured as achieving and maintaining coverage rates necessary to assure herd immunity of which the lower bounds was between 75% to 90% for most vaccine preventable diseases [42]. As shown in this study, the observed immunization rates in the

study populations are above the lower-bounds and moving toward higher coverage rates.

As suggested in the literature, nonimmunization or lower immunization rates could be partly attributable to the complexity of individual, community, and legal factors involved. The most common explanations about this outcome concern competing priorities in child immunization, working longer hours due to poverty, and being socially and legally alienated [20,23,43]. Studies of trends in disparities in complete immunization indicate other critical factors, including low parental education levels, availability and ease of access to health care facilities, and commuting difficulties for rural and remote populations [43-45]. A main challenge of this project was the distance from the highland villages to the responsible PHUs. PHU personnel and VHVs reported concerns about distance, and also about the use of bad roads and paths, especially during the rainy season. Interestingly, documents from the grey literature for the World Health Organization (WHO) have suggested demographic or sociological characteristics are underlying or secondary determinants; that a primary factor is lack of communication, and efforts to distribute information promoting immunization [43]. It has been suggested that vaccine-related communications and parent-provider interactions are critical, such that effective interaction would address concerns and motivate parents toward completing immunization schedules. Poor communication, in contrast, introduces feelings of rejection and dissatisfaction [46]. In this project, trained VHVs are considered key players, since they are the ones who actually work in the villages, encouraging those already registered, as well as newcomers from remote areas, to engage with EPI efforts. Despite VHVs being members of the 7 tribes, not even they can speak all languages in their areas of responsibility. They need to be able to maintain good relationships, and be able to open clear communication lines between the PHUs and villagers. They also need to understand basic concepts about vaccination processes, as well as national and local EPI strategies and management. Training in new ways to conduct their duties in the villages, as well as using new technologies, is important for the success of this initiative. Refresher courses on updated versions of the developed applications are also important, not only for VHVs, but PHU staff as well.

Differences in culture and beliefs in relation to the health care-seeking behaviors of hilltribe peoples represent an ongoing challenge. The BCC animations with selectable languages have been implemented and accepted by all stakeholders. As part of the development of a selectable language BCC, the script translation into 7 ethnic languages was quite a challenge. While many common and technical words are equivalent to Thai or English, sometimes no words had precisely the same meaning. Moreover, some words have different spellings and pronunciations, even within the same tribe. However, posttesting translations and back-translations and piloting their use among several tribal groups achieved a solution.

In analyzing the postlaunch success of BCC in the community, the KAP survey revealed that the mothers had good knowledge, a positive attitude, and employed proper practices at completion of the 6 month survey, and demonstrated even higher levels at the 12 month follow-up. In this study, even though knowledge of diseases under the EPI scheme measured at 2 time points were not statistically significant; the overall percentage of correct answers was higher at 12 months. As shown by studies of factors associated with completing immunization in vulnerable populations, the primary goal of EPI activities and interventions should be strengthening communication and raising awareness in the community; inadequate knowledge regarding the objectives and importance of immunization demonstrably leads to low vaccine coverage [47,48]. The BCC in different languages appears successful in increasing positive attitudes toward immunization, and also in encouraging a shift toward proper practices in terms of prompting and preparing for EPI activities. Such changes can be said to have contributed to the higher percentages of vaccine coverage seen in the project areas. As evidenced in other studies, a positive attitude and proper practices in relation to applying knowledge are significant predictors of improved maternal health-seeking behaviors toward child health [49-51]. However, it is well recognized that one of the weaknesses of the KAP study is that it is difficult to draw out a policy implication from study outcomes. The challenge of KAP outcomes after implementation of BCC regarding EPI in this study is particularly about its potential impact on promoting the awareness of the importance of the EPI program among illegal or underserved populations. The health care providers at remote areas in this study have been informed with the study results and continued using the BCC in their responsible communities. The BCC and the study results were also presented to authorities of the Department of Disease Control at the Thai Ministry of Public Health, and the BCC packages developed in this study were consequently considered and used as part of the department EPI promotion program.

Conclusions

To meet the challenge of attaining their maternal and child health Millennium Development Goals, the WHO and UNICEF have recommended countries to implement a central strategy of immunizing hard-to-reach infants and other age groups by focusing more on work carried out at district level [52]. This study reveals potential benefits of the initiative; mobile-technology applications for case ID and for behavior-change communication strategies, integrated into the routine EPI work at point-of-care through subdistrict health care systems. Immunization coverage has shown an improved trend among vulnerable populations who remain underserved and who often receive limited recognition. The BCC package appears beneficial and contributes to the overall success of the project in raising child-care awareness and concern. The BCC content used in this project is currently being revised, due to changes in the immunization schedule. The package is also expanding to cover another language, Burmese, which over a million migrants working in urban-rural settings and border areas of the country use to communicate. The BCC version for highland populations was disseminated to border area health centers in northern Thailand; the revised version for Thai and Myanmar migrants will be used all across the country at health centers under the Thai Ministry of Public Health. The BCC packages are now available as Google applications, which can be downloaded from the attachment of this manuscript and/or

Google Play Store on android system (application title, Vaccine EPI).

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Authors' Contributions

JK designed and planned the study, drafted the first version of the paper, submitted the paper, and approved the final version. TA, KJ, and SL assisted in designing and planning the study, collected data, monitored activities at study sites, wrote the submitted paper, and approved the final version. AK, SS, AS, and PW designed and programed the application module and approved the final version. JK is the chief executive officer of the Center of Excellence for Biomedical and Public Health Informatics (BIOPHICS) at the Faculty of Tropical Medicine, Mahidol University. TA is a faculty member at School of Health Science, Mae Fah Luang University, Chiang Rai Province. SL is the chief of informatics, and AK is the chief of logistics and operation at BIOPHICS. KJ is a graduate student at the Department of Tropical Hygiene and a member of the public health staff at BIOPHICS. SS, AS, and PW are system analysts and programmers at BIOPHICS.

Conflicts of Interest

The StatelessVac project was awarded via Grand Challenges Explorations (Round 7-Grant Number OPP1046158) by the Bill & Melinda Gates Foundation. This project has been receiving in-kind support from the Faculty of Tropical Medicine, Mahidol University, Bangkok, and the School of Health Science, Mae Fah Luang University, Chiang Rai Province, Thailand. Faculty members of both universities have been actively involved in planning and implementing the project at the study locations.

Multimedia Appendix 1

Example of edutainment animation on expanded programme on immunization (EPI) in each dialect languages.

[WMV File (Windows Media Video), 10MB - mhealth_v3i1e4_app1.wmv]

Multimedia Appendix 2

Google application of the BCC package in Thai version.

[APK File, 148MB - mhealth_v3i1e4_app2.apk]

Multimedia Appendix 3

Google application of the BCC package in English version.

[APK File, 136MB - mhealth_v3i1e4_app3.apk]

Multimedia Appendix 4

Google application of the BCC package in Myanmar version.

[APK File, 143MB - mhealth_v3i1e4_app4.apk]

Multimedia Appendix 5

Google application of the BCC package in Akha version.

[APK File, 145MB - mhealth_v3i1e4_app5.apk]

Multimedia Appendix 6

Google application of the BCC package in Yunnan Chinese version.

[APK File, 154MB - mhealth_v3i1e4_app6.apk]

Multimedia Appendix 7

Google application of the BCC package in Hmong version.

[APK File, 153MB - mhealth_v3i1e4_app7.apk]

Multimedia Appendix 8

Google application of the BCC package in Karen version.

[APK File, 188MB - mhealth_v3i1e4_app8.apk]

Multimedia Appendix 9

Google application of the BCC package in Lahu version.

[APK File, 167MB - mhealth_v3i1e4_app9.apk]

Multimedia Appendix 10

Google application of the BCC package in Lisu version.

[APK File, 127MB - mhealth_v3i1e4_app10.apk]

Multimedia Appendix 11

Google application of the BCC package in Yao version.

[APK File, 125MB - mhealth_v3i1e4_app11.apk]

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Abbreviations

ANC: antenatal care
BCC: behavior change communication
BCG: Bacillus Calmette-Guérin vaccine
DTP: diphtheria-tetanus-pertussis vaccine
EPI: Expanded Programme on Immunisation
HepB: Hepatitis B vaccine
ID: identification
JE: Japanese encephalitis vaccine
KAP: knowledge, attitudes, and practices
OPV: oral polio vaccine
PHU: primary health unit
UNICEF: United Nations Children's Fund
VHVs: village health volunteers
WHO: World Health Organization

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Original Paper

Implementation of a Confidential Helpline for Men Having Sex With Men in India

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Abstract

Background: In India, men who have sex with men (MSM) often face physical violence and harassment from police and the general society. Many MSM may not openly disclose their sexual identity, especially if they are married to women and have families. Due to pervasive stigma and discrimination, human immunodeficiency virus (HIV) prevention programs are unable to reach many MSM effectively.

Objective: The objective of this paper was to describe the design, operations, and monitoring of the Sahaay helpline, a mHealth intervention for the MSM population of India.

Methods: We established the “Sahaay” mHealth intervention in 2013; a MSM-dedicated helpline whose main goal was to increase access to comprehensive, community-based HIV prevention services and improve knowledge, attitudes, and behaviors of MSM towards HIV and sexually transmitted infections (STI) in three states of India (Chhattisgarh, Delhi, and Maharashtra). The helpline provided a 24x7 confidential and easy to use interactive voice response system (IVRS) to callers. IVRS function was monitored through an online dashboard of indicators. The system also provided real-time reporting on callers and services provided.

Results: The helpline received more than 100,000 calls from 39,800 callers during the first nine months of operation. The helpline maintained an operational uptime of 99.81% (6450/6462 hours); and answered more than 81.33% (83,050/102,115) of all calls. More than three-fourths of the calls came between 9:00 am-12:00 pm. The most successful promotional activity was “interpersonal communication” (reported by 70.05%, 27,880/39,800, of the callers). Nearly three-fourths of the callers self-identified as MSM, including 17.05% (6786/39,800) as rural MSM and 5.03% (2001/39,800) as a married MSM. Most callers (93.10%, 37,055/39,800) requested information, while some (27.01%, 10,750/39,800) requested counseling on HIV/acquired immune deficiency syndrome (AIDS), STIs, and other health and nonhealth issues. There were 38.97% (15,509/39,800) of the callers that were provided contacts of different HIV/AIDS referral services. Many MSM clients reported increased self-esteem in dealing with their sexual identity and disclosing the same with their family and spouse; and an increase in HIV/AIDS risk-reduction behaviors like consistent condom use and HIV testing.

Conclusions: National HIV/AIDS prevention interventions for MSM in India should consider scaling-up this helpline service across the country. The helpline may serve as an important mechanism for accessing hard-to-reach MSM, and thus improving HIV prevention programing.

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KEYWORDS

mobile phone; helpline; MSM; HIV prevention; India

Introduction

HIV Prevention Programs for Men Who Have Sex With Men in India

Men who have sex with men (MSM) have been substantially affected by HIV epidemics worldwide and better HIV prevention strategies are urgently needed; epidemics in MSM are reemerging in many high-income countries and gaining greater recognition in many low-income and middle-income countries [1]. MSM in India are more likely to be human immunodeficiency virus (HIV) infected and face distinct psychological challenges [2]. The HIV prevalence rate among MSM in India is estimated at 4.4% overall [3], well above that of the general population, 0.27% [4]. HIV/AIDS related stigma is recognized as a major barrier to HIV prevention efforts and an impediment to mitigating its impact on individuals and communities; studies have shown significant associations between HIV-related stigma and low uptake of HIV testing services, unwillingness to disclose test results, and low knowledge about HIV transmission [5,6]. In India MSM are often abused; they face physical violence and harassment from police and the general society. Many MSM may not openly disclose their sexual identity, especially if they are married and have families [7]. Stigma and discrimination acts as an important hindrance for HIV prevention programs targeting different MSM populations. Confronted with significant levels of stigma, discrimination and social exclusion, and limited access to HIV/AIDS prevention and care services, MSM in India are at high risk for HIV infection [8]. The national AIDS control organization (NACO) provides basic targeted intervention (TI) services for MSM, similar to those for other populations at high risk for HIV. These services include counseling and testing for HIV, referral systems for sexually transmitted infection (STI) diagnosis and treatment, availability of free condoms, drop-in centers (safe spaces) at community based organizations or nongovernment organizations (CBOs)/(NGOs), and peer educator outreach [9]. The TI program has been effective, potentially reflected by the trend [10] of declining HIV prevalence among high risk groups. There is emerging evidence that the concerted efforts made in HIV/AIDS prevention and control, particularly among the high risk groups, are having a positive effect on the epidemic, with a 57% reduction in new annual infections over the past decade, the adult general population HIV prevalence declined from 0.41% in the year 2000, to 0.35% in 2006 and to 0.27% in 2011 [11].

However, HIV prevalence has not declined among MSM compared to other high risk population groups [3]. The lack of change may be partly attributable to insufficient information or services accessed, by MSM. In addition, MSM who do not regularly visit cruising sites or drop-in centers are particularly hard-to-reach and have limited access to quality HIV/AIDS prevention services. The NACO recognizes that they have not been able to reach approximately 30% of identified MSM through their interventions [11]. There is an urgent need to reach this population with prevention, care, and treatment messages, as studies [12] have documented their risky sexual behaviors including high numbers of sexual partners, low rates of consistent condom and lubricant use, and high rates of STIs.

Using Mobile Technology to Promote Behavioral Change

A systematic review of literature on “telephone-delivered interventions” [13] demonstrated the effectiveness of this strategy in promoting behavioral changes such as “increased physical activity” and “dietary changes”. Information and communication technology such as the Internet and mobile phones can deliver behavioral change interventions for STD/HIV prevention and care to more people at low cost [14]. Another review of current research [15] studies published between January 1990 and March 2008 examined mobile telephone short-message service (SMS) for delivering health behavior change interventions via text messages. Positive behavior change outcomes were observed in 13 of the 14 reviewed studies.

An important mHealth experience from the HIV/AIDS sector is that of the “Text Me! Flash Me!” Helpline launched in Ghana in September 2008. It used cell phone technology to provide most-at-risk populations with friendly and accessible HIV/AIDS information, referrals, and counseling services from qualified providers. The evaluation of the project suggested that there was an increase in demand for HIV testing and counseling as well as counseling on STI diagnosis and treatment services. The helpline increased client’s knowledge of and intention to use condom and lubricants [16]. Many countries are also using mobile applications and the Internet for HIV/AIDS intervention [17-19].

mHealth could significantly transform the health care milieu in India by improving health care access for the huge underserved rural population, and enhancing the care for urban residents. India’s high level of mobile phone penetration, with over 911 million subscribers as of February 2012, comprises the world’s population of mobile phone users. The overall teledensity in India reached 78.1% by the end of February 2012 [20]. The great potentials of mHealth are seen in different settings of India [21].

In 2013, we established the “Sahaay” mHealth Intervention, a MSM-dedicated helpline whose main goal was to increase MSM access to comprehensive, community-based HIV prevention services and improve the HIV/STI related knowledge, attitudes,

and behaviors of MSM. The purpose of this paper was to describe the design, operations, and monitoring of the intervention.

Methods

Target Population

A consultation with key stakeholders, including representatives from the NACO, MSM community, and various HIV program implementing agencies, was held to outline categories of hard-to-reach MSM, defined as one who is either not registered with a TI project or registered, but has not received any service from a TI in the last six months. The hard-to-reach MSM included: (1) self-identified MSMs, (2) married MSMs, (3) clients of female sex workers, (4) migrant population, (5) clients of male sex workers, (6) rural MSMs, (7) nonself-identified MSMs in cruising sites, (8) male sex workers, (9) MSM people living with HIV/AIDS (PLHIV) network members, and (10) party MSM network members (these MSM are involved in organizing and/or attending sex parties). The categories are not mutually exclusive.

Study Sites

The project included a 9-month intervention in three states of India, namely, Chhattisgarh, Delhi, and Maharashtra, shown in Figure 1.

Family Health International (FHI) 360 worked in coordination with NACO and the State AIDS Control Societies to implement the Sahaay project. The Sahaay helpline operated 24 hours a day, seven days a week, for nine months (September 2013 through May 2014) as the intervention component of the Sahaay mHealth project.

Figure 1. The three study states in India, namely, Chhattisgarh, Delhi, and Maharashtra.

Intervention

Theoretical Basis

The mHealth Sahaay project was based on the Health Belief Model, and the Transtheoretical Model [22]. The Health Belief Model, a psychological model that attempts to explain and predict health behaviors by focusing on the attitudes and beliefs of individuals, was adapted to explore a variety of health behaviors, including sexual risk behaviors and HIV/AIDS transmission. The project used the Transtheoretical Model to provide messages specific to the different stages of condom use

(stage 1, not using and no intention to use condoms; stage 2, not using, but has an intention to use condoms in future; stage 3, using condoms sometimes; stage 4, using condoms consistently for less than six months; and stage 5, using condoms consistently for more than six months) of the callers.

Helpline Operations

The Sahaay helpline was available to all mobile and fixed phone users. The helpline was managed by four trained counselors in each of the three call centers, serving eight hour shifts (one extra person to account for leaves); at any point of time, there were three counselors available. Counselors with different local dialect backgrounds were purposively hired to provide counseling in local languages as well as Hindi. The duty hours and break-time between the three centers were adjusted to ensure there was no discontinuity in the availability of counselor. Counselors were provided with computer-based software containing a database with a comprehensive list of possible questions and appropriate responses to answer questions promptly and correctly. The database contained an area-wide list of health services that MSM can be referred to for further support and treatment like HIV testing, ant-retroviral therapy (ART), STI diagnosis and treatment, and other general and specialized health issues.

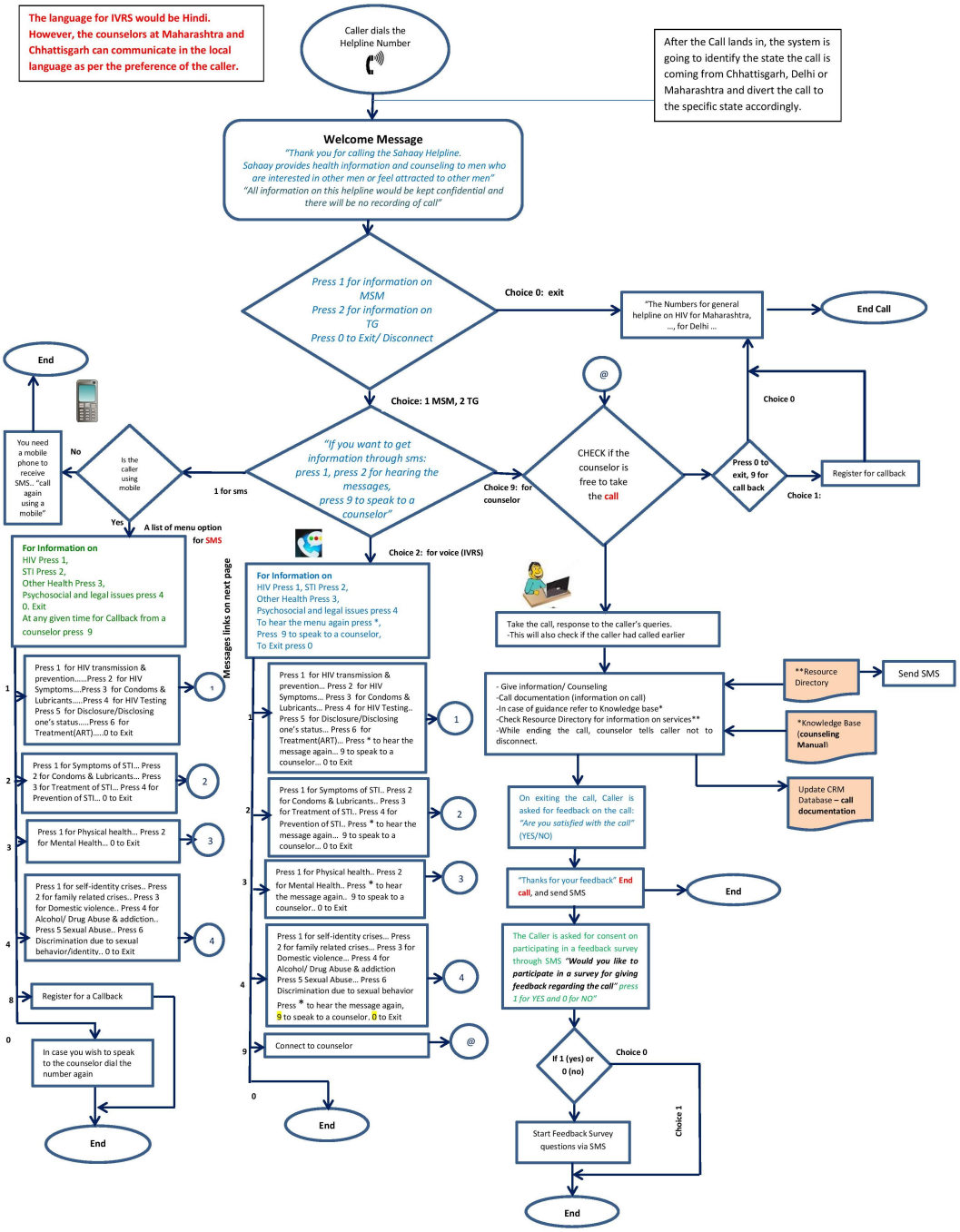
The call centers were housed in three selected MSM-led CBOs that delivered other prevention services for MSM. A caller could receive information and counseling by talking to a counselor, hearing interactive voice response, and receiving text messaging.

The client interaction process comprised a greeting message, then the helpline assured the caller of the confidentiality, and the interactive voice response system (IVRS) asked the caller if they were seeking information for MSM, transgender (TG), or other groups. For MSM or TG selections, it gave the caller different options for seeking information: talk to a counselor (this option provided the caller with an option of interaction with the counselors and to get information and counseling), voice IVR messages (consisted of prerecorded voice messages which offered options for selecting information), or SMS (when the caller selected SMS as means for information seeking on helpline, the caller was sent a SMS message to select the option from the main list of information) (SMS were charged as per the service provider). Figure 2 shows the detailed IVRS flow chart.

If the selection was not MSM/TG, then the helpline gave the caller the other general helpline numbers for HIV/AIDS (in Delhi and Maharashtra, there was a NACO supported general HIV/AIDS helpline) and the call ended. Calls where clients requested to speak to a counselor were received at any of three call centers in Chhattisgarh, Delhi, and Maharashtra where the counselor was available. In case the caller had a specific language preference, the call was transferred to the location where the counselor spoke the desired language. While the call landed with a counselor, a screen called “Call Documentation Sheet (CDS)” popped up to document the call, with the following indicators: new/duplicate caller, categories of MSM, purpose/issues for calling, accessing other sources of help, awareness of HIV and STI, attitude toward HIV/STI, condom use behavior, HIV testing behavior, willingness to pay for helpline, and how they learned about the helpline. Counselors entered this information on the CDS while speaking to the caller. The CDS also had notes from previous calls if the caller had called previously.

In the event a counselor did not have sufficient information on any topic, s/he had access to a knowledge base in the form of “Counselor Manual” and “Standard Operating Procedure”. In case the caller requested the address of any facility, the counselor had an option of searching through a resource directory and sending the address by SMS to the caller. At the end of the call, the counselor saved the information and the CDS was closed. The counselors also documented select case studies of callers and qualitative data in a notebook. Based on counselors’ feedback, the IVR and SMS messages were updated at the third and sixth month.

Figure 2. Helpline interactive voice response system (IVRS).



Services Offered

The following services were provided to the caller: HIV/AIDS counseling, including promotion and referral for HIV testing of callers and their partners to different facilities like TI projects, STI clinics (government run centers for free of cost STI diagnosis and treatment), and Integrated Counseling and Testing Centers (ICTC) (there are 1000s of government HIV testing and counseling centers across the country where the screening and the confirmatory HIV test is done free of cost); and

psychosocial counseling, with information and education on HIV/AIDS, MSM risk reduction, and condom and lubricant use.

Promotion Activities

In the Three Study States

A team of 12 Community Mobilizers (CMs; who had themselves been hard-to-reach MSM earlier), four in each study state, first mapped hot spots patronized by MSM in each district of the state and planned their recruitment approach. CMs then promoted the Sahaay helpline through interpersonal contact in the community, by distributing contact cards at cruising sites, and posting helpline posters and stickers in key locations like government TI projects, MSM preferred health care providers, and beauty and massage parlors where hard-to-reach MSM either work or go for services. The project also developed radio spots that were broadcast through the All India Radio; these particularly reached the rural population.

All States of India

Social media, including Facebook, Twitter, and PlanetRomeo, was utilized to disseminate messages widely. Each day a new message was posted on Facebook and Twitter. A promotional video ("BOL NA MERE YAAR", "Tell me My Friend") posted on YouTube and different other social media channels became very popular. Leading media houses (Times of India, Hindustan Times, Indian Express, and Time Out), prompted by the project's press releases, published articles on the Internet, and in print.

Helpline Monitoring

The software program also functioned as a management information system (MIS). It monitored the content of the call and helpline performance. Data generated by the MIS included,

1. Helpline system monitoring data generated automatically and collected daily
2. Counselor call monitoring data, for example, data the counselors documented on the CDS
3. Case studies recorded in the counselor's notebook; collected during the weekly counselors mentoring done through conference calls by FHI 360 staff.

The FHI 360 staff (Behavior Change Communication Officer and Program Officer) mentored the counselors and the CMs through weekly teleconferences. The CMs were selected from and worked within their respective states (four from each state) to address local outreach activities for hard-to-reach MSM. The CMs reported the number of new hard-to-reach contacted and motivated to make the first call daily through SMS texts.

Collection of Information and Confidentiality

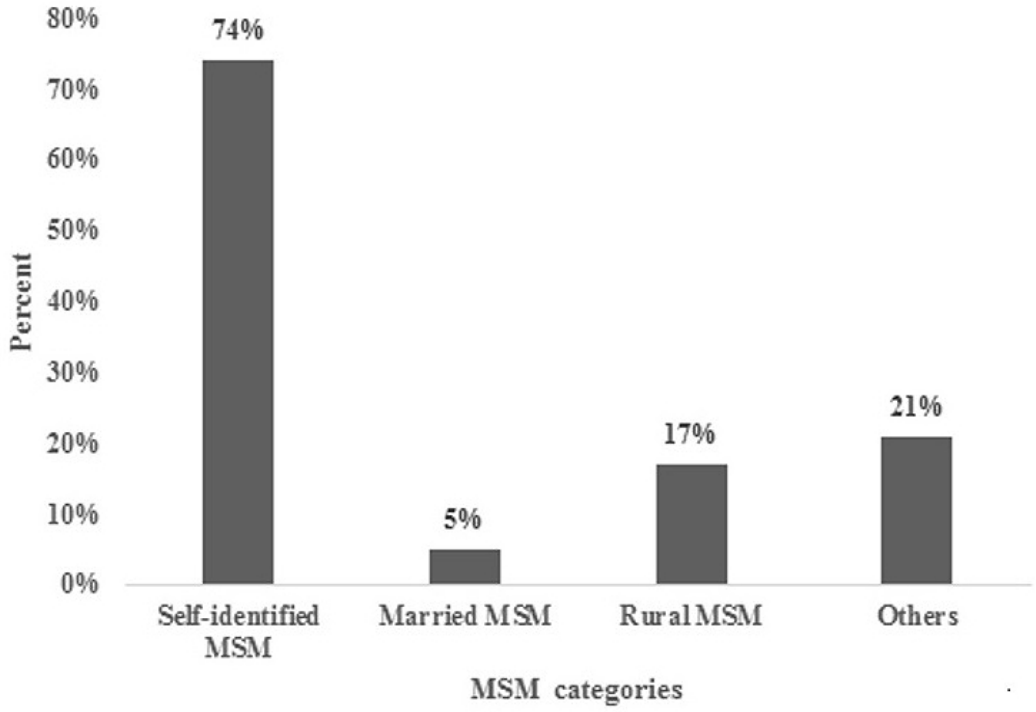
The caller's telephone number was not visible to the counselor, but was stored in the server in computer encryption. Clients making multiple calls using the same phone number were shown as duplicate callers on the computer screen of the counselor. The counselor did not ask any personal identifier (like name and address), but discussed HIV/AIDS risk behaviors and provided the required counseling and information on services. The counselor could not open the CDS after saving it. The CDS was stored as an encrypted file in the cloud-based server; consolidated information was generated periodically by the server administrator and used by the project team to monitor the helpline.

Results

Target Population

Based on responses given to the counselors, Figure 3 shows the profile of the callers. Nearly three-fourths of the callers self-identified as MSM, including 17.05% (6786/39,800) as rural MSM and 5.03% (2001/39,800) as married MSM. The remaining 21.03% (8368/39,800) were clients of female sex workers, migrants, clients of male sex workers, nonself-identified MSM in cruising sites, male sex workers, or MSM PLHIV network and party MSM network members. Over the operational period, there was an increasing number of calls from MSM belonging to the rural and others categories. During the last quarter of the helpline, only 10.05% (1463/14,559) of callers had accessed services from any CBO, demonstrating that the helpline was gradually accessed by hard-to-reach MSMs who were earlier not reached out by conventional HIV prevention programs.

Figure 3. Categories of men who have sex with men (MSM) (N=39,800; multiple counts).



Helpline Operations

Volume of Calls Received and Key Factors Which Influenced the Volume of Calls

The project had established a daily target of 260 calls to achieve a target of 50,000 unique callers (callers counted as individuals) during the nine months (September 2013 to May 2014) of the helpline intervention. The helpline maintained an operational uptime of 99.81% (6450/6462 hours). Helpline call volume is displayed in Table 1; the total number of callers was 39,800; the number of callers who called more than one time was 46.24% (18,404/39,800). The sizeable percentage of these repeat callers suggests high acceptance of the helpline by MSM. Though the helpline was actively promoted in the three study states (Chhattisgarh, Delhi, and Maharashtra), calls came from all over the country, and a few (0.75%, 766/102,115) came from outside India. The helpline software was unable to document if calls were received from fixed or mobile phones; however, during routine feedback sessions with counselors and CM, they reported anecdotally that callers preferred using mobile phones as this provided them the access on the move and the option of calling from a private location of their choice.

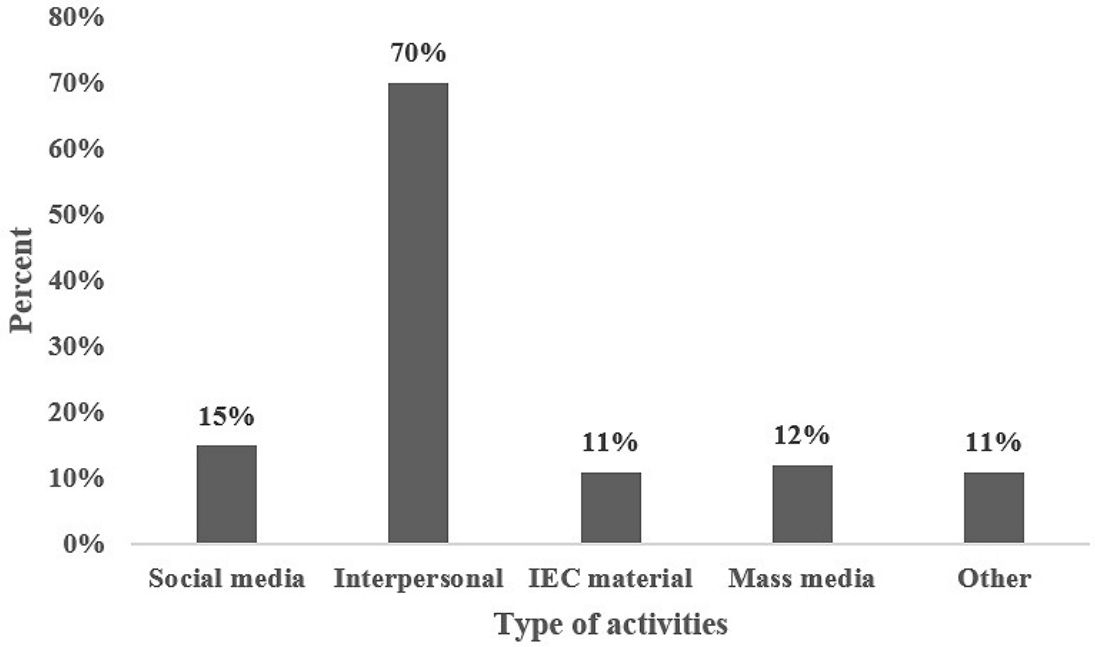
Table 1. Sahaay helpline call volume by service request (N=102,115).

Type of calls	Number	Percentage n (%)
Total calls	102,115	102,115 (100.00)
Counselor calls	51,988	51,988 (50.91)
IVR	45,212	45,212 (44.28)
SMS	4915	4915 (4.81)

Results of Promotion Activities of Helpline

Though promotion through social media; information, education, and communication (IEC) materials, news articles, and other modes of communication helped boost the number of calls, the contacts made by CMs indicate a significant role for interpersonal communication in promoting calls from hard-to-reach MSM. As Figure 4 shows, the most successful promotional activity was “interpersonal communication”, which was mostly conducted by CMs in the field, though the data also captured interpersonal communication between stakeholders (different service providers) and MSM; and MSM and their friends and other peers.

Figure 4. Promotional activities used (N=39,800; multiple counts), (Information, education, and communication = IEC).



Many callers in the beginning did not speak, while others spoke very briefly just to confirm confidentiality, and many callers opened up only after multiple repeat calls. Most callers (93.10%, 37,055/39,800) requested information on HIV/AIDS and STI; some also requested information on issues specific to transgenders, for example, breast enhancement and sex reassignment surgery, while some (27.01%, 10,750/39,800) requested counseling on HIV/AIDS, STIs, and other health and nonhealth issues (many callers requested information and also took counseling; hence the total of information and counseling is >100%; 120.11%, 47,805/39,800). Many callers faced psychosocial problems like "self-identity crisis", crisis in family relationships, violence and abuse, drug abuse, addiction, or discrimination in the work place or an educational institution. Self-identity crisis included MSM trying either by themselves or forced by others to comprehend their sexual identity (the MSM may not feel attracted to a female and start thinking why this is so with me; or his friends may tease him for his attraction toward a male). Crisis in family relationships included family members pressuring unmarried MSM to get married with women and married men pressured to abandon their sexual life choices. The majority of the callers (79.80%, 31,759/39,800) discussed HIV-related issues, while one-third (34.11%, 13,575/39,800) discussed STI-related issues. A small proportion (15.05%, 5989/39,800) of callers discussed other health issues, including psychosocial problems (4.93%, 295/5989) (many callers discussed multiple issues, hence the total is >100%; 128.95%, 51,323/39,800). Though the project did not measure knowledge of the caller, but they indicated they might know less about STI symptoms and treatment compared to HIV (Table 2).

Table 2. Type of information asked on HIV and STI (N=39,800).

Type of information[a]	HIV (31,759; 79.80%) n (%)	STI (13,575; 34.11%) n (%)
Prevention	28,365 (89.31)	9419 (69.38)
Symptoms	16,932 (53.31)	12,856 (94.70)
Condom/lubricants	16,885 (53.17)	8718 (64.22)
Treatment	2958 (9.31)	10,754 (79.22)

[a]multiple counts

Referral Services

Many of the callers, (39.25%, 15,622/39,800), asked for and were provided with contacts for various services. Referrals were made to ICTCs (39.02%, 6096/15,622), TI implementing NGOs (CBO/NGO implemented projects working mostly for HIV prevention and referral for HIV testing and treatment services) (22.95%, 3585/15,622), ART centers (government run HIV treatment centers, the services are provided free of cost) (11.04%, 1724/15,622), STI/STD clinics (9.03%, 1411/15,622), Community Care Centers (CBO run centers for providing supporting role in care and treatment of HIV/AIDS, especially during initiation of ART for early detection and management of side-effects of drugs; and where a long-term stay is required for supportive HIV/AIDS care) (6.96%, 1087/15,622), PLHIV MSM networks (5.96%, 931/15,622), and to tuberculosis directly observed treatment center (centers for diagnosing and treating tuberculosis).

Condom Use Behavior

Although none of the 39,800 callers reported consistent use of condoms during all sexual acts with all partners for more than six months, they were at various stages of the behavior change continuum, 17.98% (7156/39,800) reported that they did not intend to use condoms; 58.07% (23,111/39,800) would like to use them; 16.03% (6379/39,800) stated that they used condoms sometimes; and 7.96% (3168/39,800) used condoms always, but for less than six months. The counselors explored the reasons for inconsistent condom use. The most common reason provided was "lack of (sexual) satisfaction" (43.28%, 17,224/39,800), followed by unavailability (24.03%, 9565/39,800), partner refusal (15.03%, 5980/39,800), "does not know how to use" (12.01%, 4780/39,800), and "condom breaks" (10.02%, 3988/39,800). Only 1.00% (399/39,800) said, they do not have money to buy or are embarrassed to buy condom.

Reasons for Not Testing for HIV

Almost 70% of the callers, or 27,963/39,800, did not report HIV testing in the last one year; the counselor probed for the reasons for not getting tested. The most common reason for not getting tested was "fear" (50.82%, 14,211/27,963) followed by "lack of HIV testing awareness" (23.90%, 6682/27,963), "do not know where to go" (14.74%, 4122/27,963), and "lack of confidentiality at the HIV testing center" (11.12%, 3110/27,963). Only 1.03% (289/27,963) said that they did not have money for testing. Counselors reported that some callers were motivated to get tested after the call, of whom a small group called back to inform the counselors that they had taken an HIV test.

Monitoring

The Sahaay helpline had a capacity for 32 simultaneous calls including IVR, SMS, and counselor calls. Information technology system support (server, software, and operational glitches) was provided to ensure uninterrupted service around the clock. The helpline was monitored from the FHI 360 India office in Delhi. A continuous monitoring screen facilitated viewing of how many counselors were online and which calls were diverted to which counselor. The FHI 360 team could observe which counselors took the calls and completed the post call documentation. As part of the helpline quality control strategy, the team at the FHI 360 office used "mystery callers" posing as MSM callers with predetermined questions. The mystery calls demonstrated steady improvement in the performance of counselors in addressing the queries of the callers and counseling them on different issues. The helpline answered more than 80% (81.33%, 83,050/102,115) of all calls. More than three-fourths of the calls came between 9:00 am-12:00 pm.

Discussion

The Helpline Results Over Nine Months

It is encouraging to note that the helpline received more than 100,000 calls during the nine months of activities reaching out to different profiles of hard-to-reach MSM with information and counseling on HIV/AIDS prevention, care, and treatment. The experience of this helpline is in agreement with the findings of other mHealth service studies, which concluded that these services have wide population reach and can be individually tailored to the caller. This suggests that the service has potential as a delivery channel for HIV prevention and other health behavior interventions. HIV prevention and care programs using digital media have great potential to cost-effectively meet the complex needs of diverse and often underserved populations living with or at high risk of HIV [23]. Delivery of barrier and biomedical interventions with coordinated behavioral and structural strategies could optimize the effectiveness of HIV prevention; modeling suggests that, with sufficient coverage, available interventions are sufficient to avert at least a quarter of new HIV infections in MSM in diverse countries [1]. Unlike some similar interventions in Africa [24,25], which provided one-way SMS and voice message services to recipients, the Sahaay helpline was interactive and easily accessible, even to callers with low literacy, and demonstrates the value of using a confidential, but still human approach via phone counseling.

Strategies for Behavior Change

Innovative strategies for behavior change communication at individual, group, and community levels may include mobile phone messages, Internet-based strategies, and social marketing campaigns. Current prevention interventions for MSM in India need to consider appropriate modifications to reach out to the hard-to-reach MSM through innovative modalities, like the Sahaay model anonymous helpline service. There are various studies that advocate the use of mobile telephones in scaling up the health care delivery and outcomes. A study by Garai et al [26] argues that intervention studies have demonstrated the applications and effectiveness of mHealth in various health areas in resource poor settings.

Our findings show that interpersonal communication was more helpful in promoting the helpline services as compared to other modes of communication including IEC and social media. As reported from case studies and also from the data on issues requested by callers, there were many calls by those who were suffering from psychosocial issues. External factors, like legal and social barriers often aggravate psychosocial issues facing MSM. India needs HIV prevention approaches that simultaneously address behavioral, biomedical, and structural risks like decriminalization of same-sex behaviors, policies that safeguard MSM and transgender rights, engagement with the media, and community and health systems strengthening with participation of the MSM community. Behavioral approaches to promote safer behaviors to prevent HIV, specifically sustained efforts to increase the use of condoms, should be continued.

Limitations

Though the Sahaay helpline used a meticulously planned, technically sound monitoring system, the helpline experienced several challenges. Owing to the confidential nature of the helpline, a written referral system could not be implemented. Calls came from throughout the country though the study was located in just three states, and the resource directory of services and facilities developed only included services in the three states, hence the counselors were unable to provide the address of the services and facilities in other states. At times, some prank callers used offensive language; this negatively affected the morale of counselors. Sometimes, there were operational

glitches, such as the telephone and Internet line leading to the CDS not opening on the counselor computer, or call disturbances and disconnections. Very few callers accessed the SMS service. The Telecom Regulatory Authority of India did not allow delivery of text messages to mobile phones registered for "do not disturb" facility (in India, one can register with the telephone service provider for preventing calls from marketing agencies). It was also not possible for us to make the SMS service free, as a caller had to dial a number different from the toll free helpline number to access Sahaay messages through SMS. Additionally, the SMS service was available only in English (as most of the commonly used mobile phones in India support English and not Hindi). We also had very low utilization of an automated feedback system, potentially preventing detection and resolution of other technical problems. Because of the Indian Supreme Court ruling criminalizing same sex activity, All India Radio was very selective in terms of allowing messages for broadcast; we had to significantly reduce radio messaging.

Conclusions

In conclusion, the Sahaay helpline demonstrated that a large number of MSM could be reached over a short period of time from diverse locations in a wide geographic area with a functioning telephonic communication. The helpline was able to penetrate the hard-to-reach MSM groups and promote HIV/AIDS prevention through a nondiscriminatory approach. The helpline is also able to provide information of different health and other services required by the callers. This intervention could be a useful national strategy for reaching out to hard-to-reach MSM in India and other countries. This approach could also be tried for reaching out to other highly stigmatized and marginalized populations.

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Conflicts of Interest

None declared.

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Abbreviations

ART: ant-retroviral therapy
CBO: community-based organizations
CDS: Call Documentation Sheet
CM: community mobilizers
FHI: Family Health International
HIV: human immunodeficiency virus
ICTC: Integrated Counseling and Testing Center
IEC: information, education, and communication

IVRS: interactive voice response system
MIS: management information system
MSM: men who have sex with men
NACO: national AIDS control organization
NGOs: nongovernment organizations
PLHIV: people living with HIV/AIDS
SMS: short-message service
STI: sexually transmitted infection
TG: transgender
TI: targeted intervention

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Original Paper

Analyzing the Mobile "Digital Divide": Changing Determinants of Household Phone Ownership Over Time in Rural Bangladesh

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Abstract

Background: We had a unique opportunity to examine demographic determinants of household mobile phone ownership in rural Bangladesh using socioeconomic data collected as part of a multiyear longitudinal cohort study of married women of reproductive age.

Objectives: This paper explores how the demographics of household mobile phone owners have changed over time in a representative population of rural Bangladesh.

Methods: We present data collected between 2008 and 2011 on household mobile phone ownership and related characteristics including age, literacy, education, employment, electricity access, and household wealth among 35,306 individuals. Respondents were enrolled when found to be newly pregnant and contributed socioeconomic information once over the course of the time period serving as a "sample" of families within the population at that time. Univariate and multiple logistic regressions analyses were performed to identify the socioeconomic determinants of household phone ownership.

Results: Across 3 fiscal years, we found that reported household ownership of at least 1 working mobile phone grew from 29.85% in the first fiscal year to 56.07% in the third fiscal year. Illiteracy, unavailability of electricity, and low quartiles of wealth were identified as overall demographic constraints to mobile phone ownership. However, over time, these barriers became less evident and equity gaps among demographic status began to dissipate as access to mobile technology became more democratized. We saw a high growth rate in ownership among households in lower economic standing (illiterate, without electricity, low and lowest wealth index), likely a result of competitive pricing and innovative service packages that improve access to mobile phones as the mobile phone market matures. In contrast, as market saturation is rapidly attained in the most privileged demographics (literate, secondary schooling, electricity, high wealth index), members of the lower wealth quartiles seem to be following suit, with more of an exponential growth.

Conclusions: Upward trends in household mobile phone ownership in vulnerable populations over time underline the potential to leverage this increasingly ubiquitous infrastructure to extend health and finance services across social and economic strata.

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KEYWORDS

digital; mobile Health (mHealth); finances; mobile; phones; Bangladesh; family characteristics; Demography, ownership; socioeconomic factors

Introduction

The rapid adoption of mobile phones is changing the way individuals communicate on a global scale. Cheap, efficient, and easy-to-use mobile technology has surpassed fixed-lined networks as the primary form of communication in many developing countries. This leapfrogging of landline infrastructure was documented in most of sub-Saharan Africa by 2000 and in Asia by 2002 [1]. While it took landlines 128 years to reach 1 billion users globally, mobile network subscriptions reached 5.9 billion by the end of 2011 with mobile networks doubling in size every 2 years since 2002 [2]. The International Telecommunications Union (ITU) predicts that by 2014, mobile penetration rates will reach 96% worldwide, 100% in developed countries, and 89% in developing countries, with almost an equal number of mobile connections as human beings on the planet [1]. As a prominent driver of mobile growth, developing countries accounted for more than 80% of the 660 million new mobile cellular subscriptions added in 2011 [1]. The remarkable rise in mobile phone uptake supports the proposition that mobile telephony has leapfrogged traditional landline infrastructure to become the preferred platform for communication.

The potential to leverage mobile phones for economic growth has also increased as access to information and communication channels becomes increasingly ubiquitous in developing countries. Economic advantages engendered by mobile technology are multifaceted ranging from providing those with access the ability to search for employment opportunities, negotiate product sales, report emergencies, and reap health and finance services all while reducing associated travel costs [3]. Furthermore, mobile technology serves as a medium to essentially overcome geographic constraints, improve communication, and limit asymmetrical information, characteristic of traditional mechanisms that often require personal travel or reliance on radio, television, and print material [4].

As mobile phones become inextricably linked with development strategies to improve health or provide economic opportunities, inequities of access may prevent the ability to reach segments of the population at the “base of the pyramid”—those most in need of the public health or economic interventions being delivered. Therefore, formulating strategies to maximize access to mobile phones requires an understanding of the changing factors that either enable or limit likelihood of ownership. The concept of differential mobile phone ownership as a result of social, cultural, and economic indicators is referred to as the *digital divide*, which highlights the inequity in access to technologies and subsequent technical services [5-7].

Asia’s rapid mobile adoption has contributed a significant portion of the global market growth and underlines the importance of understanding drivers of mobile phone ownership in countries such as Bangladesh where mobile penetration rates are increasing but the pace of economic development remains slow. Although considered one of the least developed countries in the world according to the United Nations Department of Economic and Social Affairs (UNDESA), in 1993, Bangladesh became the first South Asian country to adopt cellular technology [8,9].

With the support of its parent company, Grameen Bank, Grameen Telecommunication helped spearhead the development of a telecom industry that is now one of the fastest growing industries and largest provider in the last decade [3]. The Bangladesh Telecommunications Regulatory Commission estimated coverage (ie, access to a mobile signal) for 97% of the population, whereas mobile cellular subscribers comprised 97.2% of total subscribers [10]. The total economic impact of the mobile communications sector aggregated from supply-side, demand-side, and intangible benefits across the mobile value chain translated to 2.1% of the gross domestic product in 2004 and increased to 6.2% in 2007 [11]. In 2009, the United Nations Economic and Social Commission for Asia and the Pacific (UNESCAP) conducted a survey in Bangladesh that reported 0.2 mobile cellular subscriptions per 100 population in 2000 grew to 63.8 per 100 population in 2012 with a 20.1% annual growth rate (Table 1) [12]. Table 1 shows the variability of mobile phone diffusion throughout markets in Asia and the Pacific. In addition to income, the differences in adoption suggest competing explanations of penetration drivers such as demographic determinants [13].

Table 1. Asia and the pacific mobile cellular subscriptions in 2000, 2008, and 2012.[a]

Country	Mobile cellular subscriptions			
	Per 100 population			% change per annum 2000-2012
	2000	2008	2012	
Japan	53.1	87.2	109.4	5.8
Cambodia	1.0	30.7	132.0	44.0
Kyrgyzstan	0.2	65.2	124.8	17.6
Bangladesh	0.2	30.7	63.8	20.1
Papua New Guinea	0.2	13.3	37.8	29.7
Asia and the Pacific	6.5	50.9	85.6	13.9
World	12.1	59.9	89.5	10.5

[a] Source: data extracted from UNESCAP statistics division [12].

At its simplest, basic-entry level, mobile phone ownership provides an ability to strengthen communication using voice and text messages. Bridging the mobile digital divide among economic and social groups such as the poor and women, respectively, could spur economic development and reconcile the inequitable distribution of power that stems from differential access to technology [5,11]. With such promise, socioeconomic groups within parts of rural Bangladesh where mobile phone ownership remains low is of particular concern because these populations lack the ability to leverage the maximum potential of access to information and resources through mobile communications. Often, it is membership in these lower socioeconomic status (SES) subgroups that also bear the greatest burden of ill health [14].

This paper explores how the demographics of household mobile phone owners have changed over time in a representative population of rural Bangladesh. Understanding the demographics of mobile phone ownership is essential to conceptualize, organize, and implement interventions that target vulnerable populations; if household ownership is crucial to program effectiveness, the strategy may have to provide phones or work on modifying the factors that influence ownership. Programs that target individuals, such as those offering customized reminders or information-providing messages, may require personal or household ownership of a phone for maximum impact, although there is little evidence to suggest this is true [15].

Methods

Overview

In 2008, the United Nations deemed household mobile phone ownership the best indication of adoption because household mobile phones are usually accessible to every member in the house. However, it is important to note that this assumption may not hold true in conservative communities where women's access to household assets is restricted or controlled by a patriarch [16]. Additionally, measuring household mobile phone ownership protects from identifying endogenous factors associated with multiple SIM card subscriptions per individual [2].

Recruitment

In seeking a representative population site resonant with populations across the greater Gangetic floodplain, Gaibandha and Rangpur districts were selected based on maternal health reports, remoteness, and rural quality (eg, mostly villages linked by unpaved roads, surrounded by rice fields) [17]. The defined research area is approximately 435 km^2 in size with a population density of approximately 1000 per km^2 and mainly agrarian in nature (eg, seasonality and crop mix, weekly market network) [18].

Data from JiVitA-3, a randomized controlled trial (RCT) conducted in rural northwestern Bangladesh from 2008 to 2011 [19] was used for this analysis. During this trial aiming to assess the effect of nutrient supplementation on infant mortality, 44,467 pregnant women were enrolled from a cohort of approximately 120,000 married women of reproductive age [20]. A socioeconomic assessment was conducted on all consenting newly pregnant women enrolled in the RCT and household mobile phone ownership was 1 characteristic. The aim of this analysis was to model the predictors of household phone ownership over time in a rural setting of Bangladesh where population, health, agriculture, and infrastructure broadly reflect the national rural population [17].

Statistical Analyses

The variables included in the analysis were women's age, parity (number of children), literacy (measured as the reported ability to read and write a letter in the Bengali language), education, employment, access to electricity, and SES. Age was categorized as ≤19, 20-24, 25-29, and ≥30 years; parity as 0, 1-3, and >3; and education as none, primary (class 1-9), and secondary schooling (class 10 and above). Age and parity were specific to the married female respondent, whereas level of education, literacy, and employment information were reported personally by the respondent and on behalf of her husband, providing information on both members of the household. Household access to electricity, employment of husband and wife, and literacy were categorized as dichotomous variables. As the outcome variable, mobile phone ownership was dichotomous, classified as either no household mobile phone ownership or ≥1 household mobile phones.

Exploratory data analysis was conducted to determine relevant variables. Each respective variable was incorporated into a univariate analysis to identify potential determinants of mobile phone ownership followed by a multiple logistic regression analysis to adjust for confounding and identify the significant predictors of mobile phone ownership. Univariate and multiple logistic regression analyses assessed associations between household mobile phone ownership and demographics. Variation inflation factor (VIF) was used to check for collinearity between education, employment, literacy, and SES. Outliers were accounted for using DFFITS analysis. Listwise deletion was used for a complete case analysis to omit missing data. Lastly, a test for homogeneity was used to assess effect modification of the association between literacy, education, occupation, electricity, and wealth index (WI) with mobile phone ownership. An a priori level of statistical significance was set at $P<.05$. All of the values were unique; that is, individuals were not followed longitudinally. STATA version 12.0 (StataCorp LP, College Station, TX, USA) was used for statistical analyses.

To evaluate temporal trends, the demographics of household mobile phone ownership were measured over a 3-year fiscal period that began in July and ended in June from 2008 to 2011. In doing so, the first 6 months (January 2008-June 2008) of the dataset were excluded to capture the latest entries (July 2011) in the last fiscal year. For this period, data on 35,306 trial participants were used for the analysis and are presented here. Once stratified by fiscal year, univariate and multivariate analyses were used to assess whether demographic determinants of phone ownership changed over time.

Socioeconomic Status

A principal component analysis was previously used to construct a WI, which factored durable assets, dwelling characteristics,

productive assets, and land ownership [21,22]. These indexes are representative of SES because they are more easily and reliably reported than income or consumption expenditure data in developing countries [21]. As in Filmer et al [23], WI was categorized into ordinal variables categorizing it into quartiles (lowest, low, high, and highest) of SES.

Results

Overall, the youngest respondent with a household mobile phone was aged 9 years, whereas the oldest respondent was aged 48 years. The median age of respondents who owned a household mobile phone in fiscal year 1 was 23 years (IQR 9), whereas the median age for fiscal years 2 and 3 was 22 years (IQR 8) (Figure 1). Table 2 shows the association between demographic characteristics and non–phone ownership; Table 3 shows the association between demographic characteristics and phone ownership stratified over 3 fiscal years. Overall, phone ownership increased by fiscal year (year 1: 29.85%, 4178/13,996; year 2: 39.91%, 4842/12,132; year 3: 56.07%, 5107/9109).

The proportion of households in the low socioeconomic groups owning a mobile phone changed dramatically over time. Figure 2 shows that when stratified by WI, 91.6% of households in the lowest quartile did not own a mobile phone, whereas only 3.9% of households in the highest quartile did not own a mobile phone in fiscal year 1 (Figure 2). However, by fiscal year 3, 70.5% of households in the lowest quartile and only 1.9% of households in the highest quartile did not own a mobile phone.

Tables 4-6 show the unadjusted and adjusted odds ratios of mobile phone ownership for all demographic variables across fiscal years 1, 2, and 3, respectively. Unadjusted univariate analysis shows that the older the wives (respondents) or the more children in a household, the less likely it was to own a mobile phone because it was negatively associated and continued to decrease across fiscal years 1 and 3. Wife's employment (fiscal year 1: OR 0.74, 95% CI 0.69-0.79, $P<.001$; fiscal year 3: OR 0.78, 95% CI 0.71-0.84, $P<.001$) was the only variable that had an overall increase in the odds of owning a mobile phone over time but remained negatively associated. Wife's literacy, husband's literacy, wife's education, husband's education, electricity, and WI were all positively associated with mobile phone ownership that also attenuated over time. There was a decreasing dose-response relationship over the 3-year fiscal periods for the respondents aged 25-29 and ≥30 years, all parity groups (1-3 and ≥4), wife's literacy, husband's literacy, wife's education, husband's education, and for the low and high quartiles of WI.

Figure 1. Box plot of respondents' ages who owned mobile phones by fiscal year.

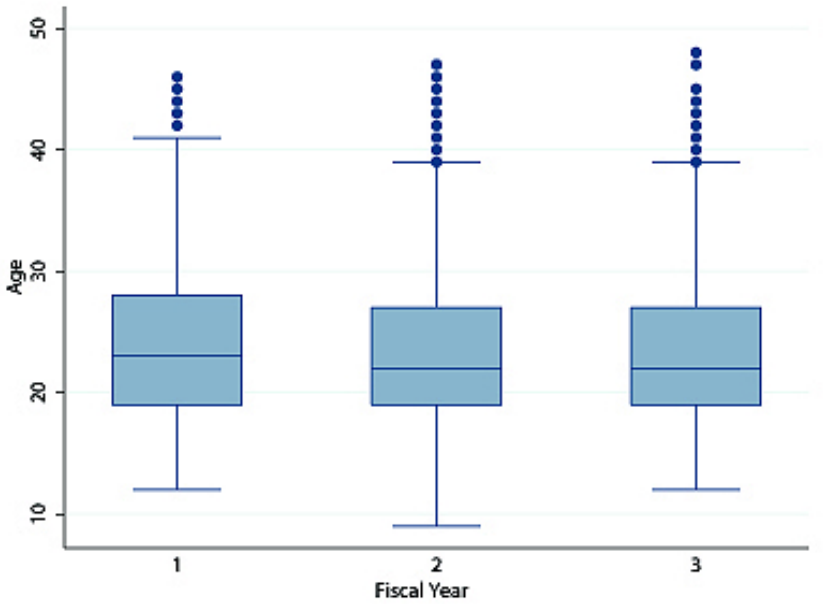


Table 2. Demographic characteristics of mobile phone nonowners by fiscal year, 2009-2011.

Demographic characteristics	July 2008 to June 2009 (n=13,996)	July 2009 to June 2010 (n=12,132)	July 2010 to June 2011 (n=9109)
Households, n (%)			
Non–mobile phone owners	9818 (70.15)	7290 (60.09)	4002 (43.93)
Wife's age (years)			
Mean (SD)	24.41 (6.5)	24.67 (6.5)	24.91 (6.5)
Range, n (%)			
≤19	2694 (69.20)	1874 (55.10)	993 (37.70)
20-24	2827 (68.63)	2090 (58.76)	1054 (41.00)
25-29	2103 (69.61)	1694 (63.19)	987 (48.31)
≥30	2194 (74.05)	1632 (65.46)	968 (52.02)
Parity, n (%)			
0	2470 (62.36)	1866 (49.69)	1082 (33.59)
1-3	6141 (71.85)	4605 (63.35)	2505 (48.09)
≥4	1207 (81.12)	819 (73.92)	415 (61.12)
Wife literate, n (%)			
No	5205 (85.79)	3761 (77.21)	2054 (62.00)
Yes	4613 (58.19)	3526 (48.58)	1947 (33.60)
Husband literate, n (%)			
No	5724 (86.96)	4307 (77.72)	2442 (63.49)
Yes	4091 (55.22)	2970 (45.18)	1555 (29.61)
Wife's education, n (%)			
No schooling	3872 (86.29)	2759 (78.49)	1532 (63.62)
Primary (1-9)	5783 (67.84)	4415 (57.15)	2412 (41.06)
Secondary (≥10)	163 (16.57)	116 (13.00)	58 (7.02)
Husband's education, n (%)			
No schooling	5361 (87.71)	3956 (78.38)	2230 (63.66)
Primary (1-9)	3574 (66.44)	2620 (54.75)	1406 (38.01)
Secondary (≥10)	883 (32.25)	714 (31.04)	366 (19.19)
Wife employed, n (%)			
No	5635 (67.63)	4042 (57.89)	2100 (41.17)
Yes	4183 (73.85)	3248 (63.07)	1902 (47.46)
Husband employed, n (%)			
No	13 (56.52)	4 (57.14)	3 (60.00)
Yes	9805 (70.17)	7286 (60.09)	3999 (43.93)
Electricity, n (%)			
No	8612 (76.79)	6364 (67.50)	3465 (50.47)
Yes	1205 (43.36)	925 (34.22)	537 (23.93)
Wealth index (WI), n (%)			
Lowest quartile	5081 (91.58)	3896 (84.02)	2155 (70.54)
Low quartile	4156 (68.31)	3066 (56.28)	1699 (39.80)
High quartile	568 (27.97)	323 (18.26)	143 (9.40)
Highest quartile	13 (3.90)	5 (1.80)	5 (1.89)

Table 3. Demographic characteristics of mobile phone owners by fiscal year, 2009-2011.

Demographic characteristics	July 2008 to June 2009 (n=13,996)	July 2009 to June 2010 (n=12,132)	July 2010 to June 2011 (n=9109)
Households, n (%)			
Mobile owners	4178 (29.85)	4842 (39.91)	5107 (56.07)
Wife's age (years)			
Mean (SD)	23.96 (6.3)	23.64 (6.3)	23.56 (6.2)
Range, n (%)			
≤19	1199 (30.80)	1527 (44.90)	1641 (62.30)
20-24	1292 (31.37)	1467 (41.24)	1517 (59.00)
25-29	918 (30.39)	987 (36.81)	1056 (51.69)
≥30	769 (25.95)	861 (34.54)	893 (47.98)
Parity, n (%)			
0	1491 (37.64)	1889 (50.31)	2139 (66.41)
1-3	2406 (28.15)	2664 (36.65)	2704 (51.91)
≥4	281 (18.88)	289 (26.08)	264 (38.88)
Wife literate, n (%)			
No	862 (14.21)	1110 (22.79)	1259 (38.00)
Yes	3315 (41.81)	3732 (51.42)	3848 (66.40)
Husband literate, n (%)			
No	858 (13.04)	1235 (22.28)	1404 (36.51)
Yes	3318 (44.78)	3604 (54.82)	3696 (70.39)
Wife's education, n (%)			
No schooling	615 (13.71)	756 (21.51)	876 (36.38)
Primary (1-9)	2742 (32.16)	3310 (42.85)	3463 (58.94)
Secondary (≥10)	821 (83.43)	776 (87.00)	768 (92.98)
Husband's education, n (%)			
No schooling	751 (12.29)	1091 (21.62)	1273 (36.34)
Primary (1-9)	1805 (33.56)	2165 (45.25)	2293 (61.99)
Secondary (≥10)	1622 (64.75)	1586 (68.96)	1541 (80.81)
Wife employed, n (%)			
No	2697 (32.37)	2940 (42.11)	3001 (58.83)
Yes	1481 (26.15)	1902 (36.91)	2106 (52.54)
Husband employed, n (%)			
No	10 (43.48)	3 (42.86)	2 (40.00)
Yes	4168 (29.83)	4839 (39.91)	5105 (56.07)
Electricity, n (%)			
No	2603 (23.21)	3064 (32.50)	3400 (49.53)
Yes	1574 (56.64)	1778 (65.78)	1707 (76.07)
Wealth index (WI), n (%)			
Lowest quartile	467 (8.42)	741 (15.98)	900 (29.46)
Low quartile	1928 (31.69)	2382 (43.72)	2570 (60.20)
High quartile	1463 (72.03)	1446 (81.74)	1378 (90.60)
Highest quartile	320 (96.10)	273 (98.20)	259 (98.11)

Table 4. Unadjusted and adjusted odds ratio (OR) and 95% confidence intervals (95% CI) of reporting household mobile phone ownership by demographics for fiscal year 1 (n=13,996), July 2008-June 2009.

Demographic characteristics	Unadjusted		Adjusted	
	OR (95% CI)	*P*	OR (95% CI)	*P*
Wife's age (years)				
≤19	1.00		1.00	
20-24	1.03 (0.93-1.13)	.58	1.25 (1.09-1.43)	.002
25-29	0.98 (0.89-1.09)	.71	1.23 (1.04-1.45)	.02
≥30	0.79 (0.71-0.88)	<.001	1.15 (0.96-1.39)	.14
Parity				
0	1.00		1.00	
1-3	0.65 (0.59-0.70)	<.001	0.80 (0.70-0.92)	.002
≥4	0.39 (0.33-0.45)	<.001	0.72 (0.58-0.89)	.004
Wife literate				
No	1.00		1.00	
Yes	4.34 (3.99-4.72)	<.001	1.63 (1.39-1.91)	<.001
Husband literate				
No	1.00		1.00	
Yes	5.41 (4.97-5.89)	<.001	1.58 (1.33-1.88)	<.001
Wife's education				
No schooling	1.00		1.00	
Primary (1-9)	2.99 (2.71-3.29)	<.001	0.87 (0.73-1.03)	11
Secondary (≥10)	31.71 (26.27-38.29)	<.001	1.84 (1.33-1.88)	<.001
Husband's education				
No schooling	1.00		1.00	
Primary (1-9)	3.61 (3.28-3.97)	<.001	1.34 (1.12-1.60)	.002
Secondary (≥10)	13.11 (11.72-14.67)	<.001	2.17 (1.77-2.68)	<.001
Wife employed				
No	1.00		1.00	
Yes	0.74 (0.69-0.79)	<.001	0.75 (0.68-0.82)	<.001
Husband employed				
No	1.00		1.00	
Yes	0.55 (0.24-1.26)	.16	1.16 (0.39-3.45)	.78
Electricity				
No	1.00		1.00	
Yes	4.32 (3.96-4.71)	<.001	1.70 (1.53-1.89)	<.001
Wealth index (WI)				
Lowest quartile	1.00		1.00	
Low quartile	5.05 (4.53-5.63)	<.001	3.41 (3.04-3.84)	<.001
High quartile	28.02 (24.47-32.09)	<.001	11.04 (9.47-12.88)	<.001
Highest quartile	267.81 (152.59-470.06)	<.001	61.73 (34.69-109.84)	<.001

Table 5. Unadjusted and adjusted odds ratio (OR) and 95% confidence intervals (95% CI) of reporting household mobile phone ownership by demographics for fiscal year 2 (n=12,132), July 2009-June 2010.

Demographic characteristics	Unadjusted		Adjusted	
	OR (95% CI)	*P*	OR (95% CI)	*P*
Wife's age (years)				
≤19	1.00		1.00	
20-24	0.86 (0.78-0.95)	.002	1.06 (0.92-1.21)	.42
25-29	0.72 (0.65-0.79)	<.001	0.92 (0.78-1.08)	.30
≥30	0.65 (0.58-0.72)	<.001	0.90 (0.75-1.09)	.29
Parity				
0	1.00		1.00	
1-3	0.57 (0.53-0.62)	<.001	0.83 (0.73-0.95)	.006
≥4	0.35 (0.30-0.40)	<.001	0.6 (0.61-0.95)	.02
Wife literate				
No	1.00		1.00	
Yes	3.59 (3.31-3.89)	<.001	1.37 (1.19-1.58)	<.001
Husband literate				
No	1.00		1.00	
Yes	4.23 (3.91-4.58)	<.001	1.52 (1.29-1.79)	<.001
Wife's education				
No schooling	1.00		1.00	
Primary (1-9)	2.74 (2.49-3.00)	<.001	1.02 (0.87-1.19)	.79
Secondary (≥10)	24.41 (19.77-30.15)	<.001	2.43 (1.82-3.24)	<.001
Husband's education				
No schooling	1.00		1.00	
Primary (1-9)	2.99 (2.74-3.27)	<.001	1.17 (0.99-1.38)	.07
Secondary (≥10)	8.05 (7.21-8.99)	<.001	1.53 (1.26-1.87)	<.001
Wife employed				
No	1.00		1.00	
Yes	0.81 (0.75-0.87)	<.001	0.86 (0.79-0.94)	.002
Husband employed				
No	1.00		1.00	
Yes	0.89 (0.19-3.96)	.87	1.69 (0.27-10.51)	.57
Electricity				
No	1.00		1.00	
Yes	3.99 (3.65-4.37)	<.001	1.76 (1.58-1.96)	<.001
Wealth index (WI) [a]				
Lowest quartile	1.00		1.00	
Low quartile	4.09 (3.71-4.49)	<.001	2.89 (2.61-3.21)	<.001
High quartile	23.54 (20.38-27.18)	<.001	10.33 (8.79-12.12)	<.001
Highest quartile	287.07 (118.13-697.66)	<.001	76.97 (31.37-188.85)	<.001

[a] WI is constructed from a principal component analysis of dwelling characteristics, durable assets, productive assets, and land ownership.

Table 6. Unadjusted and adjusted odds ratio (OR) and 95% confidence intervals (95% CI) of reporting household mobile phone ownership by demographics for fiscal year 3 (n=9109), July 2010-June 2011.

Demographic characteristics	Unadjusted		Adjusted	
	OR (95% CI)	*P*	OR (95% CI)	*P*
Wife's age (years)				
≤19	1.00		1.00	
20-24	0.87 (0.78-0.97)	.02	1.22 (1.03-1.44)	.02
25-29	0.65 (0.58-0.73)	<.001	1.03 (0.85-1.26)	.75
≥30	0.56 (0.49-0.63)	<.001	0.95 (0.77-1.18)	.67
Parity				
0	1.00		1.00	
1-3	0.55 (0.49-0.59)	<.001	0.79 (0.67-0.93)	.005
≥4	0.32 (0.27-0.38)	<.001	0.68 (0.68-0.89)	.004
Wife literate				
No	1.00		1.00	
Yes	3.22 (2.95-3.52)	<.001	1.28 (1.09-1.49)	.002
Husband literate				
No	1.00		1.00	
Yes	4.13 (3.78-4.52)	<.001	1.85 (1.55-2.21)	<.001
Wife's education				
No Schooling	1.00		1.00	
Primary (1-9)	2.51 (2.28-2.77)	<.001	0.99 (0.84-1.18)	.96
Secondary (≥10)	23.16 (17.51-30.63)	<.001	2.53 (1.76-3.62)	.03
Husband's education				
No schooling	1.00		1.00	
Primary (1-9)	2.86 (2.59-3.14)	<.001	0.97 (0.80-1.16)	.70
Secondary (≥10)	7.38 (6.46-8.43)	<.001	1.27 (1.02-1.58)	.03
Wife employed				
No	1.00		1.00	
Yes	0.78 (0.71-0.84)	<.001	0.84 (0.76-0.94)	.001
Husband employed				
No	1.00		1.00	
Yes	1.92 (0.32-11.47)	.48	2.09 (0.19-21.97)	.54
Electricity				
No	1.00		1.00	
Yes	3.24 (2.91-3.61)	<.001	1.44 (1.27-1.64)	<.001
Wealth index (WI) [a]				
Lowest quartile	1.00		1.00	
Low quartile	3.62 (3.28-3.99)	<.001	2.66 (2.38-2.96)	<.001
High quartile	23.07 (19.10-27.87)	<.001	10.73 (8.73-13.19)	<.001
Highest quartile	124.03 (51.02-301.54)	<.001	38.66 (15.71-95.15)	<.001

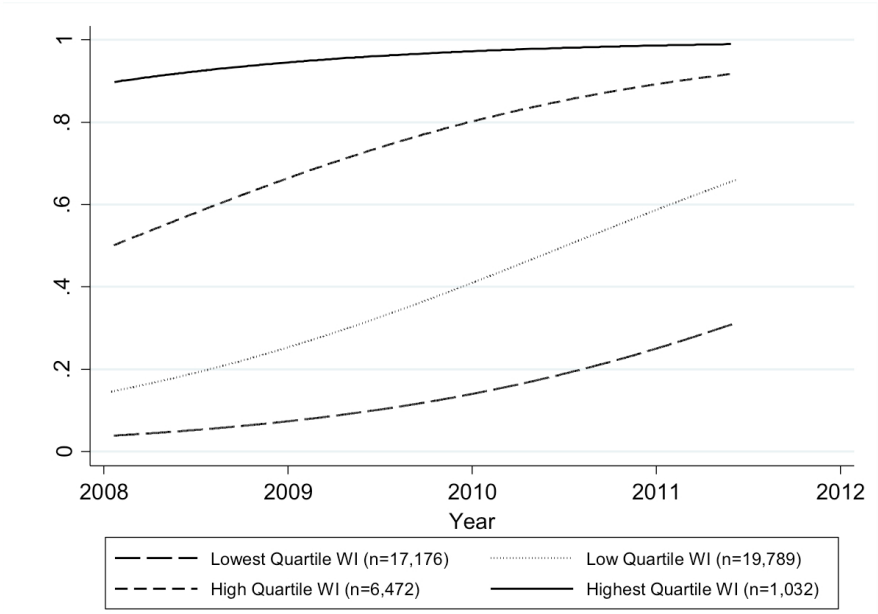
[a] WI is constructed from a principal component analysis of dwelling characteristics, durable assets, productive assets, and land ownership.

When adjusting for all variables (wife's age, parity, literacy, education, employment, WI), age, and wives and husbands with just a primary education were no longer significant by fiscal year 3, whereas husband's employment was not statistically

significant across all fiscal years. Multiple logistic regression analysis showed that wife's employment (fiscal year 1: OR 0.75, 95% CI 0.68-0.82, *P*<.001; fiscal year 3: OR 0.84, 95% CI 0.76-0.94, *P*=.001) and husband's literacy (fiscal year 1: OR 1.58, 95% CI 1.33-1.88, *P*<.001; fiscal year 3: OR 1.85, 95% CI 1.55-2.21; *P*<.001) were the only 2 demographic variables that had an overall increase from fiscal year 1 to fiscal year 3, whereas all other statistically significant demographic variables had an overall decrease in odds of owning a household mobile phone. Wives with just a primary education were negatively associated with mobile phone ownership despite having an overall increase in odds. Husbands with a secondary education, electricity, and all quartiles of WI (lowest, low, high, and highest) were all positively associated with mobile phone ownership that also attenuated over time. There was a decreasing dose-response relationship for husband's education (primary and secondary, respectively) and the low quartile WI, whereas there was an increasing dose-response relationship for households where wives had a secondary education.

Low VIF values indicate that collinearity is not present between wealth (1.28), employment (1.03), and education (2.81).

Figure 2. Trends (*P*<.001) in household mobile phone ownership by wealth index (WI), 2008-2011.



Discussion

Principal Findings

Based on global trends, the ITU suggested in 2013 that as market saturation is attained within a given population, growth rates in mobile phone ownership would decrease [1]. In our dataset, household mobile phone ownership among demographic variables changed rapidly over time. Market saturation (>90%) was observed in households where wives had a secondary education (93.0%) or in households within the high (90.6%) and highest (98.1%) quartiles of WI by fiscal year 3. Market-saturated demographic groups can be considered early adopters of mobile phones, in which uptake is fastest. These early adopters rapidly reached saturation because they were able to afford the technologies from the outset when mobile phone costs were relatively high. In contrast, low SES groups such as households in the low (60.2%) and lowest (29.5%) quartiles of WI represent a larger proportion of the total sample size (83.1%), but have a low proportion of ownership. These low SES groups are considered late adopters, in which uptake is slowest.

In examining predictors of ownership by fiscal year, the velocity of change in ownership indicates which demographic factor achieves the fastest rate of growth. Despite a slower trajectory among households of lower economic standing, the growth rate of mobile phone ownership is increasing exponentially as seen in these late adopter groups because the price of "entry" into the mobile marketplace likely declined over time. The change in the proportion of household ownership when stratified by WI shows among the lowest quartile WI there is a sustained exponential growth, where the digital divide is being bridged over time (Figure 2). The statistic of ownership of at least 1 mobile phone across the entire study period (35.8% among the households surveyed) is grossly misleading. When stratified by fiscal year, phone ownership was 29.85% (4178/13,996), 39.91% (4842/12,132), and 56.07% (5107/9109), for fiscal years 1, 2, and 3, respectively.

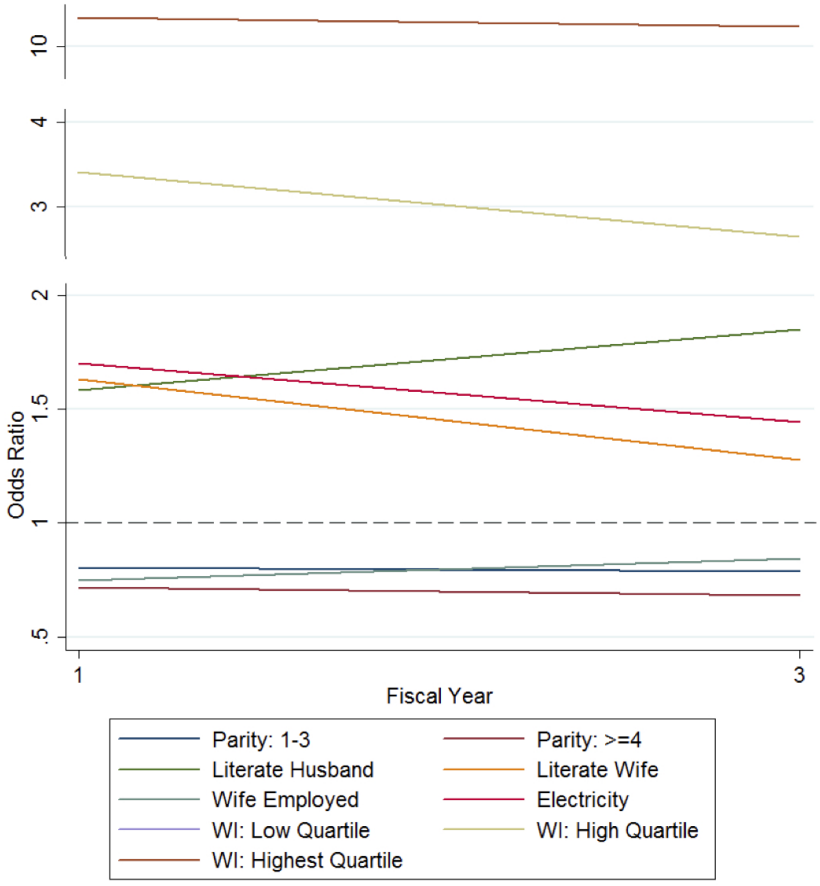
Although overall phone ownership increased by fiscal year, the overwhelming trend in which the odds of owning a mobile phone attenuated over time suggests that the factors that distinguish people from one another—education, electricity, and WI—are important early in the mobile "revolution" when prices are likely high and the technology new (Figure 3). However, as mobile phones become more available and the markets mature, access to mobile technology is more democratized and equity gaps begin to dissipate.

As market saturation is rapidly attained in the most privileged demographics (literate, secondary schooling, electricity, high WI) likely because of a combination of early adoption, willingness-to-pay, and affordability, members of the lower

wealth quartiles seem to be following suit with more of an exponential growth mirroring the global trends seen elsewhere [1]. As stated by Grameenphone in their 2010 Annual Report, price competition across network operators led to a plateauing of the annual revenue per unit reported by this major network operator, but this also suggests a decline in prices charged for services given the documented rate of subscriber growth during this period [24]. Our data support that these market forces seem to directly impact the inequity of what began in the early days of mobile introduction in Bangladesh as a marked mobile "digital divide" resulting in a trend of increasing ownership less likely to be driven by markers of SES such as literacy, educational attainment, age, or wealth.

The high growth rates of ownership among the most vulnerable subpopulations in our analysis and the decreasing predictive capacity of variables initially strongly associated with risk of phone ownership suggests that sociodemographic constraints do not represent an insurmountable barrier to mobile phone ownership over the life-course of mobile phone introduction into a population. These data elegantly illustrate how the digital divide is closing over a relatively short span of time, a likely result of changing market characteristics and resulting demographic predictors of ownership over time. Nonetheless, despite these closing gaps, there still remains a population segment that is largely without access to mobile phone ownership. Households in the lowest quartile of WI with more children, where the wife has either a primary education or no schooling despite being employed are the least likely to own a mobile phone. Recognizing and targeting this "base of the pyramid" group is important to alleviate the "inequitable distribution of power that stems from differential access to information and communications technology resources" [5].

Figure 3. Odds ratio of statistically significant demographic variables (P<.05) over fiscal years 1 and 3.



Increasing Equity to Women

The data show that the probability of owning a mobile phone is greatest in households where both the wife and husband are literate. Although there is interaction between ownership and literacy between the wife and husband, the difference in mobile phone ownership among households with discordant couples likely reflects gender-power differences in Bangladesh. In discordant couples, the probability of owning a mobile phone is greater in households in which only the husband is literate compared with households in which only the wife is literate, thereby highlighting a possible interesting proxy of inequity in purchasing power of the women for the household, even when their education level may be higher than their husbands' education level.

The disparity brings to mind the larger issue of prevailing sociocultural norms practiced in rural Bangladesh. Women are often subject to discrimination engendered by a highly patriarchal social system that determines power relations within households and the bargaining power of household members [25]. In efforts to deconstruct the associated ideologies that precipitate discrimination, it is important to negotiate cultural norms that place value on women's work and education [25]. Mobile phone ownership and access may be a vehicle through

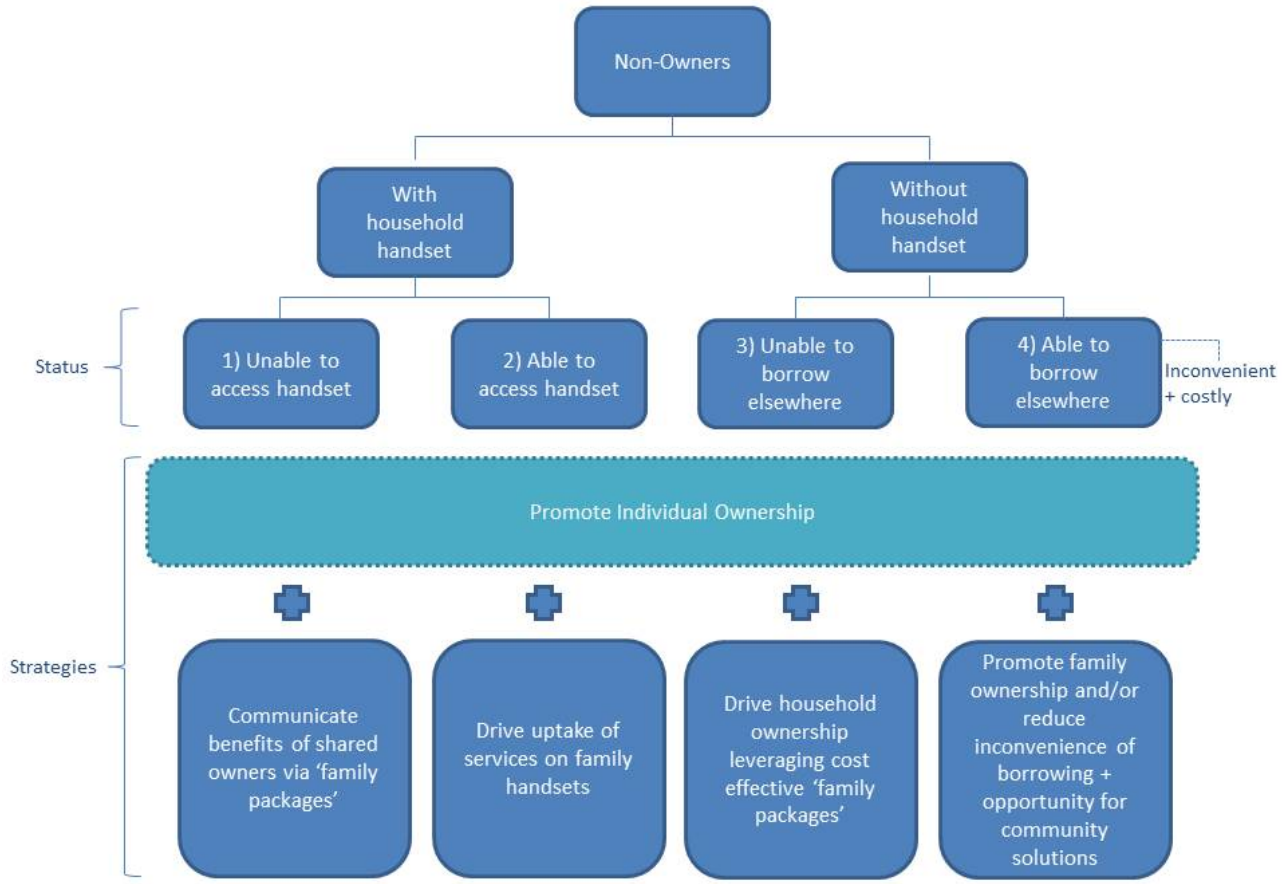
which women can reframe their role in the household or position in society, empowered by connectivity.

In a 2012 study of mobile phone access among women at the proverbial "base of the pyramid," researchers identified that, globally, a woman is 21% less likely to own a mobile phone than a man due to social, cultural, and economic reasons [16]. This specific digital divide was described as a gender gap that translated to roughly US $13 billion dollars of associated missed market opportunities [16]. Clearly, the varying social, cultural, and economic drivers of adoption, as described in this analysis, should be targeted by the mobile industry while keeping in mind the struggles of the members of these socioeconomic strata to prioritize food, housing, and health care. In 2014, the Groupe Speciale Mobile Association (GSMA) mWomen Program aims to reduce the inequitable distribution of mobile phones by 50% consequently increasing mobile connectivity to more than 150 million women in emerging markets [16]. In doing so, a number of approaches have been proposed to bridge mobile ownership inequity in an effort to provide access to more members of the lowest socioeconomic strata sooner than current trends might forecast (Figure 4).

As mobile phones continue to penetrate the developing market, economies of scale and scope, specialization and speed all play a factor in the growth of the mobile phone industry and the improvement of connectivity. To harness the full potential of connectivity using mobile phones as a platform, further studies should examine methods of increasing ownership, bridging the digital divide, and empowering communities. Potential studies could include geographic information systems that map gaps in mobile phone penetration rates. In doing so, access to mobile phones can be extended through cost-effective mobile networks such as wireless local loops in remote areas of the country. Improving rural teledensity in developing countries while increasing levels of purchasing power is essential to meeting high levels of demand in resource-constrained areas [11]. In addition to income, other demographic factors as outlined in this study could also facilitate the adoption of more recent generation mobile phones that offer more opportunities for connectivity through Internet use and operating capabilities that give rise to an analysis of second-level digital divides [26]. Other studies can assess the usability of mobile phones in specific occupations to investigate potential means toward increasing mobile capacity [27]. Accordingly, policy changes that stimulate economic productivity through more effective usage of mobile telephony could be adopted. Future studies could also incorporate trends in airtime and equipment costs, payment schemes, and competitive pricing as covariates in changing the dynamics of household access to mobile phones.

When conducting further studies, the limitations in this study must be taken into consideration. For instance, parity was negatively associated with ownership in both unadjusted and adjusted assessments suggesting that the odds of owning a mobile phone decrease with every child. However, parity is also inversely proportional to age—multiparous women are likely to be older—indicating evidence of confounding. Husband's employment was not statistically significant across all years because the sample size for husbands without employment was low (fiscal year 1: n=23; fiscal year 2: n=7; fiscal year 3: n=5) which also happens to be the reference group. This could be evidence of respondent bias as wives reported on the behalf of their husbands. These limitations must be accounted for to strengthen further analyses.

Figure 4. GSMA mWomen strategies to promote individual ownership. Source: [16].



Conclusions

This analysis provides insights into the dynamic characteristics of mobile phone ownership over time unveiling the relative contributors to the digital divide; the determinants which initially drive ownership as a privilege of the wealthy gradually lose importance as market and socioeconomic forces increase access even among the poorest members of the population. Still, this "democratization" remains a gradual process and stopgap measures must be pursued to ensure that those living at the very "base of the pyramid" are not further disenfranchised due to their relatively slower uptake of mobile telephony. mHealth and other mobile-facilitated social services targeting the ultra-poor must consider access (or the lack thereof) as an important component of program reach and impact.

The inequitable distribution of power due to differential access to mobile phones underscores the importance of reconciling the demographic barriers to ownership [11]. Mobile phone adoption rates in vulnerable populations such as households with low education, no electricity, and of low economic standing are of particular interest because they are often the slowest and the last to obtain access, as shown in this analysis. Fortunately, as competition increases and costs of ownership are driven down, affordability increases, especially among lower SES populations [11]. Social innovations, such as Bangladesh's Village Phone Program, show how communal access to phones can bridge the household mobile phone ownership gap in the lowest SES strata while these groups gradually climb the exponential curve to saturation [3,28]. These data from Bangladesh provide a heartening glimpse into the natural trajectories of the mobile phone revolution, across a sociodemographically heterogeneous population, illustrating how even in developing markets, large gaps in mobile phone ownership are unlikely to persist forever through a combination of natural market forces and technologic/socioeconomic innovation.

Conflicts of Interest

None declared.

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Abbreviations

GSMA: Groupe Speciale Mobile Association
ITU: International Telecommunications Union
RCT: randomized controlled trial
SES: socioeconomic status
UNDESA: United Nations Department of Economic and Social Affairs
UNESCAP: United Nations Economic and Social Commission for Asia and the Pacific
VIF: variation inflation factor
WI: wealth index

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Original Paper

Qualitative Evaluation of a Text Messaging Intervention to Support Patients With Active Tuberculosis: Implementation Considerations

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Abstract

Background: Tuberculosis (TB) remains a major global public health problem and mobile health (mHealth) interventions have been identified as a modality to improve TB outcomes. TextTB, an interactive text-based intervention to promote adherence with TB medication, was pilot-tested in Argentina with results supporting the implementation of trials at a larger scale.

Objective: The objective of this research was to understand issues encountered during pilot-testing in order to inform future implementation in a larger-scale trial.

Methods: A descriptive, observational qualitative design guided by a sociotechnical framework was used. The setting was a clinic within a public pulmonary-specialized hospital in Argentina. Data were collected through workflow observation over 115 days, text messages (n=2286), review of the study log, and stakeholder input. Emerging issues were categorized as organizational, human, technical, or sociotechnical considerations.

Results: Issues related to the intervention included workflow issues (eg, human, training, security), technical challenges (eg, data errors, platform shortcomings), and message delivery issues (eg, unintentional sending of multiple messages, auto-confirmation problems). System/contextual issues included variable mobile network coverage, electrical and Internet outages, and medication shortages.

Conclusions: Intervention challenges were largely manageable during pilot-testing, but need to be addressed systematically before proceeding with a larger-scale trial. Potential solutions are outlined. Findings may help others considering implementing an mHealth intervention to anticipate and mitigate certain challenges. Although some of the issues may be context dependent, other issues such as electrical/Internet outages and limited resources are not unique issues to our setting. Release of new software versions did not result in solutions for certain issues, as specific features used were removed. Therefore, other software options will need to be considered before expanding into a larger-scale endeavor. Improved automation of some features will be necessary, however, a goal will be to retain the intervention capability to be interactive, user friendly, and patient focused. Continued collaboration with stakeholders will be required to conduct further research and to understand how such an mHealth intervention can be effectively integrated into larger health systems.

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KEYWORDS

mHealth; tuberculosis; sociotechnical evaluation; text messaging

Introduction

Adherence to long-term medication therapy in the outpatient setting remains a global health challenge, particularly for tuberculosis (TB) treatment [1,2]. The World Health Organization (WHO) and others have called for patient-centered approaches that tailor interventions to meet patient needs [3-6]. Regular supervision and support provides opportunities for education and problem monitoring, and promotes medication adherence [6]. Directly observed therapy (DOT) has been the predominant TB medication management strategy since the 1950s [1,2]. However, DOT is challenging for patients and health care providers, due to limited resources, operation expenses, and daily travel burden [7-9].

Mobile health (mHealth) interventions utilize portable devices, such as mobile phones, to provide health services [10,11]. Mobile phones are increasingly prevalent across the globe [12] and there are a growing number of researchers assessing mHealth's impact on health outcomes [13,14]. Promising evidence suggests that mHealth interventions can enhance health services in low- and middle-income countries [15-17]. However, uptake at a larger scale can be slow despite growing evidence of the potential benefits [18,19]. Previous studies of mHealth interventions in TB management have focused on DOT using the mobile phone's video features [20-22], traditional phone calls to mobile phones to remind patients to take their medication [23], or sending short message service (SMS) text messages asking participants to respond with the time they took their medication [24]. The most common type of mHealth intervention reported in the literature is one-way SMS text messaging [10].

Although mHealth technology offers promise to aid in management of chronic conditions, there remains insufficient evidence to inform larger-scale implementation [25]. Leading experts recommend rigorous research of mHealth potential, as well as the implementation challenges, and warn against skipping outcome evaluations, which could threaten the understanding of the long-term value of mHealth [26]. Small-scale and pilot implementations are needed to provide evidence of acceptability and feasibility and can suggest ways to improve mHealth interventions to avoid larger-scale implementation pitfalls [25,27].

The objective of this research was to understand implementation issues encountered during pilot-testing, and to identify system improvements that will inform future implementation in a larger-scale trial.

Methods

Study Design

The research was based on descriptive observational qualitative design [28,29] guided by an adapted sociotechnical framework (see below). This study was the second phase of an interventional study that explored feasibility, acceptability, and initial efficacy of the interactive TextTB intervention to support patients with active TB (described below) [30]. Data were collected through workflow observations over 115 days and were tracked in a study log (eg, process, problems, barriers, and one-on-one and team meeting discussions). Text messages (n=2286) were reviewed for content related to technical challenges, and verbal and written stakeholder input—feedback to questions based on the sociotechnical framework—was collected. The setting was a clinic within a public pulmonary-specialized hospital in Buenos Aires, Argentina. The study was approved by the University of Utah Institutional Review Board (IRB) and an independent research ethics board of Hospital Italiano, in Buenos Aires, Argentina.

Theoretical Framework

For this study, sociotechnical models from Cornford et al [31] and Barber et al [32] were adapted. These models integrate classic Donabedian Structure-Process-Outcome quality improvement concepts with a sociotechnical perspective to understand health information technology implementation outcomes [31,32]. In addition, a Rapid Assessment Process (RAP) was used as a process guide [33]. The RAP, adapted for informatics evaluation from ethnography and other qualitative methods, has been shown to be useful for explaining health technology implementation success or failure, and for providing feedback for system improvements [33]. Informatics interventions, including mHealth interventions, often occur in naturalistic settings where certain variables are outside of the investigator's control. The basic definitions, matrix structure, and the framework from the models were adapted a priori to articulate variables relevant to this specific mHealth intervention (see Table 1).

Table 1. Theoretical framework based on the sociotechnical approach[a].

	Technical approach	Social approach	
	System function	Human perspective	Organizational context
Structure	Technical detail and content: computer-based intervention details • Hardware and software setup • User requirements for the intervention	Adapting work conditions/requirements of intervention implementation • Skill level or training needed (eg, computer skills) • Work conditions and staff patterns	Requirements for sustainability: costs, management, and equipment needs • Cost of the intervention • Organizational/technical support for management and equipment • Management (eg, team required)
Process	Information processing • What system can capture • How organized • Correct and valid • Functions of software	Participation of patient/health care team, social interaction • Team's participation in tasks • Process of sending, receiving, responding to text messages • Shift in attitudes/beliefs	Altered practice and delivery of service • Workflow changes and monitoring • Aspects of intervention (ie, how it fits) • Protocol: process/steps when patient not responding • Communication interactions
Outcome	Technical performance: efficiency and reliability • Hardware/software issues • Reliability of system • Ability to send, receive, store, and retrieve data • Intervention appropriateness	Quality of service and individual outcomes • Perceptions of quality (patients, staff) • Outcomes for individuals (eg, adoption by staff) • Changes in workflow, workload • Text message relevance	Global effect: lessons learned, potential application to other settings • Lessons learned • Implementation process • Balance tech/human perspective • Steps needed to implement larger trial

[a]Adapted from Cornford et al [31] and Barber et al [32].

The Intervention and Team

The TextTB intervention pilot study occurred from December 2011 through April 2013. Details of that study are reported elsewhere [30,34]. In brief, participants were randomized to the intervention group (TextTB, n=18) or control group (paper documentation, n=19) for the first 2 months of active TB treatment. Participants in the TextTB group were asked to (1) send an initial SMS text message to confirm connection with the system at enrollment, (2) text daily to confirm they took their TB medication that day, and (3) text any questions or concerns. They received confirmation that their text messages were received, or they received query messages if they failed to send notifications. They also received twice weekly educational text messages that were based on the Information-Motivation-Behavior skills model [34-36]. The team members were the study principal investigator (PI), a regional TB director/pulmonologist, the lead regional TB social worker, a regional TB staff member, two TB-specialized clinic registered nurses (RNs), and the hospital TB program director/pulmonologist.

Technical Platform

FrontlineSMS version 1.6.16.3 was the platform selected to send, receive, and manage text messages [37]. FrontlineSMS is an open-source, free software program that is installed on a laptop and functions with a GSM modem and a local SIM card. The GSM modem fits into the laptop and holds the SIM card. The SIM card includes the imbedded chip required for cell phone transmission [38]. The card contains identification numbers, controls which phone services the user can access, and can be moved between mobile devices. Together, the GSM modem and SIM card allow the computer to function like a mobile phone to send and receive text messages across a mobile phone network [38].

Implementation

Hands-on training and written directions in Spanish on how to operate the FrontlineSMS platform were provided by the PI to four team members. One team member primarily managed the daily patient interactions, while another did so on occasion or during vacation periods. Two pulmonologists were available for consultation for participant questions that were technical or needed expert advice (eg, recommendations for potential allergic reaction). Other nonparticipating hospital staff members were introduced to the intervention during a hospital-wide conference focusing on TB case presentations and current and future goals for TB management.

Analysis

Data from the combined sources (eg, study log, text messages, and stakeholder feedback) were assessed for implementation issues and categorized based on the evaluation framework (see Table 1). An iterative, interpretive, and flexible process was applied as recommended for RAP methods [33]. Analytic validity was strengthened with *member checking* through local stakeholder review, group consensus, and by drawing from multiple data sources. The PI conducted the initial categorization based on theoretical framework definitions. The other investigators reviewed the categorizations, which were iteratively refined until group consensus was achieved. An onsite champion (eg, local expert) who could serve as a liaison to clinical staff facilitated the evaluation process and provided member checking. Ash et al noted the importance of an onsite expert as well [33]. Based on the specific issues identified in this study and the pragmatic experience of the investigators,

potential modifications for a larger-scale trial implementation were outlined. Analysis was supported using ATLAS.ti version 6 (GmbH, Berlin, 2009).

Results

Organizational Considerations

Overview

Organizational considerations included issues that could impact sustainability, delivery of services, and potential application to other settings. Issues encountered that impacted the intervention included equipment security, intervention-related costs, and workflow changes.

Equipment Security

The original plan was for the study laptop to be located at the nursing station, but it became apparent that the laptop might be unattended at times throughout the day, raising the risk for a security breach or outright theft. Therefore, the laptop was moved to the regional TB office located upstairs in the same building. Security concerns also required that the laptop be turned off and put away in a locked cabinet when study staff members were not present, which meant that the software was available only during clinic office hours, rather than around the clock. Participants were informed that responses would be provided only within clinic hours, Monday through Friday, and emergencies were to be directed through standard routes. However, powering down the program caused other problems—see technical and sociotechnical consideration sections.

Financial Considerations

The study had associated set-up costs. The FrontlineSMS software was open source and available free of charge [37]. However, there were costs associated with the purchase of the laptop computer, GSM modem, and SIM card. The GSM modem was replaced due to technical issues, incurring additional cost.

The majority of ongoing costs were associated with text messaging over a mobile phone network (ie, SMS text messaging). A majority of participants reported having basic feature mobile phones (26/37, 70%) and pay-as-you-go mobile phone plans (22/37, 59%). In Argentina, text messages are free to receive and ranged from ARS (Argentinian peso) $0.60 to $1 (US $0.10-$0.23) to send for pay-as-you-go service plans, according to the participants and mobile phone service provider websites. However, these fees could vary substantially due to service provider promotions or by purchasing a package with unlimited text messaging for a given number of days. Based on cost range per text message, the intervention averaged US $12.80 to $29.44 per participant for a 2-month period for messages sent and received.

Although there are options for online mobile phone service providers to send text messages at a discounted rate, there were logistical problems with this service. Initially, credit was purchased as a bundle from one of the suggested online mobile phone credit providers (Clickatell). However, in order to use the credit in Argentina, the phone number had to remain a US or European number, which would have required the patients to send messages to an international number, greatly increasing the costs and potentially challenging the legitimacy of the intervention being conducted by local team members. Therefore, we chose to use a local phone number. Other cost-related considerations included two phones reported as lost or stolen, and credit used up sooner than anticipated in some instances, in which case the monthly credit was added to the patient account early.

Workflow Changes and Monitoring

Initially, the intervention was to be managed by the nurses. However, because the laptop had to be moved to a more secure area upstairs, the nurses were unable to consistently leave their area to run the intervention. The technician volunteered to be the primary operator of the messaging platform. The regional director managed the platform when others were on sick leave or on vacation. An Excel file was developed to help visually track participant stage of treatment and notifications, and to clearly identify those who did not send notifications. The technician estimated between 15 minutes to 1 hour per day was required to review and respond to the text messages. This time was broken up into two to three intervals between work responsibilities.

Another workflow impact resulted from tracking and managing mobile phone credit compensation. Participants were provided with mobile phone credit at study onset and at the beginning of the month to compensate for cost of texting daily and at the end of each month for study participation. Although adding credit was easy, it required leaving the hospital to go to a kiosk nearby where credit could be added with the phone number and name of the mobile provider. This task was additionally complicated because participants were enrolled in the study at various times and cash was required for the transaction.

Although not directly related to the mHealth intervention, the paper-based medical charting system in place was a challenge for collecting final treatment outcomes. Manual chart review, to identify and collect treatment outcomes, was time consuming and accompanied by occasional missing or incomplete data. When considering future trials at a larger scale, the integration of the mHealth data into the paper-based medical records will be challenging or impossible.

Medication Shortage

There was an unexpected TB medication shortage at the regional and national TB program levels during the study. The shortage and outage of some medication was documented in the study log from December 1, 2012 to the last text message regarding the medication shortage sent on March 20, 2013. However, availability or amount of stocked medication may have been an issue for a longer period. Because of the shortage, medication was distributed to participants for shorter time periods, for example, 5 days or 2 weeks rather than the standard 1- to 2-month supply. In some instances, only one of the medications was allocated and patients were told to keep checking back for the missing medication. Although not the focus of our study, the medication shortage may have impacted treatment outcomes, and text messages were added to inform participants when medication became available.

Human Perspective Considerations

Overview

Human/social considerations focused on requirements for implementation (eg, training), team participation, change in attitudes or beliefs, and perception of the quality of the intervention.

Training

It was necessary to train study personnel to use the messaging platform, and an extended period of technical support was required. Training was provided by the PI to the regional TB director/physician, a social worker, two nurses, and a technician. One nurse and the technician were computer novices and required instruction on basic computer functions (eg, how to save a file, how to copy and paste text). All trained team members were able to review and send text messages using the platform. All intervention participants knew how to send text messages. Participants were given verbal and written instructions on the desired format for notification messages. However, there were still problems with inconsistent formatting of notification messages (discussed below in the auto-confirmation section).

Team Participation and Process

Responding to patients' questions was often a collaborative process. The TB technician solicited assistance from team members when necessary. The technician had worked in the hospital for nearly 20 years, had conducted TB testing, had basic TB knowledge, and was familiar with the hospital/clinic setting. The office was without walls or dividers and the regional TB director (pulmonologist/TB specialist) and TB social worker were seated nearby and could provide rapid assistance.

Attitudes and Beliefs

The team indicated that the ideal would be for patients to be referred to local centers for close monitoring during their TB treatment course. However, they all agreed that the intervention appeared to be beneficial for those receiving treatment by self-administration and especially for those who lived in rural or semirural settings where access to health care was challenging. The technician, who primarily managed the intervention, indicated that he felt he was truly able to help participants through this mode of delivery. He noted that the intervention seemed to be very useful to participants, especially for those who had many questions, concerns, or needed advice. Some of the staff, however, believed that self-administration functioned well despite a documented high rate of treatment abandonment. As a result, there were some staff who hesitated to act with respect to potential abandonment before a full month had passed. In one case, the patient contact information was not entered into the medical record and, therefore, follow-up could not be initiated. The intervention did serve to identify a patient who had been documented in the notification records as abandoning treatment, but who had actually transferred to a different health care facility and had noted doing so in one of her text messages.

Technical System Function (Platform) Considerations

Overview

A number of the technical issues encountered during the pilot test were able to be remedied, while others will need further consideration for a larger-scale trial. The technical issues, including software quirks, errors in data exporting, and software inefficiencies affected the intervention flow and analysis of results, as well as the reliability of the program.

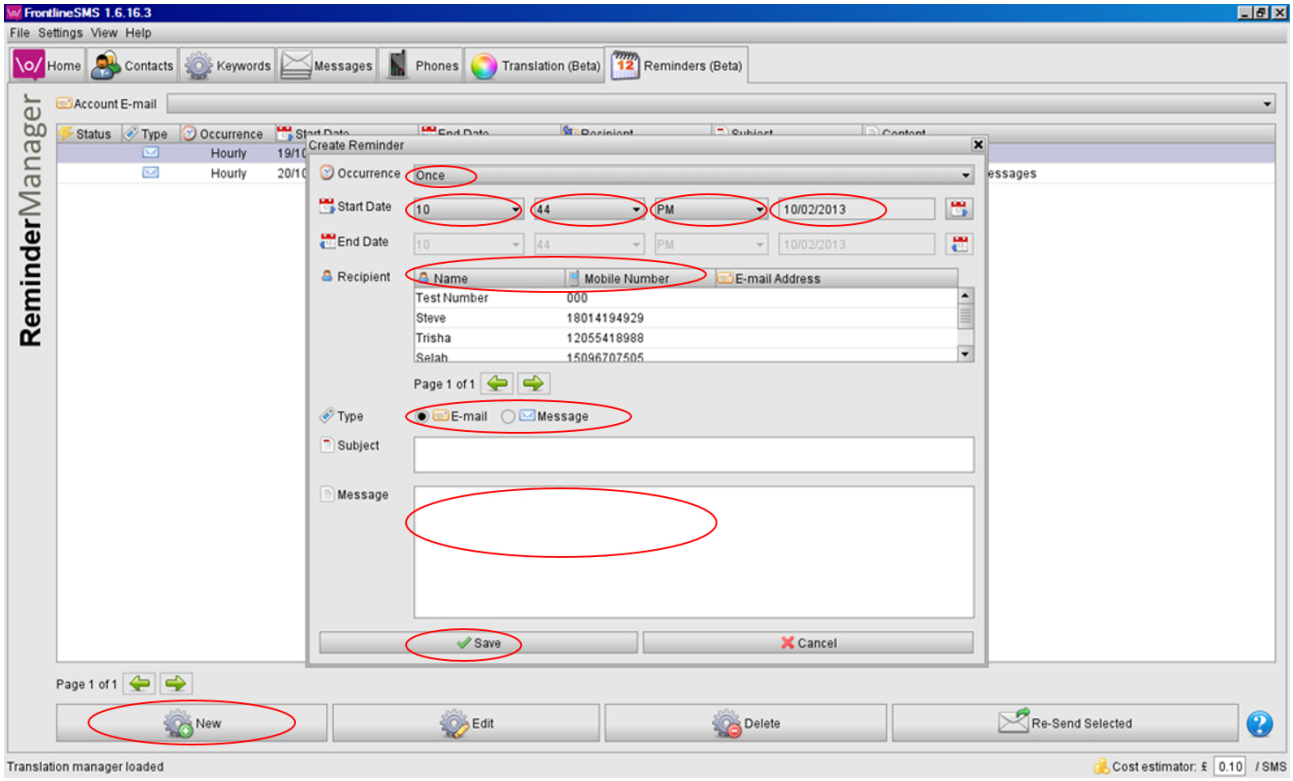
Organizing Messages

The platform software allowed messages to be organized in multiple ways (eg, by contact, sent or received, or all). However, it was identified that a "0" needed to be added to the beginning of each mobile phone number in order to match the messages to an individual. In addition, although two local area codes were used interchangeably for calls within the province, the software recognized only one (eg, 11, and not 15).

Scheduling of Reminders

The reminders software feature was used to set up the package of educational messages for automatic delivery at predetermined times, twice weekly. Figure 1 illustrates the steps necessary to create one message (eg, select date, frequency, add content). Patients entered the study on a rolling basis, therefore, the package of messages had to be created for each participant. It took 10 to 15 minutes to create each package. By trial and error it was identified that the software had a maximum capacity of 100 reminders. The system did not provide a notification or alert to indicate why new messages could not be created or that maximum capacity was near or reached. Once this issue was identified, sent messages had to be deleted at regular intervals for new ones to be added.

Figure 1. Steps required to input and create an automatic educational text message.



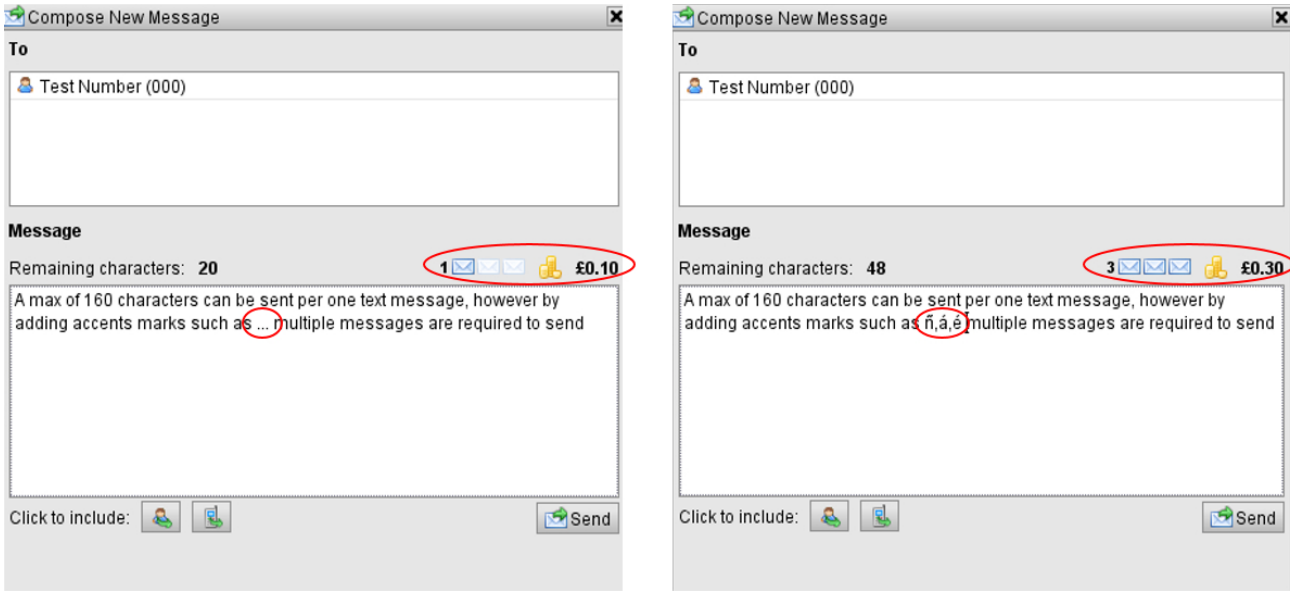
Impacting Cost and Data Analysis

Accents marks, commonly used in the Spanish language, were recognized as multiple characters. Despite not exceeding the 160-character limit, this miscount cued the platform to send multiple messages (see Figure 2). Once this problem was identified, accent marks were removed from the educational messages.

In addition, problems were encountered when exporting messages with accent marks for analysis. The software has a function to export data into an Excel file. However, letters with associated accent marks were changed to unrecognizable characters during this process. One example is the Spanish word for "I took", which is "Tomé" that was changed to "TomÃ©." The messages had to be reviewed individually and corrected in the exported data file, resulting in increased time for data analysis.

In addition, messages were time stamped 2 hours earlier than when they were sent or received. Consultation with the program staff suggested that the cause of the time discrepancy might have been because the study computer was set up in a different time zone. Changing the time zone on the computer did not correct the problem. This issue warrants further investigation to assure precision time stamping in the future.

Figure 2. Number of texts and associated costs without (left) and with (right) accent marks.



Reliability of Software

Inconsistencies were identified between the confirmation of messages sent within the platform and messages delivered after messages were not received on the study mobile phone. It was determined that when the mobile phone credit was depleted, messages were still shown as sent within the platform even though they were not sent by the mobile phone carrier. There was no link between the mobile phone carrier or credit amount remaining on the SIM card and the FrontlineSMS software. To address this problem, the mobile credit balance had to be regularly checked on the service provider website. This was another task to remember to do on a regular basis to avoid episodes where messages were believed to be delivered, but were not.

Larger System Issues Impacting Technical System Function

Network coverage variability and Internet and electricity outages were outside of the investigators' control, but impacted intervention implementation. The impact of data loss due to poor or no network coverage was minimal for the pilot study, but could be significant for a larger-scale implementation. There were participants who reported loss of network coverage when traveling as the cause for missing days' worth of notifications. In addition, one of the main mobile phone service providers had a 3-day outage and no messages could be sent or received, which likely resulted in loss of data. The company provided a compensation of ARS $10 (about US $3.5) for the loss in service.

In addition, there were 10 days logged in the field notes during which there was no Internet access and days without electricity. Access to the Internet is required to download the FrontlineSMS program, but after installment, Internet access was no longer required because the software sends messages over a mobile phone network instead of over the Internet. Disruption in Internet access could be a concern for cloud-based programs. For several days, electricity was out for all, or part, of the work day. The loss of electricity did not cause a delay in messages being received or sent because the laptop had a long battery life. However, extended periods without electricity could be a significant problem for larger-scale implementations. In addition, when the radio was on in the office, a notable static disturbance in the music was heard when texts were received.

Sociotechnical Considerations

Overview

Sociotechnical considerations reflected the interactions between people and technology and focused primarily on issues that affected study participants. Issues included inconsistent message delivery, deletion of reminder settings, challenges to using keywords for auto-confirmation messages, and messages delivered out of sync.

Inconsistent Message Delivery

For the first 2 months, reminder messages were sent to participants with some replying that they had sent their notification earlier. It was eventually identified that depending on the order of opening the software (eg, modem first and then FrontlineSMS, or vice versa) messages would go to the modem and not be delivered to the messaging platform. It was later recognized that the modem had a storage maximum at which time messages needed to be deleted in order to receive new ones. Initially, the modem inbox was reviewed daily and messages (n=55) were manually transferred into the database. Then a new modem (different model) was incorporated into the trial and there was fewer instances of data not being received. Remaining issues appeared to be caused by problems with service coverage, rather than the modem.

Deletion of Reminder Settings

The educational messages set up using the reminder feature were also not consistently delivered at the prespecified time and date. When reminders were sent, a green check mark was displayed to the left of the message row in the software window. The reminders that were not checked had to be reviewed and resent. It was later discovered that powering down the program caused the automatic reminder settings to be erased. As previously mentioned, the study computer had to be powered off and stored because of security issues.

Challenges to Using Keywords to Send Auto-Confirmation Messages

The keyword feature was used to set up auto-reply messages to daily notifications of self-administration of medication. In order for the software to recognize a keyword, it must be the first word of the message. It was identified that the software was also sensitive to case, accent marks, and punctuation. As a result, multiple similar keywords were added (eg, upper-/lowercase, with/without accent marks) in response to the different ways participants formatted messages. Although participants received both verbal and written instructions for the formatting of notification messages (eg, "Tome 3R 4B" for "I took 3 red and 4 white pills"), message format often varied (eg, "hello", "good day", or other first words). This led to failure of the system to auto-confirm receipt of notification, requiring the technician to manually review messages and respond. Some keywords were added in attempt to accommodate communication patterns (eg, "hola!!!"). However, the number and variety of keywords also led to auto-confirmation messages being sent in error (n=17) when, for example, a question rather than a notification was received.

Messages Delivered Out of Sync

Another outcome to shutting down the study computer nightly and over the weekend due to security reasons was that some messages were delivered out of sync. That is, if a message was sent outside of the office hours, the auto-response was delayed until the software was powered on. For example, if a participant sent notifications over the weekend, multiple acknowledgment messages were sent first thing Monday morning. These messages that were delivered out of sync caused confusion for some participants. Some participants texted back that they received a confirmation message, but had not yet taken their medications that day.

Discussion

Principal Findings

The goal of this research was to identify and describe practical issues that need to be considered before widely disseminating the TextTB intervention. This research uncovered generalizable issues that others may want to consider prior to developing and implementing an interactive mHealth intervention. Understanding what worked and what likely would not work at a larger scale is important for planning. Potential solutions were identified for some of the problems (see Table 2). The potential solutions need to be evaluated for effectiveness in future research.

Table 2. Identified implementation issues and potential solutions.

Issue	Potential solutions
Adding phone credit was time consuming and credit was depleted early for some participants	Free texting
	Contract with local mobile phone carriers
	Trial mobile messaging app that allows exchange of messages without SMS charge
Messaging platform shortcomings	Modify open-source software or consider other available platforms
	Improve features
	Message package upload and tailored delivery
	Alerts to health care team
	Visualization of treatment course
	Retain interactive feature to promote patient/health care personnel relationship
	Identify or develop software that provides message selection options (eg, an app)
	Structured messages (improve ease of patient reporting, maximize automaticity of program features, and reduce manual intervention)
	Free text option for questions and responses
Patient tracking	Further partner with stakeholders (eg, National TB Program director, local health care centers)
	Have dedicated intervention management staff
Sustainability	Economic evaluation
	Confirm transfers to another health care facility
	Case contact tracing
	Involve health care provider in care management
	Implement intervention for full treatment course

Intervention Strengths

The texting platform software allowed for a large number of contacts and enabled multiple view options. The software allowed interactivity, personalization, and messaging functionality without requiring access to the Internet. Although we attempted to make the intervention as automated as possible, the team also wanted to assure that it could allow personalized communication with the patients, and not be viewed as too automated.

Intervention Areas to Strengthen

We experienced issues of delayed response and multiple acknowledgment messages. After this study concluded, we learned from other researchers (personal communication) that powering off the software can cause the reminder feature to be inactivated, which would explain the inconsistencies we experienced. Our solution was a manual review of sent messages and resending unsent messages. The solution for the other researchers was to leave the computers running continuously, although they have experienced issues caused by software updates or the computer accidentally being unplugged. However, in our situation the computer needed to be powered off and stored daily because of security issues.

Patients sent notifications that they took their medication in a number of ways, although verbal and written directions were provided, which caused inefficiencies and messages sent in error. For widespread dissemination, software that provides message selection options (ie, an app instead of basic messaging) might be useful. Selecting from structured messages, with an option to include free text questions, could improve patient reporting, maximize automaticity of program features, and reduce the need for manual responses. However, the use of structured messages may also make the intervention less personal.

The software was not built specifically for the application for which it was used in this study and, therefore, we expected to find some misalignment of features. A new Web-based version of FrontlineSMS, version 2, is now available. It is advertised as more intuitive, easier to use for creating and managing messages, and capable of managing larger volumes of messages [37]. However, in the new version, a number of key features we used, such as the translation manager and reminders, are

currently not available. This exemplifies a challenge to implementing open-source software. It is difficult to purposefully use a previous version of software once the new one is released, and the new version may be quite different.

Even though sufficient credit for the intervention was added to patients' mobile phones at the beginning of each month, running out of credit early was a problem for some participants. Texting and mobile phone use habits are unique to each individual. For example, one participant indicated that when she had available funds, her usual mobile phone habit was to purchase a package that allowed unlimited calls and texting for 5 days. She would use her phone as much as possible during these periods. She reported having to use her mother's phone during the study because she had used all her credit within a short time. In addition, the workflow associated with adding phone credit for each patient at local kiosks, although feasible for a pilot study, would likely be prohibitive on a larger scale. An ideal solution for this issue would be to establish a free to-text-in number.

Easy access to the computer is an essential feature for workflow integration. The original plan was for the intervention to be managed by the nurses. When equipment security concerns required the laptop to be moved upstairs, the nurses were unable to consistently leave their area to run the program. Nurses are often overburdened with multiple tasks and patient interruptions. Leaving the nursing area daily to monitor the messages was not feasible. With large numbers of patients, the ideal solution would be to hire one individual with TB specialty knowledge to manage the messaging.

Factors Unrelated to the Intervention

Potentially, extended periods of Internet and electrical outages could have caused major problems with the research. Internet and electrical outages can occur more often in low- and middle-income countries. Hoffman et al [21] reported challenges of Internet access in Kenya with downtime due to frayed network cables and slow system access. Because the software we used did not require the Internet to operate, outages experienced during the study period were not a limiting factor to the continuity of intervention delivery. We used a computer that had a long battery life. There were a few participants, however, that reported depleted mobile phone batteries after long periods of power outages. Extended electrical outages could certainly be anticipated to cause problems for any mHealth intervention.

Loss of data was a major frustration. Data loss is not unique to the technology used in this study. Hoffman et al [21] reported technical and transmission problems resulting in an estimated 25% loss of data, and Wade et al [22] reported technical problems with variable phone signal strength.

Use of the Sociotechnical Framework

For this study, we adapted a framework [31,32] in which sociotechnical concepts (ie, technology, person, organization) were matched to classic structure-process-outcome concepts to create a matrix. There were limitations to our approach. The matrix was simple and explicit, but the interaction between components, which is a key part of sociotechnical systems theory, remained implicit and could have been overlooked. The matrix also did not account for broader contextual issues like electrical outages or a national medication shortage, and the approach does not explicate interpersonal interactions. Sociotechnical approaches have provided a powerful framework within which to analyze reasons for uptake and performance with many types of information and communications technology, and can contribute to the design of those systems [39]. Much of the richness and nuance of the sociotechnical approach was lost with our approach. However, it was pragmatically useful for the purposes of analyzing and categorizing implementation issues.

The field of mHealth is rapidly evolving, and frameworks designed specifically to evaluate mHealth interventions are beginning to emerge. For example, Leon et al [40] applied a health system framework to assess community-based health services system challenges in South Africa. Their framework included larger context and sustainability issues and identified four key dimensions: government stewardship, organizational systems, technical systems, and financial systems. Hirschhorn et al [41] and Aranda-Jan et al [42] conducted systematic reviews to identify potentially important domains for scaling up and evidence of which mHealth components worked and did not work in Africa. Mohr et al [43] focused on principles from behavior change theories in the context of mHealth.

Limitations

The purpose of this research was to identify key areas to improve for further testing of the intervention in a larger sample. We succeeded in identifying and developing solutions for most of the problems we encountered, although a few issues remained unresolved. Issue tracking, determining the cause of problems, and developing solutions occurred on an ad hoc basis. Although informatics experts were a part of the PI dissertation committee, on-the-ground IT support was limited. As such, some of the issues encountered may have been managed proactively with a local IT expert. In addition, the cost estimate was for the texting component only, and did not factor in staff time—such estimates are recommended for the next research phase.

Conclusions

Intervention challenges were largely manageable during the pilot study, but when evaluating these challenges for a larger-scale trial, issues to be addressed were identified with potential solutions outlined here. These findings may help others considering implementing an mHealth intervention to mitigate these challenges. Although some of the issues may be context dependent, other issues such as electricity and Internet outages, limited supplies, and human resources are not unique issues to our setting. Release of new software versions does not necessarily result in solutions for certain issues, particularly when specific features are removed. As such, other software options will be considered prior to moving to a larger-scale study. Improved automation of some features was recognized as necessary for use with a larger sample, however, a goal will be to retain the intervention capability to be interactive, user friendly, and meet the needs of the patients and the health care team. Continued collaboration with stakeholders will be required to conduct further research and to understand how such an

mHealth intervention can be effectively integrated into larger health systems.

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Authors' Contributions

SI contributed to the research development, implementation, analysis, and manuscript drafting. KS contributed to the adaptation of the theoretical framework, analysis, and manuscript preparation. SB, PP, and DT contributed to protocol development, analysis, and manuscript preparation. CC contributed to data collection, manuscript preparation, and verification of findings.

Conflicts of Interest

None declared.

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Abbreviations

DOT: directly observed therapy
IRB: Institutional Review Board
mHealth: mobile health
NIH: National Institutes of Health
NINR: National Institute of Nursing Research
NRSA: National Research Service Award
PI: principal investigator
RAP: Rapid Assessment Process
RN: registered nurse
SMS: short message service
TB: tuberculosis
WHO: World Health Organization

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Original Paper

A Mobile App for Securely Capturing and Transferring Clinical Images to the Electronic Health Record: Description and Preliminary Usability Study

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Abstract

Background: Photographs are important tools to record, track, and communicate clinical findings. Mobile devices with high-resolution cameras are now ubiquitous, giving clinicians the opportunity to capture and share images from the bedside. However, secure and efficient ways to manage and share digital images are lacking.

Objective: The aim of this study is to describe the implementation of a secure application for capturing and storing clinical images in the electronic health record (EHR), and to describe initial user experiences.

Methods: We developed CliniCam, a secure Apple iOS (iPhone, iPad) application that allows for user authentication, patient selection, image capture, image annotation, and storage of images as a Portable Document Format (PDF) file in the EHR. We leveraged our organization's enterprise service-oriented architecture to transmit the image file from CliniCam to our enterprise clinical data repository. There is no permanent storage of protected health information on the mobile device. CliniCam also required connection to our organization's secure WiFi network. Resident physicians from emergency medicine, internal medicine, and dermatology used CliniCam in clinical practice for one month. They were then asked to complete a survey on their experience. We analyzed the survey results using descriptive statistics.

Results: Twenty-eight physicians participated and 19/28 (68%) completed the survey. Of the respondents who used CliniCam, 89% found it useful or very useful for clinical practice and easy to use, and wanted to continue using the app. Respondents provided constructive feedback on location of the photos in the EHR, preferring to have photos embedded in (or linked to) clinical notes instead of storing them as separate PDFs within the EHR. Some users experienced difficulty with WiFi connectivity which was addressed by enhancing CliniCam to check for connectivity on launch.

Conclusions: CliniCam was implemented successfully and found to be easy to use and useful for clinical practice. CliniCam is now available to all clinical users in our hospital, providing a secure and efficient way to capture clinical images and to insert

them into the EHR. Future clinical image apps should more closely link clinical images and clinical documentation and consider enabling secure transmission over public WiFi or cellular networks.

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KEYWORDS

mobile phone; photographs; electronic health records; telemedicine

Introduction

Background

Diagnosis depends on history, physical examination, and testing. Visual assessment is of paramount importance for certain conditions, such as rashes, wounds, and infections. Recording visual data has traditionally been limited to written descriptions, though digital photography is making inroads, particularly in pathology, dermatology, and plastic surgery [1]. Digital images can help us monitor changes over time, and can be shared among providers. Mobile devices with high-resolution cameras are now ubiquitous, giving clinicians the opportunity to capture and share images from the bedside [2]. However, secure and efficient ways to acquire, store, and share digital images are lacking [3].

Some clinicians already use personal mobile phones to capture patient photos. These creative clinicians email captured images to one of their email accounts, then open their email on a hospital workstation and copy and paste the images into the electronic health record (EHR). This may create privacy and safety vulnerabilities because images and patient data may remain on personal devices, and correct image-patient pairing is not assured.

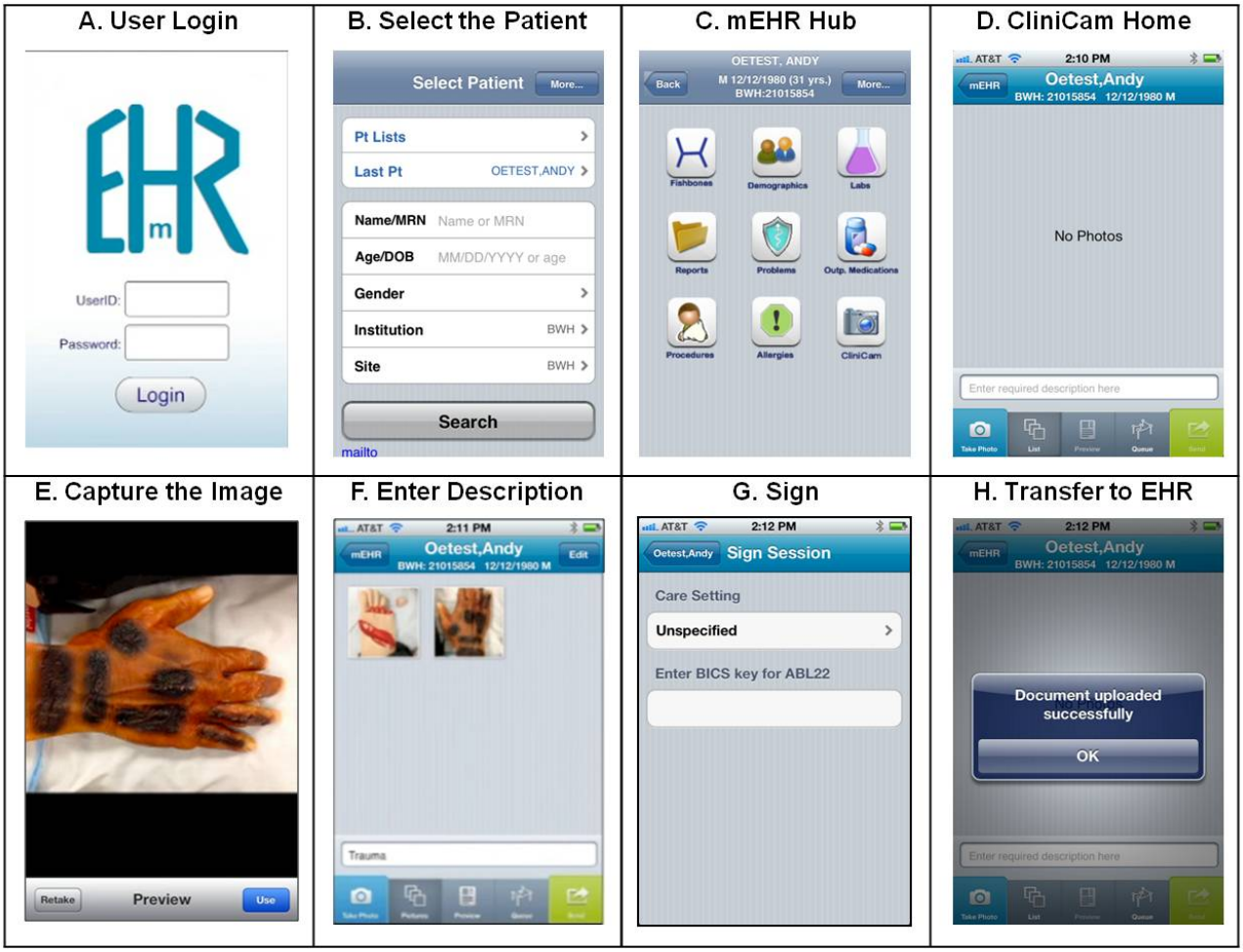
We developed CliniCam, a mobile app for clinicians to securely capture images and transfer them to the EHR. We describe the application design and report usability findings from an initial group of users.

Application Description

We developed CliniCam, an app that allows user authentication, patient selection, image capture, image annotation, and storage of the images as a Portable Document Format (PDF) file in the EHR. CliniCam is a native app for Apple iOS (iPhone, iPad) developed using Xcode (Apple Computer, Cupertino, CA). For user authentication and patient identification, we leveraged a pre-existing Partners Health Care native iOS app, mEHR, which allowed clinicians to view patients' electronic health records remotely. Users log in to mEHR with their hospital user ID and password (Figure 1A), then search for the patient using a combination of name, medical record number, age, date of birth, and gender (Figure 1B). Users are then presented with a list of potential patient matches and select the appropriate match. From the mEHR app hub, the user then selects CliniCam from the menu of available mobile apps (Figure 1C). CliniCam is launched through a uniform resource locator (URL) scheme passing user and patient context.

The CliniCam home screen then displays, including the selected patient's demographics in the top navigation bar (Figure 1D). The user selects "Take Photo" from the lower tab bar and then uses the camera to capture the image (Figure 1E). Up to six images can be captured per patient session; each image can be individually annotated. The image set must be labeled with a mandatory description. After the user is satisfied with the captured images and annotations/description, the user selects "Send" from the tab bar (Figure 1F). The user is then prompted to select the care setting from which the photo was taken and to enter their unique security key to sign the transaction (Figure 1G). The images are then transmitted to the patient's EHR and a modal message box confirms the successful transfer (Figure 1H). The video in Multimedia Appendix 1 summarizes how the CliniCam app is used to capture and securely transfer clinical images to the EHR.

Figure 1. The CliniCam app. All patient and clinical information is fictitious. EHR=electronic health record; mEHR=partners mobile electronic health record app.



Integration With the Electronic Health Record

A key feature of CliniCam is making the images available to all clinicians in the EHR. Images taken by CliniCam are viewable by all credentialed EHR users, via our institution's clinical data repository (CDR), a system that consolidates electronic patient data from multiple systems in a single portal. Our organization has an enterprise services-oriented architecture with web services or application programming interfaces (API) that enable two-way communication with our clinical systems [4]. EHR integration of CliniCam required web services to match patients with their electronic health records and to transfer images to the EHR.

In order to link the CliniCam PDF to the appropriate patient's medical records, the user initially searches for the patient by name and/or medical record number using patient directory services. Gender and date of birth may be used to narrow the search. Once the correct patient has been selected, CliniCam has the appropriate unique identifiers to match the photos to the patient's EHR. Patient selection is forced before photo acquisition to ensure photos are associated with the correct patient.

To transfer the images to our EHR, we needed to select an image format that the EHR could receive. Our clinical document repository is limited to storing text or PDF documents and does not have the ability to accept images alone. In this case, CliniCam internally transforms the captured images into a PDF file, and then calls a web service to transfer the PDF to the CDR. Using the PDF format enabled us to display both the photos and metadata (patient identifiers, name of clinician capturing photos, date/time the image was captured, and annotations) in a single file. The PDF is identified as a photo document in the clinical data repository and easily available for review by any authorized clinician in our health care system.

Security and Privacy

Ensuring the security and privacy of confidential patient information was of paramount importance in our design since the hospital and clinical users are covered entities that must comply with the Health Insurance Portability and Accountability Act (HIPAA) of 1996 [5,6]. HIPAA requires reasonable and appropriate safeguards for protecting electronic protected health information, including clinical images [7]. Despite recent calls for more clarity around HIPAA requirements for mobile health apps [8], HIPAA does not provide a list of required features and fulfillment is subject to interpretation. Therefore, we worked with our hospital's information security officer to perform a risk analysis and to design the application with attention to access control, auditing, and encrypted data storage and network transmission.

Table 1 summarizes the features used to make CliniCam secure and HIPAA compliant. On app launch, users are authenticated using their hospital user ID and password, using Active Directory authentication. All application launches as well as patient data accesses are logged. Captured clinical images are stored in temporary files within a secure temporary storage area allocated to the app (sandbox) while the app is running, but all the data are cleared when they are uploaded to the EHR or the app is closed, so that no data are permanently stored on the mobile device. If the user is interrupted or forgets to transfer the images to the EHR, CliniCam will notify the user in 15 minutes, and will then automatically delete the clinical images 5 minutes later if no action is taken. CliniCam requires a connection to our organization's secure WiFi network and will not function if the user is solely connected to a public WiFi or cellular network (eg, 3G or 4G LTE).

Table 1. Security features implemented to make CliniCam secure and Health Insurance Portability and Accountability Act (HIPAA) compliant.

Security feature	CliniCam implementation
User authentication	Requires user log-in with hospital user ID and password
Audit trail	Logs user access to patient information
Data encryption	Temporarily stores images in encrypted area of application memory
No permanent data storage	No permanent storage of patient information or clinical images. When images are transferred to the electronic health record, the images are permanently deleted from the application
Application timeout	Automatically removes clinical images from the application if not transferred to the electronic health record in 20 minutes (user receives warning notification after 15 minutes)
Secure wireless transmission	Requires connection and transmission over hospital's secure WiFi network; data transfer over public networks is not supported

Methods

Study Design

We performed a preliminary usability study of CliniCam using a survey of initial app users. We sent email invitations to resident physicians from emergency medicine, ambulatory internal medicine, and dermatology to participate in the study and use the app in clinical practice for one month. Resident physicians were eligible to participate if they owned an iOS device, were willing to use their mobile device to capture clinical images, and were on clinical service during the time of the study. Clinicians responding affirmatively to the email invitation were sent instructions for installing and using the app, including a video tutorial and a link to download the app on their mobile device.

These three clinical services were selected because they commonly capture images of patients. Clinicians currently use several methods for incorporating clinical images into our EHR. Some clinicians use a digital camera to capture images, then transfer the images from the camera to a hospital workstation and embed selected images into their clinical note. Other clinicians use their personal mobile phone to capture clinical images, then email the images to their email account and copy and paste the image from their email into the EHR.

After approximately one month of clinical use, participants were emailed and asked to complete a voluntary, Web-based survey (SurveyMonkey, Palo Alto, CA; see Multimedia Appendix 2) on their experience. We analyzed the survey results using descriptive statistics.

The Partners HealthCare Human Research Committee reviewed and approved this study. Clinicians consented to participate in the study by responding affirmatively to the initial email invitation, installing the app on their mobile device, and voluntarily completing the Web-based survey. The CliniCam app was developed for routine, nonresearch use and was approved for clinical use by the hospital prior to the study. Clinicians were asked to obtain verbal consent from each patient before taking pictures per hospital policy. Patients did not participate in this research and no patient information or clinical images were reviewed or included in this usability study.

Results

Twenty-eight resident physicians participated between July and September 2012, and the survey was completed by 19/28 (68%), with mean age 29 (53% female). They were from the following specialties: dermatology (11%), internal medicine (47%), and emergency medicine (42%). Approximately half of the respondents (53%) did not use CliniCam, many noting that they did not have a patient requiring photos during this time.

Of the respondents who used CliniCam, 8/9 (89%) found it useful or very useful for clinical practice and the same percentage wanted to continue using the application. The majority of respondents (8/9 [89%]) were also satisfied by the application's quality of pictures and ease of use, but only 5/9 (56%) of respondents were satisfied by the application's speed. Three of the users who did not have a clinical need for photos during the pilot indicated that they liked the CliniCam concept and hoped to use it in the future. Respondents critiqued app speed and location of photos.

Several respondents reported that the app was slow and one respondent reported losing a photo. CliniCam is designed to work only on the hospital's secure WiFi network. Investigation of the slowness and lost photos revealed users were often connecting to other networks and that some clinical areas did not have adequate WiFi signals. To minimize these issues, we

provided user education and enhanced CliniCam to check for correct WiFi network connection on launch.

Respondents preferred that clinical images be embedded (or linked) to clinical notes so they did not have to navigate to another EHR location to view the image. Some users also wanted to keep a copy of the image file separate from the EHR for teaching and research purposes.

Discussion

Principal Findings

We developed and implemented a mobile app that facilitates bedside photography with secure transfer into the medical record. We leveraged an existing mobile app for user authentication and patient selection, as well as an enterprise service to securely transfer images in PDF to our CDR. Participants reported that the app was easy-to-use and useful for clinical care. Users offered constructive suggestions regarding speed/network connectivity and location of clinical images within the EHR.

Two key features informed the design of CliniCam and provided value to the user and organization: (1) security features meeting HIPAA compliance, and (2) integration with the EHR. We recognized that clinicians were currently using workarounds to capture and store clinical images with their mobile devices that violated HIPAA principles. We also sought to make it easier for clinicians to automatically transfer the images to our EHR as existing workarounds were time-consuming and cumbersome. Health information technology initiatives often fail to be adopted or achieve their expected benefits because of difficulty integrating the technology with work practices [9]. In this case, adding HIPAA security features protected the patient and organization, but also had the potential to increase workload for some users. We balanced this trade-off with integration with the EHR, which reduced user workload by enabling clinicians to use their existing log-ins, to minimize manual entry of patient demographics, and to store images in the clinical document repository for easy sharing across the health care enterprise.

While planning for clinical image integration with the EHR, we discovered that our EHR does not have a predefined storage area for images or videos (similar to many current EHRs). We considered using our Picture Archiving and Communication System (PACS) that stores radiology images, but this required an electronic order be placed prior to image capture. We felt this additional step would reduce app usage and encourage workarounds. We therefore transformed captured images into a PDF, which EHRs, including ours, routinely handle. While this solution was functional, we sacrificed the ability to store and manipulate native images. Further, image storage was separate from clinical documentation. EHRs should consider enhancements to better support native clinical image storage within the EHR, and the ability to embed/link clinical images stored in external sources to EHR clinical documentation to improve image retrieval speed and efficiency.

As CliniCam and other mobile apps proliferate in health care settings [10], ensuring a robust and widely available WiFi network is critical. Given that CliniCam transfers protected health information and connects to our EHR services, we required information transmission over our secure hospital WiFi network. However, users were sometimes not connected to the secure WiFi network or did not have adequate wireless signal. Future health care provider apps should include security features enabling transmission over public WiFi and cellular networks. Hospitals should also ensure their WiFi networks have adequate coverage and bandwidth to support mobile health applications.

CliniCam is currently available to all clinicians in our hospital. Wound care nurses are documenting existing and new pressure ulcers with CliniCam [11,12], and anesthesiologists are using CliniCam to visually record Mallampati airway score during preoperative assessment. Future versions could extend this mobile platform to include video and to include other users, such as patients wishing to securely share clinical images with their health care providers [13]. Additional investigation is needed to understand CliniCam's ability to facilitate telemedicine, specialty consultation, and reduce unnecessary health care visits [14-16].

Comparison With Prior Work

CliniCam was conceived and developed between 2011 and 2012 when no health care provider-facing apps were available that could securely capture clinical images from mobile devices and transfer them to the EHR. At that time, we were aware of only one application, ClinPix, which allowed clinical image storage on local iOS devices with manual entry of patient demographics [17]. The most commonly reported use of digital clinical images was for store and forward teledermatology, where images were usually captured via digital camera, uploaded to a local desktop computer, and electronically transferred to a remote dermatologist's workstation [18]. Now mobile apps are emerging in this area, but primarily support local image storage, or secure cloud-based storage, without EHR integration. Notably, Figure1 app is becoming popular and allows de-identified image sharing with medical professionals for educational purposes, but not clinical use [19]. The lack of EHR integration was a central limitation of previous products -busy clinicians were forced to access a separate system for image capture and retrieval and there was minimal ability to seamlessly share images across the care team. More recently, EHR vendors have begun to support secure image capture and transfer to the EHR in their proprietary mobile apps [20], and may benefit from the description of CliniCam and usability findings reported here.

Limitations

There are several limitations to this study including the limitation to generalize the results, small convenience sample, and subjective outcomes.

CliniCam was designed for one hospital's EHR, extending an existing mobile app and leveraging services. The application works only on Apple iOS systems, and other tools would be needed for clinicians using other mobile devices. However, the app design is broadly generalizable. EHR vendors could add similar functionality to their own mobile applications [20] or expose web services (APIs) allowing 3rd party software developers to provide secure clinical image capture

functionality. Also, if vendors support the Substitutability Medical Applications, Reusable Technology (SMART) platform, a single version of CliniCam could be created on the SMART architecture to work across all EHR systems [21]. For institutions without access to an existing mobile EHR application and/or enterprise services, a standalone version of CliniCam could be developed with image storage in HIPAA-compliant cloud storage.

In this report, we describe the application and provide usability results from initial users. The small convenience sample may not be representative of all physicians and could be biased towards more technically savvy physicians overstating the app's ease of use. Furthermore, the results may be biased because many pilot users did not use CliniCam during the pilot -they may not have appreciated the potential value of an image capture tool or they may not have had a need for such a tool. An array of sociotechnical factors can influence a clinician's use of health information technology (HIT); including hardware and software, clinical content, human computer interface, people, workflow and communication, organizational policies and procedures, external rules, regulations, pressures, and system measurement and monitoring [22]. In this case, some potential users may not have had mobile devices available at the point of care and others may have found that CliniCam did not fit with their workflow [9]. Previous studies have been devoted to understanding the barriers and facilitators of HIT use [23,24]; a future study could similarly investigate the sociotechnical factors influencing CliniCam adoption [23,24].

A larger sample would be needed for generation of statistically robust measures of usability and satisfaction. Furthermore, our measures of app usefulness were based on a 5-point, subjective Likert scale, not process or clinical outcomes. Demonstrating hard outcome benefit would require large samples and the value of the tool seems self-evident; therefore, we suggest future work focus on improving usability and clinical workflow.

Conclusions

We created a secure and convenient mobile application for acquiring digital images and storing them in our EHR that is now available for all clinical users in our hospital. Implementation went well, though network connectivity limitations were an important shortcoming. Combining these reported experiences with mobile development tools and EHR services, other institutions and vendors should be able to implement secure image sharing applications.

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Authors' Contributions

ABL, NC, DIR, and SG conceived the app and study. ABL, SE, NC, DIR, SS, and EGP contributed to the design and development of the app. All authors contributed to the design of the study. ABL, SE, DJP analyzed and interpreted the data. AL and DJP drafted the manuscript. All authors revised the manuscript and approved the final version for publication.

Conflicts of Interest

David I Rosenthal serves on the Sonifi Health Medical Advisory Board. Narath Carlile also now serves as Chief Medical Information Officer and is a shareholder of Accountable Care Transactions Inc. No other authors have conflicts of interest associated with this article.

Multimedia Appendix 1

CliniCam video.

[MOV File, 11MB - mhealth_v2i4e59_app1.mov]

Multimedia Appendix 2

CliniCam survey instrument.

[PDF File (Adobe PDF File), 201KB - mhealth_v2i4e59_app2.pdf]

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Abbreviations

API: application programming interface
App: application
CDR: clinical data repository
EHR: electronic health record
HIPAA: Health Insurance Portability and Accountability Act
HIT: health information technology
PACS: picture archiving and communication system
PDF: portable document format
SMART: substitutability medical applications, reusable technology

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Original Paper

Patient-Provider Communications in Outpatient Clinic Settings: A Clinic-Based Evaluation of Mobile Device and Multimedia Mediated Communications for Patient Education

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Abstract

Background: Many studies have provided evidence of the importance of quality provider-patient communications and have suggested improvements to patient understanding by using video-based instruction.

Objective: The objective of this study was to understand how mobile information technology assisted video and three-dimensional (3D) image instruction, provided by a health care worker, influences two categories of outcome: (1) patient understanding of information about their condition and detailed medical discharge instructions; and (2) patient perceptions and attitudes toward their health care providers, which included physicians, nurses, and staff. We hypothesize that video and 3D image instruction, provided on a mobile, tablet hardware platform, will improve patient understanding about the diagnostic testing, diagnoses, procedures, medications, and health topics provided to them. We also propose that use of the tablet/video combination will result in improved attitudinal evaluation by patients of their providers and the treatment plan.

Methods: This study evaluated a hospital clinic-based trial (patient N=284) of video and 3D image instruction, provided on a mobile, tablet hardware platform, and its potential to improve patient understanding about the diagnostic testing, diagnoses, procedures, medications, and health topics provided to them.

Results: Results showed strong evidence that the system was perceived as helpful for improving patient understanding, and that it improved communication between physicians and patients (P<.001). The advanced age of some patients had no effect on their perceptions of the tablet-based mediation. Physician comments provided useful insights on effective use of such systems in the future. Implications for further development and future research are discussed.

Conclusions: This study added to the body of evidence that computer-assisted video instructional systems for patients can improve patient understanding of medical instructions from their health care providers and assist with patient compliance. In addition, such systems can be appealing to both patient and provider.

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KEYWORDS

patient-centered information systems; eHealth; mobile computing; medical informatics; patient education

Introduction

Research Goals and Objectives

The goal of this study was to understand how video and three-dimensional (3D) image instruction, implemented on a mobile, tablet hardware platform and provided by a health care provider, influences two categories of outcome. The first outcome is patient understanding of information about their condition and the detailed medical instructions to be followed after the patient exits the clinic. The second outcome is patient perceptions and attitudes toward their health care providers,

which included physicians, nurses, and staff. We hypothesize that video and 3D image instruction, provided on a mobile, tablet hardware platform, will inform and assist patient understanding about the diagnostic testing, diagnoses, procedures, medications and health topics provided to them. We also propose that use of the tablet/video combination will result in improved attitudinal evaluation by patients of their providers and the treatment plan.

Several studies have provided evidence of the importance of quality provider-patient communications and have suggested the potential for improvements to patient understanding by utilization of video- based instruction. This study extends past research by: (1) focusing on an outpatient clinic patient population across a broad range of conditions (ie, all adult patients visiting an outpatient health clinic), (2) utilizing larger wireless tablet computers to provide for handheld video instruction, (3) assessing use of videos in relation to patient understanding and overall provider satisfaction, and (4) including a larger number of participants than prior studies focusing on mobile video based instruction.

The specific aims of this research were to investigate if video and 3D image instruction, implemented on a mobile, tablet hardware platform and provided by a health care provider, helps health care workers to: (1) assist patient understanding, and (2) help provide a positive overall experience of the provider for patients. The research is intended to test the utility, practicality, and patient-perceived usefulness of video and 3D image instruction presented on a handheld mobile tablet device (Figures 1-3 show illustrations).

Figure 1. System screenshot 1.

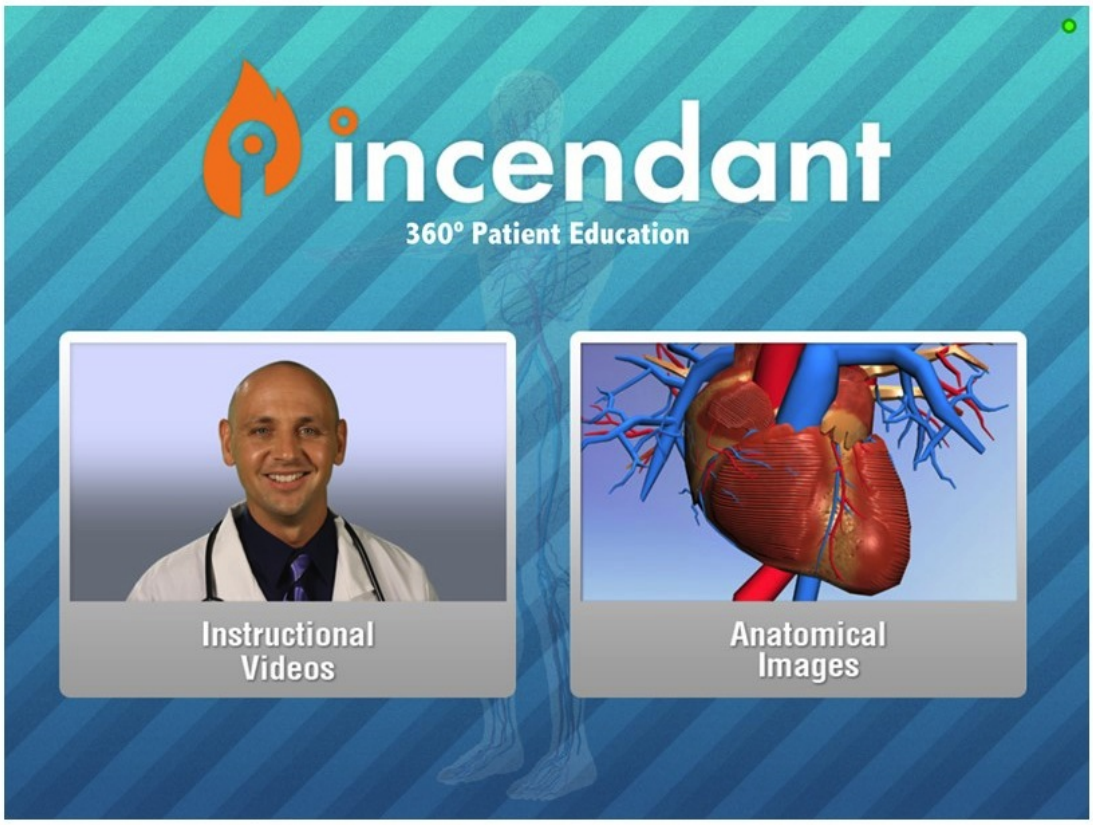


Figure 2. System screenshot 2.

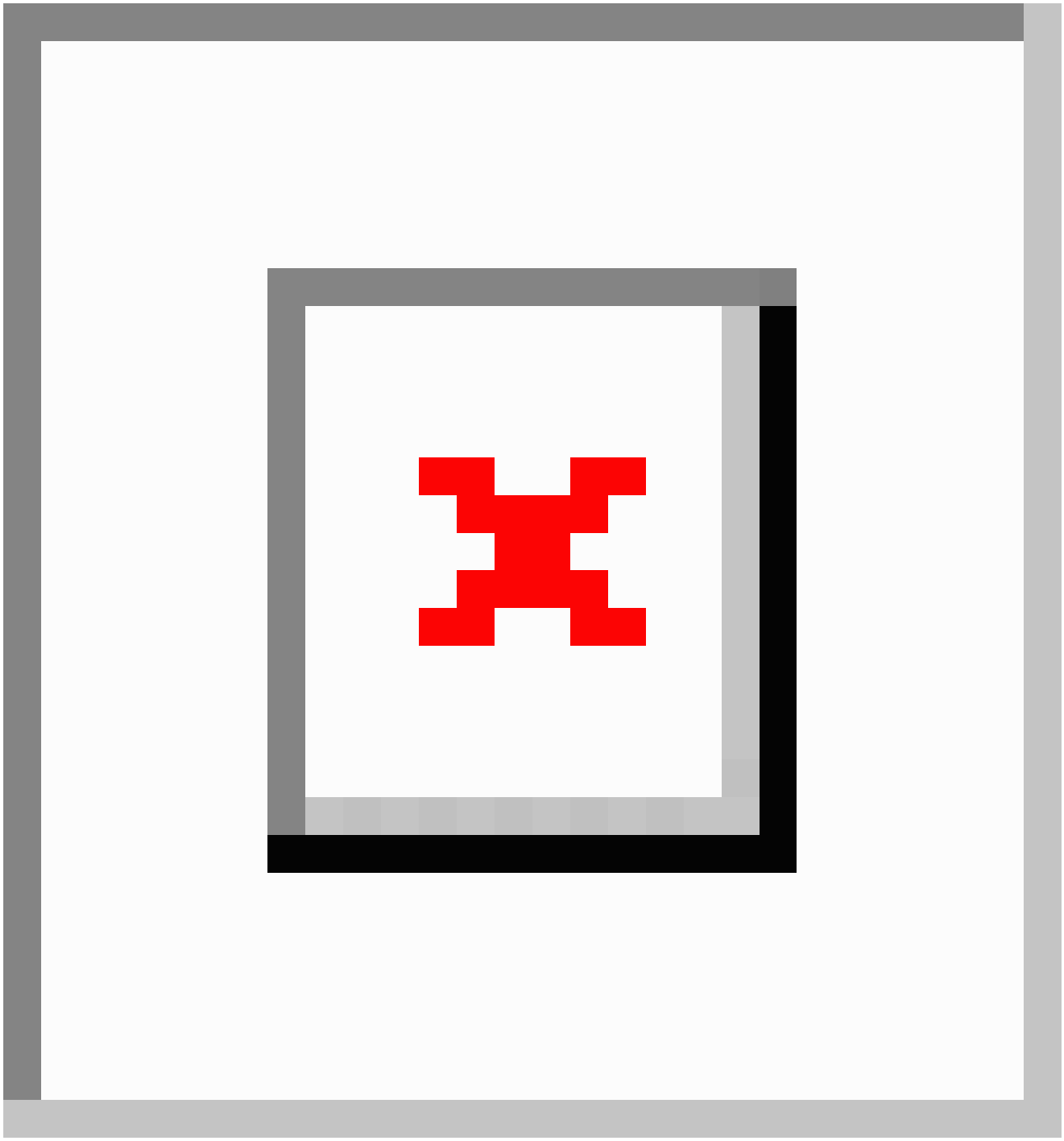
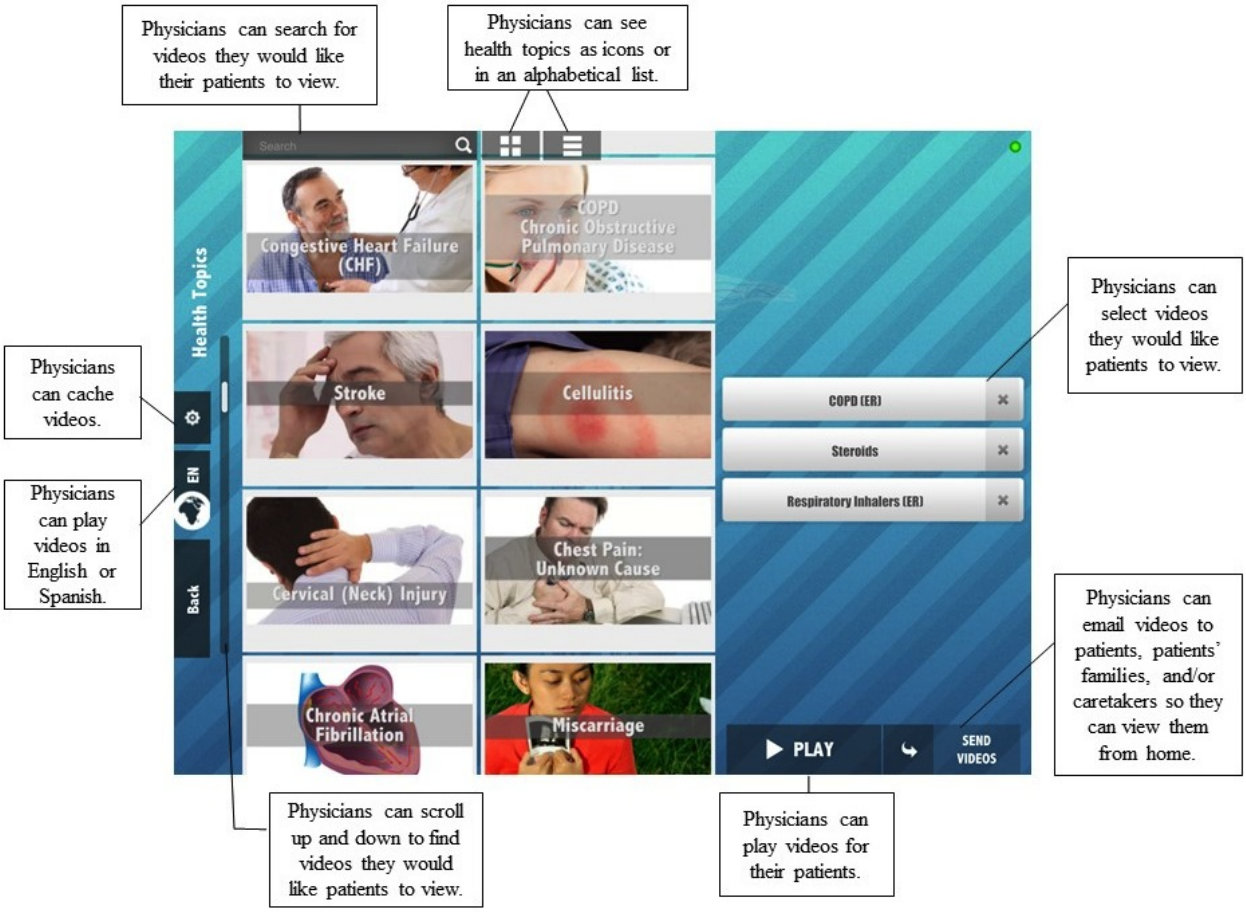


Figure 3. System screenshot 3.



Provider-Patient Communications in Outpatient Settings

Many research efforts since the early 1990s have focused on the potential of information technologies to improve communications between medical providers and patients. Areas in which information technologies have been investigated naturally involve some of the main purposes of patient provider communications. These include creating good interpersonal relationships, facilitating exchange of information, and assisting in the making of treatment related decisions [1]. The importance of these objectives is seen in the fact that the quality of physician-patient relationships have been shown to affect patient recovery from illness [2], the cost of care [3], malpractice claims [4], and patient outcomes for chronic diseases [5,6].

Technology implementations should reflect the recent focus in the provider-patient communication literature on "patient-centered communication", the idea that health care providers deliver care that is focused on patient needs and preferences, coupled with collaborative medical decision making [7]. Patient-centered behaviors that affect outcomes improve communications by responding to patient concerns and allowing for participatory decision making [8]. An open, communicative relationship between provider and patient in the management of chronic conditions helps patients understand their health conditions and helps reduce patient stress levels [9]. Patient-centered communication is found to have a positive relationship with patient health outcomes, satisfaction, and adherence to instructions in primary care [10]. Physicians who used more patient-centered behaviors inspire greater confidence, as well as greater willingness by patients to accept physician recommendations [9,11].

Technologies that assist communication become part of the environmental setting of provider-patient communications and will affect provider communication behaviors, techniques, and effectiveness. The importance of quality provider-patient communications during discussion about a patient management plans is seen in its influence on several outcomes, including patient emotional health, symptom resolution, body functions, physiologic measures (ie, blood pressure and blood sugar level), and pain control [6]. Positive health outcomes are associated with a wide range of both verbal and nonverbal communication behaviors [12].

A recent report on chronic disease detailed findings that patient education should be directed at improving quality of life, and included tailoring communications to the special needs and environment of the patient. Chronic disease settings, in particular, call for interactive, simple to follow, and practical communications that are appropriate to the intellectual and social skills of the patient and the caregiver [13].

The potential benefits of improved provider-patient communications are profound, patient knowledge and self-efficacy can improve along with increased adherence to the provider instructions and improved patient self-management [7]. When patients perceive providers to communicate clearly,

carefully, and thoroughly, patients are more likely to actively participate in their care and make better-informed decisions. Well-informed patients achieve a common understanding with their physicians, and adhere more fully to treatment instructions [5,8].

Communications at Time of Patient Exit From the Clinic

Technologies intended to assist medical communication are added to an environment in which communication skills and emotional awareness of health care providers are defined as key aspects of professional competence [8]. Unfortunately, increasing pressures placed on medical providers to process patients in a minimal amount of time work against efforts to encourage improved communication between the provider and the patient [4,7]. In time-pressured environments, some providers may regard sensitivity and clarification in communication as a luxury. Nevertheless, the quality and effectiveness of instructions at time of patient exit from the medical facility present critically important opportunities for ensuring continuity of recovery.

As a result, the routine setting of a patient leaving a health care facility at the conclusion of receiving health related services presents responsibilities for health providers to communicate effectively with their patients, that cannot be appropriately substituted with other visits [12]. Patient instructions, for example, in the form of a management plan, care plan, consultation, or ongoing medical maintenance instructions, typically include advice regarding the ongoing management of a clinical condition, medications, complications, and required follow-up [14]. For example, at patient exit from an emergency department visit, the provider must effectively complete three primary tasks: (1) communicate crucial information, (2) verify comprehension, and (3) tailor teaching to areas of confusion or misunderstanding to ensure patient safety in the home environment [15].

The term “discharge” is often applied to inpatient settings. Studies that address inpatient discharge, and the medical instructions at the time of inpatient discharge, provide many insights into the outpatient post treatment setting, especially when patients exit a clinic after treatment. In both cases, patients exit with detailed, often complex, medical maintenance instructions. Much research addressing inpatient discharge is relevant to the outpatient setting of this study.

Successful communication of discharge information is critical, as patient noncompliance with instructions can lead to safety risks for patients after discharge. The range of possible risks includes inappropriate home care, including incorrect medication use, and failure to return for concerning symptoms or follow-up as directed [15]. Such outcomes not only affect the health of the individual, but also the health care system, as patients with poor comprehension are at increased risk for adverse events and increased health care utilization [16].

A number of factors lead to patient noncompliance with discharge instructions. Patients complain that verbal instructions from physicians and/or medical staff are not provided in simple language [17], or a patients’ spoken language [18], and are therefore difficult to understand. In addition, the mean reading level of patients in some studies is reported to be equal to or below a seventh grade level [19,20], while printed discharge instructions are often written at the eleventh grade level [20], or at a college level [21]. This is a significant problem, since the discharge process happens quickly, with many instruction situations averaging a duration of approximately seventy-six seconds [22]. Patients may feel rushed and not think of or ask relevant questions that might help ensure their understanding of discharge instructions.

Medical Instructions in the Context of Health Literacy

Limited health literacy contributes major challenges to patient comprehension of medical care and self-care instructions. Health literacy includes the cognitive and functional skills needed by a person to make health-related decisions [23,24]. It is estimated that at least 26% of the population has limited health literacy [24,25]. The high prevalence of poor health literacy complicates the discharge process because many patients are not able to fully comprehend written resources [15].

Health literacy issues have added to the perceived importance among those in the medical communities of improving physician-patient communications, with a greater focus on related competencies in recent years. For example, the American Board of Medical Specialties now requires assessment of provider- patient communication for continued certification [7].

Training in communication skills for new physicians is an important part of satisfying recent national expectations for improved primary care, and learning to more effectively share information with patients is a central characteristic of such training [7]. However, newer learning techniques for the patient may also yield great benefits for improved primary care, and the foundation of the current study is that computer-based interaction that is flexible and adaptable to individual patient needs, with appropriate video and other visual enhancements, is one of the most promising methods for improving and reinforcing communication.

Medical Instructions in the Context of Special Patient Characteristics

Each patient has individual communications needs that may be influenced by several key characteristics: (1) age, including the youngest through the oldest; (2) hearing and speaking capacities; (3) cognitive capacities; and (4) language requirements. In addition, medications may affect ability to understand and retain medical discharge information.

Some studies have shown that patients with cognitive limitations often fail to remember clearly the instructions that health care providers have given them [1], which has obvious outcomes for reduced compliance and treatment effectiveness. Education of patients for recovery of medical intervention should be focused on simplicity, practicality, and messages that are “appropriate to the intellectual and social skills of the patient” [13]. Adherence outcomes are supported by recent experimental evidence that indicates that health care providers who are focused on patient centered communication are seen as more competent and trustworthy than those who are less focused on such communication [11]. Improved patient adherence is an

additional benefit thought to be associated with patient centric communications [26]. Patients may see the patient centered communication approach as a "therapeutic alliance" between provider and patient [26], and in these contexts patients may be more comfortable with asking questions and more successful at obtaining information, which can reduce patient anxiety [6].

Computer-Based Mediation for Older Patients

The ability to manage provider-patient relationships by applying good communication skills is an essential component of health care professional competence [7], and this may be particularly relevant for older patients. Providers may face the need to adapt their communication patterns for higher-risk patients, such as older patients with chronic, often painful conditions, who tend to focus more on biomedical rather than coping concerns in their communications [26].

Older patients encounter a medical environment in which desktop computers are increasingly used in diagnosis and in real time data on the appropriateness of specific prescription medications. As populations in many countries age, use of computers in the doctor-patient encounter can only be expected to increase [27]. Using computers in the patient-physician interaction, rather than office or bedside consultations, can help older patients understand the risks of their condition and how adhering to instructions can reduce their risks.

Older patients may be more accustomed to the verbal reassurances and emotional support that characterize face-to-face patient-provider communications, and in this regard, computer-mediated communications may be less effective than traditional methods [12]. For example, patients are particularly satisfied by empathy and psychosocial talk, but it may be that relatively few health care providers provide these benefits [12]. On the other hand, computers can assist in providing specific directions that are a source of satisfaction to older patients, and can lead to improved compliance in this patient group.

Visible Interfaces and Videos as Mediators Between Provider and Patient

When patients can see their current patient electronic health records (EHRs) on computer screens, their perceptions of patient provider communication are improved [28]. Computer mediated communications, including the use of the EHR at the patient side, may be a tool to enhance patient-centered communications [28], and recent studies have described ways to integrate the use of an EHR into patient communications [29]. Others have noted how multimedia may be integrated into the EHR and patient care in the future [30].

Use of video instruction for patients about disease treatment and recovery has been studied from at least as early as the mid-1990s [10]. However, while it is common for physicians to use computers for their own work during patient consultations, the delivery of computer-based video instruction directly to patients remains relatively uncommon [31], and the use of handheld devices for such instruction appears to be rare. When computers are introduced into doctor-patient communications, the relationship changes, altering the distribution of power and authority between doctor and patient [32].

Both positive and negative responses to computer mediation have been seen with both providers and patients. For example, general practitioner use of computers during patient consultations sometimes demonstrates a negative effect on patient-provider communications [27]. Other research has found no significant difference between face-to-face only versus face-to-face plus video instruction of post operative ostomy patients in regard to self-care skills or confidence in performing ostomy self-care [33].

Still other studies have suggested that patients view computer-based video use by physicians favorably increasingly often [31,34]. Thus, providers should be aware of the potential for both positive and negative results, and should be aware of usability and effectiveness of computer-based systems when communicating with patients.

Mobile Devices in Clinical and Patient Settings

As handheld devices for patient monitoring and instruction become increasingly widespread in the United States and Europe [35], smartphones are convenient and available portable devices for patient use, and many studies document experiments with smartphone applications for patients [35].

While smartphones and other mobile devices have been used in medicine to accomplish various tasks, very few high-quality studies have demonstrated appropriate application of this technology, including the few applications specifically designed for patient education [35]. In one study, nurse midwives in India were provided mobile phones to support patient education with the intent of assessing the impact of using mobile devices to provide video during patient encounters. Results showed that changing the process of patient education by using mobile video improved patient education provided by the nurses [36]. Only a small number of publicly available videos through the Internet (n=56) were found to be educationally useful for teaching medical practitioners about physical examination of the cardiovascular and respiratory systems [37].

Computer-Mediated Video Instruction Versus Traditional Media

Use of instructional videos in medical contexts, as compared with traditional printed document-based instruction, is gradually becoming more common. As educational videos for medical providers on various ailments and treatments have become common on public media channels such as YouTube, video guidance for patients has started to become more available [37]. However, use of free online channels for patient education is fraught with problems, in that a large proportion of such videos are of poor educational value, and the quality of such instruction cannot be assured [37].

It is not yet known how the introduction of instructional videos by health care providers will affect perceptions by patients of the patient-centeredness of providers or satisfaction with provider communications. [11]. There are three studies that have been published in the medical literature about the use of videos to improve patient understanding of provider instructions. Meade et al (1994) investigated whether printed or videotaped information is more effective in enhancing colon cancer knowledge [38], and results suggested that both printed and

videotaped materials enhanced colon cancer knowledge among patients with limited literacy skills. Leiner et al (2004) compared the effectiveness of a printed message about polio vaccinations with the same message converted into a production of animated cartoons using marketing and advertising techniques in a pediatric clinic. Results suggested that animated cartoons could improve knowledge among parents or caretakers about the polio vaccination. Choe et al (2009) evaluated the effectiveness of mobile discharge instruction videos in communicating discharge instructions to patients with lacerations or sprains in a prospective, controlled study on patients at an emergency center for two months. Patients received either printed discharge instructions or mobile discharge videos, with mobile discharge videos seen by patients as improving the communication of discharge instructions [34]. Finally, in another study, glyph pictographs were used to illustrate discharge instructions to patients. Discharge instruction recall improved significantly among participants in the test group over those that received nonillustrated instructions [39].

In summary, the body of evidence and field evaluations of the use of computer-based methods to mediate between health care providers and patients raises many important questions and new, unresolved challenges. In addition, the use of computer-based videos to educate patients and the application of handheld, mobile devices in these contexts remains in the early stages of development and testing.

Methods

The Study Participants

This study investigated health care worker use of information technology assisted video and 3D image instruction to assess the impact on patient perceptions of helpfulness of the intervention and patient perceptions about their provider. There were two hundred eighty-four patients that were enrolled in the study, of which half (142) were given the information technology (IT)-based instruction, and half (142) were instructed without the IT-based system. The study group consisted of patients receiving video and 3D image instruction via a wireless handheld device provided by a health care worker. The control group consisted of patients receiving ordinary, noncomputer-mediated instruction provided by their health care worker.

Study Setting

The research was conducted at an outpatient clinic in southern Colorado and all health care workers providing instruction were medical doctors serving as residents at the clinic. The clinic is part of a hospital system with Level II Trauma Care certification, 370 staff physicians, 350 critical care beds, and 2600 employees, serving a local population of nearly 400,000.

Provider use of Mobile Devices

There were ten first year residents working at the clinic that were provided with standardized training on appropriate physician-patient interactions in regards to providing patient instruction and education. All ten of the residents were provided with an Android tablet wireless mobile device capable of viewing 3D images and video. There were five of the residents that were randomly selected to provide video-based instruction that included 3D images to their patients (the study group) using the handheld wireless devices. The five selected residents were also provided access to a server containing video and 3D instruction material through the clinic's wireless network. The instructional systems, including, tablets preloaded with videos and 3D images, were provided by Incendant Corporation, a commercial provider of instructional videos and 3D images for use in hospitals, clinics, and home patient education. The videos cover topics of importance to patients, such as diagnostic testing, diagnoses, medical procedures, medications, and health topics. A complete listing of the available topics can be found in Appendix 3 (see Multimedia Appendix 3). The other five residents provided instructions to their patients using traditional, noncomputer mediated methods, such as written or verbal instructions. Residents from both groups chose the specific instruction content for each patient based on his/her determination of the instructional needs for each patient. Figures 1-3 show typical instructional images and videos on the mobile tablets.

Data Collection and Patient Groups

Any patient who visited and was treated at the clinic during the study period of 180 days was invited to participate in the study. If the patient was under 18 years old, the parent(s) or legal guardian was asked to participate in the study. The total study sample (n=284) was divided into two groups (n=142, each), with one group receiving the discharge videos, and one receiving standard discharge instruction. A set of questions preapproved by the medical center's Institutional Review Board was used to assess patient views and reactions to the discharge videos, as well as the health care providers, and the medical center. After receiving instruction and educational material from a resident, participants (patients) were asked to complete preselected questions based on the Consumer Assessment of Health Care Providers (CAHPS) Clinician and Group survey instrument for adults and children. The survey also collected data on patient self-perceived general health status, mental health status, age, gender, and education level. Medical assistants administered the paper survey to each patient in a private environment in the facility. Completed surveys were dropped into a locked, secure box at the medical assistant office desk.

Medical assistants administered an additional survey to the medical residents involved in the study (n=7) during a 60 day period. The medical residents completed a paper evaluation survey at their convenience. Evaluation surveys were dropped into the locked, secure box at the medical office desk.

The patient survey and medical resident survey are included as Appendices in this article (see Multimedia Appendices 1 and 2), respectively.

Hypotheses

Given the support found in the background literature that use of computers, with high visibility interfaces and appropriately designed software, to communicate detailed information in both patient-provider settings and the patient use alone setting, we propose H1.

H1, patients will find the provider's use of tablet device to communicate information to be helpful.

Prior research has not established whether use of computer devices, with appropriate interfaces and software, facilitates direct verbal communication between patient and provider. However, the background literature supporting H1 suggests the possibility of reasonable extension of expected improved communication to direct conversation between the patient and provider. As such, we propose H2.

H2, patients will find the provider's use of a tablet device to communicate information to them will make it easier for the patients to talk with providers.

In view of the background literature suggesting an age-related effect on individual ability and preference to use computers, we propose H3.

H3, older patients will find the provider's use of tablet device to communicate to be less helpful than will younger patients.

Results

Primary Results From the Post Medical Appointment Survey

Primary results from the post medical appointment survey of patients are shown in Table 1, below. The total number of participants was 284, split equally between the treatment group in which the provider used the tablet/software bundle in face-to-face communication with the patient group, and the control group, in which the tablet/software bundle was not used. Comparisons between groups are seen in items 2, 3, 4, 5, 6, 7, 8, 9, 15, and 16, as shown in the "Explanation" column in Table 1, below. Comparisons within groups were applied to items 11 and 12. H1 and H2 were evaluated using tests of comparative proportions, with significance provided by Fisher's exact test. Hypothesis 3 defined older age as 65 and above (37.3% of total sample, 106/284) and younger age as 18 through age 64 (62.3% of total sample, 177/284), and was evaluated using a simple *t* test for comparison of groups.

Table 1. Primary survey results, communication effectiveness, both groups.

Item	Assessment question	Response[a]	N=284, n	Percent	Explanation
2	Seen within 15 minutes?	Yes	257	90.8	Question applied to both treatment and nontreatment groups (N=284)
		No	26	9.2	
3	Provider easy to understand?	Yes	279	98.2	Question to both groups
		No	5	1.8	
4	Provider listened carefully?	Yes	282	99.6	Question to both groups
		No	1	0.4	
5	Discuss problems with provider?	Yes	275	97.5	Question to both groups
		No	7	2.5	
6	Provider gave clear instructions?	Yes, definitely	264	97.4	Question to both groups
		Yes, somewhat	6	2.2	
		No	1	0.4	
7	Provider knew important information about patient?	Yes, definitely	247	88.2	Question to both groups
		Yes, somewhat	32	11.4	
		No	1	0.4	
8	Provider respected patient comments?	Yes, definitely or somewhat	279	99.6	Question to both groups
		No	1	0.4	
9	Provider spent enough time with patient?	Yes, definitely or somewhat	278	98.2	Question to both groups
		No	5	1.8	
10	Provider used computer to show information?	Yes	136	48.9	Distinguishes treatment and control groups
		No	142	51.1	
11	Was provider's use of computer helpful to you?	Yes, definitely	123	85.4	Treatment group only
		Yes, somewhat	16	11.1	
		No	5	3.5	
12	Provider's use of computer made it easier or harder for patient to talk with provider?	Harder	5	3.5	Treatment group only
		Not harder or easier	50	35.2	
		Easier	87	61.3	

[a] Total responses to items 2, 4, 5, 6, 7, 8, 9, and 10 do not equal 284 because of nonresponse by subjects.

Table 2. Survey results, medical conditions.

Item	Assessment question	Response	N=284, n, (%)	Explanation
15	Overall health	Excellent	22 (7.9)	Question to both groups
		Very good	102 (36.7)	
		Good	98 (35.2)	
		Fair	48 (17.3)	
		Poor	8 (2.9)	
16	Overall mental / emotional health	Excellent	64 (22.8)	Question to both groups
		Very good	110 (39.2)	
		Good	72 (25.7)	
		Fair	31 (11.0)	
		Poor	3 (1.1)	

Table 3. Survey results, patient demographic data.

Item	Assessment question	Response parameter	Response	Explanation
17	Age (eight categories, minimum 18)	Mean category	55-64	Question to both groups
		Range	18 to > 85	
18	Gender	Male (n=106)	38.55	Question to both groups
		Female (n=167	60.73	
19	Education (six categories)	Mean category	Some college	Question to both groups

Table 4. Evaluation of hypotheses.

Hypothesis	Result	Interpretation
H1	z=15.24 *P*<.001 (Fisher's exact test)	Strong support for H1, provider's use of tablet/ software bundle to communicate information was perceived as helpful.
H2	z=13.21, *P*<.001 (Fisher's exact test)	Strong support for H2, provider's use of tablet/ software bundle made it easier to talk with provider.
H3	*t*=0.33, *P*=.74	H3 not supported, no age-related effect on perceived helpfulness of using tablet device to communicate was identified between low-age and high-age groups (divided at median age group).

Results of the Study

These results provide strong and highly significant support for H1 and H2. We conclude that in the context of this study, the provider's use of the tablet/software bundle to communicate information was helpful to patients. We also conclude that patients found the provider's use of the tablet/software bundle made it easier for the provider and patient to communicate about medical information related to the patient's treatment.

H3 was not supported. We conclude that acceptance and perceived helpfulness of the providers' use of the tablet/software bundle was not affected by the age of the patient.

No differences between the groups were expected and none were found on items 1 through 9, as they strictly pertained to the provider, independent of the intervention. These questions were requested by the clinic in which the study was conducted, and they provide useful context to understand the study setting. These results were independent of patients' self-perceived physical or mental health, education, or gender, none of which were related to key outcomes.

Qualitative Findings, Analysis of Physician Comments

Resident physicians who used the system in direct interaction with patients were asked to complete an online survey where they offered comments on the application of the tablet/instructional video combination, including typical uses, benefits, challenges, effect on patient satisfaction, and additional features that could improve the system, six months after patient data were collected. All five residents in the experimental group completed the survey.

eHealth applications have become more commonplace and are often developed based upon organizational or business goals. As mentioned earlier, there are a number of information systems that are used to improve communication with patients. The use of mobile discharge instruction videos is one strategy to improve communication with patients.

Residents stated that they used the tablets with instructional videos and 3D images in the outpatient adult clinic, and in the hospital during discharge or admission. To further elaborate, the following responses were received from the residents,

> *I had the patient watch the video while I was staffing with my preceptor. It helped that gap of time waiting. I also used it a few times in the hospital to help patients and families understand (diagnosis) better.* [Resident]
>
> *I can show (patient) images of anatomy of specific organ system when discussing and explaining to them their disease process.* [Resident]

Some of the residents stated that although they did use the tablet in the adult clinic, they believe that the tablet with instructional videos and 3D images are more useful in the emergency room and in-patient care facilities. Specifically, residents stated,

> *In general, I believe the videos are more beneficial in the ER, or even inpatient setting. I did not find them to be as useful in the outpatient setting where people are dealing with chronic illnesses.* [Resident]
>
> *More for in patient education. Not as appropriate for out patient. Used for diagrams of anatomy to explain illnesses.* [Resident]
>
> *...I do NOT believe the videos are appropriate for the clinic. I think they could be much better used on the in-patient side...* [Resident]
>
> *Used more frequently in-patient.* [Resident]

Video-based programs are among the most successful strategies to improve communication with patients [38,40], where it has shown a consistent increase in short-term knowledge, and have outperformed plain written materials, lectures, and individual counseling [41]. Residents reported numerous benefits to using the tablet with instructional videos and 3D images, including improved patient understanding, communication of diagnosis and treatment, and patient compliance. Specifically, the residents reported,

> *Some better understanding for my patients.* [Resident]
>
> *Very precise and clear.* [Resident]
>
> *...better patient visualization...* [Resident]
>
> *[I am] able to explain disease processes better by showing pt (patients) images of what I'm trying to explain.* [Resident]
>
> *I think the videos would be PERFECT for the setting of discharge from the hospital.* [Resident]
>
> *I think by showing pts (patients) what is going wrong in their body, rather than just telling them what is wrong, will make them more likely be compliance with medical care to improve their condition.* [Resident]

Residents further commented on how the tablet with instructional videos and 3D images impacted their interactions with patients. They stated,

> *More understanding about what I was trying to explain to them.* [Resident]
>
> *I didn't feel it impacted my interaction but I think they (patient) liked the videos.* [Resident]
>
> *It is a good tool to help augment (patient's) understanding of their medical condition.* [Resident]

There are 100 instructional videos that the residents were able to use when treating patients, and although they are going to choose videos that are appropriate for the diagnosis they are treating, they reported that the table with instructional videos and 3D images are most beneficial for specific conditions. Specifically, the residents reported that they could pull up videos and/or images for,

> *Cardiac problems.* [Resident]
>
> *Diabetes.* [Resident]
>
> *CHF, smoking cessation, PE/DVT, anticoagulation (management), diabetes.* [Resident]
>
> *In patient, especially diverticulosis, gall bladder issues/surgery.* [Resident]
>
> *Back pain, I can pull up images of spinal column to explain different disease processes such as disc herniation or spinal stenosis.* [Resident]

The residents believe that patient satisfaction was improved with the use of the tablet with instructional videos and 3D images. When videos specific to the patient's situation were available, "patients seemed to like the videos".

Although the residents reported numerous benefits to using the tablet with instructional videos and 3D images, they also reported a few challenges, including allocating time needed to launch the system and locate appropriate videos. Specifically, the residents stated,

> *...because the clinic is such a fast paced environment, I do NOT believe the videos are appropriate for the clinic. I think they could be much better used on the in-patient side. It's to time consuming in clinic.* [Resident]
>
> *...mainly taking time to turn it on and searching for and bringing up the images or videos that I'd like to show.* [Resident]

While most of the residents reported that no additional features to the tablet with health care instructional videos and 3D images are needed, two of the residents suggested that, "More pictures (that are) easier to find", and "More clinic-oriented videos (to help patients understand clinic-administered treatments) would held to increase patient understanding and satisfaction".

In summary, physician responses reported comments on uses, benefits, challenges, satisfaction, and additional features, as follows,

Typical uses of the tablet/instructional video combination included: (1) use In the hospital during admission; (2) use in the hospital during discharge; (3) use in outpatient clinic; (4) used during hospital stay to help patients and families understand diagnoses, diagrams and illustrations of anatomy helped the physician explain illnesses; and (5) tablet/instructional video combination was found to be helpful to patients during time gap presented by waiting for the next test, exam, or procedure.

Benefits to use of tablet/instructional video combination included: (1) improved understanding by patients; (2) precision, clarity, and improved patient visualization; (3) ability to explain disease processes using images; (4) possible improved patient compliance, showing patients illustrations may make them more compliant with medical instructions; and (5) assistance in explaining illnesses and treatments in specific disease processes, including diabetes, heart failure, pulmonary embolism, deep vein thrombosis, anticoagulation management, diverticulosis, gall bladder disease and surgery, back pain, and smoking cessation.

Challenges to use of tablet/instructional video combination included: (1) time limitations in terms of allocating time from treatment tasks; and (2) time required to simply launch the system and locate appropriate topics.

Patient satisfaction was improved with use of the tablet/instructional video combination in at least two ways: (1) the combination system was seen as helpful by individual patients; and (2) when videos specific to the patient's situation were available, patients "seemed to like the videos".

Additional features to the tablet (with health care instructional videos and 3D images) that would help patient understanding included: (1) additional pictures and diagrams for patients; (2) more clinic-oriented videos (to help patients understand clinic-administered treatments); (3) additional medical topics should be added, explained by additional instructional videos; and (4) videos would be most useful in an emergency room environment or a hospital inpatient setting, as opposed to outpatient encounters that address chronic conditions.

Discussion

The Promise of Computer-Assisted Guidance for Physicians and Patients

The glowing promise of computer-assisted guidance, instruction, and explanation of medical conditions and treatment methods for patients has been recognized for decades. Since the introduction of handheld computer devices with easily accessible visual and audio interfaces, the ability of information and communication technologies to help physicians and other health care providers to communicate detailed technical and instructional information to patients has become ever more clear. Yet, the reality of limited testing of such technology tools in clinical settings has not yet supplied a satisfactory body of evidence that would justify widespread agreement on the technology's potential as a successful educational and motivational approach for patients. Many important, open questions remain.

First, what is the pattern of initial patient reaction to use of such an instructional system? Technologies that employ computer interfaces and video recorded information have historically been a source of frustration and even annoyance to those who are not comfortable with use of technologies. Does exposure or familiarity help those who have had limited experience with computer-assisted instructional systems in the past? Initial reactions are not simply a function of age, as this study has shown. Responsiveness to technology-based guidance can also be a result of education, lifestyle, and even intelligence and personality factors.

Second, is the system easy to understand? How do we best understand patient comprehension of instructions in the context of use of computer-assisted guidance systems?

Third, how does such an independent, computer-assisted instructional system perform compared to direct, face-to-face interaction with a health care advisor? Is it comparable to the instructional method of sitting with a nurse who explains medications and bandage changing schedules? Is it superior to direct interaction in any way? Is it more efficient for health care providers to communicate essential information? Does its use improve patient safety? Can it substitute for or augment bedside interaction with a health care professional?

Communication skills and emotional awareness of health care providers are viewed as key aspects of professional competence [8]. Unfortunately, increasing pressures placed on medical providers to process patients in a minimal amount of time works against efforts to encourage improved communication between the provider and the patient [7]. Some providers may regard sensitivity and clarification in such communication as a luxury.

This study added to the body of evidence that computer-assisted instructional systems for patients can provide solid support for the overall objective of making sure patients understand instructions from their health care providers. As in a few recent studies, this research evaluated perceptions about the use of mobile devices in patient-provider communications. Several recent studies have focused on multimedia content provided through a computing device for patient educational purposes. However, few studies have combined both mobile devices and multimedia patient education in the same study. Further, unlike other studies on this topic, the research setting was a live field test, providing a real world, medical outpatient treatment environment to study patient perceptions. In addition, unlike other studies, this research included patient perceptions (quantitative) combined with physician perceptions (qualitative). The key findings of the study are: (1) Patients found the computer-based instructional system to be helpful. Although we did not test for openness and liking of the technology, it is clear that the measured helpfulness is clearly associated with an overall openness to the technology and the lack of intimidation produced in patients by the computer-based system. And (2) patients found that use of the computer-based instructional system made it easier to communicate with their health care providers. Clinical discharge environments can be stressful for all concerned, and time pressures are ever present for health care professionals. Any tool that can help them communicate with patients is useful. The fact that patients found that it made communication easier adds to the impression that they liked using the system, chronological age of patients, which ranged from 18 to over 85, did not affect any aspect of their perception of the computer-based instructional system. Thus, in this context, an age-based digital divide was not found. This is very encouraging, given that a large segment of the older population of the United States still has little experience with computers.

This research opens the door for continued exploration of the question of how computer-based instructional systems can be best designed and deployed to support the efforts of health care professionals on whom increasing time demands are made.

Limitations

This study has several limitations. First, although the study sample size was reasonably large (N=284), the sample itself is a convenience sample of patients who were discharged over a limited period of time. The patient sample demographics and other characteristics may not reflect the attitude of patients in other parts of the country, or those outside the United States. A second limitation is that the training provided for physicians in use of the tablet-based instructional system was adequate, but was limited by the well-known time limitations and work demands placed on medical residents. More extensive training may lead to even better outcomes. Finally, while the comments from patients showed a positive and favorable response in most areas, our use of the validated CAHPS survey instrument gives us confidence in the results.

Future Research Paths

This study opens the door to many possible pathways for interesting research. For example, the usability and readability of a small tablet screen may be enhanced by alternative form factors, including those of the larger screen devices that are currently coming available. In addition, greater personalization of the system instructions, such as adding the patient's name, the health care providers' names, and some details of the patient's individualized medical treatment can be included. Another important area is message reinforcement; patients were not able to take the tablet device home with them, and the ability to do so may reinforce the understanding and retention of the treatment instructions and enhance the effectiveness of the system. Finally, special versions of the software can be developed for defined target groups, including underserved populations, non-English speakers, and groups with specific cultural requirements.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Patient survey instrument.

[PDF File (Adobe PDF File), 44KB - mhealth_v3i1e2_app1.pdf]

Multimedia Appendix 2

Medical resident survey instrument.

[PDF File (Adobe PDF File), 22KB - mhealth_v3i1e2_app2.pdf]

Multimedia Appendix 3

List of instructional video topics available to physicians.

[PDF File (Adobe PDF File), 17KB - mhealth_v3i1e2_app3.pdf]

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Abbreviations

CAHPS: Consumer Assessment of Health Care Providers
EHR: electronic health records
IT: information technology
3D: three-dimensional

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Short Paper

Non-Work-Related Use of Personal Mobile Phones by Hospital Registered Nurses

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Abstract

Background: Personal mobile phones and other personal communication devices (smartphones and tablet computers) provide users with an ever-increasing number and diversity of non-work-related activities while at work. In hospitals, where the vigilance of health care workers is essential for patient care, the potential distraction of these devices could be hazardous to patients.

Objective: The objective of this study was to determine the frequency of non-work-related use of personal mobile phones and other personal communication devices among hospital registered nurses.

Methods: In March 2014, a previously validated 30-question survey was emailed to the 10,978 members of the Academy of Medical Surgical Nurses. There were 825 respondents who met the inclusion criteria.

Results: The use of a personal mobile phone or other personal communication device while working (excluding meal times and breaks) was reported by 78.1% (644/825) of respondents. Nurses reported regularly (sometimes, often, or always) sending personal emails and text messages (38.6%, 318/825), reading news (25.7%, 212/825), checking/posting on social networking sites (20.8%, 172/825), shopping (9.6%, 79/825), and playing games (6.5%, 54/825) while working.

Conclusions: This study found that hospital nurses frequently use their personal mobile phones or other personal communication devices for non-work-related activities at work. The primary activity reported was to send personal emails and text messages to family and friends.

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KEYWORDS

distraction; smartphone; cellular phone; Internet; nurses; hospital; non-work related smartphone use

Introduction

Personal mobile phones and other communication devices provide users with access to a wealth of electronic media such as the Internet, email, and texting, which help them fulfill tasks both at home and work. The work-related benefits of these devices to health care providers are numerous, including access to medical references, clinical tools, and patient information [1-6]. In addition to work-related sites, however, there is an ever-increasing number and diversity of recreational sites including games, gambling, and social networking. Previous research has reported that personal Internet use during working hours is increasingly common and that a majority of workers, regardless of age or occupational status, report using their personal mobile phones or other communication devices to engage in non-work-related activities in the workplace [7-13]. Personal mobile phones and other communication devices have the potential to distract health care providers from the vigilance required for patient care. Health care organizations are starting to take notice of this problem. The ECRI Institute (previously

the Emergency Care Research Institute), a non-profit organization that uses applied scientific research to improve patient care, publishes an annual top 10 technology hazards list. "Caregiver distractions from smartphones and other mobile devices" was ninth on the list of health technology hazards for 2013 [14]. However, the extent of this issue in hospitals is unknown.

The objective of this study was therefore to determine the frequency of non-work-related use of personal mobile phones and other communication devices among hospital registered nurses.

Methods

In March 2014, a recruitment email containing a link to a previously validated 30-question survey was sent to the 10,978 members of the Academy of Medical Surgical Nurses (AMSN) [15]. A total of 940 (8.56%) members completed the Web-based questionnaire and 825 (7.25%) met the inclusion criteria for the study of current full-time employment as a registered nurse in a hospital with an average of more than 5 hours a week of patient contact. The demographic distribution of the study sample of 825 was 48 (5.8%) men, 755 (93.9%) female; age ranges were 20-30 years (9.3%, 77/825), 31-40 years (18.1%, 141/825), 41-50 years (23.9%, 197/825), 51-60 years (39.2%, 323/), and >61 years (9.3%, 77/825).

The survey instrument was piloted in 2013 [15]. It consisted of four parts, with questions about (1) demographics, (2) the use of personal communication devices, (3) opinions about the effects of personal communication devices on the work of registered nurses, and (4) hospital policies concerning personal communication devices. The questions, which were developed based on a literature review and interviews with hospital nurses, asked respondents to rank the types of activities they engage in on a 5-point Likert scale to determine how frequently they participated in each activity. Psychometric testing of the questionnaire included examining internal consistency and test-retest reliability in a sample of 50 registered nurses. A Spearman rho correlation was used to determine the test-retest reliability. There was a strong test-retest reliability between the same test administered 1 week apart, with an average agreement for the Likert scale responses of 74% (range 43-100%). Accounting for responses within 1 SD range on the Likert scale increased the agreement to 96% (range 87-100%). The Cronbach coefficient alpha values examining the internal consistency in three of the domains were high: utilization (.84), impact (.96), and opinion (.85), with lower agreement in the performance domain (.45). Based on the results of the pilot survey, questions in the performance domain were rewritten to clarify the underlying concept of work performance.

Results

Overview

We examined the sample subsets to determine the representativeness of the sample relative to the United States nursing workforce data from The National Council of State Boards of Nursing and the Forum of State Nursing Workforce Centers 2013 National Workforce Survey for RNs [16]. The probability that the percentage of various subgroups in the study sample was representative of the larger population of the United States nursing workforce was calculated using a two-population *Z* test. The probabilities indicated that gender and location of primary place of employment (urban/rural) were represented appropriately in the study sample. Respondents in the age groups under age 40 years were underrepresented and age groups over age 55 years were overrepresented. The use of the AMSN membership list may have biased the age distribution of the survey sample toward older age groups. Whites, American Indians/Alaskan natives, and Native Hawaiian or Pacific Islanders were underrepresented, while Hispanic and multiple/other ethnicities were overrepresented. Consideration was given to weighting the study sample data for age and race/ethnicity, however several points argue against it. These include the small sample sizes within several age and race/ethnicity groups and the inherent subjectivity of racial/ethnic groups. While the response rate was low relative to other Web-based surveys, this may have been the result of the perceived sensitive nature of the subject, with respondents preferring not to admit that they had used their personal mobile phones and other communication devices at work for non-work related activities. In addition, Holbrook et al [17] assessed whether lower response rates were associated with decreases in the demographic representativeness of a sample. They examined the results of 81 national surveys with response rates varying from 5% to 54% and found that surveys with much lower response rates were only minimally less accurate. As a result of the issues described above, including the limitations associated with the study design and the available sample size, it was decided not to weight the current survey data, but to report the unweighted survey results with the recognition that the results, while valuable, may not be generalizable to the entire US registered nursing workforce.

Primary Personal Communication Device

The majority of respondents (73.0%, 602/825) reported that their primary personal communication device was an enhanced mobile phone (mobile phone, texting, email, Internet access, and apps), 12.6% (104/825) a mobile phone with texting, 8.0% (66/825) a basic mobile phone, 2.8% (23/825) a tablet computer, and 1.3% (11/825) did not own a personal communication device.

Frequency of Personal Mobile Phone or Other Communication Device Use

More than three-quarters (78.1%, 645/825) of respondents acknowledged that they always, often, or sometimes used their personal mobile phone or other communication device at work, excluding breaks or meal times (Table 1).

Table 1. Frequency of personal mobile phone or other communication device use while at work (n=825).

	Never	Rarely	Sometimes	Often	Always	No response
	n (%)					
How often do you use your personal mobile phone or other communication device while at work (excluding breaks and meal times)?	53 (6.4)	105 (12.7)	139 (16.8)	312 (37.8)	194 (23.5)	22 (2.7)

Use of Personal Mobile Phone or Other Communication Device While at Work for Non-Work-Related Activities

Study participants were asked which non-work-related activities they used their personal mobile phone or other communication device for while working. These activities had previously been identified by researchers as potential uses of personal mobile phones at work [8,18-20].

Respondents reported using their personal mobile phone or other communication device always, often, or sometimes for calling or checking/sending personal emails or text messages (38.5%, 318/825), reading online news (25.7%, 212/825), checking/posting on social networking sites (20.8%, 172/), shopping (9.6%, 79/825), and playing games (6.5%, 54/825) (Table 2).

Non-work-related use of personal mobile phones or other communication devices at work was significantly correlated with age. Respondents under 30 years of age were more likely to use their personal mobile phone or other communication device at work for non-work-related activities than those over the age of 30 years. There was no correlation between personal mobile phone use and gender.

Table 2. Number of study respondents who answered the question, "On an average workday, describe your use of your personal mobile phone or other communication device (excluding breaks and meal times)?" (n=825).

	Never	Rarely	Sometimes	Often	Always	No response
	n (%)					
Read news	489 (59.3)	108 (13.1)	125 (15.2)	59 (7.2)	28 (3.4)	16 (1.9)
Call or check/send emails or text messages to family or friends	278 (33.7)	218 (26.4)	191 (23.2)	70 (8.5)	57 (6.9)	11 (1.3)
Shop	648 (78.5)	82 (9.9)	39 (4.7)	23 (2.8)	17 (2.1)	16 (1.9)
Check/post on social networking sites	565 (68.5)	129 (15.6)	129 (9.1)	21 (2.5)	22 (2.7)	13 (1.6)
Play games	692 (83.9)	65 (7.9)	33 (4)	11 (1.3)	10 (1.2)	14 (1.7)

Discussion

Principal Findings

The use of personal mobile phones and other communication devices is widespread in hospitals, with 78.1% (645/825) of registered nurses reporting using their personal mobile phone or other communication device while working. Only 6.4% (53/825) of respondents reported never using their personal mobile phone at work (Table 1). These results agree with earlier research that found high rates of personal communication device use by health care providers [17,20-22]. Calling or checking/sending emails and text messages to family and friends was the most commonly reported non-work-related activity. These results support Turkle's theory of a "tethered self", where humans use their personal communication devices to connect themselves constantly to other people and places, needing the continuing reassurance of developing and maintaining their group membership [23]. Other researchers have speculated about the emotional reassurance that comes from interacting with others though a mobile phone and how it helps alleviate the "fear of missing out", a form of social anxiety that results from "a compulsive concern that one might miss out on an opportunity for social interaction, a novel experience, a profitable investment or other satisfying event" [24]. An alternative explanation for this use of mobile phones was reported by Lin et al [25], who studied the association between fatigue and Internet addiction in Taiwanese hospital nurses. They classified 6% to 10% of their study participants as Internet addicts, whose use of the Internet was associated with fatigue and a possible degradation of performance. They defined "nurse fatigue" as a subjective feeling of tiredness that persists despite periods of rest. It can be the result of several contributing factors, including high job demands, shift rotation work schedules, extended work shifts, and poor sleep quality. They speculated that accessing the Internet using mobile devices enabled registered nurses to recover from work-related fatigue. Coker [8] also speculated that use of mobile phones for workplace Internet leisure browsing allows workers to take short, unobtrusive breaks, enabling them to recover their concentration and restore their ability to focus. He found that use of mobile phones at work to access the Internet had a positive effect on productivity.

Conclusions

Registered nurses in hospitals frequently use their personal mobile phones or other communication devices for non-work-related activities while working. Personal mobile

phones allow nurses to meet their emotional needs by maintaining connections with family and friends while working. In hospitals, where vigilance is essential for patient care, the potential distraction of personal mobile phones could be hazardous to patients. However, non-work-related activities may have a positive effect on performance, allowing employees to restore their concentration, achieve a balance between work and personal life, reduce stress, and improve performance. Further study is needed answer the question of how personal mobile phones can be safely integrated into the work of hospital nurses.

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Conflicts of Interest

None declared.

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Abbreviations

AMSN: Academy of Medical Surgical Nurses

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Original Paper

An Effective Support System of Emergency Medical Services With Tablet Computers

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Abstract

Background: There were over 5,000,000 ambulance dispatches during 2010 in Japan, and the time for transportation has been increasing, it took over 37 minutes from dispatch to the hospitals. A way to reduce transportation time by ambulance is to shorten the time of searching for an appropriate facility/hospital during the prehospital phase. Although the information system of medical institutions and emergency medical service (EMS) was established in 2003 in Saga Prefecture, Japan, it has not been utilized efficiently. The Saga Prefectural Government renewed the previous system in an effort to make it the real-time support system that can efficiently manage emergency demand and acceptance for the first time in Japan in April 2011.

Objective: The objective of this study was to evaluate if the new system promotes efficient emergency transportation for critically ill patients and provides valuable epidemiological data.

Methods: The new system has provided both emergency personnel in the ambulance, or at the scene, and the medical staff in each hospital to be able to share up-to-date information about available hospitals by means of cloud computing. All 55 ambulances in Saga are equipped with tablet computers through third generation/long term evolution networks. When the emergency personnel arrive on the scene and discern the type of patient's illness, they can search for an appropriate facility/hospital with their tablet computer based on the patient's symptoms and available medical specialists. Data were collected prospectively over a three-year period from April 1, 2011 to March 31, 2013.

Results: The transportation time by ambulance in Saga was shortened for the first time since the statistics were first kept in 1999; the mean time was 34.3 minutes in 2010 (based on administrative statistics) and 33.9 minutes (95% CI 33.6-34.1) in 2011. The ratio of transportation to the tertiary care facilities in Saga has decreased by 3.12% from the year before, 32.7% in 2010 (regional average) and 29.58% (9085/30,709) in 2011. The system entry completion rate by the emergency personnel was 100.00% (93,110/93,110) and by the medical staff was 46.11% (14,159/30,709) to 47.57% (14,639/30,772) over a three-year period. Finally, the new system reduced the operational costs by 40,000,000 yen (about $400,000 US dollars) a year.

Conclusions: The transportation time by ambulance was shorter following the implementation of the tablet computer in the current support system of EMS in Saga Prefecture, Japan. The cloud computing reduced the cost of the EMS system.

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KEYWORDS

emergency medical services; EMS; EMS communication systems; prehospital; ambulance; tablet computers; cloud computing

Introduction

The Ageing Society of Japan

Japan is a world's fastest aging society [1]. According to the Cabinet Office, Government of Japan, people age 65 and over are estimated to reach 3,657,000 (the percentage of the population age 65 and over, 30.3%) in 2025 [2]. Changing demographics caused by the aging population have been increasing concern about longevity crisis, especially the national burden of long-term care insurance costs in Japan. All regions in Japan have been urged to deal effectively with the aging of the population. Now the efforts of Japan are focus of other societies.

In the Japanese emergency medical services (EMS), like the aging society, the increase in ambulance dispatches and the transportation time by ambulance has become a significant social problem. There were over 5.4 million ambulance dispatches during 2010 in Japan, and the time for transportation is increasing with a national average of 37.4 minutes [3]. As with all regions in Japan, Saga Prefecture, the northwest part of the island of Kyushu (population 850,000), has the problems of increased time of transportation, an increased number of emergency transports, and a decreased number of emergency facilities. In Saga, the number of emergency transports has increased from about 22,000 cases in 2000 to about 30,000 cases in 2010 and the transportation time has also gradually increased with an average of 35.5 minutes [3].

In Japan, emergency transport service is controlled and managed by each local government, and Japanese emergency personnel; for example, paramedics belong to the fire department as public civil servants [4]. Although Japanese emergency personnel are nationally licensed, the law restricted their medical practices. Their main role at the scene is to make triage and destination decisions. When the emergency personnel select a destination to transport the patients from the scene, their experience and knowledge in the past and information of each local fire department are matched to an appropriate hospital in their community. Unfortunately, it frequently occurs that it takes time to select a destination to transport due to reasons such as all beds occupied and doctors out of their specialty.

Levels of Emergency Medical Services

There are three levels of EMS classified by function and scale in Japan [4,5]. Primary care facilities represent small outpatient clinics without beds that deal with patients with relatively mild symptoms and do not necessarily require emergency medical treatment or hospitalization. Secondary care facilities are capable of providing more advanced patient care, including operations and other interventions requiring hospitalization for patients with serious illnesses. Tertiary care facilities are medical emergency centers for critically ill patients who need intensive care or emergency surgery. In Saga, the number of tertiary care facilities has decreased from about 64 in 2000 to 48 in 2010, while the number of emergency cases is increasing [3,6]. Therefore, the required amount of transportation to tertiary care facilities has increased from 27.5% in 2007 to 32.7% in 2010 [3,6]. A solution to reduction of the transportation time by ambulance is to shorten the time of searching for an appropriate facility/hospital during prehospital phase.

Telemedicine

Evidence of beneficial telemedicine was demonstrated in other medical fields [7-9], and studies have examined information sharing via the Internet or telecommunication devices throughout the world [10-14]. For instance, in the management of stroke cases, a system using a mobile device in which shared data and the diagnostic image of the patient has developed, and the system was shown to be efficient for early patient treatment [10]. Bouri and Ravi [11] reviewed previous researches regarding mobile health, and suggested the potential benefits and challenges of telecommunication with mobile devices in emergency response in the United States. Most of EMS systems in previous studies are to transmit electrocardiogram [14-19] and images [10,13,18-20] from the scene or an ambulance to the hospital. In the EMS, to send "the right thing in the right way to the right patient at the right time"[21] is the most crucial to critically ill patients. Although the telemedicine of transmitting electrocardiogram and images is useful, it is more significant for EMS to share information related to emergency medical demand and acceptance between the emergency medical personnel in the prehospital and the medical staff in the hospital.

To realize real-time information sharing during emergencies, we focused on cloud computing that has been receiving considerable attention by organizations. "Cloud computing is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (eg, networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction" [22]. Cloud computing provides more flexible, cost-effective, and efficiency in information and communication technology (ICT) services to end users [23]. Previous studies expressed that cloud computing is a promising model with a big potential [24,25]. In recent years, researches showed many benefits of cloud computing for health care fields, especially the biomedical informatics community, which has already demonstrated good use of cloud computing [23,26-28]. As with these studies, several other researches suggested that they could improve emergency health care service [11-14,23]. Thus, it should serve the purpose to share information related to emergency medical demand and acceptance between prehospital and in-hospital.

The conventional hospital searching system for EMS in Saga Prefecture was seldom utilized, mainly because data was unavailable from the ambulance without Internet access. In the old system, some data could be shared only among the hospitals, but not from an ambulance, creating obstacles to obtain the latest information due to limited server capacity and slow Internet connection. In an attempt to improve the drawbacks of the previous system, we established a new system that is able to obtain the latest information regarding emergency demand and acceptance in one view using a tablet computer [18]. The focus of the new system was to share information related to emergency demand and acceptance.

The purpose of this study is to evaluate if the new system promotes efficient emergency transportation for critically ill

patients. The following was examined to: compare the data for mean transportation times in Saga Prefecture before and after introducing a new system, compare them to nationwide trends observed over the same time period, examine the utilization of a new system by a user of emergency personnel and the medical staff, and, finally, investigate the cost effect of introduction of a new system.

Methods

System Function and Operation

The new system to check emergency demand and acceptance adopted cloud computing so that both emergency personnel in the ambulance and the medical staff in each hospital are able to share up-to-date information about available hospitals. While the emergency personnel usually operate the application outside of the hospital, the medical staff mainly operates it with the desktop computer in the hospital. The Web application is developed and is compatible with both desktop/laptop computers and tablet devices. All of the operations on any device are run through a Web browser. All 55 ambulances in Saga Prefecture are equipped with tablet computers continuously connected with third generation (3G)/long term evolution (LTE) networks (Figure 1 shows this).

When the emergency personnel arrive on the scene and discern the type of patient's illness, he or she can open the application on their tablet computer to search for an appropriate facility/hospital based on specific conditions (eg, severity, trauma, burn) and specialties (Figure 2 shows this). The system then shows the list of available facilities (Figure 3 shows this). The search result includes the following information: the updated time and date, the number of patients each hospital accepted over the last 24 hours and the last time of acceptance, the telephone number of the facilities, the availability of each hospital with available specialties (subdivided into always available, available on weekdays only, available depending on the day of the week or roster), and detailed information of the last five transportation records within 24 hours (time of day, the address of the scene, condition of the patient, accepted or denied by facilities, the mechanism or cause of the disease and injury at the scene). Facilities that do not update the information about their availability are moved to the bottom of the list.

In addition, the new system visualizes the real-time monitoring of the number of acceptances in each hospital within 24 hours on a map so medical personnel can easily recognize the current status of each hospital located within and surrounding the region of Saga Prefecture (Figure 4 shows this).

The emergency personnel and medical staff input data for each case to the database in the new system through their tablet computer either in the ambulance on their way back to the fire department or in the hospital after transportation. On the other hand, the medical staff enters data about the availability of their hospital two or three times in the morning and evening. Since facilities that accepted emergency patients have to input data on the outcome of each patient, the new system includes information not only about the status of transportation by ambulance in each area, but about a final outcome including types of injury and disease.

Figure 1. The emergency medical service (EMS) personnel handling with the tablet computer to check the status of patients' transfer.

Figure 2. Search page to find available hospitals.

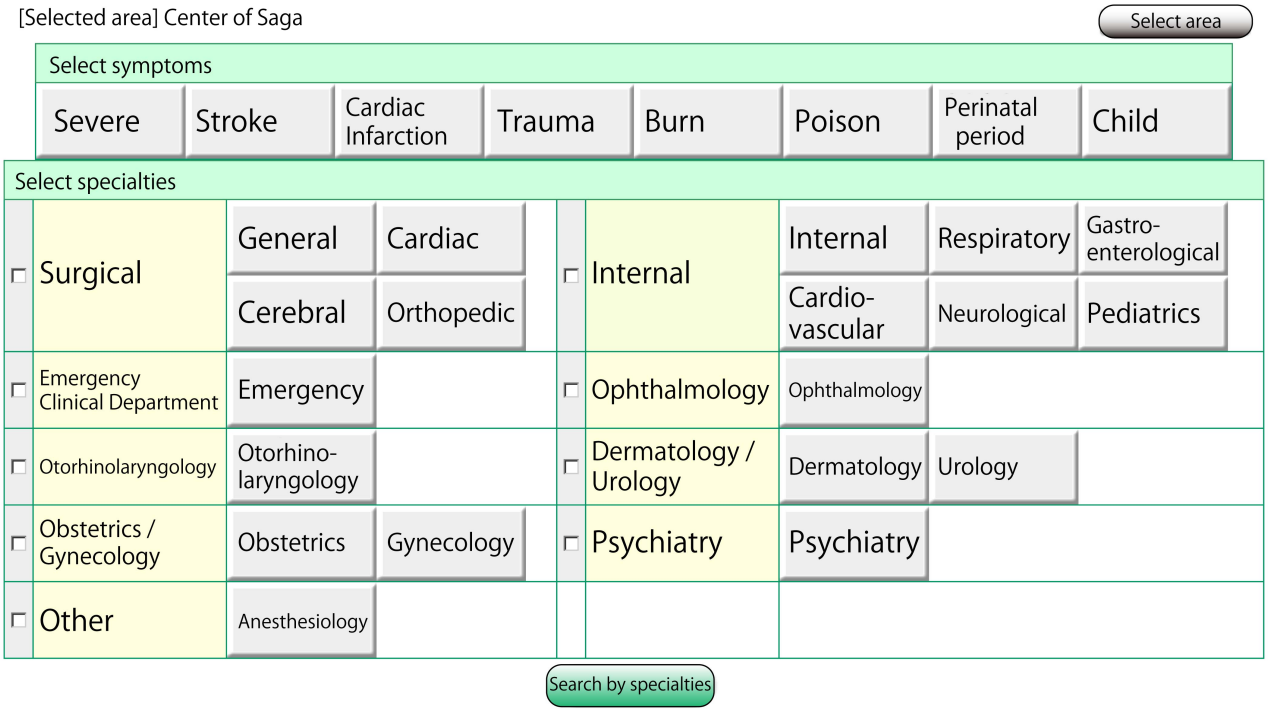


Figure 3. A search result page for severe cases.

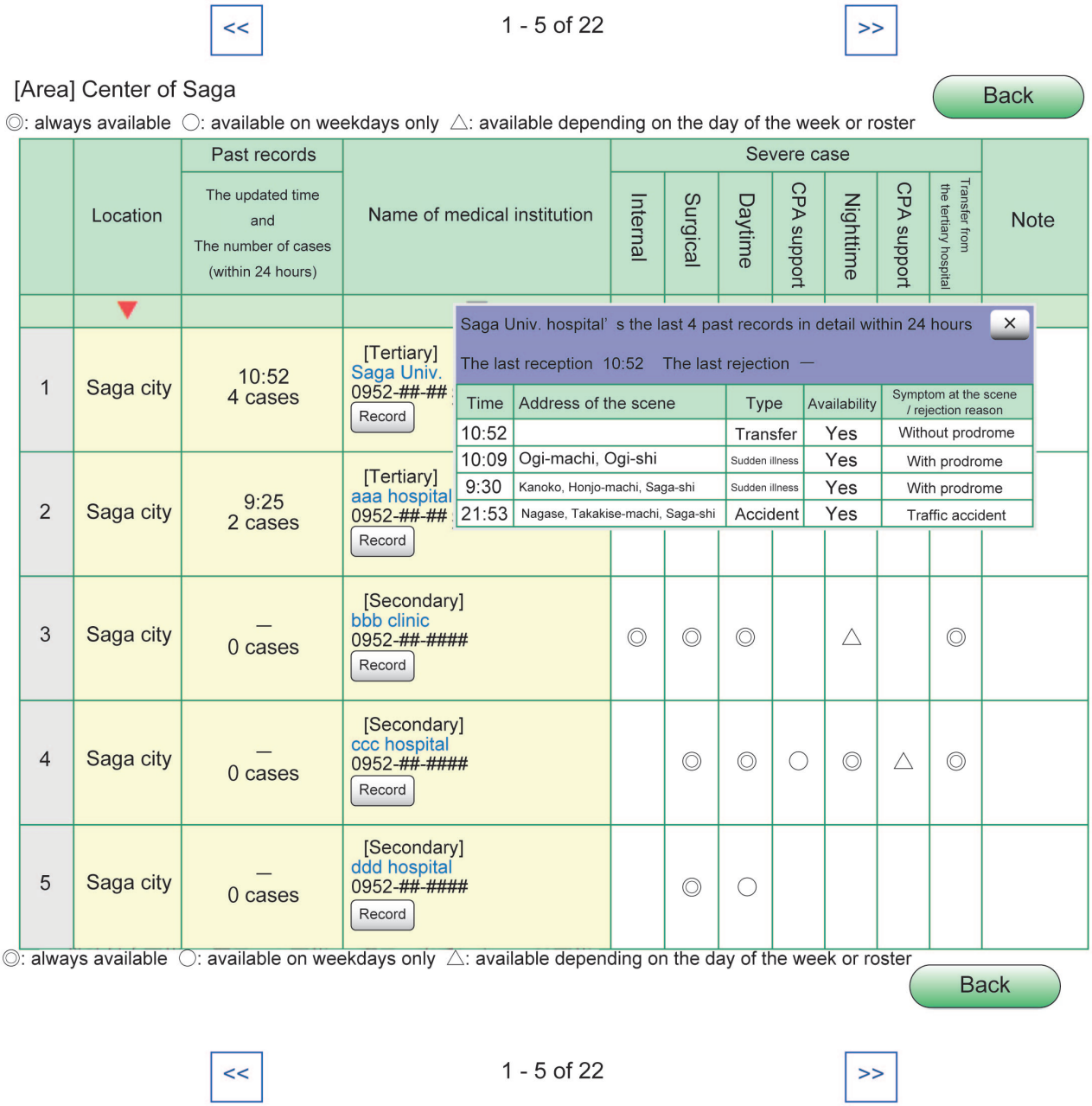


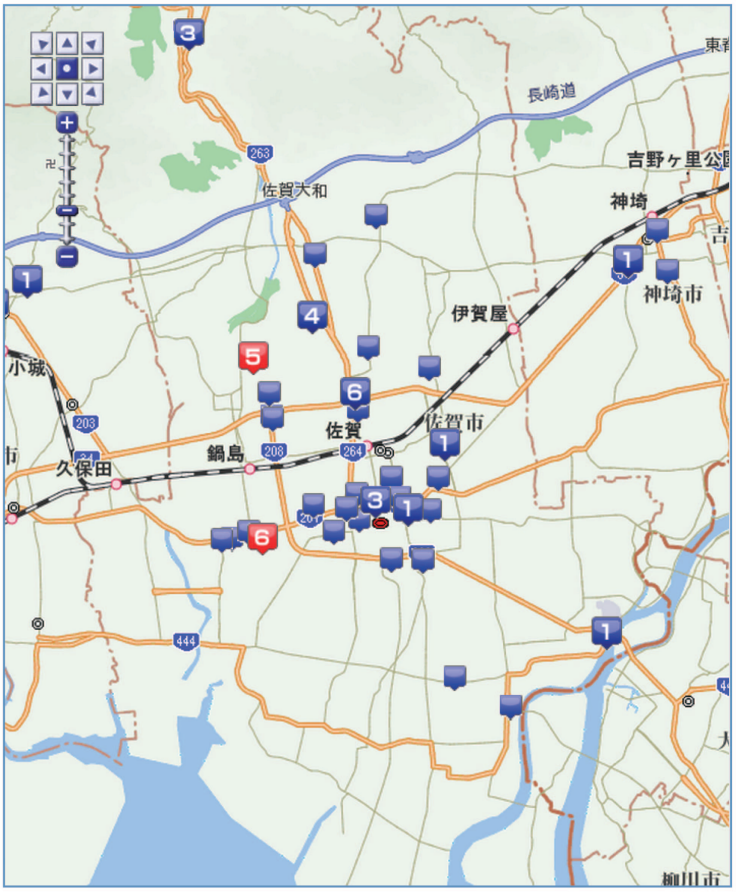
Figure 4. Real-time monitoring page with a map.

Central | East | North | West | South | Fukuoka | Nagasaki | All

<< Back | Forward >> | 1 - 10 of 43

Facilities	Location	Acceptance (total:38)		Rejection (total:16)	
		Cases	Last	Cases	Last
aaa hospital Map	Saga-shi	6	17:53	0	
bbb hospital Map	Saga-shi	6	16:19	2	22:59
ccc hospital Map	Saga-shi	5	14:49	0	
ddd hospital Map	Saga-shi	4	11:16	1	22:59
eee hospital Map	Saga-shi	3	8:58	2	13:57
fff hospital Map	Fuji-machi, Saga-shi	3	10:31	0	
ggg hospital Map	Ogi-machi, Ogi-shi	2	11:36	0	
hhh hospital Map	Taku-shi	2	12:56	0	
iii hospital Map	Kanzaki-machi, Kanzaki-shi	1	14:22	1	13:57
jjj hospital Map	Saga-shi	1	0:49	2	22:59

* Within 24 hours



Measures

Data including the following four measurements were collected prospectively between April 1, 2011 and March 31, 2013.

Transportation Time in Minutes

Transportation time was defined as the time required for transporting from emergency "119" calls to arrival to the hospital. This measure is expressed in the mean, and commonly used as an indicator representing the conditions of present EMS in Japan [3].

Ratio of Transportation to the Tertiary Care Facilities as a Percentage

Ratio of transportation to the tertiary care facilities was calculated by dividing cases of transportation to the tertiary care facilities by all cases of transportation.

System Entry Completion Ratio as a Percentage

When the entering of all the data into the system is completed, the system automatically records flag information. For the emergency personnel, flag information is recorded when they input all the data such as date, types of the incident, gender and age group of patients, and time of day for receiving 119 calls or arriving at hospitals for each case to the database in the system. For the medical staff, flag information is recorded when they input data on the outcome of each patient. The system entry completion ratio was calculated by dividing flagged cases of transportation by all cases of transportation for both the emergency personnel and the medical staff.

Operational Costs

Although the Saga Prefectural Government traditionally provided the operation of the old system, the operation of the new system was entrusted to the private sector. The company entrusted with operation provided cloud computing services. All the Saga Prefectural Government has to do is to pay the rate for the service corresponding to the payment ratio. The operational costs in this article were a service charge to be paid by the Saga Prefectural Government to the entrusted private sector.

Results

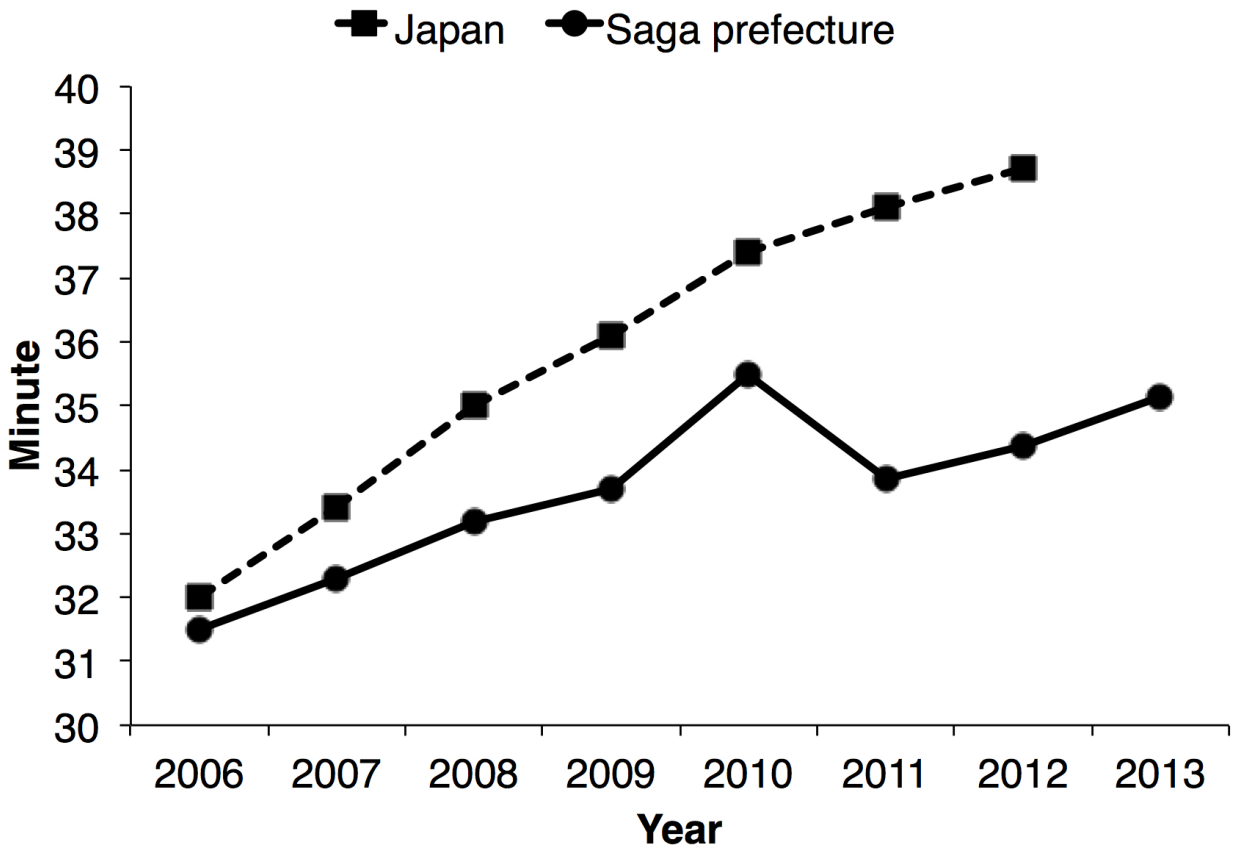
Number of Transportations

Over a three-year period, the number of transportations by ambulance in Saga was 30,709, 30,772, and 31,629, in 2011, 2012, and 2013, respectively. All the data were cleaned and analyzed in this article.

Transportation Time in Minutes

In Saga, the transportation time by ambulance was shortened for the first time since the statistics were first kept in 1999. The transportation time was 35.5 minutes (min) in 2010 (national average) and 33.9 min (95% CI 33.6-34.1 min) in 2011 (Figure 5 show this). Then it prolonged gradually 34.4 min in 2012 (95% CI 34.1-34.6 min) and 35.1 min in 2013 (95% CI 34.9-35.4 min). Although nationwide trends of the transportation time in Japan continued to expand, that in Saga was temporarily shortened in 2011, and was lower than that in Japan.

Figure 5. Mean transportation time in minutes in all of Japan and Saga Prefecture.



Ratio of Transportation to the Tertiary Care Facilities in a Percentage

The ratio of transportation to the tertiary care facilities in Saga has decreased by 3.12% from the year before, 32.7% in 2010 (regional average) and 29.58% (9085/30,709) in 2011. Then that has slightly decreased to 29.53% (9088/30,772) in 2012 and 28.86% (9127/31,629) in 2013.

System Entry Completion Rate in a Percentage

The system entry completion rate entered by the emergency personnel was 100.00% (93,110/93,110) over the observational time period from 2011 to 2013 (30,709/30,709 in 2011; 30,772/30,772 in 2012; 31,629/31,629 in 2013). The data on the transportation time by ambulance has been continuously stored in the system and data analysis is ongoing. The system entry completion rate entered by the medical staff was 46.11% (14,159/30,709), 47.57% (14,639/30,772) and 47.12% (14,905/31,629), in 2011, 2012, and 2013, respectively.

Operational Costs

The new system reduced the operational costs by 40,000,000 yen (about $400,000 US dollars) in 2011. Although the previous system cost 67 million yen (about $670,000 US dollars) a year, the new system has kept a total annual cost for the cloud computing services less than 20 million yen (about $200,000 US dollars). There was seven million yen (about $70,000 US dollars) that was spent on the tablet computers to manage and operate them.

Discussion

Benefits of the New System

Incorporation of this new system offered a number of positive effects on our emergency care system and reduced costs associated with the system. Particularly, the new system shortened transportation time by ambulance, which had been previously increasing every year. In addition, the ratio of transportation to the tertiary facilities was also reduced through the introduction of the new system. Finally, incorporation of the new system could get a serious cost reduction.

In the past, emergency personnel would have to make phone calls to nearby hospitals based on their experience and knowledge, or refer to the control center to find available hospitals for patients to be transferred. Therefore, neither the medical staff nor the emergency personnel could grasp the status as to which hospital is available to accept new patients and which one is accepting more or less emergency cases unless they check the information with each other. The introduction of this new system utilizes a mobile environment (3G/LTE networks) so that all medical personnel involved in prehospital patient care are able to check and share valuable information anytime and anywhere in real time. It is extremely useful that the emergency personnel can operate their tablets on the road or in/out of the hospital depending on the situation. The search result also shows the reasons that hospitals did not accept patients, such as fully occupied or an insufficient number of specialized doctors. It is imperative to apply suitable technology

to the workflow of prehospital care right at the scene for efficient patient care and distribution to the appropriate hospitals. The introduction of this new system has enhanced information sharing among the emergency personnel and the medical staff in prehospital settings. This new system allowed the patients to be transferred to a suitable hospital for them and led to a decrease in the number of unnecessary transportations of mild cases to the tertiary facilities (level I trauma centers).

Very few EMS and medical staff utilized the old system. Even though some medical personnel input the information into the system, it was not certain whether the data was updated. Therefore, EMS was forced to contact a potential hospital by phone to obtain more reliable information. However, usage of the new system has significantly increased both in the hospitals (46 .11%, 14,159/30,709-47.57%, 14,639/30,772) and fire departments (100.00%, 30,709/30,709), compared with the previous system. Each member of the personnel can recognize updates on time and which hospital is neglecting to update in the new system. This motivates emergency personnel and medical staff to use the system and update the information more frequently because of a psychological effect provided by being evaluated and seen by others.

After the inception of the new system, it has successfully reduced the operational costs by 40 million yen ($400,000 US dollars) a year. The Saga Prefectural Government sought competing bids for running the new system. Total operational costs of the old system included the cost of power consumption of a server, the cost of the location of a server, the labor costs, and the cost for apparatus replacement. Cloud computing technology and services included above costs resulted in a significant cost reduction. Many studies also concluded that cloud computing is cost-effective [23-29]. The old system required many more expenses for purchasing and installation of the server and to maintain the operation and maintenance of the system. In contrast, cloud computing cut these costs, and its fees are on a pay-per-use basis. As a result, a 60% reduction in cost came from this new system [30]. The local government officers, to improve additional public services, could utilize the 40 million yen saved each year.

Unlike conventional emergency transfer support systems in Japan, the new system records not only the data of response rate to a demand, but also the clinical outcome after transportation. Therefore, the data of this new system enables us to review if an emergency patient is transferred to the appropriate hospital. Moreover, since each local government has their own regional arrangements and policies for EMS, they can amend the policies of their EMS using the regional data obtained from the new emergency support system.

Limitations

This study has several limitations. While the new system provides the function of the real-time monitoring, data input timing differentiates information displayed on the real time monitoring page from the actual situation. For example, despite of the fact that a facility is available in search results and real-time monitoring, it actually is unavailable when the emergency personnel confirm the availability by call. It would be necessary to add and modify a function of displaying the course of transportation.

There are little scientific data to validate whether patients are transported to the appropriate hospitals. Although the ratio of transportation to the tertiary care facilities was decreased, it is obscure if the triage performed by the emergency personnel at the scene is suitable for selecting a destination to transport the patients. To improve quality of the medical care and public services, it would be essential information for the EMS system regarding the triage by the emergency personnel and diagnosis on arrival [31].

Last, data are insufficient to analyze evidence of the effects of transportation by ambulance on patient outcomes. In the new system, data of patient outcomes entered by the medical staff in hospitals are about the final result of patients at the hospital of a transport destination. If a patient is transferred to another hospital, the outcome of that patient is missing without an additional follow-up survey. It could be important for patient outcomes to create an integrated EMS system connected to electronic health records [32,33].

Conclusions

This article reported that incorporation of ICT offered significant positive impact on the emergency medical setting. It is important for emergency personnel to share information about transportation records and available hospitals with the medical staff in real time for an effective EMS and appropriate patient distribution. Further studies are warranted to sufficiently identify the current state and issues of regional EMS to be improved by analyzing the recorded data in this new system.

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Authors' Contributions

YS conceived and designed the study. KCY and SI were responsible for searching the literature. KCY wrote the first and revised version of the draft.

Conflicts of Interest

None declared.

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Abbreviations

3G: third generation
EMS: emergency medical services
ICT: information and communication technology
LTE: long term evolution
min: minutes

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Original Paper

Quit4baby: Results From a Pilot Test of a Mobile Smoking Cessation Program for Pregnant Women

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Abstract

Background: Text messaging (short message service, SMS) programs have been shown to be effective in helping adult smokers quit smoking. This study describes the results of a pilot test of Quit4baby, a smoking cessation text messaging program for pregnant smokers that was adapted from Text2quit.

Objective: The study aimed to demonstrate the feasibility and acceptability of Quit4baby for women currently enrolled in Text4baby, a perinatal health text messaging program.

Methods: Pregnant women enrolled in Text4baby and who were current smokers or had quit within the last 4 weeks (n=20) were enrolled in Quit4baby. Those under the age of 18, not pregnant, not current smokers, those using nicotine replacement therapy, and those not interested in participating were ineligible. Participants were surveyed at baseline and at 2 and 4 weeks postenrollment.

Results: Most participants responded to the program favorably. Highly rated aspects included the content of the program, skills taught within the program, and encouragement and social support provided by the program. Participants reported that the program was helpful in quitting, that the program gave good ideas on quitting, and that they would recommend the program to a friend. Suggestions for improvement included increasing the message dose and making the quitpal more interactive.

Conclusions: This pilot test provides support for the feasibility and acceptability of Quit4baby. Future studies are needed to assess whether Quit4baby is effective for smoking cessation during pregnancy.

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KEYWORDS

mobile health; tobacco cessation; pregnancy; text messaging

Introduction

Cigarette smoking in pregnancy poses serious health risks to both the woman and the fetus. It has been shown to cause adverse fetal outcomes, including stillbirths, spontaneous abortions, premature births, low birth weight, and sudden infant death syndrome (SIDS), and has been linked to cognitive and behavioral problems in children [1]. It is estimated that greater than 20% of low-birth-weight births could be prevented by eliminating smoking during pregnancy [2].

Among the general population of adult smokers, pregnant smokers in the United States are typically younger, less educated, and more likely to be white or of Native American ancestry [3]. They are twice as likely to be on Medicaid, the government-sponsored insurance program for low-income Americans [4,5]. About 45% of pregnant smokers are able to quit during their pregnancy [6]. Barriers to quitting include a lack of willpower, limited access to cessation services, stigma, stressful life events and relationships, and smoking among family and friends [7]. Currently, many pregnant smokers do not receive recommended smoking cessation counseling [8]. Pregnant smokers are less likely than non-pregnant smokers to call quitlines, and uptake of programmatic offerings aimed at pregnant smokers is low [8]. In addition, medications that are effective for smoking cessation and a staple in treatment programs are not recommended in the US for use among pregnant women [2].

In the US, 85% of all adults have mobile phones [9] and 72% of mobile phone owners send and receive text messages (short message service, SMS) [10]. Among 18- to 29-year-old women (the group most likely to be childbearing), 96% own a mobile phone and 95% send and receive text messages [9]. Texting is also more common in people with Medicaid health insurance compared with other forms of private insurance [11]. Text message-based smoking cessation programs have been found to increase abstinence among adult smokers [12-14].

Mobile phone smoking cessation programs may be especially promising with pregnant women because of the almost universal penetration of mobile phone messaging in this population [9], and because services can be received anonymously, reducing the effect of stigma as a barrier to help seeking [15]. To date, few text messaging studies have been conducted on pregnant smokers [16,17], and existing studies consist of pilots with mixed results. One pilot study of an SMS text-based trial with pregnant smokers found that most women read most texts received. The study also found that women receiving scheduled, gradual reduction texts had a higher rate of cotinine-confirmed, 7-day point prevalence at the end of pregnancy and greater reductions in smoking compared with those who received supportive texts [16]. Another study of pregnant smokers in the United Kingdom who were offered a text messaging program in conjunction with a tailored brochure found that the program modified intentions to quit and resulted in higher levels of self-efficacy for quitting and beliefs about the harms of smoking. However, at a 3-month follow-up, the intervention group showed no difference in 7-day point prevalence or cotinine-confirmed abstinence, regardless of baseline differences in prenatal smoking history [17].

The current study was aimed at demonstrating the feasibility and acceptability of Quit4baby, a smoking cessation text messaging program for pregnant smokers in the US. This program was novel for two reasons. First, unlike previous programs, it was developed from an existing program that has been previously studied in adult smokers and proven to work [13]. Text2quit, a smoking cessation text messaging program for adults, has been shown to increase biochemically confirmed quit rates in adult smokers [13,18]. Second, this program was designed around a large, existing service for pregnant women in order to maximize its potential to reach large numbers of pregnant smokers. Quit4baby was designed to serve as a potential add-on service for Text4baby, an existing national texting program for pregnant women that provides perinatal health information, and has enrolled over 800,000 users since its launch in 2010 [19]. Text4baby has been shown to increase healthy beliefs and attitudes related to taking prenatal vitamins, visiting a health care provider, and avoiding alcohol during pregnancy [20-21]. Given the large subscriber base of Text4baby, Quit4baby may have the potential to increase the reach of smoking-cessation programs that are specifically targeted to pregnant smokers.

Specifically, this study reports on participants' experiences with the program after a 4-week trial. Areas of interest include their overall rating of the program, their level of engagement and use of the interactive features, and the types of interactions that were favored.

Methods

Procedures and Sample

Recruitment was conducted between December 17, 2013 and January 31, 2014, after the study received Institute Review Board (IRB) approval from the George Washington University (GW). Recruiting took place through a broadcast text message sent to all Text4baby subscribers less than 30 gestational weeks pregnant and living in the states of Pennsylvania, Maryland, West Virginia, North Carolina, Kentucky, and Tennessee (n=4450). These states were selected because of their moderate to high prevalence of smoking during pregnancy [22]. The text recruitment message was as follows: "Hi Mom! We are working to make Text4baby better. May we call and talk with you at this number about being part of a study? Reply 1 for Yes, 2 for No." Subscribers who replied 1 (Yes) were notified via SMS text message that they would be called.

Of the 4450 women contacted by text message, 409 (9.19%) responded that they were interested in being part of a study. GW research staff called all interested subscribers, reached 120 women and, of those, 20 (16.7%) were found to be eligible. Text4baby subscribers were eligible if they were aged 18 years or older, a current smoker or had quit within the last 4 weeks, and currently pregnant. Reasons for not being eligible for the study included age (less than 18) (4/100, 4.0%) and smoking status (96/100, 96.0%).

All eligible participants agreed to enroll in the study. GW research staff administered the baseline survey over the phone and enrolled participants in Quit4baby. All participants were asked by GW research staff to set a quit date within the next 2 weeks. Once enrolled, participants activated the program via SMS text messaging and began receiving Quit4baby program messages, while continuing to receive Text4baby messages at the usual frequency (3 messages per week). Follow-up phone surveys were conducted at 2 and 4 weeks postenrollment. Participants were sent a $25 gift card for each survey completed.

Intervention

Quit4baby 1.0 was developed by modifying Text2quit, a proven smoking-cessation text messaging program [13,18], in order to

adapt content and tailor the program to the context of pregnancy and to be consistent with the US Public Health Service Clinical Practice Guideline [2] (Figure 1). Like Text2quit, Quit4baby was based on the Social Cognitive Theory [23] with messages aimed at improving self-efficacy for quitting (with encouragement and motivational messages), describing outcome expectations from quitting, increasing social support for quitting (via the quitpal), enabling vicarious learning through the modeling of effective quitting strategies and coping skills (with keyword TIP and the quitpal), increasing behavioral capability for quitting (with keyword CRAVE, a quit plan, quit date, and interactive support), and regularly recommending calling a quitline.

Content for Quit4baby 1.0 was developed by GW with input from Voxiva and the National Healthy Mothers, Healthy Babies Coalition, and was reviewed by representatives from the Text4baby Content Council and an expert pregnancy smoking cessation consultant. Messages were developed to be consistent with the US Public Health Service Clinical Practice Guideline for smoking cessation during pregnancy [2]. There were six changes made to Text2quit to develop Quit4baby 1.0.

1. The medication protocols from Text2quit were suspended—all mentions of medications, including nicotine replacement therapy (NRT), were removed from the messages, consistent with clinical guidelines [2].

2. The language in the messages was revised to recognize that all enrollees were pregnant and to include pregnancy-specific information, such as the harms of smoking on mother and baby, as this type of educational messaging is clinically recommended to encourage cessation among pregnant women [2]. Messages were revised to include reminders about quitting for the baby's health, as well as the mom's health, in addition to other information about a healthy pregnancy.

3. The peer ex-smoker, quitpal, was changed to a woman who quit smoking while pregnant.

4. The daily tracker was changed so that participants did not have a specific preset goal for cutting down, as is the case in Text2quit, and participants were asked to only track their smoking in the prequit period as a way of self-monitoring.

5. The program period was shortened to 43 days after enrollment to fit the period of the pilot test.

6. The default date to quit was set to the following Monday, based on research that this may be an appropriate day each week to encourage quitting [24].

Participants received 1 to 5 text messages per day, with the highest dose of text messages sent on their quit date and on the days immediately preceding and following that date. The texts were sent out around three main message protocols: prequit, postquit, and not-quit. Most messages originated from the Quit4baby program, though 12 text messages originated from a fictitious peer female ex-smoker quitpal who had quit during pregnancy and who offered evidence-based advice on quitting. The characteristics of, and messages sent by, the role model were based on real-life experiences of pregnant women. Participants were not told that the quitpal was fictitious, although many assumed she was. Participants were assumed to have quit on their chosen quit date unless they replied to a message to say that they had not quit. In this case, participants were prompted to reset their quit date and if they were not ready to do so, they were routed into the not-quit protocol where they were regularly reminded of the benefits of quitting smoking for mom and baby and urged to set a quit date.

Quit4baby pilot participants had the opportunity to text keywords to the program for additional support. Keywords included WHYQUIT (sends messages about what motivated others to quit), DATE (allows users to reset quit date), CRAVE (provides distractions to get users through craving period), TIP (provides tips on abstaining from smoking), GAME (sends users a trivia game to get through a craving period), REASONS (reminds users of their chosen reasons for quitting), SMOKED (helps users get back on track if they slip or relapse midprogram), and STOP (allows users to end the receipt of the text messaging program). Although these same keywords were used in Text2quit, actual messages were modified to reflect the pregnant status of the participants.

Figure 1. Quit4Baby screenshot.

Measures and Analysis

Measures for this study were collected in the baseline, 2-week and 4-week postenrollment telephone surveys. The baseline survey captured demographic information, text messaging habits, smoking behaviors, beliefs about smoking and quitting, and needs and motivations for quitting while pregnant. Responses to items on the baseline survey, such as selected quit date and reasons for wanting to quit, were used to tailor the content of the text messages within Quit4baby. Nicotine dependence was measured on the baseline survey with the Fagerstrom Test for Nicotine Dependence (FTND) [25].

Participant demographic traits, smoking traits, self-efficacy, and smoking outcomes were also examined in a closed-ended format. A truncated version of the Attitude-Social Influence-Efficacy Model (ASE) [26-28] was used to assess smoking beliefs, smoking knowledge, and self-efficacy at baseline. Participants were asked to rate a variety of smoking belief statement items about the negative effects of smoking on their health and the health of their baby. These statements were rated on a 5-point Likert scale from *completely disagree* (1) to s*trongly agree* (5). Participants were also asked to rate their confidence in their ability to quit smoking while pregnant. These statements were rated on a 5-point Likert scale from *not at all confident* (1) to *completely confident* (5). Participants were asked to clarify why they rated each question that way to elicit further qualitative and open-ended feedback.

Information on current smoking behaviors, smoking beliefs, and perceptions of how the Quit4baby program fit with the Text4baby messages they currently received were obtained from the 2- and 4-week follow-up telephone interviews. Participant satisfaction with the program was measured by a series of questions in which participants were asked to rate their agreement with statements about the texts (eg, "The program was helpful in getting me to try to quit," "The program gave me good ideas on how to quit," "I would recommend the program to a friend interested in quitting.") These statements were rated on a 5-point Likert scale from c*ompletely disagree* (1) to s*trongly agree* (5).

Participants were also asked to make suggestions for improving the program and to note which features they liked and disliked. The majority of questions were closed-ended, but several open-ended questions that elicited qualitative feedback were also elicited. Some open-ended probes were used to learn why a participant responded a certain way to a closed-ended question, for example, "Why did you rank (the messages) that way?" and "How would you improve them?" Others questions were purely qualitative in nature, for example, "How do you feel about your ability to stay quit?" and "Can you tell me if there was anything confusing about the texts?" At 2- and 4-week follow-up, participants were asked if they had smoked at all for the past 7 days as a measure of smoking abstinence.

A retrospective review of the computer records of participants was done to characterize the text message engagement of each participant. Each participant was asked about the number of text messages read (*all, most, some, none*) and the number of text message responses was calculated. Responses included replies to interactive text message surveys, for example, when a participant texts Yes or No after receiving a text which says, "Please be honest, did you quit today?" Responses also included unsolicited requests for help with quitting via keyword, for example, when a participant texts CRAVE for help with a craving. Also of interest was the timing of responses in relation to enrollment and the quit date, for example, "Is there anything you would like to change about the timing of the messages?", as well as the types of responses that were most used by participants, for example, "Which keywords did you text to the system?" and "Why did or didn't you initiate conversations with the system?"

Descriptive statistics were used to determine the demographic profile and smoking history of the pilot participants, as well as markers of program engagement, user satisfaction, and recommendations for future improvements. Quantitative analyses were performed using Microsoft Excel 2010 and qualitative analyses were housed in Microsoft Excel 2010 and analyzed by a thematic analysis.

Results

Participant Demographics

A total of 20 women enrolled in the Quit4baby pilot program and completed the baseline survey. Of the 20 enrolled, 16 completed the 2-week follow-up survey (80% response rate), and 13 completed the 4-week follow up survey (65% response rate). Basic demographic and smoking characteristics of participants at baseline are indicated in Table 1.

Table 1. Participant demographics and smoking characteristics.

Demographic and smoking characteristics of participants[a] (n=20)		Mean (SD) or n (%)
Age in years, mean (SD)		28.1 (6.1)
Race, n (%)		
	White	13 (65)
	Black	5 (25)
	More than one race	2 (10)
Educational attainment, n (%)		
	Some high school	3 (15)
	High school degree, technical or trade school	10 (50)
	Some college	4 (20)
	College graduate	3 (15)
Employment status, n (%)		
	Employed full time	2 (10)
	Employed part time	4 (20)
	Not employed	14 (70)
Marital status, n (%)		
	Single	10 (50)
	Separated	1 (5)
	Partnered	7 (35)
	Married	2 (10)
Children status, n (%)		
	Has other children	14 (70)
State of residence, n (%)		
	Pennsylvania	7 (35)
	Tennessee	5 (25)
	North Carolina	4 (20)
	Kentucky	2 (10)
	Maryland	1 (5)
	West Virginia	1 (5)
Smoking status, n (%)		
	Smoked in past 7 days	19 (95)
Average number of cigarettes per day, mean (SD)		7.2 (4.9)
Time to first cigarette after waking, n (%)		
	Within 5 minutes	5 (25)
	6-30 minutes	8 (40)
	31-60 minutes	4 (20)
	After 60 minutes	3 (15)
Believe or strongly believe smoking, n (%)		
	...is bad for my own health	19 (95)
	...is sociable	18 (90)
	...makes my baby weigh less	18 (90)
	...makes my baby smaller	17 (85)

Demographic and smoking characteristics of participants[a] (n=20)	Mean (SD) or n (%)
...is soothing	8 (40)
...tastes good	1 (5)

[a]Pregnant women aged 18 and older.

Rating and Perceptions of the Quit4baby Program

As shown in Table 2, participants gave overall high ratings to the program. Participants agreed and completely agreed that the program was helpful in quitting, that the program gave good ideas on quitting, and that they would recommend the program to a friend. One participant indicated that she found the texts helpful and supportive: "Texts were very helpful...gave (me) extra support." Another participant reported that the messages contained good ideas on how to quit: "They had ideas I didn't know about before."

Participants rated programmatic messages and the following message categories were deemed most helpful: messages that asked them to track their smoking, messages that came from a quitpal, and messages that promoted behavioral substitutions (eg, core messages aimed at providing alternative healthy behaviors to replace smoking, or responses to participant-input TIP keyword). One participant commented on the tracking suggestions in the messages, saying, "(the texts) held me accountable." Participants called the quitpal, "personal," "a friend," and stated that, "It just helps to know someone's there." However, one participant felt the messages were a trigger: "Getting this message makes we want to smoke." Another participant wanted more detail: "(There) was nothing specific in the message."

Message frequency is an important characteristic of any SMS text message behavior-change program. Out of the 16 pilot participants who responded at the 2-week follow-up about the number of messages received, 14 (88%) felt they received "just the right number," while 2 (12%) felt they received "too few" messages. No participants reported receiving too many messages. Moreover, pilot participants felt that the Text4baby program messages and the Quit4baby program messages "fit well together" (12/16, 75%), or at a minimum, "fit ok together" (3/16, 19%). Only 1 participant out of 16 (6%) felt the messages from the two programs did not fit well together.

Participants were also asked to share what they liked and did not like about the Quit4baby program. These were open-ended questions that allowed for multiple comments from each individual. Participants most commonly reported liking the content, the skills the program helped them develop, the encouragement the program gave, and the constant reminders the program sent about quitting. Specifically, participants mentioned skills related to cravings (eg, "I didn't realize that just walking and games made a difference to get through cravings,") and the social support provided (eg, "Makes you feel like you have more support—someone else is going through the same thing.")

More than half (10/16, 63%) of all responses to questions regarding program dislikes were "nothing." The next most commonly reported dislike was participants' wanting more tips and hints for how to quit smoking. Others mentioned wishing the quitpal "Erika" was a real person, or at a minimum, a programmed mechanism that could respond to their text messages, versus only sending unidirectional information. Table 2 displays participants' ratings and perceptions of the Quit4baby program elements.

Table 2. Participant ratings and perceptions of the Quit4baby program at the 2-week follow-up survey.

Category and item (n=16)	Mean (SD) or n (%)
Program rating, [a] mean (SD)	
Program was helpful in trying to get me to quit.	4.5 (0.6)
Program gave me good ideas on how to quit.	4.4 (0.9)
I would recommend the program to a friend interested in quitting.	4.7 (0.7)
Message category helpfulness rating, [a] mean (SD)	
Tracking	4.5 (0.8)
Quitpal	4.3 (0.9)
Behavioral substitution	4.3 (1.2)
Social support	4.2 (1.2)
Stress reduction	3.9 (1.2)
Message timing rating,[a] mean (SD)	
Messages came at the right time of day.	4.0 (0.8)
Message frequency, n (%)	
Just right	14 (88)
Too few	2 (12)
Too many	0 (0)
Program fit with Text4baby, n (%)	
Fit very well	12 (75)
Fit ok	3 (19)
Didn't fit well	1 (6)
Programmatic likes, n (%)	
Content/skills	6 (30)
Encouragement	3 (15)
Reminders	3 (15)
Message tailoring	2 (10)
Social support	2 (10)
On-demand help	1 (5)
Programmatic dislikes, n (%)	
Nothing	10 (63)
Content/info	3 (19)
Message frequency	1 (6)
Personal interaction (lack thereof)	1 (6)
Message timing	1 (6)

[a]Items were ranked on a scale from 1 (completely disagree) to 5 (strongly agree).

Program Engagement

Table 3 provides an overview of program engagement. At the 2-week follow-up, all participants reported having read all of the text messages that the program sent. On average, participants sent 5.4 (SD 6.6) text message responses, but there was some variability in responses during the program. Participants were actively engaged in the program for an average of 24.2 (SD 17.0) days from their date of enrollment. This average was calculated by subtracting the participant's enrollment date from their last recorded date of activity (eg, responding to a survey or texting a keyword). Other enrollees may have still been engaging with the program passively by reading SMS text messages. Lastly, more than half of participants remained engaged in the program by replying to messages after their quit date had passed.

The keywords used by the largest subset of participants were REASONS (11/20, 55%), CRAVE (10/20, 50%), and TIPS

(7/20, 35%). Also of interest was the use of the keyword DATE—almost half (9/20, 45%) of the participants requested to reset their quit date mid-program by texting the keyword to the program. No participants used the keyword STOP to unsubscribe from the program.

Table 3. Program engagement and characteristics of responses to text messages.

Category and item[a] (n=20)		n (%) or mean (SD)
Overall engagement		
	Read all texts received,[b] n (%)	16 (100)
	Average total number of responses,[c] mean (SD)	5.4 (6.6)
	Average response period in days, mean (SD)	24.2 (17.0)
	Participants who replied after their quit date, n (%)	12 (60)
Survey and keyword use		
Prequit surveys, n (%)		
	Prequit smoking tracker	18 (90)
	Are you ready to quit (on quit date)?	14 (70)
	Are you ready to quit (before quit date)?	12 (60)
	Are you smoke free?	9 (45)
Postquit surveys, n (%)		
	Postquit status tracker	10 (50)
	Pledge to stay smoke free	3 (15)
Anytime keywords, n (%)		
	REASONS	11 (55)
	CRAVE	10 (50)
	DATE	9 (45)
	TIPS	7 (35)
	Requested a keyword GUIDE	7 (35)
	STATS	6 (30)
	SLIP	5 (25)
	SMOKED	5 (25)
	WHYQUIT	3 (15)
	GAME	1 (5)
	STOP	0 (0)

[a]Measures were collected from Voxiva programmatic records.

[b]Measures were collected at the 2-week follow-up (n=16).

[c]A response includes a reply to a text survey or an unsolicited request for support with quitting via text (eg, CRAVE).

Self-Efficacy and Smoking-Related Outcomes

Participants were asked to rate their confidence in their ability to quit smoking while pregnant. At baseline, the average confidence rating was 3.6 (SD 1.2), demonstrating above-average levels of confidence in their ability to quit. At the 2-week follow-up, confidence levels rose to 3.8 (SD 1.3), and at the 4-week follow-up, confidence had risen to 4.8 (SD 0.5).

At baseline, participants smoked an average of 7.6 (SD 4.9) cigarettes per day. At the 2-week follow-up, the average number of cigarettes smoked had decreased to 4.7 (SD 5.2). At the 4-week follow-up, this number had decreased to 2.4 (SD 1.8) cigarettes per day. At the 2-week-follow-up, 5 participants out of 13 (38%) had reported abstaining for the past week, and 7 participants out of 13 (54%) reported abstaining for the past week at the 4-week follow-up.

Discussion

Principal Findings

Overall, we found support for the feasibility and acceptability of the Quit4baby program, with most participants agreeing that they liked the program overall. Participants overwhelmingly agreed that the texts were helpful in getting them to try to quit, that the texts gave them ideas on how to quit, and that they

would recommend the program to a friend. Readership of the texts was high and sustained over time. The positive responses—plus the lack of negative responses—imply that the program was generally well liked and congruent with the target population's needs.

It was encouraging that many participants used the interactive features of the text messaging system, a prominent feature of the program. Almost all participants initiated/replied to a text message and, on average, participants sent in more than 5 responses over the program period. While health-promotion programs that stimulate interaction and engagement have been found to be more likely to result in behavior change [29], it remains to be seen to what degree engagement in this program will be associated with smoking cessation.

As in previous studies [18], a significant proportion of participants stopped responding to the system by text once their quit date arrived. This finding likely reflects the fact that many participants did not follow through with their chosen quit date or quickly relapsed and then disengaged from the program as messages arrived, giving the erroneous impression that they had indeed quit smoking. It is possible that participants were hesitant to report relapse due to a variety of negative emotions, such as embarrassment or guilt. However, it is somewhat encouraging that the level of disengagement was lower than in previous studies and that numerous participants reset their quit dates. Still, the program could be redesigned to better engage such participants.

Pregnant smokers are hard to reach and have been reluctant to participate in offered programs. Since the Quit4baby program is being designed as an add-on service to Text4baby, it is hoped that the high reach of Text4baby and the offer of confidential, automated self-enrollment will provide a way to extend services to this hard-to-reach audience. This study helps demonstrate the plausibility of recruiting from Text4baby, one of the largest text messaging programs in the US [30], and concurrently offering an add-on, quit-smoking text messaging service. Most participants in our study—who continued to receive Text4baby messages while enrolled in Quit4baby—expressed that the programs fit well together. This is encouraging and validates the design plans. Though our enrollment rates were low, it is hoped that in future programs that directly screen for smoking and use automated systems, enrollment rates would increase.

Additional strengths of this study include that it involves the testing of a novel text messaging system for an at-risk and underserved population that makes use of interactive and personalized text messages. While the study sample was small, the pilot benefited from a follow-up rate of 80% (16/20) at the 2-week follow-up and 65% (13/20) at the 4-week follow-up.

Limitations

Weaknesses of this study include the lack of a control group and that participation may have been limited by some Text4baby subscribers' unwillingness to disclose their smoking activity. Due to low response rate (less than 3% response rate for all potentially eligible Text4baby subscribers), small sample size, and unique demographics of the sample (ie, 50% were single and 10% were married), the results are not generalizable to all pregnant women smokers. Another potential limitation includes the possible inflation of the DATE keyword engagement as GW research staff, in an estimated 2 cases, counseled participants on how to enter this command during the follow-up phone surveys. Once this practice was noted, it was discontinued.

Conclusions

Findings show that a text messaging system that makes use of interactive and personalized text messages is acceptable to pregnant smokers enrolled in Text4baby. Insights gained from this study have informed the redesign of Quit4baby for a larger study and for possible dissemination. Given the emerging evidence for the efficacy of text messaging for smoking cessation [14], it is recommended that future text messaging studies strive to understand the utility of such programs for priority subgroups like pregnant smokers.

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Conflicts of Interest

Pamela Johnson is the Chief Health Officer and a stockholder and member of the board of Voxiva, Inc. The George Washington University has licensed the Quit4baby program to Voxiva, Inc.

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Abbreviations

ASE: Attitude-Social Influence-Efficacy Model
FTND: Fagerstrom Test for Nicotine Dependence
GW: George Washington University
IRB: Institute Review Board
NRT: nicotine replacement therapy
SIDS: sudden infant death syndrome
SMS: short message service

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Review

Behavioral Functionality of Mobile Apps in Health Interventions: A Systematic Review of the Literature

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Abstract

Background: Several thousand mobile phone apps are available to download to mobile phones for health and fitness. Mobile phones may provide a unique means of administering health interventions to populations.

Objective: The purpose of this systematic review was to systematically search and describe the literature on mobile apps used in health behavior interventions, describe the behavioral features and focus of health apps, and to evaluate the potential of apps to disseminate health behavior interventions.

Methods: We conducted a review of the literature in September 2014 using key search terms in several relevant scientific journal databases. Only English articles pertaining to health interventions using mobile phone apps were included in the final sample.

Results: The 24 studies identified for this review were primarily feasibility and pilot studies of mobile apps with small sample sizes. All studies were informed by behavioral theories or strategies, with self-monitoring as the most common construct. Acceptability of mobile phone apps was high among mobile phone users.

Conclusions: The lack of large sample studies using mobile phone apps may signal a need for additional studies on the potential use of mobile apps to assist individuals in changing their health behaviors. Of these studies, there is early evidence that apps are well received by users. Based on available research, mobile apps may be considered a feasible and acceptable means of administering health interventions, but a greater number of studies and more rigorous research and evaluations are needed to determine efficacy and establish evidence for best practices.

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KEYWORDS

smartphone; app; health behavior; systematic review; interventions

Introduction

Since 2007, mobile phones like Apple's iPhone and Google's Android have taken over the mobile market; 56% of Americans now own a smartphone [1]. Third-party apps are software programs that serve to expand the utility of mobile devices. Within just 6 years, Apple celebrated its 50 billionth app download with Google trailing only slightly behind with 48 billion as of May 2013 [2]. This new market of software apps has resulted in over $9 billion being paid to developers for Apple alone [2]. Health apps have also become a part of this market, with over 31,000 health and medical apps available for download [3]. With mobile phone ownership and the number and complexity of health apps likely to increase, the potential for technology-based health interventions to impact populations is possible like never before.

Health-related apps now number more than 31,000 [3], and their utility for promoting health behavior has been analyzed [3-5]. Most published literature regarding health apps has focused on preventing and managing chronic disease [6,7], monitoring health behaviors and vitals [8], content analyses of health and fitness apps [9-11], app acceptability and utility [12-15], and qualitative studies of user experience and desired functions [4,16,17]. However, most studies are descriptive. Recently, several published studies have utilized apps in health behavior interventions; however, it is unclear how substantial this body of literature currently is, or the extent to which mobile apps are shown to be efficacious at facilitating behavior change. The purpose of this systematic review was to describe the current body of literature on apps used in health behavior interventions, describe the behavioral features and focus of apps, and evaluate the potential of apps to efficaciously disseminate health behavior interventions.

Methods

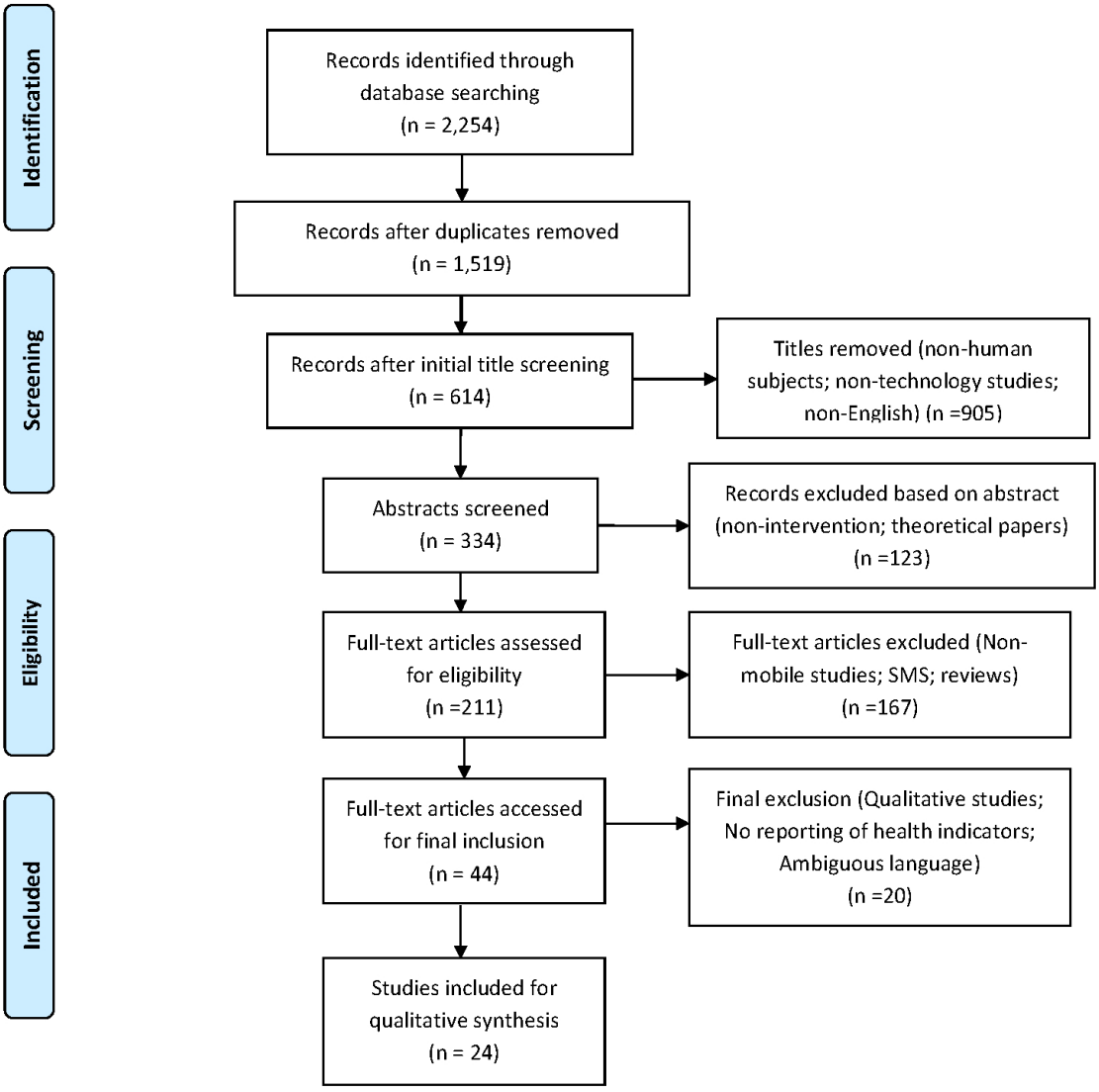
A search of published, peer-reviewed literature was conducted in September 2014 for articles that studied health behavior interventions that utilized mobile apps. The researchers used key search terms to identify potential articles (see Table 1). We queried JMIR, Academic Search Premier, CINAHL, Communication and Mass Media Complete, Computer Source, Computers and Applied Sciences Complete, Health Source—Consumer Edition, Health Source—Nursing/Academic Edition, Medline, PubMed, PsychARTICLES, Psychology and Behavioral Sciences Collection, Web of Science, and PsycINFO. Only articles published after 2007 were considered because that was the year the first app-ready mobile phone entered the market.

Table 1. Search terms for systematic review.

Search lines	Search terms	Filtered by
Line 1	Smartphone OR mobile phone OR Mobile device* OR tablet OR iphone OR “mobile technolog*” OR “Smart Phone” OR ipad OR mhealth OR android OR windows	Title/ Abstract
2. AND	App OR apps OR “mobile app” OR application*	Title/Abstract
3. AND	health OR BMI OR “heart disease” OR “physical activity” OR diabetes OR smoking OR exercise OR cancer OR obesity OR nutrition OR “public health”	Title/ Abstract
4. AND	behavior OR behaviour OR intervention OR “controlled trial” OR RCT	Title/ Abstract
5. NOT	developing OR telemedicine OR “text messaging” OR SMS	Title

Our query returned 2254 articles. The authors reviewed the titles of articles and abstracts and eliminated duplicates and studies of non-human subjects, which reduced the sample to 334 articles. Further inclusion and exclusion criteria were applied to the sample of articles. Inclusion criteria included using a mobile app (iPhone, Android, or Windows); an intervention study of some type; use of behavioral theory, constructs, or strategies; studying a public health topic with health indicators reported; and published after 2007 to the time of the search (September 19, 2014). Studies were excluded if they were non-English studies, if they assessed an app through qualitative data only, if they had ambiguous language pertaining to whether or not they used a mobile phone app, or if they used a Web-based app and not specifically a mobile phone app. This resulted in a final sample of 24 articles selected for inclusion in the current systematic review (see Figure 1) [12,18-40].

Figure 1. Systematic review of the literature flowchart.



Results

Overview

Seventeen of the studies had a sample of less than 100 participants. Gajecki et al [24] had the largest sample (N=1929) and was a randomized multi-group trial. Eleven of the studies reviewed were feasibility or pilot tests, and the majority of the studies used a randomized study design (15 studies). Post-intervention follow-up assessment for the 9 studies ranged between 4 weeks and 6 months, with the exception of Quinn et al [32] and Mattila et al [31], where the follow-up periods extended to 1 year. Eighteen of the studies tested an app that had been developed specifically for the intervention, while the remaining five tested existing apps. The majority of studies (18) reported testing one app. Hebden et al [26] tested four, which was the most in any study (see Multimedia Appendix 1).

Of the studies reviewed, 14 involved interventions for physical activity and diet, four studies involved diabetes management, four for improving mental health, and only two studies involved interventions for addiction.

Behavioral Components of Mobile Apps

All of the studies incorporated at least one prominent health behavior theory construct or strategy. Self-monitoring was the most common, included in 18 of the studies. The next most commonly used constructs were cues to action and feedback (both included in nine studies each), followed by social support (six studies). Major theories used as frameworks included social cognitive theory (four studies) and self-determination theory (two studies).

Every app used for mental health and addiction was either designed with a specific behavioral strategy or selected with a behavioral construct in mind (eg, the theory of planned behavior, self-determination theory, behavioral activation approach) (100%, 6/6), and all but one of the physical activity and diet interventions were constructed after a specific construct or theory (93%, 13/14). The diabetes apps were the least likely to be designed or chosen with specific behavioral constructs in mind (25%, 1/4), or rather, the apps selected happened to include behavioral constructs.

User Retention and Acceptability

The mean retention rate for smartphone use throughout the intervention period was 79.6%, with a low of 29% and a high of 100%. Retention rate for these studies was defined as the number of initial study participants who remained in the study through the intervention period and follow-up. Of the studies that reported on user acceptability (13 studies), most reported high user acceptability and feasibility of using smartphone apps for behavior change interventions, except Gajecki et al [24] and Matilla et al [31] who reported average and low-to-moderate acceptability, respectively.

Of the diet and physical activity apps, Allen et al [19] reported that users were most satisfied with the accountability and structure of the app and the use of a smartphone platform. Users suggested a stronger emphasis on exercise and additional feedback. Bond et al [20] reported that real-time smartphone display and feedback significantly increased their motivation to engage in physical activity. Users in the Brindal et al [21] study indicated that most found the app easy to use and that weight tracking and prompting were the most popular feature, while trophies and meal graphs (visual presentation) were the least. Burns et al [22] indicated that users felt the intervention was helpful in understanding negative mood triggers and managing distressing behaviors and thoughts. Receiving the mood predictions was the most helpful component of the intervention, and many suggested a verbal component when using the smartphone. Carter et al [40] reported that users found the apps convenient and easier to use than other methods of tracking diet. Additionally, users felt more comfortable using the smartphone app in public.

Matilla et al [31] utilized three separate apps and found that users most enjoyed the ability to see progress over time, having a record of personal progress and seeing development in long-term health outcomes, and adaptive exercises and coaching. Unexpectedly, some users noted that they did not like being pressured by the apps to do healthy activities and viewed it as a barrier to use. King et al [27] reported that the main acceptable features of the apps developed for the study were ease of use, limited time per use, and high acceptability of awareness raising and alerts to action. Robinson et al [12] reported similar findings, with users reporting high acceptability of ease of use and convenience of the app. Users reported acceptability of more automatic functions, and an app that worked into their daily routine. Additionally, users reported acceptability of awareness raising of behaviors and wanted discrete interactions with the app in public. Smith et al [33] reported that users particularly enjoyed the "push prompt" used in the app and that teacher satisfaction with the app was particularly high. Thomas et al [34] reported that almost all users indicated maximum rating for both satisfaction with the app and likelihood in recommending it to others. Finally, Kirwan et al [28] also reported that the most important/acceptable components of the app were ease of use and time, with the average time of use being 9.3 seconds.

Only one of the diabetes studies reported acceptability; Cafazzo et al [23] reported that users were more satisfied with using the app for diabetes monitoring, and the interactions with the app were considered "fast". Additionally, users wanted the interactions to be discrete in public to avoid embarrassment in social settings. Rewards and sharing of information with family members was also rated high in acceptability. Similarly, only one of the addiction studies reported details concerning acceptability. Gajecki et al [24] did not report specifics about acceptability or user opinion and only assessed how easy the app was to use, how suitable it was for helping those with risky alcohol consumption, and whether participants would recommend it to friends. On all three, scores were average (3.2-3.6 on a 5-point scale).

Efficacy of Mobile App Interventions

Ten studies targeted physical activity as a primary measure, and eight of them reported increases. Allen et al [19], King et al [27], Mattila et al [31], Turner-McGrievy et al [35], Turner-McGrievy et al [36], and Van Drongelen et al [37] measured physical activity from either self-reporting on their apps or through questionnaires, and all but Turner-McGrievy et al [35] reported increases in physical activity, with Allen et al [19] reporting only a slight increase. Bond et al [20], Hebden et al [26], Kirwan et al [29], and Smith et al [33] utilized objective measures, either from the apps themselves or from accelerometers. All but Smith et al [33] reported significant increases in physical activity.

Ten studies targeted Body Mass Index (BMI) or weight loss, and all but one reported either decreases in BMI, weight loss, or decreases in body fat except one. Allen et al [19], Brindal et al [21], Carter et al [40], and Hebden et al [26] all reported higher amounts of weight loss or lower BMIs in the smartphone interventions, but the weight loss was not statistically significant, including when compared to controls. Mattila et al [31] noted that weight, body fat, and BMI all decreased, and there was a significant difference between sustained app users and non-sustained users. Robinson et al [12] noted decreases in body weight, but it was a secondary measure and few details of the weight loss were reported. Smith et al [33] reported no significant decreases in BMI or body fat. Thomas et al [34] reported significant decreases in body weight at 12-week follow-up, but not at 24 weeks. Turner-McGrievy et al [35,36] reported no significant difference in weight loss between intervention groups in the 2011 study, while in the 2013 study, users experienced a significant drop in BMI at follow-up. Of the four interventions related to diabetes, three reported a positive change in glycated hemoglobin: Kirwan et al [29] and Quinn et al [32] showed a significant decrease in HbA1c levels, while Wayne et al [39] showed a significant decrease only for those whose baseline HbA1c levels were above 7%. Cafazzo et al [23] reported no change.

The three mental health interventions that addressed depression reported significantly decreased depression levels at follow-up, while the last one, a stress management intervention (Ahtinen et al [18]), reported significantly better stress ratings and life satisfaction at follow-up. Of the two apps addressing addiction, one showed a significant improvement in number of risky drinking days, while the other reported no effect on alcohol consumption, with one app possibly showing a negative effect on alcohol consumption.

It is also worth noting that many studies (Hebden et al [26], Mattila et al [31], both Turner-McGrievy studies [35,36], and Quinn et al [32]) utilized apps as part of a comprehensive intervention strategy; that is, the interventions were not specifically designed for a smartphone, and the apps were used as part of a multicomponent strategy.

Discussion

Principal Findings

Despite the thousands of health and fitness apps now available for download and the emerging interest in using them for improving health behaviors, very few have been tested in intervention settings. This lack of evaluation may be concerning because smartphone owners have an average of 41 apps installed [41], with 52% using their phones for health purposes and 19% using health apps [42]. Additionally, the types of published, peer-reviewed app studies that were available for review were predominantly small sample pilot or feasibility studies, instead of more rigorous randomized controlled trials (RCTs) with adequately powered samples. Notwithstanding the small number and nature of the studies included in this review, the majority of evaluated apps were found to be inclusive of health behavior theory constructs such as self-monitoring and goal-setting. The existing literature does illustrate high user acceptability of smartphone apps for health interventions and shows preliminary potential of these apps to change behaviors and, subsequently, health outcomes.

Behavioral Components of Mobile Apps

Constructs from Bandura's Social Cognitive Theory (SCT) were the most used in the reviewed studies as is evidenced by the presence of self-monitoring and social support, both prominent in SCT [43]. Other studies and articles have focused on the accuracy of self-monitoring with mobile technology [8], a trend that is consistent with the Quantified Self-Movement [44]. Additionally, social support was emphasized in several of the studies reviewed. In both her studies, Turner-McGrievy et al [35,36] utilized Twitter as a supplementary tool for participants to share tips and comments with one another. Cafazzo et al [23] utilized a similar tool, allowing for participants to interact on a social network with parents, peers, and clinical staff to report progress. King et al [27] divided participants into groups to interact online so each group could support one another and see each other's progress. Wayne et al [39] provided health coaches as additional support and personal counseling to help participants adhere to behavioral goals. Social support has been shown to be useful for increasing motivation or providing reinforcement for changes in behavior [45,46].

App Acceptability and Efficacy

The findings of this review may demonstrate the potential of using apps to increase retention in health behavior interventions. These findings also mirror larger societal trends wherein consumer acceptance and demand for health and fitness apps to change behavior is growing [3], which has resulted in increased profitability [2].

Several of the articles reported improvements in physical activity. For example, King et al [27] reported that participants increased physical activity and decreased sedentary time, Kirwan et al [28] reported that use of an app was associated with greater number of steps logged, and van Drongelen et al [37] reported that users increased the number of days they experienced both moderate and strenuous intensity exercise each week. In other research, a content analysis of 127 physical activity apps for behavior change theory showed that most apps had low behavior change potential and recommended that developers partner with experts in behavior change to increase app quality [9]. Many of the apps reviewed in this study were developed specifically for the purposes of their respective interventions, which may account for their effectiveness for increasing physical activity. This raises questions about the potential for effecting behavior change between existing apps and apps developed for a specific intervention.

Ten interventions reviewed in this study reported a change in weight loss or reduction in BMI or body fat, but only three (Mattila et al [31], Turner-McGrievy et al [36], and Thomas et al [34]) reported significant results, and Thomas et al [34] only reported significant results at the first follow-up, with significance diminishing after further study. The results of this review point to significant potential barriers in the use of health apps as interventions for weight loss. This should be studied further in light of recent qualitative research that has identified barriers to using calorie counting apps for diet change, mostly due to the complexity of calorie counting apps [47]. Additional research of weight-loss apps has also been completed concluding that many apps have low evidence-informed content, demonstrating lack of industry standards and inclusion of evidence-based practices [48].

The diabetes studies showed conflicting results. Cafazzo et al [23] reported no measurable change in HbA1c, although glucose monitoring did increase during the intervention period. After a 1-year follow-up, Quinn et al [32] found improvements among participants' glycated hemoglobin. However, previous reviews of self-management diabetes apps report that apps may not be adequate for providing comprehensive self-management care and adhering to clinical guidelines [49,50]. Further research is needed to determine the benefits of app interventions for diabetes management.

Watts et al [38] measured depression and psychological distress among individuals diagnosed with major depression. There were no measurable differences between the intervention and control group, but depression was lowered among participants using the smartphone app. The current literature is lacking in the area of mobile technology interventions and mental health. The number of mental health apps available for download is also low [51], and future research in the field of mental health should focus on developing and integrating mobile technology into providing treatment for mental disorders.

For developers and future researchers, several of the findings of this study on acceptability of certain components of apps may be found useful. For instance, many of the studies found that users want apps that are fast and easy to use and that allow for discrete interactions in public, with many users reporting being socially conscientious of writing down or reporting personal data in public. Additionally, users reported high

acceptability of apps that raised awareness of certain behaviors and provided potential cues to action. Finally, developers and researchers may find promise in integrating rewards into the interventions with smartphone apps to drive better behavioral outcomes.

Limitations and Future Directions

The inclusion and exclusion criteria were developed in order to capture the most relevant studies involving mobile apps in behavioral interventions to impact health. However, there was no distinction made between studies that used a mobile app in one arm of a multi-group study, or if they were used as the principle focus of the study. Our aim was to not attempt to interpret the original study author's intentions and to be more inclusive of studies involving mobile apps. Additionally, due to the dearth of apps that met the aims of this systematic review, it was beneficial to be more inclusive to better reflect the current literature. It should be noted that it may be difficult to compare these types of studies. Future systematic reviews may be able to be more restrictive once more studies begin to appear in the academic literature that are more robust and concrete in purpose.

Key future directions are recommended based on the findings of this study. The majority of these studies were pilot or feasibility studies with small samples. Considering the capacity of mobile technology to offer interventions to populations at minimal cost, this finding was surprising. Additionally, with the app industry extending into the billions of dollars, it is concerning that more money is not being put into researching the efficacy of these apps on a large scale. Several apps available for download in the Apple App and Google Play stores have several thousands of customer reviews. Some app companies boast hundreds of thousands of consistent users as well. In the future, health researchers should partner with successful app companies and producers in studying the efficacy of apps to impact health behavior on a much larger scale.

Conclusions

The purpose of this systematic review was to provide a description of app-based intervention studies, describe common behavioral features, and explore the acceptability and potential for apps to change behavior as currently dictated by the literature. In the small sample of reviewed studies, the majority of apps were viewed as acceptable, inclusive of theory, and efficacious at changing behavior. Moreover, the potential for scalable behavioral interventions through these technologies is promising, but largely untapped. Moving forward, researchers should focus on conducting rigorous RCT studies with adequately powered sample sizes to determine the utility of app-based health interventions. Future researchers may also focus on the potential benefits to behavior change when multiple apps are combined together in one single intervention.

Authors' Contributions

HP and CL conducted the initial systematic review of the literature, and CL and JW created the search terms for the review. HP, CL, JW, and JB all conceptualized the formatting and direction of the paper, conclusions of the findings, and contributed substantially to the writing and editing of the submitted manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Characteristics of eligible studies.

[PDF File (Adobe PDF File), 120KB - mhealth_v3i1e20_app1.pdf]

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Abbreviations

BMI: Body Mass Index
RCT: randomized controlled trial
SCT: Social Cognitive Theory

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Original Paper

A Mobile Phone Food Record App to Digitally Capture Dietary Intake for Adolescents in a Free-Living Environment: Usability Study

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Abstract

Background: Mobile technologies are emerging as valuable tools to collect and assess dietary intake. Adolescents readily accept and adopt new technologies; thus, a food record app (FRapp) may be a useful tool to better understand adolescents' dietary intake and eating patterns.

Objective: We sought to determine the amenability of adolescents, in a free-living environment with minimal parental input, to use the FRapp to record their dietary intake.

Methods: Eighteen community-dwelling adolescents (11-14 years) received detailed instructions to record their dietary intake for 3-7 days using the FRapp. Participants were instructed to capture before and after images of all foods and beverages consumed and to include a fiducial marker in the image. Participants were also asked to provide text descriptors including amount and type of all foods and beverages consumed.

Results: Eight of 18 participants were able to follow all instructions: included pre- and post-meal images, a fiducial marker, and a text descriptor and collected diet records on 2 weekdays and 1 weekend day. Dietary intake was recorded on average for 3.2 (SD 1.3 days; 68% weekdays and 32% weekend days) with an average of 2.2 (SD 1.1) eating events per day per participant. A total of 143 eating events were recorded, of which 109 had at least one associated image and 34 were recorded with text only. Of the 109 eating events with images, 66 included all foods, beverages and a fiducial marker and 44 included both a pre- and post-meal image. Text was included with 78 of the captured images. Of the meals recorded, 36, 33, 35, and 39 were breakfasts, lunches, dinners, and snacks, respectively.

Conclusions: These data suggest that mobile devices equipped with an app to record dietary intake will be used by adolescents in a free-living environment; however, a minority of participants followed all directions. User-friendly mobile food record apps may increase participant amenability, increasing our understanding of adolescent dietary intake and eating patterns. To improve data collection, the FRapp should deliver prompts for tasks, such as capturing images before and after each eating event, including the fiducial marker in the image, providing complete and accurate text information, and ensuring all eating events are recorded and should be customizable to individuals and to different situations.

Trial Registration: Clinicaltrials.gov NCT01803997. http://clinicaltrials.gov/ct2/show/NCT01803997 (Archived at: http://www.webcitation.org/6WiV1vxoR).

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KEYWORDS

adolescents; dietary food records; smartphone app; dietary assessment; food record app

Introduction

Assessing dietary intake accurately is imperative to understanding the impact it has on health risk and developing intervention programs. Unfortunately, obtaining dietary intake records from adolescents is difficult at best, as their eating behaviors are influenced by a complex interaction of sociological, psychological, and biological factors [1-3]. Self-image, sporadic eating (meal skipping, random snacking, school events that interfere with scheduled meals), frequently eating outside the home, and the complexity of our food supply add to the difficulty of obtaining an accurate assessment of adolescent dietary intake [1,4,5]. More importantly, Goodwin et al [6] reported adolescents as being reluctant to record their dietary intake via the traditional pen and paper method, especially around peers, "for fear of what they would say." Furthermore, these adolescents were reported as saying that they would alter what they ate to simplify their dietary recording.

Mobile technologies are emerging as a valuable tool to assist in the collection and assessment of dietary intake [7-17]. Approximately 75% of American adolescents carry some form of mobile technology on their person at all times (eg, iPod, mobile phone); hence a mobile youth culture has emerged [18]. Compared to adults, adolescents are more confident and efficient at using mobile technologies and have expressed a preference toward assessment methods that use technology [7,8]. Accordingly, employing readily available technology that is incorporated easily into their lifestyle may help involve adolescents in dietary intake assessment and increase reporting amenability and accuracy. Indeed, when asked to capture images of foods consumed for one day, adolescents (11-15 years) went so far as to capture images of single food items [7].

Methodological advancements have been made in image-based dietary assessment tools that use mobile telephone native technologies (eg, camera, Wi-Fi). With images of foods, beverages, and a standard reference object of known size (fiducial marker) captured before and after an eating event, portion sizes can be estimated and completeness of the record can be evaluated by trained individuals and computer programs, providing a more accurate assessment of dietary intake [9,12]. In adolescents, mobile technologies have been used under controlled conditions to aid in method development and to determine user proficiency [7-9,13]. Therefore, we sought to determine the amenability of adolescents, in a free-living environment, to use a mobile phone food record app (FRapp) to record their dietary intake.

Methods

Participants

We collected data from a convenience sample of healthy, community-dwelling adolescents (n=18) participating in an after school program. The only inclusion criterion was grade level (6th, 7th, or 8th); there were no exclusion criteria. The project was approved by the Institutional Review Board of the University of North Dakota. Written informed assent and consent were obtained prior to participation from the adolescent participants and their parents, respectively. Participants were recruited during an open house at a local middle school. School administrators approved of the project and students were given permission to use the study mobile phones during school. Participants were instructed to continue all regular activities of daily living and maintain their usual diet. Height was measured in duplicate to the nearest 0.1 cm using a stadiometer. Body weight was measured using a calibrated digital scale to the nearest 0.1 kg. Parents and participants completed a demographic form regarding race, ethnicity, birth date, age, sex, and number of people living in the household. The participants also were asked their grade level.

Experimental Protocol

Participants were assigned a mobile phone (Motorola Defy, Motorola Mobility LLC.) with the FRapp (ActiPal; MEI Research, LTD) installed. Mobile phones did not have active cellular contracts to ensure compliance with school regulations but had internet access when Wi-Fi was available. We asked parents to not involve themselves when their child recorded dietary intake because we wanted to determine the quality and quantity of data that the adolescent would provide.

Participants received a one-on-one demonstration on how to use the FRapp, including where to place the fiducial marker and how to hold the mobile phone when capturing images to achieve the requested 45° angle. A fiducial marker is needed in all captured images to serve as a size reference. The fiducial marker was 2 inches by 1 inch and printed on standard white paper (Figure 1). Participants practiced capturing images of simulated food items and entering text descriptions until they were comfortable using the FRapp. Participants were asked to capture before and after images of all foods and beverages consumed, along with the supplied fiducial marker (Figure 2) and to enter text descriptions that provided as much detail as possible about the foods and beverages consumed using the FRapp for 3-7 days, ensuring that at least 2 of the days were during the week and 1 was a weekend day. Text descriptions were to include descriptors (eg, 2% milk, low-fat yogurt) and estimated amounts (eg, 1 carton, 2 cups, 3 ounces). When at home, participants were asked to measure the amount of food they were planning on eating using kitchen scales and measuring implements if possible (kitchen scales and measuring implements were not provided).

Figure 1. Fiducial marker.

Figure 2. Fiducial marker with food.

Food Record App

The FRapp was designed for natural settings using smartphone technologies. Unlike previous apps and single-purpose electronic devices to record dietary intake [7,9,10,13,17,19], the FRapp integrated not only the camera function but also text entry, prompts predefined for eating occasions (eg, breakfast, lunch, dinner, snack), and real-time communication between user and clinician/researcher (when connected via cellular contract or Wi-Fi, not used in this study). It is important to note that the FRapp could be used in numerous ways. There are six dietary intake input methods that can be enabled within the FRapp by the investigator: (1) capturing and annotating meal images, (2) typing in free text food descriptors, (3) speech-to-text conversions with food item extraction, (4) record voice for later playback, (5) capturing food label/nutrition facts/barcode photos, and (6) selecting from recently consumed food sets. These input methods can be used singly or in combination by participants [20]. For this study, we employed capturing and annotating meal images and typing in free text food descriptors. We felt that using only two input methods would minimize any participant apprehension and increase amenability to using the FRapp.

Food Record Input

The FRapp guided participants through the process we configured to enter their daily dietary intake. When the FRapp was first opened, the participant was asked if they wanted to Add Food to a Meal, Take a Picture, or View History (Figure 3). During the practice session, participants were shown how to select the Take a Picture option. After selecting this option, the FRapp required the participant to select a meal occasion. After the participant selected breakfast, lunch, dinner or snack (Figure 4), the camera function initiated automatically. We instructed the participants to hold the phone at a 45° angle and to confirm that all foods and beverages plus the supplied fiducial marker were visible on the mobile phone screen before capturing the image. If the fiducial marker was not available (left at home or misplaced), the participants were instructed to use an object of a known/predictable size (eg, coin, ballpoint pen). The image then was displayed for review and the user was given the choice to retake, cancel, or save the current image (Figure 5). Each participant was asked to verify again that all items were captured in the image before saving. The participants were allowed to retake images as many times as needed. Once the participants were satisfied with the images, they pressed Save and the image was time-stamped and securely uploaded to a data storage server to be viewed in real-time (when connected via cellular contract or Wi-Fi) or analyzed later. The image(s) was then displayed on the screen in the meal tab that had been chosen before the image was captured (Figure 6).

After capturing meal images, the participants were asked to record information about the food and beverage items. We instructed the participant to tap on the Add Item button at the bottom of the screen which would display a keyboard (Figure 7). The participant would then enter a description about each food and beverage item, including type (eg, 2% milk, Diet Sprite, light ranch dressing) and amount (eg, 1 cup, 1 can, 6 ounces). After annotating each item, the participant pressed Add and the text description was displayed under the captured image. The participant was asked to review all items and make any necessary corrections before pressing Submit. The images and food items were then shown under each meal tab (Figure 8). Participants were asked to capture an image of their eating utensils with any leftover food and beverage when they were finished eating. After capturing pre- and post-meal images and entering all text descriptions, the participant was asked to carefully review all items entered before pressing Done and exiting the FRapp. All data were uploaded to a secure data storage server and accessed through a management website (PiLR Healthware, MEI Research).

Figure 3. Initialization of the FRapp.

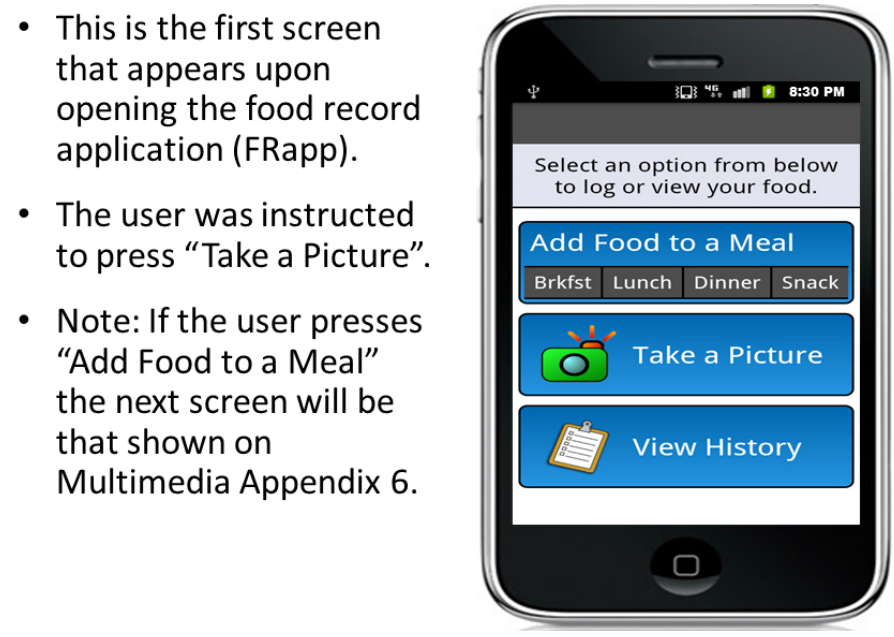

Figure 4. Identification of the eating event that is going to be recorded.

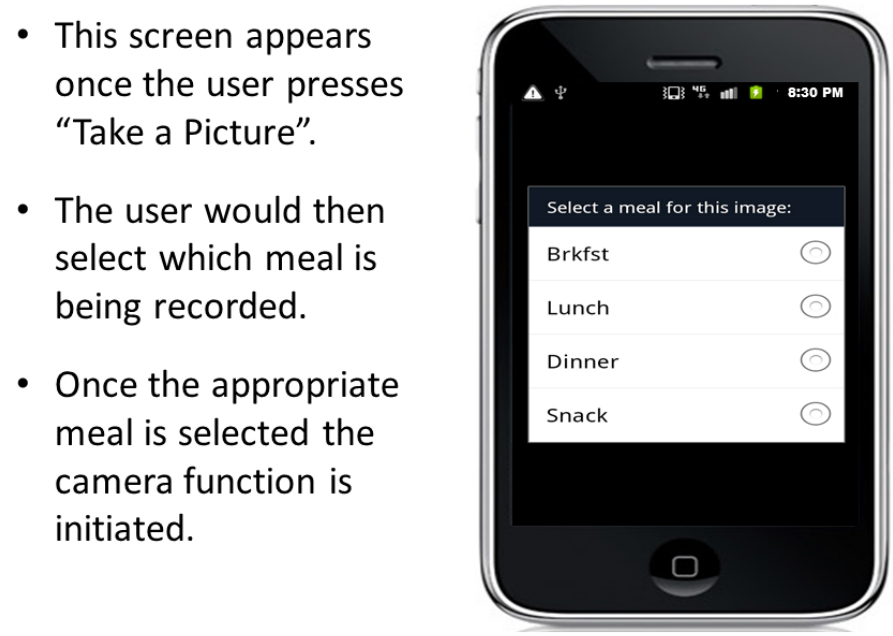

Figure 5. Using the camera function to digitally capture food and beverage images.

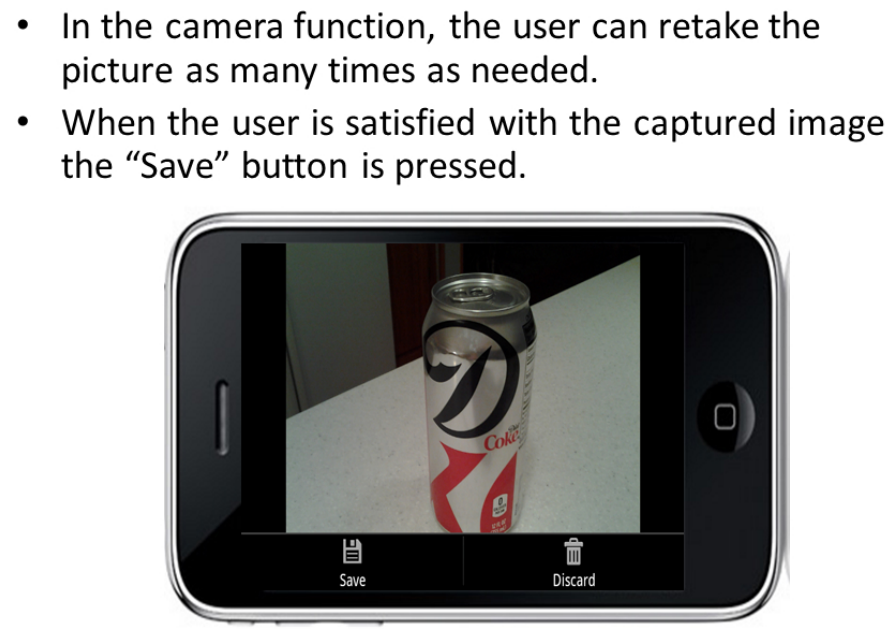

Figure 6. All images for the eating event are displayed.

- As each image is saved it is time stamped and appears in this screen.
- Additional images are captured by pressing “Photo”.
- Once all the images are captured the user would then press “Add Item”.
- Note: Pressing “Done” returns the FRapp to the initial screen.

Figure 7. Text entry of all food/beverage descriptions.

- This screen is used to add food and beverage descriptors.
- The user types a text description of their meal. If connected via cellular network or Wi-Fi the user can use voice record or voice-to-text.
- Once all text descriptions have been entered the user would press “Submit”.

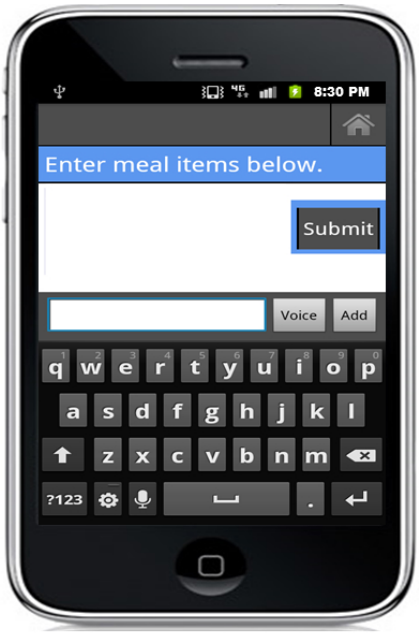

Figure 8. Display of everything entered for each eating event.

Image and Text Description Evaluation

Amenability was assessed by how well participants followed the instructions to capture meal images (ie, all foods, beverages, and a fiducial marker are shown in the image; pre- and post-meal images are captured), provide text descriptions, and record a minimum of 3 days of dietary intake (2 weekdays and 1 weekend day). Images were coded as pre-meal only if no post-meal image was captured, post-meal if no pre-meal image was captured, and pre/post if both images were captured. Images were then compared to corresponding text descriptions to determine if all items were included. Images were coded as complete if all foods and beverages available for consumption during the eating event, a fiducial marker, and the eating utensils were completely visible. Images were coded as incomplete if any item was missing or not completely visible. In addition, the image was coded as yes if a text description was provided or no if no text description was proved. If no image was captured, the text description was coded as text only.

Statistical Analysis

The numbers of captured images of meals and snacks along with text descriptions were evaluated with frequencies. A log-linear model was fit to the frequency counts to test whether the inclusion of a text description was associated with the completeness of the captured images or if post-meal images were captured. The Glimmix procedure in SAS V9.3 (SAS Institute, Inc.) was used to fit the models.

Results

Participant characteristics are presented in Table 1. Dietary intake was recorded on average for 3.2 (SD 1.3) days (68% weekdays and 32% weekend days) with an average of 2.2 (SD 1.1) eating events per day per participant. Twelve of the 18 participants collected dietary intake records for at least one meal on 3 or more separate days. Eight participants followed all directions, assuming that breakfast, lunch, or dinner meals with no data entry were not consumed by the participants, 3 recorded dietary intakes on 2 weekend days and 1 weekday, and 1 recorded dietary intake only on weekdays. Eight participants recorded an eating event for breakfast, lunch and dinner on the same day. It is not known if meals were skipped or if a participant forgot to record eating events. On weekdays the evening meal was the primary eating event with no recorded entry and on weekend days the morning and mid-day meals were the primary eating events with no recorded entry.

Table 1. Subject characteristics. Anthropometric data are presented as mean (SD). All other data are presented as the total number of participants for each category.

	Males (n=5)	Females (n=13)
Age, y	11.8 (1.1)	11.2 (0.7)
Weight, kg	45.4 (9.9)	57.7 (22.9)
Height, cm	150.2 (8.4)	154.0 (10.3)
Body mass index (BMI), kg/m^2	19.9 (2.6)	23.7 (7.1)
BMI, percentile		
≥95th		5
85th-94th	1	2
5th-84th	4	6
Race/ethnicity		
Non-Hispanic White	5	6
American Indian/Alaska Native		6
African American		1

A total of 143 eating events were recorded: 36, 33, 35, and 39 were breakfasts, lunches, dinners, and snacks, respectively. One participant recorded all eating events (10 total on 5 different days) as snacks. Images were captured for 109 eating events, and only a text description was provided for an additional 34. Of the 109 eating events with captured images, 23 included a pre- and post-meal image, a fiducial marker, and a text description. Table 2 summarizes the recorded eating events.

Of the 109 eating events with captured images, 66 of the images were coded as complete (all foods and beverages available for consumption during the eating event, a fiducial marker, and the eating utensils were completely visible). While the participants were provided with a fiducial marker, the instructions also stated that they could use a standard object of known/predictable size. Thirteen participants used the supplied fiducial marker for at least one eating event. The supplied fiducial marker was used for 36 eating events while an object of known size (for this study eyeglasses and click-top ballpoint pens) were used for 30 eating events coded as complete.

Participants had difficulties remembering to capture a post-meal image. Of the 109 eating events with captured images, only 44 post-meal images were captured. When asked, participants simply stated that they forgot or that they didn't think we wanted a picture of a dirty plate. Notably, when a post-meal image was captured, 32 included a complete place setting with a fiducial marker.

Thirteen participants provided text descriptors although only 5 attempted to report the amount consumed. A greater (P<.001) number of eating events included a text description than did not. Text was provided for a total of 112 eating events of which 78 were paired with a captured image.

For this project only 3 participants recorded eating events only at home, whereas 15 recorded a total of 28 eating events outside the home. Ten participants recorded eating events outside the home only at school, 3 recorded eating events outside the home only at restaurants/fast-food establishments, and 2 recorded eating events outside the home at both school and restaurants/fast-food establishments. Of the 28 eating events outside the home, 21 (75%) were recorded at school (5 breakfasts and 16 lunches) and 7 (25%) were recorded at a restaurant.

Table 2. Evaluation of the dietary intake records provided through FRapp usage.

Image	Completeness	Text included	Eating event (n=143) Breakfast n (%)	Lunch n (%)	Dinner n (%)	Snack n (%)
Pre/post-meal images captured	Complete	Yes	6 (4.2)	5 (3.5)	8 (5.6)	4 (2.8)
		No	4 (2.8)	3 (2.1)	0 (0.0)	0 (0.0)
	Incomplete	Yes	4 (2.8)	2 (1.4)	1 (0.7)	2 (1.4)
		No	1 (0.7)	2 (1.4)	2 (1.4)	1 (0.7)
Pre-meal only images captured	Complete	Yes	5 (3.5)	0 (0.0)	5 (3.5)	16 (11.2)
		No	4 (2.8)	2 (1.4)	1 (0.7)	3 (2.1)
	Incomplete	Yes	1 (0.7)	6 (4.2)	7 (4.9)	5 (3.5)
		No	2 (1.4)	2 (1.4)	0 (0.0)	3 (2.1)
Post-meal only images captured	Complete	Yes	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
		No	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Incomplete	Yes	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
		No	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)
None	Text only	Yes	9 (6.3)	9 (6.3)	11 (7.7)	5 (3.5)

Discussion

Principal Findings

Our goal was to determine the amenability of adolescents, in a free-living environment with minimal parental input, to use the FRapp to record their dietary intake. The data from this study support the use of a FRapp to assist in the collection of adolescent dietary intake records, as the adolescents did a reasonable job of following instructions to capture meal images, provide text descriptions, and record a minimum of 3 days of dietary intake.

Any tool that provides a simple means to improve adolescent amenability with collecting dietary information without changing usual eating behaviors is an important advance. Compared to the traditional pen and paper method of collecting dietary intake records, the utilization of captured images provides similar [9] or improved reporting accuracy [19] in children and adolescents under controlled, supervised conditions in the home setting. In a study by Higgins et al [9], 50% of the participants provided a complete 3-day photographic food record while the other 50% had missing images (ie, no images or missing either the pre- or post-meal image). Nonetheless, they reported no difference in energy intake between photographic food records and a 3-day food diary. In a study by Svensson et al, participants captured images for 65% of their recorded foods using a digital camera, resulting in a more accurate estimate of dietary intake (24% underestimation of energy intake) [19] compared to the traditional pen and paper food record alone (35% and 41% underestimation of energy intake) [21,22]. It is important to note that in these 2 studies parents played a significant role in recording the adolescent's dietary intake, and the captured images were used to assist in preparing traditional pen and paper dietary intake records [9,19]. Unique from previous studies, the FRapp was used as a standalone tool for the collection of dietary intake with minimal parental input. Adolescents have great autonomy of use of cell phones so this study was designed to test their amenability to use a FRapp without parent supervision and in a less controlled free-living environment. Dietary intake information was collected on 143 eating events with 44% of the participants recording dietary intake for the standard 2 weekdays and 1 weekend day and an additional 17% recording dietary intakes on 2 weekend days and 1 weekday.

A primary concern with using mobile technologies to record adolescent dietary intake is capturing all dietary intake. For the current project, dietary intake was recorded on average for 2.2 (SD 1.1) eating events per day per participant. It is important to determine whether meals were skipped or the participant forgot to record an eating event. To address the issue of low report rates while attempting to keep participant burden low,

an additional prompt will be added to the FRapp. Upon initializing the FRapp, the participant would be asked "Did you eat and/or drink anything since your last entry at [time] on [date]?" The participant would have to answer yes or no before the FRapp would progress to the next screen. If the participant answers yes, the keyboard will be displayed for the participant to record a description about each meal for which they forgot to capture images (when connected via an active calling plan or Wi-Fi, voice recording or voice-to-text could be used). This prompt would elicit participant recall and possibly reduce the number of eating events not being recorded due to forgetfulness.

Another concern with using mobile technologies to record adolescent dietary intake is capturing both a pre-meal image that includes all foods and beverages and a post-meal image showing what was consumed. This includes capturing before and after images for all additional food servings (second and third helpings). Without these images, dietary intake cannot accurately be determined. In the current project, the majority (61%) of images captured included all foods and beverages that were known to be consumed during that particular eating event. Nonetheless, remembering to capture a post-meal image was problematic. These results are in line with previous reports [8,13] and support the need for delivery of triggers and prompts to remind participants to capture images before and after each meal. One example of an automated trigger is a simple timing function that would initiate a sound and/or vibration after a specified duration following an event [23]. The timing of the trigger would be customized to each participant.

A concern in evaluating adolescents' electronic dietary food intake images is the inclusion of a fiducial marker [8,13]. Daugherty, et al [8] found that a large fiducial maker (approximately 4× 4 inches) was difficult to include without being partially concealed. Six, et al [13] found that adolescents had a difficult time including a USB flash drive-sized fiducial marker. In both studies adolescents stated that a marker the size of a credit card might be easier to carry and use. To address this issue we supplied a fiducial marker (Figure 1) that would adhere to the back of the smartphone and be easily removed and reapplied to decrease the burden of carrying an additional item and to serve as a reminder to include the marker in the image. We found that 13 of the 18 participants used the supplied fiducial marker. Overall, 61% of the captured images included a marker that could be easily used to estimate portion sizes. Designing a fiducial marker that is easily remembered and used by adolescents remains an important consideration. A notification that appears on the screen asking the participant if the marker is in place before allowing the image to be captured may be helpful to ensure that a marker is included in every captured image. Perhaps a more viable solution for adolescents would be an electronic fiducial marker that is applied automatically when the camera function is active. The camera pixels subtended by an object would then be used to register size, thereby forgoing the need to remember to include an external fiducial marker in the image.

While captured images increase the accuracy of estimated portion sizes [11], identification of some food and beverage items (eg, mineral water vs a clear sugary carbonated beverage, different brands and types of cooked cereals, condiments on a sandwich) proved to be challenging. Participants were asked to provide a text description of all food and beverage items to be consumed, including amounts, to avoid misinterpretation of the items in the captured images. Text descriptions were then compared to the accompanied captured image. On several occasions the text descriptions were needed to identify the food item (eg, twice baked potatoes, Sprite). Furthermore, the text descriptions provided details on foods not visible in the image. While informative as to what was consumed, the text descriptions did not fully quantify the food item. Some participants recorded the number of food items consumed (ie, 2 chicken strips) but not the amount (ie, 4 oz. chicken strip, 2 tbsp. peanut butter on toast). In contrast, when only the text description was provided there was no way to determine the accuracy of the information. Therefore, using both images and text descriptions is necessary to optimize assessment of dietary intake.

Limitations

A limitation of the present study was the use of the FRapp as a stand-alone tool to collect adolescent dietary intake. Only 16% of recorded eating events using the FRapp included the necessary components of pre- and post-meal images, a fiducial marker, and text descriptions of the foods. Missed meal images cannot be recorded in retrospect; however, the information can be retrospectively recorded via text or by voice recording. Moreover, a live connection with study personnel would allow for real-time follow-up when data are missing. The use of set meal designations may have increased variability. For example, drinking a caloric beverage may not have been recorded because the participant did not consume it during a meal and may not have regarded it as a snack. This limitation would apply whether the recording method was electronic or the more traditional paper and pencil method. If researchers have no need to determine meal designation, the FRapp can be adapted to collect intake data without a meal designation. A follow-up interview by trained staff is a valuable methodological addition to increase the likelihood of collecting complete and accurate dietary intake from all age groups. Nevertheless, capturing meal images, either pre-meal only or pre- and post-meal, will offer an additional source of dietary intake verification and strengthen records.

Conclusion

The FRapp was used by adolescents in a variety of settings, although they were not amenable to following all of the directions. Giving investigators and study participants flexibility to employ a dietary intake recording method that is most suited to their needs will maximize the accuracy, quality, and completeness of the data. In addition, when used with an active cellular contract or Wi-Fi, real-time monitoring by research or clinical staff can provide individual customized prompts (ie, text messages, emoticons) when items in the image are not fully visible, the image is blurred, or post-meal images have not been received within a specified time period. Results from this project provide direction for further mobile phone app development to maximize the quality and completeness of adolescent dietary intake records.

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Conflicts of Interest

JS and JM are employed by and receive salary through MEI Research Ltd.

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Abbreviations

FRapp: food record app

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Original Paper

Dose-Response Effects of the Text4baby Mobile Health Program: Randomized Controlled Trial

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Abstract

Background: Mobile health (mHealth) is growing rapidly, but more studies are needed on how to optimize programs, including optimal timing of messaging, dose of exposure, and value of interactive features. This study evaluates final outcomes of text4baby (a text message service for pregnant and postpartum women) from a randomized trial performed in a population of pregnant female soldiers and family members.

Objective: The study aims were to evaluate (1) treatment effects and (2) dose-response effects of text4baby on behavioral outcomes compared to control (no text4baby) condition.

Methods: The study was a randomized trial of text4baby at Madigan Army Medical Center. Female military health beneficiaries who met inclusion criteria were eligible for the study. Participants provided consent, completed a baseline questionnaire, and then were randomized to enroll in text4baby or not. They were followed up at 3 time points thereafter through delivery of their baby. Generalized estimating equation models were used to evaluate outcomes. We examined treatment effects and the effects of higher doses of text4baby messages on outcomes.

Results: We report descriptive statistics including dosage of text messages delivered. The main finding was a significant effect of high exposure to text4baby on self-reported alcohol consumption postpartum (OR 0.212, 95% CI 0.046-0.973, *P*=.046), as measured by the question “Since you found out about your pregnancy, have you consumed alcoholic beverages?” The text4baby participants also reported lower quantities of alcohol consumed postpartum.

Conclusions: Studies of text4baby have helped to build the mHealth evidence base. The effects of text4baby offer lessons for future scalable mHealth programs and suggest the need to study dose-response effects of these interventions.

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KEYWORDS

mobile health; prenatal health care; health communication

Introduction

Mobile health (mHealth), the use of mobile phones as a tool for health care treatment and public health behavior change, is a rapidly expanding field that has significant promise to improve public health and increase the effectiveness of disease prevention and health promotion programs [1-3]. Mobile phones are poised to be powerful tools to promote health in a number of domains and settings worldwide [4]. In particular, mHealth programs have proven effective in drug adherence, as patient reminder systems, and in some areas of areas of chronic disease management, prevention, and control [5,6]. Researchers from multiple disciplines, including population health, social sciences, computing, and engineering sciences are engaged in mHealth [1], and major government research sponsors including the National Institutes of Health and major private sponsors such as the Bill and Melinda Gates Foundation have initiatives in these areas [7-8].

Some of the best mHealth evidence comes from smoking cessation studies [9,10]. Free and colleagues [11] systematically reviewed the evidence on mHealth interventions and found that antiretroviral treatment (ART) and smoking cessation interventions had sufficient evidence of effectiveness to be considered for inclusion in health care services. The authors noted that the ART and smoking cessation studies exhibited no evidence of bias and had significant effects on reduced viral load (ART) and biochemically validated smoking cessation [11]. Abroms and colleagues designed and evaluated the text2quit intervention, which delivers text messages using a tailored feedback approach to promote smoking cessation, and found that 11.1% of former smokers who participated in the intervention remained abstinent after 6 months compared to 5.0% among the comparison group [12]. Whitaker and colleagues [13] specifically reviewed mobile phone-based cessation interventions and found them to be effective in long-term quitting outcomes.

Although the evidence from mobile phone studies is less conclusive in these areas, preliminary research has shown promise in delivering healthy eating and active living (HEAL) interventions. Patrick and colleagues [14] found that, compared to control, short message service (SMS) text messaging and multimedia message service (MMS) participants achieved 1.97 kg greater weight loss. A follow-up study among overweight men also found higher weight loss using Internet and mobile phone [15]. Hurling and colleagues [16] found that an Internet and mHealth intervention among overweight adults that included reminders produced more than 2 hours more physical activity (PA) per week compared to adults with no access. Joo and colleagues [17] found that weekly text messages about diet and PA behavior promoted weight loss. Additionally, there have been studies that used combinations of mobile phone and other new technologies for weight control and found positive effects [18]. A study of postpartum women employed a team approach to encourage women to use a Facebook app to promote PA [19].

Additionally, there is growing evidence that mHealth programs are effective in promoting diabetes self-management [20], as treatment adherence tools, and as reminder systems for health behavior and treatment [11]. Although the evidence for use of mobile phones beyond these areas is still emerging, the overall trend is that they can be effective tools for health promotion, disease prevention, and as adjunct treatment tools.

Interventions using mobile phones are growing worldwide, and some are achieving significant scale and population-level reach. As reported by the United Nations Foundation, Project Masiluleke in South Africa reaches 1 million people each day via mobile phone with human immunodeficiency virus (HIV) prevention, testing, and treatment information [21]. In Mozambique, mobile phones are used to link inventory, distributors, and marketers of socially marketed products, such as condoms and mosquito bed nets, to reach low income consumers [22].

Although the literature from rigorous studies of smoking cessation, treatment adherence, and some other chronic disease prevention and management studies show that mHealth programs can promote behavior change, more randomized controlled trials (RCTs) are needed [11]. There is also a need for more studies on what specific features and approaches in mHealth programs are most effective, including studies on the optimal timing of messaging, dose of exposure, and value of interactive feature [23].

The text4baby program is an example of scaled mHealth for behavior change [24](see Figure 1). The service launched in February 2010 and delivers text messages to pregnant women and new mothers. Since inception, it has enrolled more than 700,000 participants and is one of the largest public health text messaging programs in the United States. It consists of a library of prenatal and postpartum text messages delivered on a schedule timed to the baby's due date or birthdate [25]. It represents one of the largest mHealth text-based programs developed to date. Recent studies of the text4baby program have found that it changes attitudes and beliefs, but effects on behavior have not previously been established [23,26].

The text4baby program also offers an example of using behavioral theory to the design mHealth interventions [1]. The program applies and adapts Social Cognitive Theory, the Health Belief Model, and Diffusion of Innovation theory [27-29]. The program is branded as a "trusted friend and advisor" and promotes a broad range of maternal and child health behaviors [30]. Future mHealth interventions may build on these lessons to engage audiences in health programs through multiple digital channels [31,32].

The US military has made major investments in mHealth programs to promote health and improve treatment among enlisted personnel and their families [32]. Female service members and spouses of active duty soldiers are a group exposed to multiple stressors that may increase health risks during pregnancy [33-35]. These soldiers and family members could benefit significantly from mHealth programs such as text4baby because it is a free resource and is highly portable, permitting families to receive these messages anywhere in the world where text messages can be received.

The present study evaluates the final outcomes of text4baby from a randomized trial of pregnant female soldiers and family

members [23]. The study tested 2 primary hypotheses: (1) text4baby group participants would demonstrate increased health-promoting behaviors and decreased risk behaviors compared to control at postpartum follow-up and (2) text4baby participants would demonstrate a dose-response effect of receiving the text messages in which higher doses of text messages would produce greater behavioral outcomes.

Figure 1. Screenshot of You Have text4baby.

Methods

Design and Measures

As previously reported [23], the investigators conducted an RCT of text4baby prenatal messages at Madigan Army Medical Center (Madigan), a large tertiary-care Army Medical Center in Tacoma, Washington. Female military health care beneficiaries aged 18-45 years who first presented for prenatal care at Madigan prior to 14 weeks gestation were eligible for the study. Participants were also required to have a working cell phone, and speak and read English. Following medical consultation, the health care provider asked if the patient would be willing to participate in the research study and those who agreed underwent informed consent and then were offered the opportunity to complete a baseline survey on a secure computer in a private setting in the clinic. Follow-up data collection was conducted remotely primarily through a secure survey website [23].

After baseline survey completion, participants were assigned to the text4baby (plus usual care) or to control (usual care only) groups. We used an algorithm to generate randomized individual assignments to condition for each participant. After baseline, participants in both groups were surveyed again after 4 weeks, at 28 weeks of gestation, and at the time of first postpartum medical appointment. Data collection started in December 2011 and follow-up ended in January 2013. This study reports on analysis of the full dataset from baseline to postpartum follow-up. Detailed data collection procedures have been published elsewhere [23].

The survey instrument included 24 validated items on participant attitudes, beliefs, and behaviors related to the text messages contained in text4baby, which were repeated in the 4 surveys in this study as described in detail elsewhere [23]. Participants took an average of 12 minutes to complete the questionnaire. Follow-up participants answered additional questions on recall, reactions, and receptivity to the texts. Investigators separately obtained available demographic information from each participant's medical record. The study was approved as minimal risk research by the Madigan Institutional Review Board (IRB) on July 26, 2011. The George Washington University approved this study under an institutional agreement with the Department of Defense (DOD) Human Research Protection Program on August 1, 2011.

Intervention

Participants assigned to the control condition were excused immediately after completing the baseline survey. The on-site study coordinator assisted treatment participants in enrolling in text4baby by texting "DODBABY" to a designated SMS short code that tagged them as participants in the study. Voxiva, the information technology firm that delivers the text4baby messages and maintains data provided by participants on enrollment, maintained records to identify participants as members of the Madigan study. More information on Voxiva and text4baby has been published elsewhere [24]. Only text4baby participants who were enrolled in the Madigan study were counted in our treatment group. We monitored the control group to ensure that none of these participants separately enrolled for text4baby (none did).

Voxiva collected data on all text4baby participants through enrollment and follow-up service contacts [36]. As noted, we received information on enrollment and service end dates, and from those data determined the number of texts delivered to participants as part of the Madigan study. This was covered under a data use agreement (DUA) between the Department of Defense, National Healthy Mothers, Healthy Babies (HMHB) Coalition, Voxiva, and The George Washington University. HMHB and Voxiva, joint owners of the text4baby service, did not have access to any data collected through the study or any patient information stored at Madigan. Participants in the study received 3 text messages per week throughout their enrollment, which were tailored to the date of enrollment and gestational age. Slight modifications to the standard text4baby messages were made due to specific health care resources (eg, toll-free numbers for prenatal health information) available to military women [23,25]. The standard text4baby message libraries are summarized on the text4baby website [37].

If a fetal loss occurred at any time during the pregnancy, patients were disenrolled from text4baby and appropriate perinatal grief counseling was offered to the patient and her partner. Patients were also provided the option to disenroll from text4baby by texting "STOP" from their mobile phones if they no longer wanted to participate in the program.

Sampling

As detailed elsewhere, the sampling frame consisted of all female military health care beneficiaries first presenting for initial prenatal care at Madigan. We drew a random sample of all women meeting criteria at the Madigan Obstetrics and Gynecology Clinic between December 2011 and January 2013. Recruitment took place over this time period until the targeted sample was reached. Follow-up data collection began in January 2012 and was completed by September 2013. Previous interventions to promote reproductive health care utilization among low- and middle-income women suggested an approximate 12% effect (intervention vs control) of such programs after a 12-month time period [38]. Power analysis estimated the required sample to be 996 participants in total assuming a 10% attrition rate at postpartum follow-up.

Data Collection Procedures

Investigators held an introductory meeting and training session on the study protocol with clinical staff at Madigan in November 2011. Surveys were self-administered and baseline surveys were completed usually in clinic, with a small number completed remotely online. Follow-up surveys were primarily completed remotely online. We used several methods to address noncontact and noncooperation, including (1) text messages, (2) a local phone number for participants to call the investigators or a clinic nurse with questions, and (3) assurances of confidentiality. Reminder texts were sent 1 week before each follow-up survey prompting online or in-clinic survey completion. Participants were considered to have quit the study if they were unreachable after 7 recontact attempts, and no further follow-up attempts were made.

Data Analysis

Stata version 12 (StataCorp LP, College Station, TX, USA) was used in all analyses. Analyses were conducted from March 24 to June 13, 2014. Descriptive statistics including means, percentages, and standard deviations were calculated for all outcomes and demographic variables. Crosstabs of these same variables by study condition and survey time points were also calculated. Also, intervention exposure, as measured by estimated number of antepartum messages delivered and number of antepartum days enrolled in the messaging campaign, were assessed for all study participants in the intervention group. Based on the distribution of messages, investigators examined estimated dosage levels, dichotomized on whether a participant received lower or higher than median message exposure to messaging. Exposure was measured by an estimated count of total messages delivered to participants based on service enrollment and end dates validated by the Voxiva text4baby service database, which were linked to individuals and provided to the investigators under the DUA.

Generalized estimating equations (GEE) logistic regression was used to construct separate models for each of the attitudes, beliefs, and behavioral outcomes over the 3 follow-up periods, estimating population-attributable effects for treatment vs control groups, and high (more than the median message exposure of 224 days) vs lower intervention exposure. Investigators estimated the odds of change over time in response to each of the behavioral outcome variables as a function of text4baby text message exposure through use of an interaction term including program exposure and progression to follow-up measurement.

In addition to an unadjusted model, which strictly looked at the effect of the intervention on those who completed baseline and at least 1 follow-up interview (n=459), a second adjusted model included several maternal covariates: age quintile, parity, marital status, and race. For missing data and attrition of participants, a *t* test was used to compare covariates, including sociodemographic and other variables used in the regressions, between cases with and without missing data to verify whether or not data were missing completely at random. It was determined that both maternal race and marital status (both missing for 215/943, 22.7% of baseline participants) were potentially variables that were differentially missing for women of certain racial and marital statuses. Therefore, a multiple imputation model was constructed to account for missing race and marital status through use of a logit function with parity, age, and treatment status as predictors of both race and marital status.

A confirmatory factor analysis of related knowledge, attitudes, and beliefs (KABs) was also conducted to examine correlation in agreement and changes in agreement of beliefs. A factor loading criteria of 0.4 was used to determine whether to retain individual items in a single principal factor. Following widely accepted practice, Cronbach alpha of .6 was used to confirm interitem agreement for use of the factor in descriptive and regression analyses [39]. We found that 6 of the 9 KAB items formed a single factor. However, GEE models using the KAB factor did not show significant results and have not included those data.

Results

Of 1078 women who presented for care during the study period, 996 met criteria and were asked to participate (92.39%). Of these, 94.7% (943/996) completed a baseline survey. Among the baseline participants, 48.7% (459/943) completed a 4-week follow-up survey and 24.5% (231/943) completed a postpartum follow-up. A total of 6 participants discontinued text4baby during the follow-up period. Figure 2 depicts the CONSORT flow diagram for the study.

Table 1 provides the baseline sample characteristics. Overall, the sample was predominantly white (69.6%, 656/943), with a mean age of 26.5 (SD 74.4) years. Most (63.1%, 595/943) reported currently attending school or working outside of the home. A total of 70.3% (663/943) of the participants reported being married. Nearly half of the participants (47.8%, 451/943) reported having had a prior live birth. The vast majority of participants were enlisted service members or a dependent family member of an enlisted service member (86.8%, 819/943) and all but 4 of the remainder were commissioned or warrant officers (14.2%, 120/943).

Table 1. Baseline sample descriptive statistics (N=943).

Variables	Participants
Age (years), mean (SD)	943 (26.5)
Age range (years), n (%)	
<20	31 (3.3)
20-34	837 (88.8)
≥35	75 (7.9)
Race, n (%)	
White	656 (69.6)
Black	75 (7.9)
Asian-Pacific Islander	25 (2.6)
Western Hemisphere Indians	2 (0.2)
Other/unknown	185 (19.6)
Ethnicity, n (%)	
Filipino	206 (21.8)
Hispanic	53 (5.6)
Other Asian/Pacific Islander	19 (2.0)
Southeast Asian	6 (0.6)
Other/unknown/non-Hispanic	659 (69.9)
Marital status, n (%)	
Single/never married	72 (7.6)
Married	663 (70.3)
Separated/divorced/widowed	7 (0.7)
Unknown/null	201 (21.3)
Sponsor rank, n (%)	
Enlisted	819 (86.8)
Commissioned officers	107 (11.3)
Warrant officers	13 (1.4)
Other	4 (0.4)
Parity, n (%)	
No	492 (52.2)
Yes	451 (47.8)
Prepregnancy body mass index (BMI), mean (SD)	327 (27.2)
BMI category, n (%)	
Underweight	7 (0.7)
Normal	154 (16.4)
Overweight	97 (10.3)
Obese	63 (6.7)
Ever participated in WIC program, n (%)	320 (33.9)
Currently in school or working outside the home, n (%)	595 (63.1)
Ever gone online to search for prenatal care information, n (%)	711 (75.4)

Equivalence of means at baseline was tested by comparing the baseline treatment and control condition samples. The comparison revealed a larger, statistically significant percent reporting smoking in the last 30 days: 15.3% (95% CI 12.08-18.58) in the control vs 9.6% (95% CI 6.95-12.32, P=.048) in the treatment group, respectively. There was also a

larger, statistically significant percentage who reported consuming 3 or more vegetables per day in the control vs treatment group: 37.8% (95% CI 33.44-42.19) in control vs 30.0% (95% CI 25.81-34.15, *P*=.046) in the treatment group, respectively.

As noted, we obtained data on the number and timing of text messages delivered to the text4baby participants. Three text messages were delivered per week at random times during waking hours on weekdays. We identified the week of pregnancy in which participants enrolled using the assumption of a 40-week gestation period and subtracting the total number of days between the participant's date of enrollment and due date recorded by the study site. Using this calculation, we identified the number of messages delivered to each participant during the study period. This calculated variable was used for the GEE dose-response models. Table 2 displays a summary of the mean messages delivered to participants based on the calculated variable, standard deviation, and range of estimated total text messages delivered.

Table 2. Summary of pregnancy text4baby text messages delivered (n=192).

Text message delivery variables	Mean (SD)	Range
Total number of messages sent	61.3 (43.2)	10-151
Week of pregnancy when enrolled	8.1 (1.9)	4-14
Weeks in pregnancy protocol	12.6 (10.9)	0-33.7

Table 3 presents results of unadjusted and adjusted versions of the first set of GEE models. In these models, we examined the effects of text4baby participation (treatment condition) on postpartum KAB and behavioral outcomes targeted by the text messages. No significant effects of text4baby were observed in these models.

Table 3. Adjusted and unadjusted GEE models comparing treatment (text4baby group) and control (no text4baby enrollment).

Questionnaire items	Treatment vs control			
	Unadjusted		Adjusted[a]	
	OR (95% CI)	*P*	OR (95% CI)	*P*
KAB items				
Eating 5 or more fruits and vegetables per day is important to the health of my developing baby	1.781 (0.409, 7.760)	.44	2.261 (0.400, 12.787)	.36
Taking a prenatal vitamin is important to the health of my developing baby	2.931 (0.463, 18.551)	.25	1.512 (0.162, 14.092)	.72
I am prepared to be a new mother	0.923 (0.563, 1.514)	.75	0.976 (0.495, 1.924)	.94
If I visit my health care provider on a regular basis, I will be a healthy new mother	1.016 (0.666, 1.549)	.94	0.759 (0.461, 1.251)	.28
If I visit my health care provider on a regular basis, my baby will be healthy	1.188 (0.771, 1.829)	.43	0.949 (0.595, 1.513)	.83
Smoking will harm the health of my developing baby	0.880 (0.583, 1.328)	.54	0.753 (0.473, 1.198)	.23
Secondhand smoke will not harm the health of my developing baby (reverse coded)	1.189 (0.944, 1.497)	.14	0.978 (0.715, 1.336)	.89
Drinking alcohol will harm the health of my developing baby	1.018 (0.619, 1.675)	.94	1.253 (0.717, 2.188)	.43
Taking prenatal vitamins will improve the health of my developing baby	0.943 (0.722, 1.233)	.67	0.709 (0.488, 1.030)	.07
Behaviors				
Since you found out about your pregnancy, have you consumed alcoholic beverages?	0.699 (0.293, 1.665)	.43	2.310 (0.491, 10.874)	.29
In the last 30 days, did you smoke?	0.927 (0.533, 1.615)	.79	0.938 (0.318, 2.770)	.91
Ate 3 or more servings of fruit a day	1.160 (0.924, 1.456)	.20	1.107 (0.835, 1.468)	.48
Ate 3 or more servings of vegetables a day	1.065 (0.846, 1.339)	.59	1.042 (0.755, 1.438)	.80
Have you ever gone online to search for prenatal care information?	0.853 (0.584, 1.246)	.41	0.822 (0.476, 1.420)	.48

[a] Adjusted for age, parity, imputed marital status, and race.

Table 4 presents results of unadjusted and adjusted versions of the second set of GEE models. In these models, we examined the effects of high vs low dosage of text4baby, as measured by a median split variable in which the top 50% of the distribution

of text message exposure among text4baby intervention participants was compared to the bottom half among that same group. In these models, we found a significant effect of text4baby on self-reported alcohol consumption postpartum (OR 0.212, 95% CI 0.046-0.973, *P*=.046), as measured by the question "Since you found out about your pregnancy, have you consumed alcoholic beverages?" The lower OR indicates lower odds of consuming alcoholic beverages at postpartum follow-up.

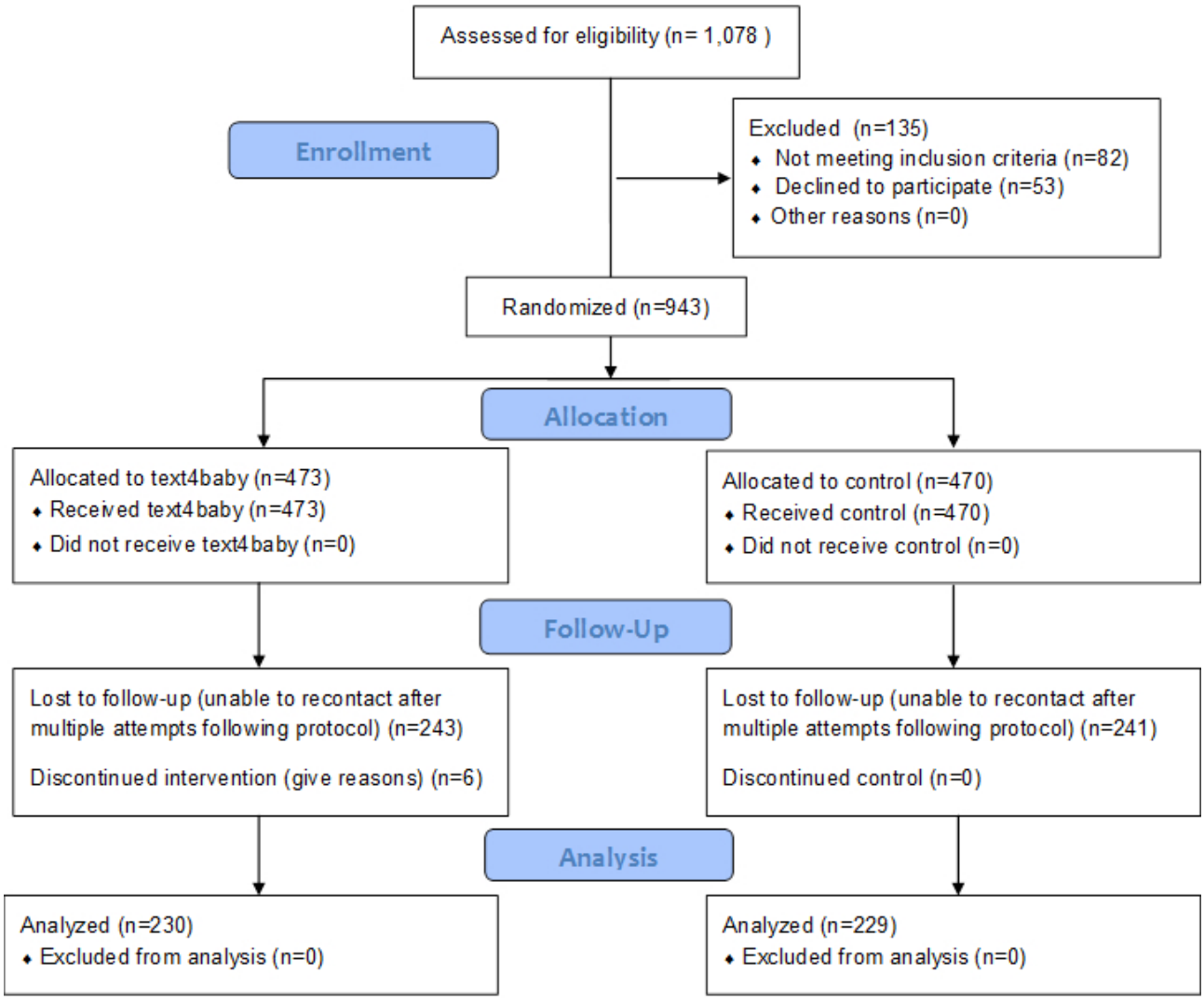
Table 4. Comparison of high and low exposure to text4baby messages: adjusted and unadjusted GEE models.

Questionnaire items	High vs low exposure			
	Unadjusted		Adjusted[a]	
	OR (95% CI)	*P*	OR (95% CI)	*P*
Eating 5 or more fruits and vegetables per day is important to the health of my developing baby	0.744 (0.138, 4.003)	.73	2.511 (0.158, 39.867)	.51
Taking a prenatal vitamin is important to the health of my developing baby	0.760 (0.115, 5.000)	.77	4.216 (0.201, 88.417)	.35
I am prepared to be a new mother	1.471 (0.788, 2.746)	.22	1.609 (0.607, 4.268)	.34
If I visit my health care provider on a regular basis, I will be a healthy new mother	1.033 (0.607, 1.759)	.90	1.288 (0.585, 2.834)	.53
If I visit my health care provider on a regular basis, my baby will be healthy	0.783 (0.468, 1.313)	.35	1.328 (0.737, 2.393)	.34
Smoking will harm the health of my developing baby	1.139 (0.717, 1.810)	.58	1.236 (0.651, 2.350)	.52
Secondhand smoke will not harm the health of my developing baby (reverse coded*)	0.892 (0.668, 1.193)	.44	0.947 (0.631, 1.423)	.79
Drinking alcohol will harm the health of my developing baby	1.088 (0.655, 1.808)	.74	0.803 (0.451, 1.431)	.45
Taking prenatal vitamins will improve the health of my developing baby	1.090 (0.782, 1.520)	.61	1.378 (0.861, 2.204)	.18
Behaviors				
Since you found out about your pregnancy, have you consumed alcoholic beverages?	1.344 (0.473, 3.820)	.58	0.212 (0.046, 0.973)	.046
In the last 30 days, did you smoke?	0.938 (0.490, 1.794)	.85	1.271 (0.406, 3.980)	.68
Ate 3 or more servings of fruit a day	0.852 (0.647, 1.122)	.25	0.908 (0.649, 1.271)	.57
Ate 3 or more servings of vegetables a day	0.889 (0.679, 1.164)	.39	0.969 (0.673, 1.394)	.86
Have you ever gone online to search for prenatal care information?	0.992 (0.661, 1.488)	.97	0.893 (0.519, 1.536)	.68

[a] Adjusted for age (quintile), parity, imputed marital status, and race.

Additionally, if participants answered yes to having consumed alcoholic beverages, we asked them "How many drinks do you normally drink per day." At baseline, 97.3% (918/943) of all participants reported zero drinks per day and this rate remained fairly constant at 97.6% (448/459) at the first follow-up, with no differences between study conditions. At the postpartum follow-up, the overall rate declined to 55.4% (128/231). However, of the 128 respondents who indicated zero drinks per day, only 51 (40%) of them were in the control group and 77 (60%) in text4baby.

Figure 2. Madigan text4baby CONSORT flow diagram.



Discussion

The text4baby program is significant in that it represents one of the largest worldwide mHealth programs to date, with more than 800,000 enrollees from inception in February 2010 through November 2014 [40]. To date, there have been very few large-scale mHealth programs shown to be effective. The future of mHealth will include going beyond small-scale pilots and trials and reaching population-level effects through large-scale implementation.

This study is significant for at least 3 reasons. First, it provides a randomized trial of text4baby with a large sample over the full course of the prenatal texting module. The Madigan study was ambitious in that it followed a baseline sample of nearly 1000 women for a total study period of nearly 2 years. Second, it provides one of the most comprehensive studies to date evaluating the effect of mHealth on the health of pregnant military female soldiers and family members. As noted, military women's health is an understudied topic and the multiple stressors that they face compared to civilian women suggest that it deserves greater attention from mHealth and other health studies [34,41]. Third, the study demonstrates a behavioral effect of text4baby among high-exposure users. Previous studies demonstrated short-term effects on KAB among participants, including the initial outcomes of the Madigan study [23,26]. However, until these results, no behavioral effects had been observed. We found that among the subgroup of high-exposure participants, text4baby had a positive effect on reducing alcohol use behavior of pregnant and postpartum women.

Specifically, we disconfirmed our first hypothesis that there was no direct treatment effect of text4baby. The GEE models to estimate treatment effects on measured outcomes did not demonstrate any significant postpartum text4baby participation effects on health-promoting behaviors. However, we confirmed our second hypothesis that there was a dose-response effect of text4baby, with higher levels of text message exposure predicting lower self-reported alcohol consumption. This was an important focus of text4baby messages, including both recommendations not to drink and also warnings about the health risks of fetal alcohol syndrome for unborn babies. Our results show that dosage was a predictor of lower alcohol consumption response. Although self-reported alcohol consumption would be expected to be lower after pregnancy given social cues and available information about health risks for all participants, the dose-response effect among text4baby participants was pronounced, as high-dose participants were

more than twice as likely to abstain from drinking compared to low-dose participants. The brief, text-based intervention format of text4baby is consistent with other brief prenatal alcohol interventions found to be effective in recent studies [42].

Moreover, descriptive analysis showed that the quantity of drinking was lower among text4baby participants postpartum. In total, there were 6 messages related to risks of alcohol consumption, spread over the intervention period, among the pregnancy messages delivered. Although this is not a large number of total messages, it is worth noting that they reinforce information women are already receiving from other sources regarding avoiding alcohol use. These data suggest that dosage of texts received regarding risks of alcohol use, which included messages regarding risks due to alcohol while breastfeeding, had a cumulative effective.

There are several implications of the Madigan study and text4baby for future mHealth interventions and research. First, text4baby is a broad, relatively "low-touch" intervention. The program addresses a wide range of health topics, as compared to other studies that focused on 1 or a few closely related health behaviors. It does not include substantial participant investment of time and effort, or interactivity. However, initial short-term findings demonstrated multiple KAB effects [23], and this study demonstrated a behavioral effect on alcohol use. Broad, low-touch interventions can be effective and given low participant burden should be considered as scalable program options.

There is a need to understand optimal levels of dosage and other factors that affect mHealth intervention outcomes. It is important to recognize that many individuals who use text messages receive large numbers of texts per day. We did not have measures of total texts or potentially competing messages received by participants in this study, and those are important topics for future research.

Delivering high doses of mHealth interventions has implications in terms of cost, participant burden, and potential "wear out" effects (ie, overexposure). Thus, identifying optimal mHealth dosages could have potential major benefits for future programs in terms of cost effectiveness and outcomes. Although this study does not indicate an optimal dose, it suggests the need to understand dosage thresholds and delivery methods.

Future research should include more discrete and refined dosage and other optimization studies. For example, studies have examined point-of-decision prompts to increase exercise and nutrition [43], and use of mobile technologies for health interventions [11,44], but no study has combined both. Text messaging interventions can do much more than simply deliver text reminders—they can deliver right into the hands of highly targeted population the public service announcements that in years past would have appeared in mass media [45]. Future interventions can tailor text message and other mHealth message content (eg, through social media or apps) both to a specific target audience and to an optimal time for delivery. By getting messages to a specific population group when they are at risk of engaging in unhealthy behavior (eg, teens watching TV, being exposed to junk food advertising, being sedentary and snacking at times such as after school or on weekends), interventions can influence them at the optimal time [46,47].

There are 2 important limitations of this study. First, we had a low follow-up rate and, thus, used imputation techniques to support the analysis. As a result, the study may be underpowered. Despite this fact, the overall direction of results was consistent with previous text4baby studies and additionally we found a behavioral effect. Much of the attrition was attributable to redeployments and, thus, lack of access to participants at the Madigan clinic. Second, although we observed dosage effects, we are only able to conclude that higher levels of text messages had an effect on alcohol use. This leaves the important question of exact dosage and timing of delivery requirements for future studies.

Studies of text4baby have helped establish and expand the mHealth evidence base. The demonstrated KAB and behavioral effects of this broad, low-touch program offers lessons for future scalable mHealth efforts. The dose-response effects observed here suggest the need to study methods to evaluate exposure and achieve optimal dosage effects in future research. Program dosage and optimization research should be included to address other features of the mobile phone, such as ubiquity, constant use, and potential to act as a point of decision prompt.

Conflicts of Interest

None declared.

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Abbreviations

ART: antiretroviral treatment
BMI: body mass index
DOD: Department of Defense
DUA: data use agreement
GEE: generalized estimating equation
HEAL: healthy eating and active living
HIV: human immunodeficiency virus

HMHB: Healthy Mothers, Healthy Babies Coalition
IRB: Institutional Review Board
MMS: multimedia message service
PA: physical activity
RCT: randomized controlled trials
SMS: short message service

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Original Paper

Effectiveness of 6 Months of Tailored Text Message Reminders for Obese Male Participants in a Worksite Weight Loss Program: Randomized Controlled Trial

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Abstract

Background: Worksite nutrition and physical activity interventions are important to help overweight and obese employees lose weight, but costs and insufficient sustained motivation prevent the majority of these programs from succeeding. Tailored text messaging in aiding weight management has been effective in several studies, but no studies have evaluated the effect of a tailored text message service on weight loss in a worksite health promotion program.

Objective: We studied the efficacy of a tailored text-messaging intervention for obese male participants in a worksite weight loss program of 6 months duration.

Methods: The study was an unblinded, randomized controlled trial. Men with a body mass index greater than 25 kg/m^2 were recruited from the Korea District Heating Corporation, the Korea Expressway Corporation, and the Korea Gas Corporation. The participants were identified by nurse managers. Participants were randomly allocated to 1 of the following 2 groups for 24 weeks: (1) intervention group, which received tailored text message reminders every other day plus 4 offline education sessions and brief counseling with monthly weight check by nurses for weight control over 6 months and (2) control group, which received the 4 offline education sessions and brief counseling with monthly weight check by nurses about weight control over 6 months. The primary outcome was the difference in weight loss at 6 months. A mixed-model repeated-measures analysis was performed to evaluate the effect of the intervention group's weight loss compared with the control group.

Results: A total of 205 obese men were randomized into either the intervention (n=104) or the control group (n=101). At the end of 6 months, the intervention group (n=63) had lost 1.71 kg (95% CI –2.53 to –0.88) and the control group (n=59) had lost 1.56 kg (95% CI –2.45 to –0.66); the difference between the 2 groups was not significant (mean difference –0.15, 95% CI –1.36 to 1.07). At the end of the study, 60% (34/57) of the intervention group rated the message program as helpful for weight control and 46% (26/57) would recommend the text message service to their friends.

Conclusions: Tailored text message reminders did not have a significant effect on weight loss in obese men as part of a worksite weight loss program.

Trial Registration: International Standard Randomized Controlled Trial Number (ISRCTN): 39629189; http://www.isrctn.com/ISRCTN39629189?q=39629189&filters=&sort=&offset=1&totalResults=1&page=1&pageSize=10&searchType=basic-search (Archived by WebCite at http://www.webcitation.org/6VsFkwJH6).

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KEYWORDS

weight reduction program; text messaging; worksite; health promotion

Introduction

Obesity is an important and modifiable risk factor for many of the leading causes of death worldwide, such as myocardial infarction, stroke, and obesity-related cancers [1,2]. Obesity also has negative effects on work performance and increases absenteeism [3,4]. Worksite weight management [5] is important for educating employees about the benefits of maintaining a healthy, sustainable weight and in helping to influence behavior, such as by encouraging healthier food choices and physical activity. Worksite weight management programs also support behavior change over time by establishing a more consistent and healthy environment. Retention [6] within worksite programs has been found to be twice that observed in commercial weight loss programs, improving long-term weight management [7].

The use of text messaging in health behavior change [8-10] has been adopted more and more frequently, not only because of its wide availability, low cost, and instant effects on users, but also because of its effectiveness in encouraging health behavior changes.

As a rule, developing and implementing worksite weight management programs requires sufficient resources, including funding, time, staff, and space. Additionally, there are reported barriers to participation [11,12] in worksite programs, including insufficient incentives, inconvenient locations, and time limitations.

Using text messages in worksite weight management programs can be useful for overcoming the time, location, and cost barriers. Some studies have used telephone coaching [13] or online weight management programs [14] in worksite weight management programs, but no studies have reported on the effects of text messaging on weight loss in worksite weight management programs. Therefore, we conducted a 6-month randomized controlled trial to determine whether a tailored text-messaging reminder service would be more effective in encouraging weight loss compared with the standard care in worksite weight management programs.

Methods

Recruitment

The study population consisted of employees of public institutions undergoing standardized annual medical examinations at local cooperative hospitals. The standardized medical examinations include evaluating lifestyle risk factors, such as smoking, drinking, and lack of exercise; anthropometric measurements, such as weight, height, and blood pressure; and laboratory tests, such as fasting glucose and lipid panel. Nurses managed worksite disease prevention efforts in the health promotion programs at these public institutions.

The World Health Organization (WHO) Regional Office for the Asia Pacific Region recommends defining obesity in Asians as those with a body mass index (BMI) ≥25 kg/m^2 [15]. The Korean Society for the Study of Obesity also studied the cutoff of BMI for obesity-related disease [16] and adopted the definition. Now Korean government organizations officially use this definition when defining and implementing health policies regarding obesity in Korea.

Participants were recruited in 2011 from 3 public institutions with the help of managing nurses: the Korea Gas Corporation (KOGAS), the Korea District Heating Corporation (KDHC), and the Korea Expressway Corporation (KEC). KOGAS was incorporated by the Korean government in 1983 and has grown to become the world's largest liquefied natural gas importer with 3437 employees working as of January 2014. KDHC was established in 1985 and 1345 people are employed in the district cooling and heating business, community energy system business, electricity business, and the new, renewable energy business. KEC was established in 1969 and has contributed to a speedy, convenient, safe transport service by constructing and maintaining expressways with a total of 4484 employees working. All headquarters of these companies are located in Seongnam and all potential participants in our study were working at headquarters of these companies mostly as teams within the administrative, management, or research departments.

The nurses screened potential participants for the following inclusion criteria: age between 20 and 60 years, obesity determined by a BMI >25, not taking medications known to cause weight gain, owning a mobile phone, and using text-messaging services. Most employees of KOGAS, KDHC, and KEC are male. In particular, more than 98% (217/222) of the employees who were eligible for this study were male. Only 5 females wanted to participate in our program and 4 were in their twenties and had no significant metabolic risks; therefore, we decided to include only males in the final study. Finally, 80 male employees of KOGAS, 81 of KDHC, and 44 of KEC agreed to participate in our study. The Institutional Review Board of Seoul National University Bundang Hospital approved this study (IRB number: B-0908-082-014).

Intervention Group

The study evaluated a text message-based application that was tailored to participants' individual dietary behaviors and physical activity levels using responses to questionnaires and metabolic risk profiles that were assessed by laboratory examinations and anthropometric measurements. We assessed total calorie intake

with relative proportions of macronutrients such as carbohydrate, protein, and fat, sodium intake per day, as well as eating patterns such as regularity of meals, night eating, and frequent snack intake during an education session using self-administered 24-hour dietary recall [17]. The 24-hour dietary recall was collected by self-administered methods instead of being evaluated by trained interviewers and was only used for development of content of tailored text-messaging program and not for outcome evaluation.

Eating behaviors such as emotional eating, social influences, convenience food, and alcohol consumption by frequency and amount were also assessed for the purpose of the text-messaging program.

Physical activity level was assessed and categorized using the International Physical Activity Questionnaire-Short Form [18] (IPAQ-SF).

Fasting glucose, uric acid, and serum triglyceride levels were also categorized to aid in the development of tailored text messages. The contents of the text messages were developed to be both automatic and personally tailored to participants' lifestyles, eating pattern with behaviors, and metabolic risk factors, and the messages were unidirectional. Three family physicians, 1 psychiatrist, and 2 dietitians collaborated to develop the text message contents with regard to motivation, nutritional tips, helpful recipes based on individual risk factors, and exercise tips with motivation. Text messages were sent to the intervention group 3 times a week in the morning and consisted of "goal setting and behavior change," "education and tips for nutrition," and "exercise and get more active" themes.

Goal setting and behavior change included reminders of the target goal set by participant and motivational messages for encouraging self-monitoring of their weight, the need for weight control, overcoming barriers, and reducing emotional eating. We especially subcategorized first attempters and history of fluctuating weight loss cycles, or yo-yo dieters, and sent tailored motivational messages to those 2 groups. For first attempters, messages were sent to start and stick to their plan, but for yo-yo dieters messages were focusing on how to prevent weight cycling again. Education and tips for nutrition included general information such as meal replacements and substitutions, meal planning, tips for eating out, and tailored information according to self-administered 24-hour dietary recalls with questionnaires. If a participant got more than 60% of energy by carbohydrate intake or 20% of energy by fat intake, messages were sent to inform them of the ideal proportion of macronutrients and to recommend healthy alternative choices. If a participant was drinking more than 35 g/day of alcohol by the frequency and amount of drinking over the past week, then he would get reminder messages regarding risk of alcohol with weight, education about empty calories, and suggestions of safe drinking amount. We also categorized tailored text messages by laboratory results based on health examination data. We applied the criteria of metabolic syndrome by the National Cholesterol Education program Adult Treatment Panel lll [19] for tailored text message contents. If systolic blood pressure was more than 135 mm Hg or diastolic blood pressure was more than 85 mm Hg or participants were on hypertension treatment, the participant received tailored messages about nutritional tips for lowering blood pressure [20] from randomized clinical trials. We classified as high triglyceride group when a participant had a triglyceride level more than 150 mg/dL or was on medication for dyslipidemia, and as prediabetic group or diabetic group if the glucose level was more than 100 mg/dL or participant was on antidiabetic medication.

For exercise and get more active, we categorized physical activity levels according to guideline of IPAQ-SF and personalized messages were sent according to low, moderate, and high activity levels. We also sent general tips for increasing nonexercise physical activity; education on the type, duration, and frequency of exercise; and showing the calories burned per exercise type per hour. Examples of the text messages' contents are shown in Table 1.

Because we generated the content of text messages according to the results of a routine annual health examination, study participants were not reclassified in terms of types of text messages received during the study period.

Our research group visited the worksites and provided educational group sessions with printed materials on managing obesity and feedback based on self-reported questionnaires at baseline, 1 month, 3 months, and 6 months. At baseline visits, participants were told about obesity-related comorbidities, the importance of healthy weight, methods of losing weight by choosing healthy low calorie foods with examples of 1500 to 1800 low calorie meal plans, and a brief explanation of the purpose and methods of our study again. At the 1-month visits, a detailed explanation of types and frequencies of exercise for losing weight was given with videos. Also, methods for increasing nonexercise physical activities and healthy carbohydrates, such as whole grain or high-fiber foods, were given to participants. At the 3-month visits, we gave a lecture regarding stress-related eating and how to cope with that problem. We also gave nutritional information regarding healthy fat and adequate protein intake to participants. At the final visits, we focused on maintenance of weight loss (eg, problems with regaining weight) and how to prevent them. After the education session, participants were required to fill in brief questionnaires such as the IPAQ-SF and measure their weight and body fat. The printed materials were different at each educational session according to the topic. Each session was held for 40 minutes with 20 to 30 attendees. For each worksite, a total of 6-8 educational sessions took place during the 6-month study period depending on available numbers of participants. For each individual who completed the study, total educational sessions would be 4 maximum.

Nurses checked weights and offered brief counseling about diet, exercise, coping with emotional eating, tips for avoiding overeating, weight maintenance strategies, and encouraged participation in the program every month.

We used a commercial automated text message sender (Munjanara, Seoul, Korea) [21] for the tailored messages, and we could not provide interactive feedback or track and show cumulative weight changes.

Table 1. Text message contents.

Category subcategories classification	Example of content	Frequency
Goal setting and behavior change		
Goals		Once a week rotating
Target weight reminder	Remember, your goal is 77 kg in 6 months. Imagine your healthy body and get started!	
Motivation		Once a week rotating
First attempt	You just started a great jump in your healthier life. Congratulations!	
History of yo-yo dieting	Weight cycling can be a normal process in weight loss, but you need to keep track of your weight.	
Education and tips for nutrition		
Eating behavior		Once a week rotating
Rapid eating	Take time to eat your meals and save yourself from future health problems.	
Irregular eating	Skipping your meal can lead to overeating at the next meal.	
Emotional eating	If you are upset or frustrated, stop and think for a moment, and then choose your action.	
Alcohol consumption [a]		Once a week rotating
Problem drinking	Problem drinking can put you in danger in both body and mind.	
Increased blood pressure		Once a week rotating
SBP ≥130 mm Hg or DBP ≥85 mm Hg	Make your meal with colorful vegetables and protein-rich foods.	
Dyslipidemia		
TG ≥150 mg/dL	Diets high in refined carbohydrates and heavy alcohol use can increase triglycerides.	Once a week rotating
Impaired fasting glucose		Once a week rotating
FPG ≥100 mg/mL	You are at high risk for diabetes. Eating nutritious, balanced meals with regular exercise can protect you.	
Exercise and get more active		
Level of physical activity [b]		Once a week
Low	Move yourself for just 30 minutes a day, and you have your healthy body shape.	
Moderate	If you want to lose weight, you need to add vigorous-intensity activity at least 75 minutes per week.	
High	You are doing great, but be careful of your joints.	

[a] At-risk drinking: assessed by the frequency and amount of drinking over the last week and categorized as high-risk intake if participants had an average daily consumption of >35 g/day.

[b] Level of physical activity: assessed with the International Physical Activity Questionnaire-Short Form (IPAQ-SF) and categorized as follows: low: Individual does not meet the criteria for category 2 or 3; moderate: 5 or more days of any combination of walking, moderate-intensity, or vigorous-intensity activity to achieve a minimum total physical activity level of at least 600 MET-minutes/week; high: vigorous-intensity activity on at least 3 days to achieve a minimum total physical activity of at least 1500 MET-minutes/week or 7 or more days of any combination of walking, moderate-intensity, or vigorous-intensity activities achieving a minimum total physical activity level of at least 3000 MET-minutes/week.

Comparison Group

The comparison group received the same educational group sessions with printed materials at baseline, 1 month, 3 months, and 6 months, and their weights with percent body fat were checked. Also, questionnaires regarding physical activities were evaluated and they got brief counseling about diet, exercise, coping with emotional eating, tips for avoiding overeating, and weight maintenance strategies by nurses at their offices. The comparison group received identical support as the intervention group with the exception of not receiving automatic tailored text messages.

Study Design

Individuals eligible for this study were invited to participate in the program by the study coordinator after they completed their annual health examinations at the hospital. Participants were informed about the text-messaging intervention at their worksites' weight reduction education programs and gave written informed consent to use their hospital information in the text messages. Participants were asked to contact the researchers by telephone or email if they had questions regarding the trial.

Evaluation of the text-messaging program was based on an unblinded, randomized controlled trial with a 1:1 match of the intervention group to the comparison group. Random allocation was performed by blocked randomization, with block sizes of 4 and 6, and using Web-based randomization at the Medical Research Collaborating Center of Seoul National University Hospital. A trained research assistant who did not participate in running the educational sessions or in recruiting potential participants scheduled and sent the text messages to the intervention group using the commercial automatic text message sender. There were no methodological changes during the study period.

Both groups received the equivalent of US $10 in reimbursement at each educational session. The study took place between May and December 2011 in Seongnam, Korea. A screenshot of this study app is shown in Figure 1.

Figure 1. Screenshot of text message reminders in worksite weight loss program.

Measurement

Weight and Percent Body Fat

Weight change was the primary outcome and was evaluated with percent body fat at baseline, 1 month, 3 months, and 6 months, and measured by nurses using portable bioelectrical impedance analysis (InBody U20, Seoul, Korea).

Physical Activity Questionnaires

Physical activity was assessed using the Korean version of IPAQ-SF [18] at baseline, 1 month, 3 months, and 6 months.

Obesity-Related Quality of Life

We also evaluated the Korean versions of validated obesity-related quality-of-life scales [22] at baseline and 6 months. These were self-administered questionnaires to measure obesity-related quality of life.

Satisfaction and Acceptability

Satisfaction with and acceptance of this text message program in the intervention group were evaluated at 6 months by rating the overall program (eg, Were you satisfied with the text message program? How much did the text messages help you with weight management?) with a 5-point Likert rating (from strongly agree to strongly disagree). "Somewhat agree" and "strongly agree" were considered positive responses.

Eating Behavior

We evaluated eating behavior based on eating speed, irregular eating, and emotional eating at baseline to develop the content of the tailored text messages, but we did not use eating behavior

for outcome measurement. We also evaluated baseline alcohol intake as the frequency and amount of drinking over the last week and categorized intake as high risk if participants had an average daily consumption of more than 35 g/day based on the risk of metabolic syndrome [23]. Alcohol consumption was only used for the content of the text messages, not for outcome evaluation.

Statistical Analysis

We calculated sample size to detect a group difference of 1.65 kg at 6 months based on a previous study [24], which was a mean 1.72 kg (SD 3.3) difference in changes of body weight at 4 months between intervention and control groups. A total of 124 participants provided a power of 0.8 with alpha=.05. Allowing for an attrition rate of 30%, a total of 207 participants were needed to perform this study. Differences in the baseline categorical variables between groups were analyzed using chi-square tests and continuous variables were compared using *t* tests. Group differences in the effects of the text-messaging intervention on weight changes were analyzed using a linear mixed-effects model for repeated measures [25], which used all available data and provided valid results in the event of missing data (which were under the missing at random mechanism). The model considered age, treatment group, time, and group by time interactions as fixed effects and incorporated random effects for individual participants to consider variabilities in individuals across time. As we weighed study participants with the same portable bioelectrical impedance measurement device, we also evaluated the change of percent body fat.

Physical activity levels and obesity-related quality-of-life scores were also analyzed with a linear mixed model. All analyses were performed using SAS 9.3 (SAS Institute, Cary, NC, USA) and R version 2.15.2 [26] software. *P* values less than .05 were considered statistically significant.

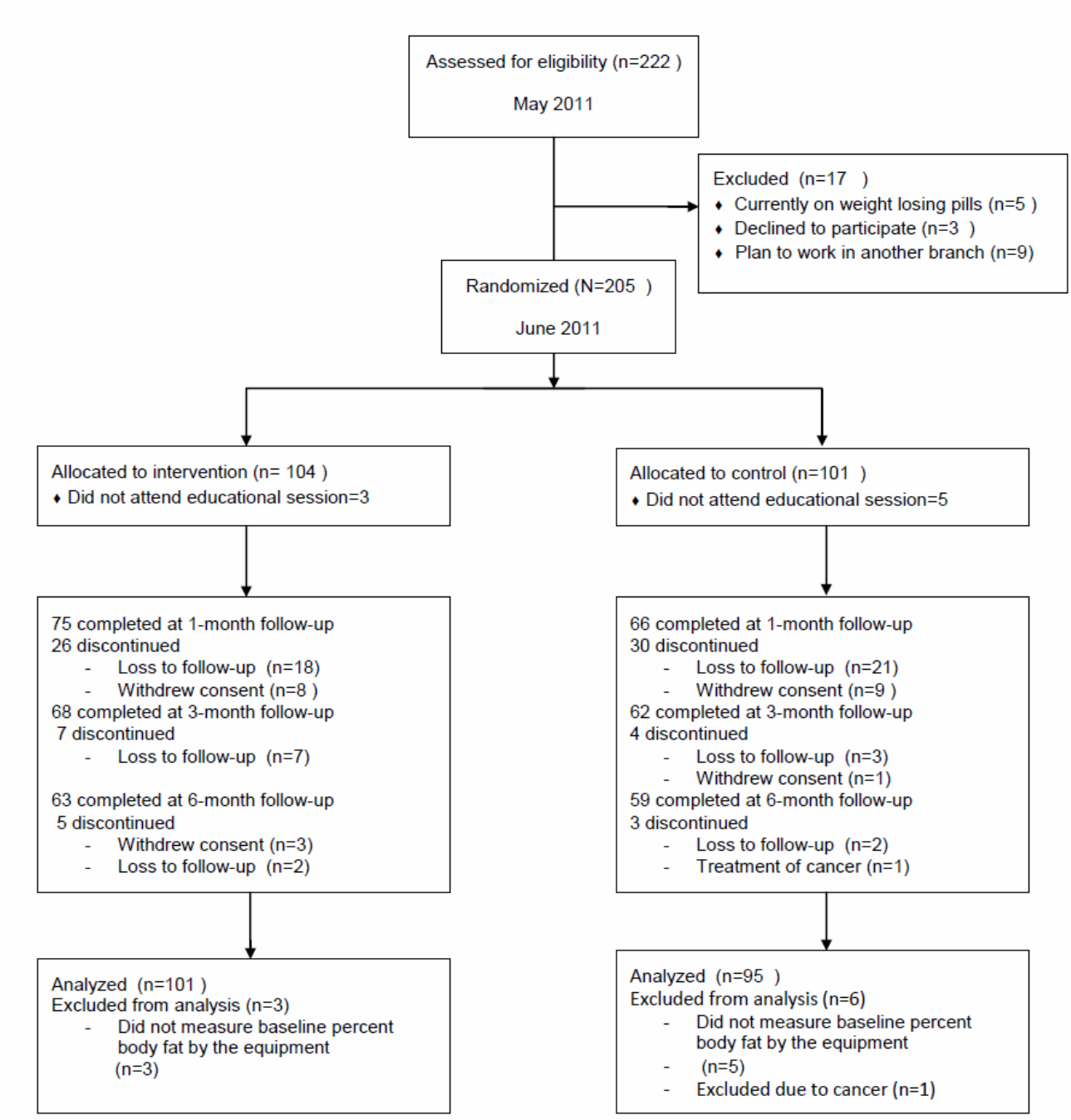
Results

Enrollment and Retention

Study enrollment and retention flow are shown in Figure 2. A total of 222 individuals were eligible for participation as assessed by the managing nurses. Among those eligible, 205 agreed to participate and comprised the final study population and were randomized to either the text message group (n=104) or the control group (n=101). Baseline weight and body fat percentage were measured at the educational sessions with portable body impedance analysis; if a participant did not attend the session, we could not obtain his baseline body weight. Because 9 individuals did not attend the baseline session, the final analysis included 101 men from the text message group and 95 from the control group using the intention-to-treat protocol.

At 6 months, 62% (63/101) of the text message group and 62% (59/95) of the control group had completed their follow-up schedules. There were no significant differences in the attrition rates between the 2 groups. When baseline characteristics of study completers (n=122) were compared with those of noncompleters (n=74), there were no significant differences except for obesity-related quality-of-life scales. Study completers had lower obesity-related quality-of-life scale scores with mean of 24.30 (SD 10.87) versus those of noncompleters (mean 27.55, SD 7.29).

Figure 2. Flow diagram for participant enrollment and retention.



Baseline Characteristics

There were no significant differences in sociodemographic variables between the randomized groups as shown in Table 2. Mean age was 41.02 years (SD 6.82) in the intervention group and 41.55 years (SD 6.98) in the control group. In the intervention group, mean body weight and BMI were 83.24 kg (SD 8.75) and 28.00 kg/m^2 (SD 2.15), respectively; in the control group, mean body weight and BMI were 81.89 kg (SD 9.29) and 27.61 kg/m^2 (SD 2.45), respectively. Half of the study participants (50.0%, 98/196) were making their first attempt at weight reduction, and more than one-third (44.4%, 87/196) were categorized as having moderate to high physical activity. Nearly 40% (78/196) of the study participants self-reported as rapid eaters and the most common comorbidity was hyperlipidemia (28.6%, 56/196).

Table 2. Baseline characteristics of the participants in each group (N=196).

Variables	Text message group (n=101)	Control group (n=95)	*P* [a]
Age (years), mean (SD)	41.02 (6.82)	41.55 (6.98)	.59
Body mass index (kg/m^2), mean (SD)	28.00 (2.15)	27.61 (2.45)	.25
Weight, mean (SD), kg	83.24 (8.75)	81.89 (9.29)	.30
Percent body fat (%), mean (SD)	25.23 (3.67)	25.75 (3.45)	.31
Systolic blood pressure (mm Hg), mean (SD)	125.62 (14.74)	123.27 (13.45)	.25
Diastolic blood pressure (mm Hg), mean (SD),	78.97 (10.38)	77.14 (9.98)	.21
Fasting glucose (mg/dL), mean (SD)	96.33 (17.06)	96.19 (14.51)	.95
Triglycerides (mg/dL), mean (SD)	169.10 (94.83)	175.17(98.06)	.66
First attempt at weight loss, n (%)	52 (51)	46 (48)	.77
Current smoker, n (%)	32 (32)	26 (27)	.61
At-risk drinking, n (%)[b]	31 (31)	28 (29)	.97
Physical activity, n (%) [c]			
Moderate	17 (17)	26 (27)	.19
High	25 (25)	19 (20)	
Eating pattern			
Rapid eating	41 (41)	41 (43)	.83
Irregular eating	7 (7)	9 (9)	.69
Emotional eating	4 (4)	6 (6)	.67
Married, n (%)	84 (83)	77 (81)	.84
Obesity-related QOL scales,[d] mean (SD)	26.21 (8. 78)	25.57 (10.08)	.74
Comorbidities, n (%)			
Hypertension	15 (15)	12 (13)	.81
Diabetes	6 (6)	4 (4)	.82
Hyperlipidemia	26 (26)	30 (32)	.45

[a] *P* value was calculated by the *t* test for continuous variables and the chi-square test for categorical variables.

[b] At-risk drinking was defined by average alcohol intake more than 35 g/day.

[c] Physical activity assessed by IPAQ-SF (International Physical Activity Questionnaire-Short Form) and categorized.

[d] Korean version of obesity-related quality-of-life (QOL) scales.

Weight Changes

Table 3 summarizes the mean body weight changes and percent body fat, physical activity, and obesity-related quality-of-life scores for the text message (n=101) and control groups (n=95) using intention-to-treat analysis. Both groups significantly reduced their body weights compared with baseline. The text message group lost a mean 1.71 kg (95% CI –2.53 to –0.88) and the control group lost a mean 1.56 kg (95% CI –2.45 to –0.66) at 6 months (Figure 3). The difference in weight loss between the 2 groups was –1.07 kg (95% CI –1.85 to –0.30) at 1 month, which was statistically significant (*P*=0.01). But, at the end of study, the difference in weight loss was –0.40 kg (95% CI –1.09 to 0.29), which was not significant. Percent body fat decreased at 3 months in both the text message (mean difference –1.68, 95% CI –2.60 to –0.79) and control (mean difference –1.29, 95% CI –2.61 to –0.37) groups but there was no significant difference between the groups (Figure 4).

Table 3. Baseline and changes in weight, percent body fat, physical activity, and obesity-related quality-of-life scores at each assessment point using missing data[a] method.

Variable	Text message group (95% CI)	Within-group difference (95% CI)	*P*	Control group (95% CI)	Within-group difference (95% CI)	*P*	Between-group difference (95% CI)	*P*
Weight								
Baseline	83.24 (81.46, 85.02)	ref		81.89 (80.06, 83.73)	ref			
1 month	82.12 (80.35, 83.89)	–1.11 (–1.62, –0.60)	<.001	81.85 (80.00, 83.70)	–0.04 (–0.62, 0.54)	.89	–1.07 (–1.85, –0.30)	.01
3 months	81.38 (79.54, 83.21)	–1.86 (–2.48, –1.24)	<.01	80.21 (78.29, 82.14)	–1.67 (–2.42, –0.93)	<.01	–0.18 (–1.15, 0.79)	.85
6 months	81.53 (79.75, 83.31)	–1.71 (–2.53, –0.88)	<.01	80.33 (78.48, 82.18)	–1.56 (–2.45, –0.66)	<.001	–0.15 (–1.36, 1.07)	.78
Percent body fat								
Baseline	25.23 (24.53, 25.93)	ref		25.75 (25.03, 26.48)	ref			
1 month	24.57 (23.51, 25.62)	–0.67 (–1.62, 0.28)	.17	26.17 (24.91, 27.48)	0.42 (–0.75, 1.59)	.48	–1.09 (–2.60, 0.43)	.16
3 months	23.55 (22.51, 24.58)	–1.68 (–2.60, –0.76)	<.01	24.26 (23.04, 25.48)	–1.29 (–2.61, –0.37)	<.009	–0.19 (–1.64, 1.25)	.80
6 months	24.67 (23.82, 25.52)	–0.56 (–1.24, 0.13)	.11	24.91 (23.99, 25.84)	–0.83 (–1.60, –0.07)	.03	0.28 (–0.75, 1.31)	.60
Physical activity level (MET-minutes/week)								
Baseline	1569.6 (1161.1, 1978.1)	ref		1778.1 (1350.9, 2205.3)	ref			
1 month	1547.3 (1053.1, 2041.4)	–22.4 (–501.8, 457.1)	.93	1807.5 (1241.6, 2373.4)	29.4 (–515.1, 573.9)	.92	–51.8 (–777.3, 673.7)	.89
3 months	2103.3 (1620.9, 2585.6)	533.6 (47.9, 1019.3)	.03	1830.7 (1243.9, 2417.5)	52.6 (–537.5, 642.8)	.86	481.0 (–283.3, 1245.3)	.22
6 months	2261.6 (1757.6, 2765.7)	692.0 (185.7, 1198.2)	<.008	1889.7 (1336.2, 2443.1)	111.6 (–454.7, 677.9)	.70	580.4 (–179.2, 1340.0)	.14
Obesity-related QOL [b]								
Baseline	26.85 (24.18, 29.52)	ref		25.61 (23.32, 27.90)	ref			
6 months	27.07 (24.65, 29.50)	0.92 (–1.79, 3.63)	.51	26.2 (23.97, 28.34)	1.24 (–1.71, 4.19)	.41	–0.15 (–1.36, 1.07)	.78

[a] Linear mixed model was used.

[b] Korean versions of obesity-related quality-of-life (QOL) scales.

Figure 3. Changes in body weight between text message group and control group from baseline to 6 months.

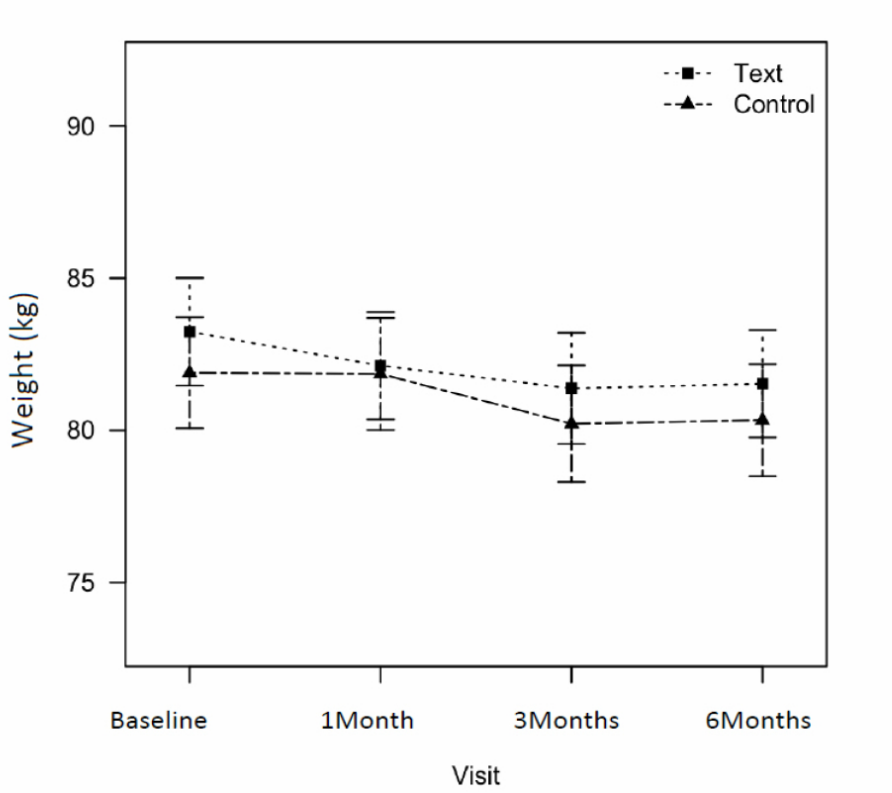
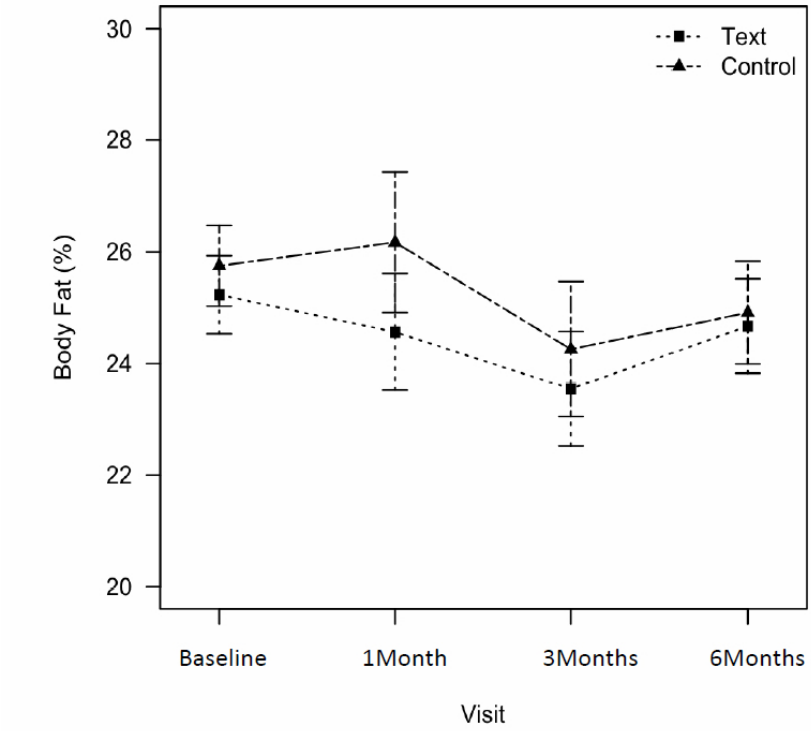
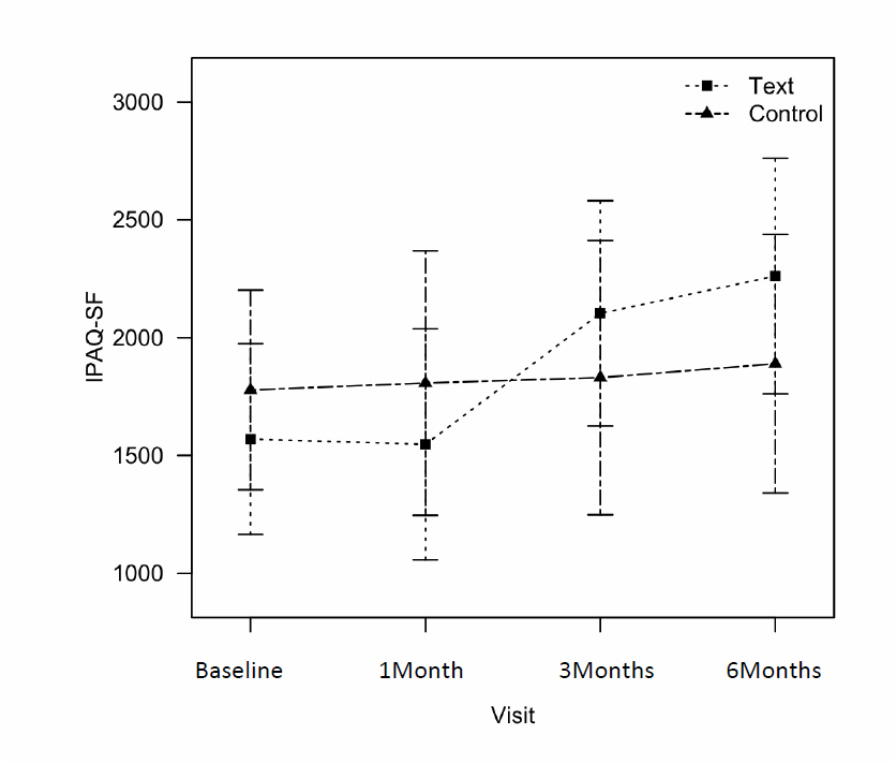


Figure 4. Changes in percent body fat between text message group and control group from baseline to 6 months.



Physical activity significantly increased in the text message group by a mean 533.6 metabolic equivalent (MET)-minutes per week at 3 months (95% CI 47.9-1019.3) and 692.0 6 MET-minutes per week at 6 months (95% CI 185.7-1198.2) (Figure 5), but no significant differences were observed between the groups. There was no change in obesity-related quality-of-life scores in either group.

Figure 5. Changes in physical activities assessed by International Physical Activity Questionnaires Short Form (IPAQ-SF) between text message group and control group from baseline to 6 months.



Satisfaction With and Acceptance of Text Messages

In the text-messaging intervention group, approximately two-thirds of the study participants showed positive responses to the text messages, finding them helpful (60%, 34/57), convenient (65%, 37/57), and reliable (75%, 43/57) at the 6-month evaluation (Table 4). However, the rates of positive responses for the personalized contents (39%, 22/57) and for recommending the text service to other people (46%, 26/57) were less than 50%. Still, satisfaction with the text-messaging service (63%, 36/57) and intent to use it again (63%, 36/57) was mostly positive.

Table 4. Satisfaction with and acceptability of the text message service (n=57).

Items	Positive response, n (%)
It helped with my weight reduction	34 (60)
It provided personalized messages	22 (39)
It was a convenient method	37 (65)
The contents were reliable	43 (75)
I was satisfied with the service	36 (63)
I would recommend it to my family or friends	26 (46)
I will use it again	36 (63)

Discussion

Principal Results

To the best of our knowledge, this was the first study to evaluate text messaging in a worksite weight reduction program in obese male participants. In contrast to the many positive results reported in previous trials of text-messaging interventions, our results did not indicate any significant weight reduction compared with the control group despite an overall positive perception of text messaging by the participants. At the 1-month follow-up of the study, the text messaging group reduced their weight more significantly than the control group by a difference of 1.07 kg, but at the end of the study the weight reduction difference did not show any significant change. Because both groups significantly reduced their weight by an average of 1.71 kg in the text message group and 1.56 kg in the control group compared with their baseline weight, identifying a statistically significant benefit of text messaging was more difficult to demonstrate in this cohort. In addition, study participants increased their physical activity levels and showed decreased percent body fat, but without significant differences between the groups. These surprising findings in the control group might reflect the effectiveness of the health examinations and educational sessions on weight management in the work environment.

Clinically, weight loss of 5% to 10% of initial weight are known to reduce cardiovascular disease risk factors, prevent the development of type 2 diabetes mellitus, and improve other health consequences of obesity [27,28]. At the end of the 6-month study, the text-messaging group lost 2% of their baseline weight and the control group lost 1.9% of their baseline weight. This would be considered a meaningful first step toward clinically significant weight loss.

Worksite weight management [5] is crucial in that it can provide awareness and a more structured approach for employees to address weight management. However, what is required to develop a successful program is not yet fully known [29], although the incorporation of some elements are considered essential: health education, supportive social and physical environments, and screenings followed by counseling and necessary follow-up with medical services. Employers must consider the most appropriate allocation of human, financial, and administrative resources in worksite health promotion programs to optimize their cost-effectiveness. In this regard, text messaging by mobile phone has a number of merits. Mobile phones with text messaging have a high penetration rate in nearly every society, regardless of age, socioeconomic status, and culture. Moreover, texting is fast, convenient, easy to use, broadly scalable, and can give users immediate feedback.

However, there are several core components for successful text message programs for weight loss that were lacking in our trial. For example, regular self-monitoring of physical activities, dietary intake, or tracking weight, which arise from self-determination theory [30] and have been shown to play an important role in weight loss, were not applied in our program. Also, we did not have interactive components, such as feedback or social support from peer group, based on social cognitive theory [31]. If these systems of feedback were dependent on manual input by health care workers, additional resources such as time, persons, and costs should be considered. On the other hand, if feedback systems are automated, a technique that was adopted in a number of clinical trials [32,33], after an early investment in the text message content, a messaging infrastructure could be built with adaptive flexibility.

In our program, the main function of the text messaging was to provide education and motivation in the form of personalized reminders so that the service could help participants make changes in lifestyle. Systemic review [34] regarding periodic messaging intervention on health behaviors also showed that periodic messaging interventions yield positive results for short-term health behavior changes. But the review also suggested the provision of feedback and specific strategies appeared to be important for the success. We did not provide participants with bidirectional communication capabilities or self-monitoring functions. This kind of additional functionality might have increased the effectiveness of our text messaging intervention, increasing the likelihood of finding a significant improvement compared with the control group.

In terms of adherence to study, obesity-related quality-of-life scales were significantly lower in the study completers than in noncompleters, but these scales were originally developed to measure various quality of life in obese patients whose mean BMI was more than 30 and diverse age and gender group. Our study participants were relatively mildly obese as classified by BMI and primarily an active working male population in their forties. So it is possible that the Korean version of the quality-of-life scales did not reflect quality of life in our study participants very well.

Comparison With Prior Work

According to a recent meta-analysis [35] regarding text messages for weight management, there were several elements of behavior modification as well as function of text messaging in qualitative analysis of 13 trials. Among elements of behavior modification, all messages contained nutritional information and exercise was the second most common target behavior (92%, 12/13). Social support with nutritional education was used in more than half of trials (54%, 7/13). Our study also used physical activities with tailored nutritional tips for the contents of text message, but social support was not part of the program.

In function of text-messaging formats, more than half of trials (54%, 7/13) used text messaging to report self-monitoring data and to provide tailored feedback responses to participants around food intake, physical activity levels, and weight. Approximately one-third of trials (31%, 4/13) adopted group sessions, and one-quarter of trials (23%, 3/13) employed individual consultation or telephone coaching. In our trial, monitoring, tailored feedback, or telephone coaching were not provided, but group sessions for education and individual care by nurses on request were given during study period. In terms of self-regulation theory-driven health behavior change [36], self-monitoring with immediate feedback is especially important in making text messaging successful in weight reduction. Recent clinical trials with minority women [37] and in Beijing [38] used text messaging as a reminder and monitoring tool for predetermined behavior goals, and showed positive outcomes in weight reduction.

Limitations and Strengths

There could be multiple reasons that text messaging did not prove its effectiveness in our study. First, our study participants were recruited on the recommendation of managing nurses based on routine health examinations, whereas most other trials recruited from volunteers; thus, there may be differences between our participants and volunteers. Second, we attempted individual randomization within organizations, which could have led to contamination between the text messaging and control groups.

Third, the most successful text-messaging program participants in prior studies have been women, in contrast to our male participants, and in our study the retention rate was approximately 60%, lower than the 90% that has been reported for female participants [37]. Fourth, in our survey regarding satisfaction and acceptance, most participants in the intervention group did not feel that they had received personalized messages, although we tried to personalize the messages based on each participant's health behavior and cardiovascular and metabolic profiles. The absence of the self-monitoring with feedback functionality in the text messaging reduced the potential

desirable effect on the subjective recognition of personalized contents and also on weight management.

In spite of the preceding limitations, our study had multiple strengths. First, we evaluated the text-messaging reminder function in a randomized clinical trial, which alone did not appear to have an effect on weight reduction. Second, with our focus on male participants, our study adds to the limited evidence base of possible interventions for obese males. Third, we attempted to use text messaging in work environments, which could have great impact on individual health behavior changes with proper implementation. Future studies that focus on text messages with self-monitoring and feedback in the workplace setting are needed.

Conclusions

In a 6-month trial, adding tailored text messages as reminders did not show any significant effects on weight reduction in obese male participants in worksite weight management programs. Further testing is needed to study the potential benefit of immediate interactive feedback and an emphasis on self-monitoring activities on its effectiveness in worksite wellness programs.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.2 [39].

[PDF File (Adobe PDF File), 991KB - mhealth_v3i1e14_app1.pdf]

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Abbreviations

BMI: body mass index
IPAQ-SF: International Physical Activity Questionnaire-Short Form
KDHC: Korea District Heating Corporation
KEC: Korea Expressway Corporation
KOGAS: Korea Gas Corporation

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Original Paper

Design and Multi-Country Validation of Text Messages for an mHealth Intervention for Primary Prevention of Progression to Hypertension in Latin America

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Abstract

Background: Mobile health (mHealth) has been posited to contribute to the reduction in health gaps and has shown fast and widespread growth in developing countries. This growth demands understanding of, and preparedness for, local cultural contexts.

Objective: To describe the design and validation of text messages (short message service, SMS) that will be used for an mHealth behavioral change intervention to prevent hypertension in three Latin American countries: Argentina, Guatemala, and Peru.

Methods: An initial set of 64 SMS text messages were designed to promote healthy lifestyles among individuals in different stages of behavior change, addressing four key domains: salt and sodium intake, fruit and vegetable intake, consumption of high fat and sugar foods, and physical activity. The 64 SMS text messages were organized into nine subsets for field validation. In each country 36 people were recruited, half of them being male. Of the participants, 4 per country evaluated each subset of SMS text messages, which contained between 6 and 8 SMS text messages regarding different key domains and stages of change. The understanding and appeal of each SMS text message was assessed using a 7-item questionnaire. The understanding and appeal ratings were used to reach a final set of 56 SMS text messages.

Results: Overall, each of the 64 SMS text messages received a total of 12 evaluations (4 per country). The majority of evaluations—742 out of a total of 767 (96.7%) valid responses—revealed an adequate understanding of the key idea contained in the SMS text message. On a scale from 1 to 10, the average appeal score was 8.7 points, with a range of 4 to 10 points. Based on their low scores, 8 SMS text messages per country were discarded. Once the final set of 56 SMS text messages was established, and based on feedback obtained in the field, wording and content of some SMS text messages were improved. Of the final set, 9, 8, and 16 of the SMS text messages were improved based on participant evaluations from Argentina, Guatemala, and Peru, respectively. Most SMS text messages selected for the final set (49/56, 88%) were the same in all countries, except for small wording differences.

Conclusions: The final set of SMS text messages produced had very high rates of understanding and appeal in three different Latin American countries. This study highlights the importance of developing and validating a package of simple, preventative

SMS text messages, grounded in evidence and theory, across three different Latin American countries with active engagement of end users.

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KEYWORDS

cross-cultural comparison; developing countries; health literacy; hypertension; Latin America; mHealth; preventive medicine; prehypertension; text messages; validation studies

Introduction

It has been more than a decade since multimedia, electronic communications, and networking technology were raised up as, and expected to be, useful tools to increase health literacy [1]. Health literacy has been defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions" [1,2]. Health literacy remains challenging in both developed and developing countries [2,3]. From a public health standpoint, this is worrisome at a global scale—individual knowledge about risk factors and behavior to prevent or ameliorate risk to poor health is key for primary prevention activities, as well as for actual health care seeking, provision, and compliance [4].

Simultaneously, the expectations on mobile health (mHealth) to reduce large health gaps have increased. The term mHealth is defined as the use of mobile and wireless devices to improve health-related outcomes, services, and research [5]. For developing countries in particular, one of the key mHealth applications used to deliver health education to patients is the use of text messaging (short message service, SMS) [6,7], yet the evidence of health improvement generated from this application is limited [8,9]. The potential advantages to contacting large numbers of laypeople or patients through SMS text messaging make this an enticing route for the delivery of health education.

However, different researchers and health care providers have realized that the use of mHealth technologies, including SMS text messaging, needs to accommodate, and be tailored to, potential literacy challenges, as it has been increasingly obvious that health literacy is not only about reading [10]. In addition to this, mHealth technologies have experienced fast and wide geographical spread. This demands understanding of local cultural contexts, as well as the adaptation of contents and strategies, to guarantee adequate understanding and appeal of mHealth innovations by end users. The objective of this study is to describe the process and results of the development and validation of SMS text messages to be used in an mHealth behavioral change intervention for the primary prevention of hypertension in three Latin American countries: Argentina, Guatemala, and Peru.

Methods

The Problem: Progression to Hypertension

In developing countries, hypertension is the leading risk factor contributing to global disease burden [11]. Prehypertension requires no medical treatment and is defined as the condition where an individual has systolic blood pressure values in the 120 to 139 mmHg range or diastolic blood pressure in the 80 to 89 mmHg range [12]. However, the rate of progression to hypertension is relatively high—10 to 20% per year [13]. Lowering systolic blood pressure by as little as 2 mmHg in a prehypertensive individual, before the appearance of clinical hypertension, could have a significant impact on lowering vascular mortality—about 10% lower stroke mortality and about 7% lower mortality from ischemic heart disease or other vascular causes in middle age [14]. The prevalence of prehypertension among the adult population in Latin American urban settings is between 22% and 35% [15,16]. However, not all prehypertensive subjects become hypertensive individuals, as this condition can be prevented through the adoption of healthy lifestyles and without the use of medication [12,17].

Description of the mHealth Intervention

The design and validation of SMS text messages was one of the components of the larger trial "Use of Mobile Technology to Prevent Progression of Pre-hypertension in Latin American Urban Settings" (ClinicalTrials.gov NCT01295216). The main objective of this trial is to evaluate the effectiveness of an intervention to reduce blood pressure and prevent progression to hypertension in prehypertensive individuals living in low-income urban settings in Argentina, Guatemala, and Peru. The primary hypothesis of this trial is that prehypertensive subjects who receive mHealth support for 12 months (intervention group) will have lower blood pressure compared to individuals who receive the usual primary health care (control group).

The mHealth intervention included monthly mobile phone calls and weekly SMS text messages to promote lifestyle modification that may help to reduce blood pressure. The mobile phone calls were developed according to the motivational interview technique [18,19] and tailored to the individual stage of change [20]. Each phone call, delivered by trained nutritionists, focused on a specific domain and was followed by 4 to 5 domain-specific text messages, delivered once per week.

The contents of the mHealth intervention were developed to improve lifestyle habits in four key domains related to hypertension prevention: salt and sodium intake, fruit and vegetable intake, consumption of high fat and sugar foods, and physical activity. The manual developed for community health workers by the National Heart, Lung, and Blood Institute, "Su Corazón, Su Vida. Manual del Promotor y Promotora de Salud" (Your Heart, Your Life) served as the basis to inform the four selected domains [21]. Activities described in this manual were complemented by other recommendations and were specifically

reviewed to support the content of the text messages designed for the mHealth intervention [22,23].

Development of SMS Text Messages

Development of the SMS text messages content was based on the Transtheoretical Model, also known as the Stages of Change Model. This model proposes five stages toward behavior change: precontemplation, contemplation, preparation, action, and maintenance [24,25]. For this intervention, these five stages were grouped into three stages. A detailed description of the type of content and number of text messages required per stage of change is shown in Table 1.

Each of the four key domains required a minimum of 14 text messages, for a final set of 56 text messages. In working toward this aim, we designed and tested 64 text messages for all four domains, assuming that some would not be as well understood as others. Of the 64 text messages, 6 were targeted to men only (eg, addressing situations such as eating outside the home), 6 were for women only (eg, focused around cooking practices), and the remaining 52 were targeted at both men and women.

Table 1. Stages of change, type of content, and number of SMS text messages per key domain.

Stage of change	Type of content of SMS text message	Example of SMS text message[a]	Number of SMS text messages per key domain	
			Developed for validation	Required for intervention
Stage 1: precontemplation and contemplation	Information about the benefits of developing healthy lifestyles.	If you use just a small amount of salt when cooking, you are helping your family to keep healthy blood pressure.	6	5
Stage 2: preparation and action	Tips and suggestions for behavioral change toward healthy lifestyles.	Cook your own lunch to take to work. This way you can use less salt and make it healthier than sandwiches and fast food.	6	5
Stage 3: maintenance	Positive reinforcement of achievements in healthy lifestyles.	Keep protecting your heart. Eat less than a teaspoon of salt each day.	4[b]	4[b]
Total text messages per key domain			16	14
Total text messages for all four key domains			64	56

[a]All examples provided are text messages from the salt and sodium intake key domain.

[b]The variety of content amenable to reinforcement by text messages was much more limited for stage 3 than for the other two stages. Thus, to avoid repeating content, only 4 text messages were required in this stage of change. During validation these text messages were not discarded, but reworded to make their content clearer.

For each key domain, the design of the text message content was defined according to some specific topics or behaviors (see Table 2). For example, the text message within the domain *salt and sodium intake* included the following topics: reduction in the use of salt when cooking and at the table, replacement of salt with other spices, reduced consumption of salty foods, and benefits of sodium reduction on cardiovascular health and blood pressure.

Table 2. Selected key domains and examples of specific topics prioritized in the design of SMS text messages.

Key domain	Examples of specific topics prioritized
Salt and sodium intake	Reduction in the use of salt when cooking and at the table.
	Replacement of salt with other spices such as oregano, pepper, and chili.
	Reduction or avoidance of deli meat, fast food, chips, snacks, and other salty foods.
	Replacement of deli meat sandwiches with nonprocessed meat and vegetable sandwiches.
	Benefits to blood pressure and cardiovascular health.
Fruit and vegetable intake	Replacement of snacks with fruits and vegetables.
	Benefits of buying seasonal fruits and vegetables.
	Benefits to blood pressure and cardiovascular health.
	Benefits to body weight and physical appearance.
Consumption of high fat and sugar foods	Reduction or avoidance of soft drinks, sweets, and added sugar.
	Reduction or avoidance of deli meat, margarine, chips, and other fatty foods.
	Replacement of saturated fats with unsaturated ones.
	Benefits to blood pressure and cardiovascular health.
	Benefits to body weight and physical appearance.
Physical activity	Increase of activity in daily routines.
	Involvement in group activities.
	Benefits to physical and mental health.
	Benefits to body weight and physical appearance.

All 64 SMS text messages met the following criteria: maximum length of 140 characters, preferably only one (in some cases, up to two) concepts covered, and the use of simple and direct language, understandable by laypeople from poor Latin American urban settings.

Before reaching the field validation stage, all 64 text messages were reviewed in each country by local communicators to assure adequacy of language, since there are regional variations around common words or phrases. This yielded three country-specific sets of 64 text messages that then underwent a validation process in each country.

Validation of SMS Text Messages

Overview

In this section we describe the guiding principles for the SMS text message validation, its design, and methodology, as well as the analysis approach.

Guiding Principles

The following guiding principles were agreed upon beforehand between participating countries: (1) the process would accommodate local timelines and resources, (2) the validation process would be carried out for each SMS text message, and (3) the final set of text messages could differ between countries.

During the validation, two main areas were to be prioritized: SMS text message understanding and appeal. This process would lead to the elimination of some text messages and to improvements in the wording of others.

Design and Methodology

All 64 SMS text messages were grouped into nine subsets for validation, with 6 to 8 text messages in each subset. As planned, some of the topics would be gender oriented, so one of the subsets had 6 text messages targeted to women and another subset had 6 text messages targeted to men. The remaining seven subsets had mixed text messages that were not gender specific. Each subset had a combination of text messages covering different key domains and stages of change to guarantee that participants—with unknown status of their stages of change across the four key domains—had a chance to comment on a variety of text messages. An example of one text message subset used during the validation process is provided in Table 3.

Table 3. Example of a subset of SMS text messages used for validation (set 3, Peru).

SMS text message number	Key domain	Stage of change	SMS text message used in testing	
			Spanish [a]	English
1	Salt and sodium intake	Stage 2: preparation and action	Prueba preparar tu sanguche con tomate, lechuga, y pollo en lugar de usar embutidos como jamon o salchichas, que tienen mucha sal.	Try and use chicken and fresh vegetables, such as tomato and lettuce, instead of deli meat for your sandwiches. Deli meat is high in salt.
2	Fruit and vegetable intake	Stage 1: precontemplation and contemplation	Frutas como platanos, ciruelas, melones, melocotones, y naranjas te ayudan a tener la presion normal.	Fruits, such as bananas, plums, melons, peaches, and oranges, help you keep normal blood pressure.
3	Fruit and vegetable intake	Stage 3: maintenance	Sigue asi. Las frutas y verduras no tienen grasa, por lo que te ayudan a bajar de peso y a verte bien.	Keep it up. Fruits and vegetables are fat free—they help you lose weight and look good.
4	Consumption of high fat and sugar foods	Stage 1: precontemplation and contemplation	Si comes menos manteca, visceras, salchichas, jamon, y otros embutidos, podras bajar tu colesterol y tu presión.	Eating less animal fat, liver, heart, kidneys, gizzard, sausage, ham, and other deli meat helps lower your cholesterol and blood pressure.
5	Consumption of high fat and sugar foods	Stage 2: preparation and action	Para comer menos grasa, quítale el pellejo al pollo y la grasa a la carne antes de cocinarla o comerla.	To eat less fat, remove skin from chicken and fat from meat before you cook or eat it.
6	Physical activity	Stage 1: precontemplation and contemplation	Haciendo actividad física al menos 30 minutos al día podrás bajar tu presión y evitar enfermedades.	Doing physical activity at least 30 minutes per day can lower your blood pressure and prevent diseases.
7	Physical activity	Stage 2: preparation and action	Si tienes que ir cerca de tu casa, no tomes combi o mototaxi.[b] ¡Es mejor caminar! Así no gastas en pasaje y haces actividad física.	If you are not going far, avoid riding a bus or mototaxi.[b] It's better to walk! It's cheaper and allows you to do some physical activity.

[a]Peruvian wording. SMS text messages were written without accents to avoid having mobile phones replace them with other characters.

[b]Mototaxis are a type of Peruvian rickshaw widely used in shanty towns.

A 7-item questionnaire with open- and closed-ended questions was designed for the assessment of each SMS text message. The questionnaire included 3 questions about the understanding of SMS text messages, 3 questions about text message appeal, and 1 final question requesting suggestions on how to improve the text messages (see Multimedia Appendix 1). Trained interviewers administered the questionnaires in face-to-face interactions and registered the participants' answers in writing.

Understanding was evaluated by asking each person to describe the content of the message as if she or he was explaining it to another person. If the core message was communicated, the message was rated as being understood. If the core message was not communicated, the message was rated as not being understood. Additionally, interviewees were asked whether there was any word whose meaning was not understood.

Appeal was rated on a *dislike-like* point scale from 1 to 10, asking interviewees to assign a numerical rating from low (1, *disliked the most*) to high (10, *liked the most*) according to how much they liked or disliked the message.

Validation instruments were first tested in Peru in August 2011. Following this, instruments were revised and improved, and all three countries conducted the validation study in October 2011.

Setting and Participants

Consistent with the larger trial that would utilize the SMS text messages, the validation was conducted in low-income, urban Spanish-speaking communities in or around the capital city of Argentina, Guatemala, and Peru.

In each country, 4 people evaluated each of the nine SMS text message subsets. In all countries, 108 participants (36 per country) were recruited for a one-on-one, 30-minute interview. Participants were aged between 30 and 60 years old, equally divided by gender, could read, and owned a mobile phone. The gender-specific text message subsets were evaluated either by women or men, accordingly.

Analysis of Validation

The analysis of each SMS text message was focused around two main areas: understanding of the content and an appeal score. Questions used in the validation process are provided in Multimedia Appendix 1.

The assessment of text message understanding was performed by two reviewers (FDC, JAZ) as in the following four steps.

1. Reviewers jointly examined all the written descriptions provided by participants and agreed on whether they revealed an understanding of the text message's key message or not.

2. For those text messages where participants reported a lack of understanding, or where judges agreed that the participant did not understand the text message, the message was checked for wording and grammar.

3. Specific words that did not appear to be understood or were disliked by participants were identified.

4. The content and wording of the text messages were improved by taking into account the comments and suggestions made by the participants.

To evaluate appeal, in every country, 4 participants ranked each text message on a point scale from 1 (*disliked the most*) to 10 (*liked the most*). These four scores were averaged for each country, and an appeal score per text message was used to rank the messages within the same stage of the same key domain. For example, in each country, the 6 text messages developed for stage 1 in the physical activity domain were ranked based on their average appeal score. This ranking by domain, stage of change, and country was needed to identify the lowest-scoring text messages to be potentially discarded (see Multimedia Appendix 2).

The 2 text messages with the lowest scores were reviewed again. Priority was given to the understanding of the messages' key ideas, and taking into account the participants' opinions and suggestions about each message. After this exercise, 1 of the 2 messages was discarded by consensus between reviewers.

Ethics

The study protocol, field instruments, and informed consent forms were reviewed and approved by local Institutional Review Boards (IRB) in Argentina, Guatemala, and Peru, as well as RAND Corporation's IRB. All participants were informed about the study and gave oral consent.

Results

Overview

A total of 108 participants (36 per country) took part in the study. The average age was 42 (SD 8.5) years old and 50% (54/108) were male. We expected to collect four evaluations for each of the 64 text messages in every country, with a target of 768 total evaluations. One evaluation was missing at the end of the validation study, thus, a total of 767 valid evaluations were analyzed.

Understanding of SMS Text Messages

According to the judges, 96.7% (742/767) of the evaluations revealed an adequate understanding of the key idea contained in the text message. This figure was very similar in Argentina (248/255, 97.3%), Guatemala (247/256, 96.5%), and Peru (247/256, 96.5%). Of all the responses, feedback provided by Argentinian participants tended to be more detailed and clearer than that from Guatemala and Peru.

Across countries, only 4.0% of answers (31/767) indicated that participants did not understand the text message, or at least one word in it (8/255, 3.1% in Argentina, 8/256, 3.1% in Guatemala, 15/256, 5.9% in Peru). Examples of words or expressions that were not understood by some respondents included nutrition- and health-related words, such as "fibras" (fiber, in Peru), "frutas de estación" (seasonal fruits, in Argentina), and "físicamente activo" (physically active, in all three countries).

Appeal of SMS Text Messages

The appeal scores for text messages ranged from 4 to 10 points. The average score for all 64 text messages in all three countries was 8.7 (SD 1.8) points. The average scores for Guatemala, Argentina, and Peru were 9.4 (SD 1.4), 8.4 (SD 1.5), and 8.3 (SD 2.2), respectively. Detailed scoring per country, key domain, and stage of change are shown in Table 4.

In Guatemala, 19 out of 64 (30%) SMS text messages received the highest average score of 10 points. Only 2 out of 64 (3%) text messages in Argentina and 0 out of 64 (0%) messages in Peru received a score of 10. Within each domain and stage of change subset, the lowest-ranked text messages were not always the same across countries, although some coincidences were noted. Detailed scoring per text message by country is provided in Multimedia Appendix 2.

In all three countries, 1 text message that did not appeal to some participants was "¿Por qué no haces algo distinto? Empezar tu día con una fruta te ayudará a estar sano y no engordar," which translates into English as "Why not try something different? Starting your day with fruit will help you be healthy and avoid getting fat." This message was unappealing to some participants because "getting fat" was considered slightly hurtful by some people. Also, 1 text message in particular that was criticized across all countries was "Cuéntales a las mujeres de tu hogar que las frutas y las verduras ayudan a bajar el colesterol y protegen el corazón," which translates into English as "Tell the women in your household that fruits and vegetables help lower cholesterol levels and protect the heart." The latter was a male-directed text message with instructions targeting the women of the household. Therefore, participants considered this information to be not only relevant for communicating to females, but for all the family members.

Table 4. SMS average appeal scores by country, key domain, and stage of change.

Key domain and stage of change	SMS text message appeal score, mean (SD)			
	Argentina	Guatemala	Peru	Total
Salt and sodium intake				
All stages	8.13 (1.54)	9.16 (1.60)	8.30 (2.11)	8.53 (1.81)
Precontemplation and contemplation	7.83 (1.61)	8.92 (1.84)	8.42 (1.72)	8.39 (1.76)
Preparation and action	8.25 (1.51)	9.33 (1.55)	7.79 (2.45)	8.46 (1.97)
Maintenance	8.38 (1.50)	9.25 (1.29)	8.88 (2.03)	8.83 (1.64)
Fruit and vegetable intake				
All stages	8.42 (1.50)	9.44 (1.51)	8.64 (1.67)	8.84 (1.62)
Precontemplation and contemplation	8.58 (1.53)	9.38 (1.44)	8.75 (1.15)	8.90 (1.41)
Preparation and action	8.41 (1.33)	9.29 (1.99)	8.42 (2.15)	8.71 (1.89)
Maintenance	8.19 (1.72)	9.75 (0.45)	8.81 (1.60)	8.92 (1.50)
Consumption of high fat and sugar foods				
All stages	8.27 (1.73)	9.28 (1.33)	7.80 (2.75)	8.45 (2.11)
Precontemplation and contemplation	8.54 (1.64)	9.25 (1.26)	7.96 (2.61)	8.58 (1.97)
Preparation and action	7.63 (2.02)	9.46 (1.25)	7.67 (2.87)	8.25 (2.29)
Maintenance	8.81 (1.05)	9.06 (1.57)	7.75 (2.93)	8.54 (2.05)
Physical activity				
All stages	8.76 (1.35)	9.59 (1.03)	8.56 (1.98)	8.97 (1.56)
Precontemplation and contemplation	9.00 (1.21)	9.63 (0.97)	7.83 (2.62)	8.82 (1.89)
Preparation and action	8.43 (1.65)	9.54 (0.98)	8.75 (1.51)	8.92 (1.46)
Maintenance	8.88 (1.02)	9.63 (1.26)	9.38 (0.89)	9.29 (1.09)
Total (all domains and stages)	8.39 (1.55)	9.37 (1.39)	8.32 (2.17)	8.70 (1.80)

Selection and Improvement of the Final Set of SMS Text Messages

As per the protocol to provide enough variation per week throughout a year, the final SMS text message set was planned to include 56 messages in each country—6 targeted to men, 6 targeted to women, and 44 for both genders. As mentioned in the methodology section, of all the text messages tested within each domain and stages of change 1 and 2, a total of 8 messages were discarded. Finally, to assemble the final set, some of the remaining 56 messages were modified to improve understanding. Out of a total 56 messages per country, 16 were modified for Peru, 9 were modified for Argentina, and 8 were modified for Guatemala.

The text message selection followed the same process in all three countries and, as anticipated, most messages selected for the final set (49/56, 88%) were the same except for small wording differences. The final text message sets can be seen in Multimedia Appendix 3.

Discussion

Principal Findings

A standardized process for the design and validation of SMS text messages, a key component of an mHealth intervention for the prevention of hypertension, was developed. Through this methodology we were able to obtain three country-specific sets of 56 text messages with high levels of appeal and understanding among individuals from low-income, peri-urban communities. This process and its product, the final set of text messages, were designed to accomplish an ambitious and complex challenge—to promote behavioral change among nonsymptomatic individuals at risk of developing hypertension. In so doing, it embraced the following: (1) the tackling of four behaviors—salt and sodium intake, fruit and vegetable intake, consumption of high fat and sugar foods, and physical activity, (2) the discrimination between three distinct stages of change within each behavior, and (3) being mindful of gender differences.

As text messaging interventions become more common, it is necessary to make the procedures behind their development explicit [26]. In this scenario, our study yielded a number of valuable lessons related to the design and validation of text messages: (1) application of theoretical frameworks in the behavioral change and health communication domains, (2) evidence-based selection of lifestyle habits to target, (3) language and cultural adaptation of text message content, and (4) involvement of end users in message validation. These four aspects, further detailed below, were devised for the implementation of a prevention strategy for hypertension, but can be applied effectively to other conditions.

First, regarding theoretical frameworks, it has been postulated that "if SMS (text message) intervention studies are built on evidence and theory, the potential impact of these studies will be much greater" [27]. In our case, the use of the Transtheoretical Model [24,25] signaled the need to develop SMS text messages that were tailored to specific stages of change, and guided the phrasing of initial versions of the messages. This procedure was further supported by health communications frameworks [28] that recommend the use of "gain-framed messages" [29], which emphasize the benefits of taking action, when developing initiatives to promote behaviors that prevent the onset of disease.

Second, reviewing available evidence on hypertension prevention was useful on two fronts. Initially, this approach helped in selecting the four lifestyles to focus on. For example, reducing tobacco and alcohol use were excluded during the initial planning phases due to their smaller effects on lowering blood pressure. Then, this evidence-based approach was also helpful in prioritizing actions and recommendations within each habit to be delivered via text message.

Third, being aware that social context influences behavioral change and that "communication is not simply message repetition" [30], we placed special attention onto the cultural and language adaptation of the text message content. This was done in all three countries and involved researchers, health communicators, and end users. The tailoring of health messages and counseling strategies to be sensitive to the cultural beliefs, values, language, literacy, and customs of the target population has been labeled with the strongest level of evidence [31].

Fourth, as depicted by the quote "focus on the user and all else will follow" [32], our validation process incorporated an engagement phase with end users. Their evaluations and opinions were a major contribution to defining the final set of text messages.

We believe that our validation design is strong as it brought together aspects of theory, evidence, and context to develop and validate three sets of 56 SMS text messages across Latin American settings. Our text messages had a 97% level of understanding and an average of 8.7 out of 10 points in appeal, thus they could be useful beyond the original study for which they were developed. Noticeably, in all countries the understanding and appeal of the text message contents were quite high, when on an *a priori* scenario, we could have expected more differences given the diversity of contexts. In this sense, the absence of major differences in understanding or appeal between the three countries or by gender reflect, importantly, that the linguistic and cultural adaptation conveyed during the development process of the study was adequate at all sites. When subjects elaborated in their own words about understanding, however, there were some slight differences by country. Argentinian subjects tended to give more extended or detailed responses when asked about understanding, which may be a reflection of the higher average level of education in Argentina compared to Guatemala or Peru. There were also slight country-specific differences in terms of appeal. Guatemalans tended to be kinder in their ratings, as shown by their higher average ratings compared to the other sites. For example, 19 text messages received the maximum of 10 points in Guatemala, compared to only 2 in Argentina and 0 in Peru. Yet, overall understanding and appeal were not markedly different across countries or by gender and, thus, pose no threat to the validity of our findings.

Limitations

Any validation study requires striking a balance between depth and breadth of the exercise, together with its matching resources. Our study introduced, to its strength, a combination of multi-country sites, four key behavioral domains, and three behavioral stages of change aiming to achieve a final set of 56 SMS text messages to be used weekly during a 12-month period. The resources available, in terms of project's time allocation and financial means, to accomplish such a considerable goal, only allowed 4 people per country to review each text message. Despite the limited number of evaluators per individual message, this process was systematically repeated for all 64 messages, resulting in high levels of understanding and appeal. Future studies should find the right balance between the number of text messages to be developed per domain, stage of change, and gender to determine the optimal sample size needed for subsequent validation studies.

An additional minor limitation was that we did not have the means to audiotape the answers provided, and having interviewers' handwritten notes may have introduced some observer bias or resulted in missing information that was not recorded. Despite this limitation, overall, the registries were considered by the research team to be very good. To assess text message appeal, we used a short focused instrument with only 7 items for each message to avoid introducing unnecessary complications to the participant's assessment of the message. We acknowledge that other instruments may be able to capture appeal features in greater detail. Again, a balance between the size of the task and available resources will clearly impact such decisions regarding which instrument to use. Future studies could have greater focus on tailoring the text messages to actual transitions between stages of change, be it on the direction of change, or in the number of behaviors that demonstrate actual change. As this was not part of our study design, we did not consider these temporal changes in designing our text messages.

Conclusions

In today's global health context, mHealth has secured a place as a dynamic field with the potential to reduce health gaps and disparities by improving health behaviors and disease self-management, as well as facilitating health care delivery processes [33,34]. As with any evolving area, more emphasis on process and methodology, such as those described in this validation study, is required. Taking into consideration that SMS text messaging is one of many delivery channels, clarity of the communication is key [2], and very few studies have properly described their methods and criteria used for the development and validation of the content of text messages [26,35,36].

This study highlights the importance of developing and validating a package of simple, preventative SMS text messages, grounded in evidence and theory, across three different Latin

American countries with active engagement of end users. We anticipate that the potential impact of these text message sets will be much greater—they could serve as a resource for several different mHealth approaches geared toward improving lifestyle-related behaviors for the prevention of hypertension and other related chronic noncommunicable diseases.

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Authors' Contributions

FDC and JJM conceived and designed the study. FDC, JAZ, AB, RK, MRZ, AR, HM, and JJM conducted the study. FDC and JAZ analyzed the data. JJM and FDC wrote the manuscript. All authors gave final approval of the version submitted for publication.

Conflicts of Interest

None declared.

Multimedia Appendix 1

SMS text message validation questionnaire.

[PDF File (Adobe PDF File), 598KB - mhealth_v3i1e19_app1.pdf]

Multimedia Appendix 2

Ranking of SMS text messages per country.

[PDF File (Adobe PDF File), 311KB - mhealth_v3i1e19_app2.pdf]

Multimedia Appendix 3

Final sets of 56 SMS text messages per country.

[PDF File (Adobe PDF File), 348KB - mhealth_v3i1e19_app3.pdf]

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Abbreviations

IRB: Institutional Review Board
SMS: short message service

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Tutorial

Translating Behavioral Interventions Onto mHealth Platforms: Developing Text Message Interventions for Smoking and Alcohol

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Abstract

The development of mHealth applications is often driven by the investigators and developers with relatively little input from the targeted population. User input is commonly limited to “like/dislike” post- intervention consumer satisfaction ratings or device or application specific user analytics such as usability. However, to produce successful mHealth applications with lasting effects on health behaviors it is crucial to obtain user input from the start of each project and throughout development. The aim of this tutorial is to illustrate how qualitative methods in an iterative process of development have been used in two separate behavior change interventions (targeting smoking and alcohol) delivered through mobile technologies (ie, text messaging). A series of focus groups were conducted to assist in translating a face-to-face smoking cessation intervention onto a text message (short message service, SMS) delivered format. Both focus groups and an advisory panel were used to shape the delivery and content of a text message delivered intervention for alcohol risk reduction. An in vivo method of constructing message content was used to develop text message content that was consistent with the notion of texting as “fingered speech”. Formative research conducted with the target population using a participatory framework led to important changes in our approach to intervention structure, content development, and delivery. Using qualitative methods and an iterative approach that blends consumer-driven and investigator-driven aims can produce paradigm-shifting, novel intervention applications that maximize the likelihood of use by the target audience and their potential impact on health behaviors.

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KEYWORDS

mHealth; text message; smoking cessation; alcohol; qualitative methods

Introduction

Background

Mobile Health or “mHealth” is the use of mobile devices to improve health outcomes, health care services, and health related research. The emergence of mobile devices, the swift adoption of these devices across the global population [1], and the rapid expansion of device capability present many challenges for developers of mHealth applications and interventions. One challenge is the complex problem of developing, integrating, and adopting mobile communications into existing health care

systems. This includes device management, privacy and security, data quality, workflow integration, interface design, and resistance to change among health care workers [2]. A second set of challenges concern the structure and content of mHealth interventions themselves. Specifically, most mHealth programs have not used behavioral theory to guide intervention development [3-4], although this is changing [5]. In addition, relatively few follow evidence-based principles for health behavior change [6]. This limits our ability to determine *why* an intervention was effective, that is, what the mechanism of action or "active ingredient(s)" might be. A third challenge that has received little attention thus far is that of "technological cultural consistency", that is ensuring the developed applications and modes of access (including research methodologies) are compatible (culturally consistent) with the ways in which the intended audience uses technology.

To successfully deliver interventions that impact health behaviors and outcomes, mHealth applications should be designed in a manner consistent with the way that individuals use the devices on which the content is to be delivered. Using qualitative methods and an iterative approach that blends consumer-driven and investigator-driven aims can result in the development of paradigm-shifting, novel applications that maximize the likelihood that the intervention will be of use, and will be used by the target audience -thereby maximizing the potential impact on health behaviors and outcomes. However, the development and implementation of mHealth applications has often used a top-down approach driven by the developers and programmers, with relatively little input from the target population [7]. Often, when user-input is requested, it is limited to post-intervention consumer satisfaction ratings or device/application-specific user analytics such as usability testing of the device and its functionality [8-11]. More recently, some investigators have begun to incorporate feedback from the target population during the formative process of developing mHealth interventions [12-13]. However, for mHealth and other technology-based interventions to have a lasting effect on health behaviors, it is not sufficient to develop applications that function as designed and are easy to use (usability) by individuals in the target audience. It is also important, perhaps even crucial, to develop applications that will be stimulating to participants, and what they *want* to use. This process requires input from users from the start of the project and throughout development.

This paper presents examples of mHealth development using qualitative methods in an end-user participatory framework, and demonstrates how use of this model led to a paradigm shift in the approach to behavioral mHealth interventions. This paper describes the results from the formative research of two studies, and the resulting novel approaches to mHealth intervention development.

Text-2-Quit (T2Q): Changing the Way Tobacco Interventions are Delivered

Each year, smoking kills 443,000 Americans [14]. Currently, 19% of adults in the United States smoke, and adults under age 35 have the highest smoking prevalence of all age groups (25.3%) [14]. Despite the existence of effective, evidence-based smoking cessation therapies and medications, younger adult smokers are least likely to seek treatment, compared to older smokers [15-16]. To see significant reductions in smoking rates, innovative interventions and treatment delivery systems are needed to reach smokers effectively and efficiently.

Use of mobile phones has saturated the general population, and SMS text messaging is widely used, particularly among younger adults (those under age 35) [17-18]. Previous research has shown that even brief behavioral interventions for smoking cessation are effective, and conventional (ie, voice) telephone counseling has long been preferred by a majority of smokers (>75%) compared to face-to-face treatment programs [19], and is often well-received even by unmotivated smokers [20]. Therefore, a logical next step is to adapt smoking interventions for delivery through SMS text messaging. However, there is little theory to support this modality [21], although the evidence base is rapidly expanding.

To date, there have been several studies of text message-based interventions to aid smoking cessation [21-24]. Most of these studies showed significantly greater quit rates among those getting the active text intervention compared with controls. Quit rates among those given text message delivered interventions compare favorably against cessation rates seen for conventional phone (ie, voice) counseling (7-day point prevalence abstinence rate [mean]= 11.1%, rate 8.7-13.4%) [25]. While the majority of interventions using text messaging have demonstrated efficacy, results are not consistent across studies and populations, and there is not yet sufficient data to determine its influence on longer-term smoking abstinence (ie, >6 months) [24, 26]. Importantly, although these programs were largely adapted from evidence-based smoking cessation treatments, little focus has been placed on the characteristics that would be optimal for use within a mobile delivery system.

Text-2-Quit (T2Q) was originally conceived as top-down adaptation of a traditional cognitive-behavioral intervention for smoking cessation that would be delivered through text messages. Core features of interventions for smoking cessation typically include: (1) education about the addictive nature of tobacco and use of medications to aid cessation, (2) identifying "triggers" such as situations and emotions that cue the individual to smoke, (3) setting a definite future "quit day," (4) problem solving around anticipated difficult situations, (5) enlisting social support, (6) teaching behavioral strategies to break old habits and establish new ones, and (7) one or more face-to-face or telephone (ie, voice) counseling sessions.

The original design for the T2Q intervention included a 2-week program of daily text messages to prepare users for quit day, followed by an 8-week program of text messages beginning with 4 times daily during quit week and tapering to once daily by week 8 post-quit day. The program had different "tracks" to tailor the content, based on the user's smoking status: "Prepare" (preparing for quit day); "Quit" (quit weeks 1-8); "Not Ready" (designed for those not yet ready for the "Prepare" program); and "Prepare-2" (getting ready for a new quit day after a relapse). Messages in the "Prepare-2" track were similar, but not identical to those in the "Prepare" track, to avoid redundancy and boredom for individuals who had prepared to quit, relapsed,

and were now getting ready for a second attempt. The program also allowed users to request additional automated messages to help them deal with immediate cigarette cravings (by texting the keyword "Crave").

Formative Research: Asking Targeted Questions of Individuals From the Targeted Population

Formative qualitative research, conducted prior to intervention development or adaptation, enables researchers to understand what representatives of the target audience think about the proposed intervention [27]. It can assess the feasibility of the intervention, identify possible implementation problems and also elicit participant opinions on alternative implementation strategies [28]. The T2Q focus groups were designed to elicit feedback on the planned program content and delivery, so that modifications could be made before the intervention trial. Because little mHealth smoking cessation research had been conducted, we needed to know how people in the target population were using their rapidly evolving mobile technology for communication, and whether they would be willing to use it to engage in a smoking cessation program.

Internet advertisements and flyers posted in local commercial venues were used to recruit participants for focus groups. Individuals calling in response to these ads were screened for eligibility (age 18-35, current smoker or ex-smoker quit less than 1 month, daily user of text messaging). Eligible individuals were invited to attend a single focus group to view a demonstration of the proposed system and provide feedback as potential end-users. Participants (N=21, mean age=25.6, age range= 20-33) included 18 current smokers (mean cigarettes/day=12.8) and 3 individuals who had recently quit (< 3 months) who used text messaging. Prior to the start of the 2-hour focus group all participants completed consent procedures and questionnaires that had been approved by the Institutional Review Board (IRB).

For this study three focus groups were conducted. Focus groups began with a discussion of the participants' use of computer, social media, and other technologies, narrowing to a discussion of their mobile phone use. Then a short graphical and verbal presentation was given describing the overall problem of smoking, and evidence-based therapies for smoking cessation, followed by the planned design for Text-2-Quit program. The focus group was then opened for more discussion of the planned program itself, using *a priori* semi-structured interview guide to promote discussion of the content and functionality of the intervention. Focus groups were audio-recorded, then transcribed and coded. The agreed upon coding values and transcripts were entered into NVivo10 qualitative data analysis software.

Our analysis of these data showed that there was strong support for a text message-based cessation program. Participants' suggestions drove us to create a more technologically broad-based program, and led to adjustments to the planned program structure. In particular, participants recommended not only social networking functions, but also more user control of the program —preferably through an online profile "like a Facebook for smokers", variability in the timing and delivery of messages, and features that would promote additional interaction with the system. Many participants also stated that the program should be able to start on the user's quit day, even if that day happened spontaneously with no preplanning.

In response to this feedback, the intervention was revised in several ways. First, to enhance user control of the program, additional "key words" were developed that users could text to the program phone number to control their "track" within the program. For example, texting "Slip" increased the number of daily texts to the individual by adding four messages focused on coping with slips and avoiding relapse. Texting "Relapse" would prompt a response asking whether the user was ready to set another quit day (and thus, go into the "Prepare-2" track), or not (and as a result be assigned to the "Not Ready" motivation-focused track). Second, some focus group participants had indicated that receiving messages at standard times would be helpful: "*Something in the beginning of the* day*...right in the morning to motivate you*." However, others said clearly that receiving messages at fixed times would lead them to ignore the message:

> *If I know that I'm getting a text at, let's say, 9:00 in the morning and 5:00 in the afternoon every day, after a while I'm just going to be like "I'm not even going to answer that, [because] I already know what that's about"*

These data showed that participants valued the number and frequency of messages, but also that we needed to vary the timing of messages over the course of the program. Therefore, the intervention was programmed to have both a fixed (start of day, end of day) message delivery and variable timed messages.

Finally, and most significantly, many participants wanted to sign up for this program on the day they decided to quit smoking, rather than in advance of quit day. This response contradicts a significant convention used in most behavioral smoking cessation programs, which are designed to prepare individuals for a specific, future quit date typically several days or weeks after program enrollment. Focus group participants indicated instead that they would sign up for a text message-based program only when they decided that "today's the day [that I'm ready to quit]". This feedback led to two important changes: The system was programmed to allow users in any stage of the program to text "Quit" if they decided to quit ahead of their targeted quit day, and they then immediately begin receiving texts appropriate to the first days of quitting. We also wrote post-quit day messages to include the information users may have missed if they had not received the Prepare track of the intervention.

An important theme that emerged from the focus groups was participants' strong interest in exchanging messages with others enrolled in the intervention. They perceived this feature as another opportunity to interact with the program and have access to social support from others who were trying to quit at key times: "*If there was like a group, you could text and say, 'I really need a friggin' cigarette right now*.'" They also wanted the program to provide immediate support for cravings. This was consistent with the way they used phones in other situations *…When I try quitting, you know, I'll call my husband...[and say] 'I really want to have a cigarette,' and he'll tell me 'It's*

not worth it, just, you know, think about what you can get.' So you definitely need someone to interact back with you."

To address this request, a method was needed that would provide individual social support while simultaneously protecting the privacy of program users. Some previous studies have provided users with contact information to another program user (ie, a "quit buddy") when requests were made to study staff [22]. However, individuals using technology for social support typically use social networking services and platforms (eg, Twitter). Thus, calling the study staff to receive an individual contact number for a quit buddy is not culturally consistent with the way people use technology. Using online user groups in which users can post messages anonymously (using a UserID) as a model, a separate phone line texting protocol was constructed that allowed individuals to text "Help@*" messages that would be sent to a group comprised of nine other users. It was decided to have 10 members for each @*group to maximize the probability that one or more other users would respond while limiting the chances of an overwhelming number of responses. Conversations in response to these group help messages functioned much like an online chat. By using this protocol filtered through the central phone line, the actual phone numbers of all participants in the group were protected while providing smoking peer contact.

Process Evaluation: The T2Q Pilot

The Text to Quit (T2Q) study was a randomized controlled trial in which the newly developed smoking cessation texting intervention was tested against a comparison condition in which participants received daily motivational (not smoking related) texts [29]. All procedures for the trial were approved by the Institutional Review Board prior to initiating recruitment. The planned recruitment procedures were similar to those used to recruit the focus groups: advertisements were placed in local media outlets (internet sites, radio programs) asking interested individuals to call or text the study phone. A Research Assistant (RA) contacted callers by voice-phone, provided a brief description of the study (prescreening introduction), and screened callers for study eligibility. Eligible individuals met the following criteria: (1) current daily smoker, (2) interested in quitting smoking in the next 30 days, (3) have a mobile phone with text messaging capability, and (4) use text messaging at least once monthly. Eligible individuals were then scheduled for an in-person baseline visit during which they provided written consent and took part in a single in-person smoking cessation counseling session. Following initial counseling, participants were to be randomized to either the T2Q intervention or the control condition.

Over a period of 3 months 147 contacts (96 calls, 51 texts) were received. However, 28 of those had "text only" phone plans and could not be screened. Eighty-three individuals were contacted by voice-phone for screening, the vast majority were eligible (88%), but most were no longer interested when they were told they would be required to attend an in-person orientation and counseling session. Altogether, a total of 7 participants were enrolled and randomized using these procedures. These slow recruitment and high attrition rates necessitated a change in recruitment methods. In particular, study procedures were needed that were consistent with the way the target audience used technology. Traditional methods of in-person orientation, screening and smoking treatment were clearly not acceptable to most respondents.

Study recruitment was suspended for three months to develop a web portal that would deliver all recruitment procedures seamlessly. The initial web page provided the pre-screening introduction to the study. Interested individuals clicked through to a second page that presented an online screener that was programmed to determine the individual's eligibility. Eligible individuals were then presented with an online consent form to sign electronically. The online consent included a brief quiz to ensure that individuals understood: that this was a research trial, that participation was voluntary and could be stopped at any time, and that data were confidential. After indicating consent, the participant provided identifying and contact information, and completed an online baseline assessment. Given the length of these procedures and the limitations of attention-span for online surveys, participants were allowed up to two days to return and complete the baseline survey. At the conclusion of the assessment, the web program randomly assigned individuals to the two study arms and presented an online Google calendar that participants used to schedule their counseling session. Users also selected whether they wanted to receive their counseling session in person, by voice phone, Skype, or Google Chat. New advertisements were developed that included the website URL as an alternative to calling the study phone line. Using these methods, 96 individuals were screened, 11 were found ineligible, and 51 signed consent and were randomized over the next 21 days. Study results are published elsewhere [29].

Summary: Lessons Learned From Text-2-Quit

TXT-2-Quit used an iterative mixed-methods approach in which formative qualitative assessment was an integral, preplanned part of the intervention development and product design. Initial investigator-initiated design was followed by focus groups, and the analysis of qualitative data obtained in those groups was used to modify the design. Following this, the program was implemented and both quantitative data (such as recruitment numbers) and qualitative feedback (conversations with callers regarding why they were unable to participate) resulted in further changes to the program design. From this process several major improvements were made to the program, including adding more user control of program delivery, a peer-to-peer social network for support, and other features that enhanced user-interaction with the program. From a clinical perspective, the most striking change from the original design was allowing for the smoking cessation program to begin on the individual's quit day, based on individual preference. It also became apparent that using traditional recruitment methods with a new technology-based intervention not optimal. The study was greatly enhanced by revising recruitment and intervention delivery methods to match the way in which the target audience normally uses technology and mobile devices.

Developing an Alcohol Intervention for Community College Students

Excessive alcohol use is the third-leading preventable cause of death in the United States [30], and is a widespread problem among college students [31]. Nearly half of all community college students (CCS) engage in heavy alcohol use [32], which is similar to the high rates seen among students at four-year colleges [31,33]. However, compared to students at four-year/residential colleges [34], there has been relatively little effort to assess and intervene with community college students on hazardous alcohol use, despite these students comprising 40% of all college students nationwide [35]. Epidemiological and observational studies of CCS have reported high levels of alcohol consumption [36], binge drinking [37-38], and drinking more heavily than students at four-year/residential colleges [39-40]. CCS are also at higher risk for negative consequences of heavy drinking including social and health impairment, physical or sexual assault, and unintentional fatal injuries, and are at significantly higher risk for driving under the influence compared to students at residential colleges [31, 39-40]. CCS also tend to come from low-income families, have more diverse ethnic/racial backgrounds than students at residential colleges [35], and have multiple roles and responsibilities (eg, child rearing, single parents, full and part time employment, etc), which speaks to the need for intervention approaches that are tailored to the needs and life-circumstances of this at-risk population. Intervention delivery modalities, particularly mobile health approaches that can be inexpensively provided in an appealing format with wide reach are particularly compelling for reaching this population.

Text message delivered programs have been developed recently for university students [11] but work with community college students is still lacking. The goal of "Text Message Alcohol Program" (TMAP) was to develop an intervention for alcohol-related harm reduction for community college students delivered using text messaging with components that included motivational messages, harm reduction strategies, evocative questions, and social networking support.

Formative Research

Phase 1 of the TMAP project involved program development and evaluation and again, formative qualitative work was essential because we needed to know what CCS thought about the planned intervention, including whether they would use it and what they thought of sample messages. CCS from Rhode Island & Southern Massachusetts age 18-28 years, were recruited to participate in the focus groups. Recruitment strategies included campus media outlets, flyers, email, radio advertisements, and presentations in classrooms. Students were eligible if they met the following criteria: (1) age 18-28 years (2) current CCS (3) reported at least three heavy drinking episodes in the past two weeks (4) have a mobile phone and use text messaging at least weekly. A heavy drinking episode was defined as four or more standard drinks for females and five or more standard drinks for males on one occasion in the past two weeks (a standard drink is a 12-ounce beer or wine cooler, a 5-ounce glass of wine, or one mixed drink, or 1 shot of liquor). Of the total 40 participants screened, 26 were found to be eligible for the study. The study was approved by the Institutional Review Board and informed consent was obtained from all participants.

Five focus groups were conducted with a total of 26 students (mean age 22.3 years [SD 3.5]). Each focus group lasted about 2 hours. The focus group guide was developed to learn how students used their phones, including if and when phones were turned off, when students ignored texts, and if they had either mobile phones or text-only services. Plans for the text messaging program and sample messages written by the research team were then shown to participants. These sample messages fell into three categories: safer drinking strategies, myths, and facts about alcohol use, and links to related on-line content. Students were asked for specific feedback on the content of the texts and their preferences for message tone (eg, funny, scary, factual), and format (eg, text only, texts + links to other information). Students were also asked what kind of messages they might text a close friend who was out drinking if they wanted to encourage the friend to be safe about his/her drinking.

As in the T2Q study, focus groups were audio-recorded, transcribed and de-identified. A detailed codebook was constructed based on *a priori* research questions and emergent content. Two research team members individually coded each transcript then met to review the coding. The agreed upon coding values and transcripts were entered into NVivo10 qualitative data analysis software.

CCS reported that messages should apply to specific drinking contexts, including "pre-game" and "post-game" messages for before and after a drinking occasion, and for purposeful drinking (ie, times when drinking is done specifically to get high/drunk). They also said messages should be tailored to the different drinking habits of younger versus older drinkers, and to those who are less experienced with alcohol and its effects, compared with more experienced individuals.

Focus group participants felt that texts should deliver a message of caring. For example: "*Drink responsibly, someone at home loves you*" And *"Hey girl, I hope you have fun tonight, but at the same time, be safe. Enjoy your night.*"

Participants in all the groups indicated that they did not want to be told NOT to drink, but that they did not mind being helped or encouraged to make wise choices when they did drink. And they provided specific feedback on sample messages and why they might not work. For example, in response to the sample message *"Still thirsty? Switch to water. You'll thank yourself tomorrow!"* participants said that they were not drinking alcohol because they were thirsty, so the message sounded like it was written by people who did not know how or why community college students drink, or how they texted.

It became evident that the intervention should include both fact-based texts to inform and motivate safe drinking as well as texts that sounded like they were written by and for community college drinkers. The research team wrote the first category of texts, and received feedback on them during the focus groups. Methods to craft the second category of texts were informed entirely by the focus group members themselves.

During the first group, one participant asked for a paper and pen, and on the spot, began to (re)write texts in his own words. After this occurred, all subsequent groups were provided with note cards and pens and invited (but not required) to revise the researcher written text messages, or to write original messages of their own.

Comparing the students' texts to the messages written by researchers revealed that although texts are typed, their construction and usage more closely resembles casual speech than written language. The sociolinguist John McWhorter suggests that, in fact, texting is a form of "fingered speech": a language that has its own structure and specific rules [41]. This new linguistic form is developing and evolving, driven by adolescents and emerging adults who are typing speech and then sending it to one another as text. It is not, therefore likely to be effectively "spoken" by older adults and behavioral scientists.

This realization from the qualitative work led to a redesign of the project procedures, and development of a novel in vivo method of text message content development and collection. An advisory panel of 8 individuals from the target population (CC students who drink and use text messaging) was convened to help construct the actual content of the intervention messages. The advisory panel met once weekly for five weeks. During those meetings and on days between panel meetings, panelists actively composed sample text content using their mobile phones and sent these texts to the study phone line for data collection. Texts were written about the topics that had emerged from the previous focus groups (eg, caring, timing, planning to go out, pre-gaming, morning after messages). Panelists rated a list of factual and strategic messages written by researchers, indicating to what degree each might influence them to engage in safe drinking. They were also asked to rewrite messages to sound more natural –as if they were written by peers. A total of 328 messages were generated by the panelists. These student-generated texts were reviewed by five investigators independently. Messages liked by at least 3 reviewers were included in the pilot randomized controlled clinical trial along with factual and strategic messages that were liked by most panelists. The final program content included 14 panelist-generated messages, 12 factual messages re-written by panelist and 10 strategic messages. The message pool for female participants was modified to include 2 messages about alcohol and sexual safety. These messages are currently being used in the randomized controlled trial.

Conclusions

Using qualitative methods in an end-user participatory framework produced important changes in the delivery and content of two distinct mHealth interventions designed to be delivered through text messaging. Results of the T2Q study showed that younger adult smokers were interested in participating in a smoking cessation program delivered through text messages. However, qualitative feedback from the target audience regarding the perceived optimal features and structure of a technology-based intervention challenged traditional methods of implementing smoking cessation interventions. Similarly, focus group feedback obtained from community college students about alcohol harm reduction messages was compelling and resulted in using the intervention modality itself (texting) to collect message content examples from students in vivo. That is, messages were created by students texting messages to our phone line both during the focus group itself, and while out in the community during the week between meetings. This in vivo methodology may result in particularly effective message content in that messages written using texting may result in intervention content that "sounds" like real text messages, and may convey a feeling of authenticity to the receiver that content written by other methods may not. To our knowledge, the TMAP study is the first to use this in vivo method of developing text message intervention content.

It may not be sufficient to develop mHealth interventions that function as designed and are usable by individuals in the targeted populations [42]. To have an impact on health and health behaviors, interventions must be perceived by individual users as both useful and desirable. These applications must be something that an individual would *want* to use. To accomplish this, mHealth applications may need to include participation from individuals in the targeted population in the initial design process. Additionally, researchers and developers should document their thought process and rationale for decisions made during the initial stages of protocol and content development [43]. Feedback obtained from these individuals, when obtained early in the design and development process can fundamentally change the organization, delivery and content of planned interventions. Likewise, designing mHealth programs that are culturally consistent with the way individuals already use technology is important. Developing interventions and associated applications in ways that are consistent with how people use technology may result in higher perceived utility and desirability of the final application product and ultimately more efficacious interventions. Further testing will reveal whether these changes result in more used, and therefore, more impactful interventions.

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Authors' Contributions

BB, NB and RKR wrote the original study design and oversaw the conduct of the study. RKR and HT performed qualitative data analysis. KW recruited participants and acted as liaison with the community college. RF and CD programmed the text message delivery system. All authors contributed to the writing of this manuscript.

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Abbreviations

CCS: community college students
IRB: Institutional Review Board
T2Q: Text-2-Quit, the smoking cessation text message program developed in this study

TMAP: Text Message Alcohol Program

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Original Paper

SMSaúde: Design, Development, and Implementation of a Remote/Mobile Patient Management System to Improve Retention in Care for HIV/AIDS and Tuberculosis Patients

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Abstract

Background: The widespread and low cost of mobile phones and the convenience of short message service (SMS) text messaging suggest potential suitability for use with alternative strategies for supporting retention in care and adherence to the treatment of various chronic diseases, such as HIV and tuberculosis (TB). Despite the growing body of literature reporting positive outcomes of SMS text message-based communication with patients, there is yet very little research about the integration of communication technologies and electronic medical records or electronic patient tracking systems.

Objective: To design, develop, and implement an integrated mobile phone text messaging system used to follow up with patients with HIV and TB in treatment in Mozambique.

Methods: Following the design science research methodology, we developed a Web-based system that provides support to patients. A case study involving three health care sites in Mozambique was a basis for discussing design issues for this kind of system. We used brainstorming techniques to solicit usability requirements, focus group meetings to discuss and define system architecture, and prototyping to test in real environments and to improve the system.

Results: We found six sets of system requirements that need to be addressed for success: data collection, telecommunication costs, privacy and data security, text message content, connectivity, and system scalability. A text messaging system was designed and implemented in three health facilities. These sites feed data into a central data repository, which can be used for analysis of operations and decision support. Based on the treatment schedule, the system automatically sent SMS text message appointment reminders, medication reminders, as well as motivational and educational messages to patients enrolled in antiretroviral therapy and TB treatment programs.

Conclusions: We successfully defined the requirements for, designed, and implemented a mobile phone text messaging system to support HIV and TB treatments. Implementation of this system could improve patients' self-management skills and strengthen communication between patients and health care providers.

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KEYWORDS

mobile health; text messaging; SMS system; patient management; design science research; Mozambique

Introduction

The HIV and Tuberculosis Problem

HIV/AIDS and tuberculosis (TB) are major public health problems in many developing countries around the world [1]. Globally, in 2012, an estimated 35.5 million people were living with HIV and some 2.3 million people were newly infected [2]. Of the global burden, Sub-Saharan Africa had 25 million people living with HIV and nearly 1.6 million new HIV infections [2]. In 2013, an estimated 9.0 million people developed TB and 1.5 million died from the disease, 360,000 of whom were HIV-positive [3]. In Mozambique, in 2012, 1.6 million were living with HIV and there were 120,000 new infections [2]. In 2013, nearly 140,000 developed TB and close to 18,000 died from the disease in Mozambique [3].

One major problem with HIV/AIDS and TB treatment is ensuring patients pursue their treatment, including medication and medical checkups until completion. Hence, there is a need to improve the adherence and retention in care. While there may be many reasons for the lack of endurance, there may be ways to improve completion of treatment programs by maintaining better contact (communication) between doctors and patients.

Mobile Interventions

Mobile phone technology has the potential to serve as a strategic intervention medium to improve patient management [4]. Due to the widespread use and low cost of this technology, it pervades all age groups and many cultures and socioeconomic backgrounds, including in developing countries. It allows communication across geographic boundaries and reaches people directly where they are located [4].

Mobile phone short message service (SMS) text messaging is well suited for supporting self-management and improvement of patients' self-efficacy skills through, for instance, medication reminders [5-10] and motivational text messages [8,11]. But there is also a need for interactive program management by reacting promptly and effectively to deviations from program plans. This may include operational decisions for short-term management of patient retention at individual care centers, tactical decisions such as reconfiguring the messaging based on performance, and strategic decisions such as data collection or preservation.

Mobile phones integrated with electronic health records (EMR)—in the context of HIV and TB programs called electronic patient tracking systems (EPTS)—could have the potential to empower the health care system and improve patients' welfare, as well as help patients improve self-management of their disease. For instance, mobile phones could be used to transmit data collected from a patient's mobile phone to a remote system [12,13] where data is processed and accessible for physicians. This data could then be used to send medical recommendations to patients [14-16]. For example, mobile phones were incorporated into a central terminal for personal health examination, where a system referred to as mobile health examination launched on the phone (M-HELP) could generate electronic health records and send them to physicians via email or multimedia messages [17].

Effects of the use of mobile phone text messaging on antiretroviral therapy (ART) adherence have been investigated in a number of studies. A study in Kenya examined adherence and found that weekly text messaging enhanced ART adherence and improved suppression of viral load [18]. In Brazil, SMS text messages were able to help Brazilian women living with HIV/AIDS to remain adherent to ART for a period of 4 months [19]. Daily text messaging was found to be a feasible and acceptable way to remind HIV-positive youth with poor adherence to ART to take their medications, and there was a significant increase in adherence rates, postintervention [20]. In a study with participants from Cameroon and Kenya, text messaging was found to have a significant effect on adherence to ART [21]. A systematic review by Nglazi and colleagues [22] found only four studies that compared the outcomes of the SMS text message intervention group with controls for promoting adherence to TB treatment. One example is a study in South Africa, where SMS text message reminders were equally effective compared to the more resource-requiring directly observed therapy, short-course (DOTS) strategy [23]. In another study, SMS text message reminders were utilized when patients were delayed in opening their medication bottles, and increased TB cure and smear conversion rates were reported compared to DOTS [24]. In Kenya, SMS text message reminders increased rates of clinic attendance on scheduled days compared to standard care [8]. However, not all SMS text message interventions yield positive results. For instance, in Argentina SMS text message intervention did not significantly improve adherence to tuberculosis treatment compared to self-administration [25]. A study by Mills and colleagues [26] found 14 interventions using daily and weekly text messages as treatment supports, alarms, and counselling. The study found that treatment supports with enhanced standard of care (SOC) and weekly text messages were significantly better than basic SOC [26]. A similar Cochrane review reported that SMS reminders improved outcomes—adherence to medication or to treatment in 49% (24/60) of the studies, appointment attendance in 18% (11/60) of the studies, and nonattendance rates decreased in 18% (11/60) of the studies [27]. In summary, there are many positive reports, but as not all cases are successful there appears to be an implementation factor—implementation can be done in many ways and the above Cochrane review suggests that only some of them are successful.

Justification for the Study

Despite the growing body of literature documenting the outcomes of text messaging-based intervention and, in some cases, its integration with EPTS, it has become important to document not only outcomes, but also development procedures. To this end, it is of great importance to report the engineering behind such positive or negative effects of the use of mobile phone text messaging-based technologies. In the literature, few studies are available that routinely provide sufficiently detailed descriptions about the requirements—design, development, and implementation processes—of these interventions [28], which are particularly important as not all studies show positive results. Ngabo and colleagues [29] described requirements for designing and implementing a mobile phone-based communication system aimed at monitoring pregnancy and reducing bottlenecks in

communication associated with maternal and newborn deaths [29]. Consolvo and colleagues [14] reported their experiences with developing a prototype mobile phone app and presented four design requirements for technology that encourages physical activity: (1) give users proper credit for activities, (2) provide personal awareness of activity level, (3) support social influence, and (4) consider the practical constraints of users' lifestyles [14]. What is yet largely lacking in the research literature, however, are studies analyzing all the practical technical decisions taken in developing the integrated system. For this reason, this paper focuses especially on the design, development, and implementation of a text messaging system integrated into the electronic medical records of HIV/AIDS and TB patients to help them efficiently manage their treatment.

Case Description

In 2008, Absolute Return for Kids (ARK)—a United Kingdom-based international organization whose purpose is to transform children's lives—in partnership with the Ministry of Health in Mozambique, launched a 5-year program in five health facilities in the Maputo province aiming to put in place a sustainable model of care to keep HIV-positive parents, caregivers, and children alive. In 2012, ARK started pilot-testing an SMS text messaging study (SMSaúde) to encourage patients to return to the health facilities for treatment, sending text messages about appointment dates and the need to take medication regularly. This system was pilot-tested over 1 year and 3 months. Toward the end of 2012, ARK planned to scale up the project to 16 more health centers, but there was a need to improve the system. The pilot system lacked some features, such as automatic reply to patients' messages and an interface for the visualization of (patient's) data. Also, the administration of the system was complicated, laborious, and error-prone as it was distributed to each heath care site.

In this paper, we show how we took part in helping ARK to overcome the barriers facing the plan to improve the system and scale up the project to reach another 16 health centers in the Gaza province, Mozambique.

Study Objective

The study objective of SMSaúde was to evaluate the use of mobile phone text messaging to improve retention in HIV and TB care in Mozambique. This paper focuses on three key activities—defining the requirements, design and development, and implementation—in the creation of a prototype of SMSaúde aiming to facilitate communication between patients and the health care system, and to improve patient retention to HIV/AIDS and TB treatments.

Methods

Research Framework

The research framework applied in this study is design science research (DSR) [30]. DSR involves a rigorous process to design artifacts to solve observed problems, to make research contributions, to evaluate the designs, and to communicate the results to appropriate audiences. The design-science paradigm draws on the sciences of the artificial [31] and is constructive to its nature—"The process of constructing and exercising innovative IT artifacts enable design-science researchers to understand the problem addressed by the artifact and the feasibility of their approach to its solution" [30].

The project followed the design science research methodology (DSRM) [32] and the proposed solution was operationalized in a prototype developed by the authors of this paper. To implement the prototype, three health care centers within the ARK organization were selected for the case study. DSRM comprises six steps: (1) problem identification and motivation, (2) objectives of a solution, (3) design and development, (4) demonstration, (5) evaluation, and (6) communication [32]. DSRM focuses on solving real-world problems through creation and evaluation of information technology (IT) artifacts [30]. DSRM is, therefore, appropriate in this research since the situation required intervention in real-world operations. In this paper, we focused on the first five steps of DSRM.

Problem Identification and Motivation

This step requires a definition of the specific research problem and justification of the value of the solution [32]. As part of this exercise, it is necessary to provide a problem definition that will be used to develop an artifact that can effectively provide a solution [32]. As part of justifying the value of the solution, it is important to motivate the researcher and the audience of the research so as to pursue the solution and accept the results [32].

To investigate the current system, the first author of this paper (JAN) had four meetings with ARK staff. The output of these meetings was a document describing a new approach. The approach proposed to redesign the SMSaúde system attempting to meet specific requirements and adding more functions that would allow ARK to use the system in another province with 16 health facilities.

Objective of a Solution

The aim of this step is "to infer the objectives of a solution from the problem definition and knowledge of what is possible and feasible" [27].

Solution objectives were formulated through discussions between two ARK's staff (project coordinator and project director) and the first author of this paper. Several iterations were made in the process of formulating the objectives for the new systems. During these iterations, the researcher first presented and explained the initial version of the objectives. Subsequently, the project coordinator from ARK reviewed the solution objectives. The feedback provided by the project coordinator was used by the researchers to reformulate the solution objectives. Again, this presentation and review cycle continued until satisfactory solution objectives were achieved.

Design and Development

This activity creates the artifacts—constructs, models, methods, or instantiations—and includes determining the artifacts' desired functionalities and their architectures [32].

A broad set of usability requirements was identified during two brainstorming design sessions between the researchers and two medical doctors. The doctors were researchers with strong

clinical backgrounds and substantial experience in health care and transversal understanding of the problems faced by patients and health workers. During the first session, the medical doctors outlined the requirements that they anticipated the system should offer. These requirements were then documented and elaborated in more detail as new ideas were exchanged within the design team (two medical doctors and two computer experts). All sessions were recorded, transcribed, and analyzed. The design principles of the system were derived from these sessions.

The general architecture of the system was analyzed and refined in discussion with the development team. The development team was composed of three undergraduate students in informatics and lead by the first author. Next, the team went through an interactive process that frequently switched between programming steps and discussion meetings where the prototype was tested. Mainly, the discussion meetings focused on informing rapid prototyping via identification of implications for technology design and enhancement.

The development team and the two medical doctors assessed the responses from patients in the current system, which were stored in a Microsoft SQL server, to identify patterns that could be used to define relevant answers. The output was a list of possible automatic SMS text message replies.

Demonstration

In this step, it is necessary to demonstrate the use of the artifact to solve instances of the problem [32]. The activity of demonstration could be effectuated in experimentation, simulation, case study, or other appropriate activity [32].

The SMSaúde system was pilot-tested in five health facilities: Machava 2, Matola 2, Matola 1, Ndlavela and Namaacha. All five centers provide both routine HIV treatment and support to patients in treatment for HIV/AIDS, and standard TB chemotherapy. In the pilot study, 750 patients were selected using the following inclusion/exclusion criteria: 1) currently in first line of antiretroviral treatment, 2) aged 18 years or older, 3) have basic literacy skills in Portuguese, 4) own a cell phone, and 5) not be part of other ongoing research.

Evaluation

Here, the artifact is observed and measured to find out how well it supports a solution to the problem [32]. Evaluation "involves comparing the objectives of a solution to actual observed results from use of the artifact in the demonstration" [32].

We evaluated the SMSaúde system in terms of functionality, completeness, consistency, accuracy, performance, reliability, and usability quality attributes [30].

Ethical Approval

The design of this study was approved from an ethical perspective by the Institutional Bioethics Committee on Health of Faculty of Medicine and Maputo Central Hospital (CIBS FM&HCM), Maputo, Mozambique (study code CIBS FM&HCM/18/2013).

Results

Problem Identification and Motivation

When planning for the new system, a number of problems were encountered. There was no concise documentation of the current system requirements, or of how the system was designed. Cost of operation and maintenance was high and plans for scaling up implied signing a new deal with the designer of the system. Administration was complicated—because the system was decentralized, each time there was a problem with the system the administrator had to travel long distances to solve the issue. Operation of the system made a single person indispensable—if the computer operator was absent from work and others did not know the initiation sequence of system components, the system would not be operational. There was no automatic reply function, something that would allow responses to text messages from patients. There was also no Web-based user interface for management and visualization of information (eg, statistics of incoming and outgoing text messages).

We designed and pilot-tested a new system that we believe solves the aforementioned problems. The next sections map the results of the process followed for design and development, and for implementation of the new system.

Objectives of the Solution

The objectives finally arrived at were threefold:

1. Design, develop, and implement a text messaging system (SMSaúde) capable of sending four types of SMS text messages—appointment reminders, medication reminders, motivational messages, and educational messages. It should also be capable of receiving text messages from patients and respond to them automatically in a meaningful way.

2. Integrate SMSaúde with EPTS.

3. Integrate SMSaúde across multiple locations with EPTS.

Design and Development

Requirements

Overview

Prior to system design, a comprehensive and detailed set of requirements was developed. There were six different requirements, which concerned data collection, telecommunication costs, privacy and data security, the content of text messages, connectivity, and system scalability.

Data Collection

It is imperative that the information systems can retrieve data from remote health facilities on a frequent, preferably daily, basis and provide it to the central part of the system, which decision makers use for planning, evaluation, and control of activities. There is also the issue of how often the data is filed in the electronic data system. The team from ARK worked hard to train the data entry clerks so they could enter the data in a very short period of time. The initial agreement was daily data entry with a possible delay of a maximum of 3 days.

Telecommunication Costs

In this kind of system there are telecommunication costs involved. It is imperative to be able to make favorable bulk SMS text messaging contracts on the part of the health care provider, but also to be efficient in messaging so as to reduce the traffic. Regarding text messages from patients, there may be some price sensitivity on the part of the patients, but in most cases there should not be that many messages per patient. Another major problem is that in Mozambique, as in most health care systems, costs are measured but not benefits. This means that even if the system leads to more people being cured, the system would still be seen as a cost to the health care system. For innovation to take place, ways to also calculate the benefits must be conceived. To overcome the two problems, ARK signed an agreement with Vodacom, a mobile communications company, that allowed ARK to send free text messages and enabled patients to send free text messages to a short code number.

Privacy and Data Security

Data security is a crucial issue in any health care process. We developed an authentication mechanism for clients' personal computers (PCs) located at the health center. All transactions go in one direction—only the client computers can send data to the server and changes in the server do not affect the data at client computers. The connection between the server and the client computer is made using a Web service.

Text Message Content

A set of text messages was developed based upon discussion involving the design team and the medical doctors. Suggestions for message formulations were reviewed and amended during team meetings, resulting in a final set of 32 messages for ART patients and 39 messages for TB patients, which were approved by all involved. In both sets, messages were divided into four categories: appointment reminders, medication reminders, educational messages, and motivational messages. Examples of the types and content of messages are provided in Table 1.

The messages did not include general information about the health status of the patient. This was for privacy reasons, but also because such status information may be difficult to communicate in an unambiguous way. The same goes for additional medical information that may be useful but difficult to communicate accurately.

Table 1. Examples of text messages in the four categories.

Category	Example text messages[a]
Appointment	Hello! Your health is above everything. We are waiting for your visit scheduled for xx-xx-xxxx at your Health Center!
	With health there is joy. Remember that you had a visit scheduled for xx-xx-xxxx. Come to your Health Center. We are waiting for you!
Medication	Dear friend. Do not stop taking the pills otherwise the disease will become stronger and resistant and the retreatment more difficult.
	Hello! Remember to come and collect your medications to cure TB. You or a relative must always come within the week. Keep on taking them every day without stopping!
Education	Dear friend! It is important that you have a healthy lifestyle, have good nutrition, do not drink alcohol, do not smoke, and get enough rest.
	Dear friend, your health comes first. Always take your pills daily, at the same time and before eating. It is possible to cure TB!
Motivation	Congratulations! You are now in the maintenance phase. You have completed X weeks. Don't give up! You may feel better but you are NOT better yet. Keep coming! We know you can do it!
	Dear friend, good job! You are almost done! You have completed XX weeks of treatment and must follow up! We know you can do it. Keep coming!

[a]All messages were translated from Portuguese by the first author.

Connectivity

Some Internet access is necessary for a system like this, mainly for data synchronization. Global System for Mobile communications (GSM) modems were used for data communication. As the GSM networks in Mozambique are often unreliable, especially in rural areas, we designed a mechanism of storing data locally and sending it to the main server whenever a connection was established. This way, we were able to in most cases get daily updates, although not necessarily at a predefined time every day.

System Scalability

Scalability here means that the system must be able to accept addition of new health centers and more patients. Addition of a health center should not disrupt the normal function of the system. The system was developed with this in mind as there is a need for expansion in the coverage of health centers.

System Development

Selection of Tools

The system platform selected for the text messaging system was based on the choice of the Web client for the Web-SMS. The Web client provides an interface that allows the professional users on the health care provider side to visualize, navigate, and analyze patient and text message data. We selected three open source-based tools for testing: playSMS, FrontlineSMS, and RapidSMS. The selection of Web-SMS was based on the following criteria: (1) user-friendly interface, (2) ease of interface customization, plug-ins, and functions compatibility, (3) system features (sending, receiving, autoreply, etc), (4)

programming languages supported, (5) established community of users and developers, and (6) support of popular SMS text message gateways (eg, Gammu, gnokii, smstools, Clickatell, or Kannel). Based on these criteria, playSMS was eventually selected as it met the majority of the requirements, and a prototype tool was developed. The playSMS system is a flexible, Web-based mobile portal system based on PHP programming language. We installed and preconfigured the Web server environment required to establish playSMS (comprising the Apache Web server, database server MySQL, and PHP).

To accommodate the requirements, an architecture was developed (see Figure 1). The main elements of this architecture include the following:

1. The databases. There were four databases. The first two databases—Microsoft Access (database system used by the EPTS) and MySQL—were located at the health centers and were used to store patients' health records. The other two databases—HealthRecordsDB and smsDB—were located at the server side and stored patients' information received from the health centers, and text messages (outgoing, incoming, and scheduled).

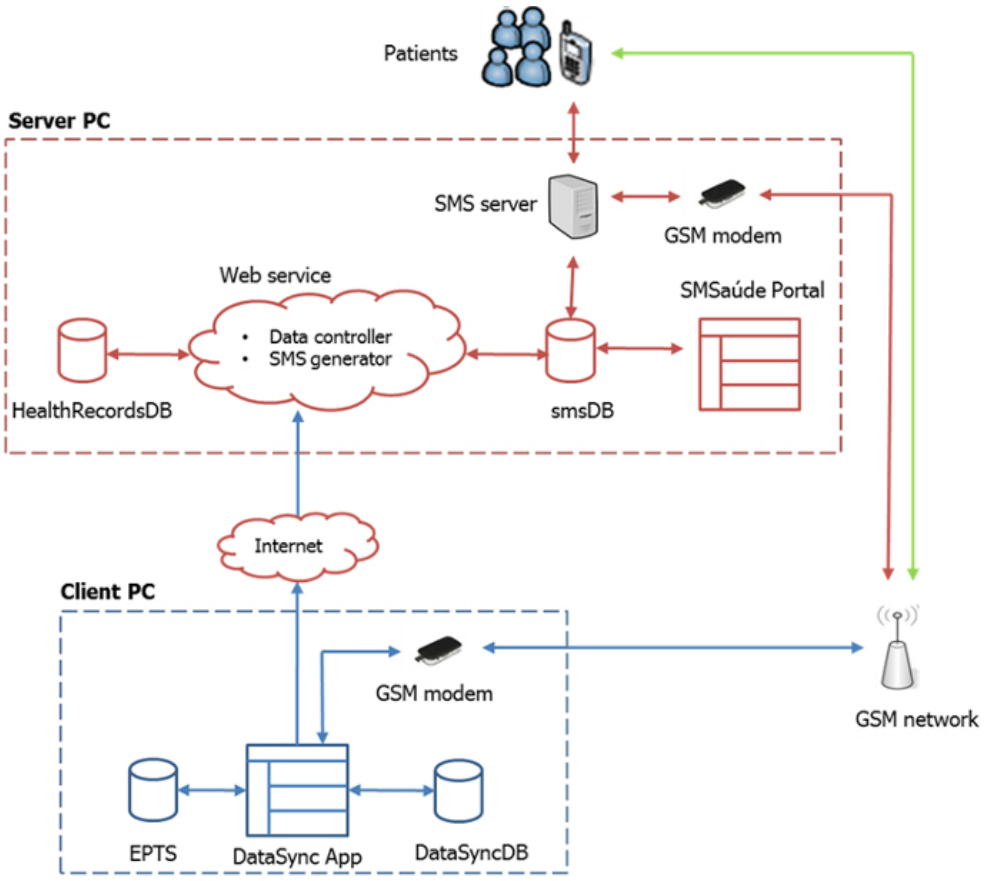
2. Data service (DataSync). DataSync is a service installed in computers located at the health centers. This service connects with the Microsoft Access and MySQL databases and sends filtered data to the central server. Data is sent using a GSM modem.

3. The Web service. The Web service features classes exposed to client computers (client PCs) by using a Web services description language (WSDL)-generating tool using extensible markup language (XML)-based service. Part of these classes are responsible for communicating with DataSync, storing the data in the central database (HealthRecordsDB), and for generating SMS text messages, as well as storing them in the SMS server database (smsDB).

4. The SMS server. The SMS server, as shown in Figure 1, interacts with patients that use their mobile phone set and the SMS messaging service to receive and send messages to the system. At the lowest level, the SMS server interfaces with a GSM modem that sends and receives patients' SMS text messages through an SMS service provider (mobile operator). Once an SMS text message is received by the modem, the SMS server performs checks on its content and responds to the patient accordingly (automatic reply feature). Every incoming message, after processing by the SMS server, is deleted from the GSM modem, but stored in the smsDB.

The health centers were registered in the remote server. Data from these health centers was sent to the remote server over a secured connection. Safeguarding the privacy, confidentiality, and security of any public health information is an important undertaking. The system only collects data necessary for the server to process and send text messages. The system was operational 24 hours a day, 7 days a week.

Figure 1. SMSaúde architecture.



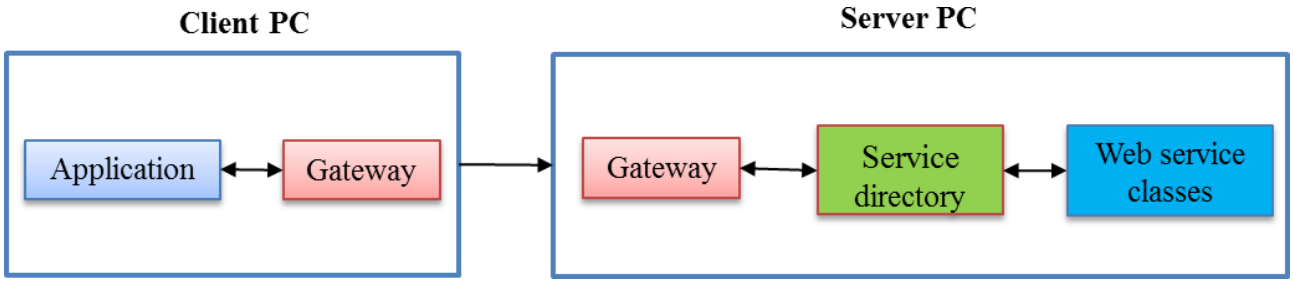
Communication Between Client PC and Server

The client PC at times must connect to the server and synchronize data. We defined a generic unidirectional gateway. A unidirectional gateway server provides centralized access to required data from the client PC to the server. Thus, integrating any client PC requires only integrating the bridge. In addition, the bridge separates the services that are available remotely from the ones proposed as normal Web services. The gateway server is responsible for formatting the data properly before receiving it from the client PC. Once the data is received from the client PC, its embedded classes are responsible for handling the data.

Figure 2 shows the link between the client PC and the server. The server has a component-based architecture, and is service and message oriented. A specific gateway has been built to ease communication with client PCs, providing secure access to data structures. It allows the transport of a description of classes from the server to the client PC. When a client PC sends data to the server, it communicates with the server gateway that transmits the request. The service directory is then queried to identify the appropriate service where the received information can be stored. All data transiting through the channel are formatted in XML.

What the new protocol needed was a client PC with the capability to work independently when a data connection was not available. This feature was necessary for those client PCs in rural or low-resource areas who had spotty data connections. The client PC layer (DataSync) was designed as an independent local app, yet it was able to synchronize with the server in real time when an Internet connection was available. Thus, DataSync featured a synchronization mechanism that allowed for the checking of an available Internet connection every 10 minutes.

Figure 2. Communication architecture between the client PC and the server.



Communication With Patients

The focus of the interactions between patients and SMSaúde was to promote self-management and adherence to treatment. SMS text messages were sent to patients according to the following scheme: (1) *appointment reminders* were sent 15, 7, and 2 days before their scheduled outpatient appointments, and 4 and/or 7 days after scheduled appointments if the patients had failed to show up in the health center, (2) *medication reminders* were sent monthly and every 2 months, (3) *motivational messages*, and (4) *educational messages* were both sent monthly. SMS text message types (2), (3), and (4) were scheduled to be sent on Monday, Wednesday, and Friday, respectively. Overall, SMS text messages were scheduled to be sent on weekdays.

A two-way information exchange protocol was needed to support this self-management model and address a major weakness of the old system. What the new protocol needed was the capability to respond automatically to patients' text messages. We developed an algorithm that reads the content of the message sent by the patient, interprets it, and decides what message to use for autoreply. This algorithm relies on a database table of keywords. The keywords were generated based on the text messages received from patients during the initial system implementation tests, and on the medical doctors' experience and knowledge of patients' needs. The algorithm not only looks for keywords, but also tries to make sense of the entire SMS text message. This is a function that holds great promise because it can increase the "density" in treatment communication and reduce the marginal cost for information, but must be used with care as misunderstandings will decrease patients' trust in the system.

Portal Interface

We developed a Web-based user interface to allow clinicians to view patient information, including personalized text messages, and appointment and medication data. The interface is shown in Multimedia Appendix 1. The main components of the portal are the Dashboard, Messages (Mensagens), Patient Data (Dados dos Pacientes), and Charts. The Dashboard was designed to provide an overview and some statistics (frequencies) of patient information, such as appointment data, and scheduled, incoming, and outgoing messages. The Messages component was designed to display outgoing, incoming, and scheduled messages. The Patient Data component was designed to display patients' information and appointment data received from the client PC. The Charts component displays statistics of messages (outgoing, incoming, and scheduled) in the form of a pie chart, bar chart, histogram, and timeline chart.

Demonstration

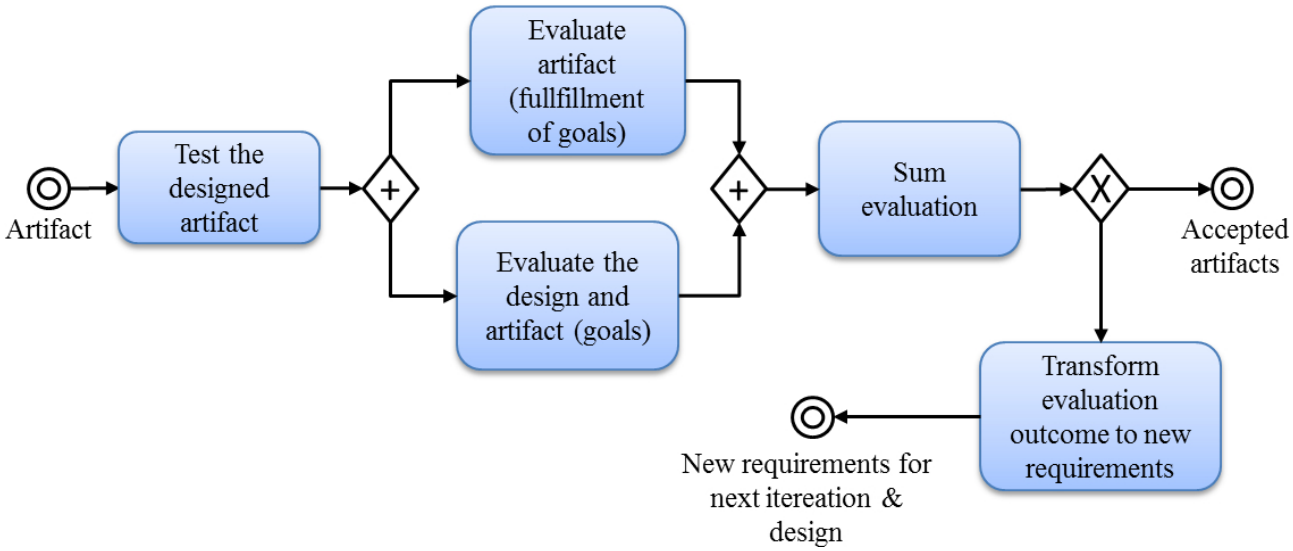
The SMSaúde system was implemented in five health facilities: Machava 2, Matola 2, Matola 1, Ndlavela and Namaacha at Maputo province in Mozambique. The choice of sites was based on ARK's strategy and consisted of making sure that the following resources existed: human resources that included at least one nurse, one medical doctor, one medical counsellor, one pharmacy technician, and one data entry clerk, as well as one computer and one GSM modem connected to the computer. These resources were necessary as the system required that information generated by different health workers be populated in the EMR.

Evaluation

Testing and evaluation of the SMSaúde system—based on seven quality criteria—was done by collaborative teams composed of researchers, the development team, and two medical doctors. These quality attributes were functionality, completeness, consistency, accuracy, performance, reliability, and usability. The SMSaúde artifact was input into this process. Figure 3 shows the process of testing the SMSaúde artifact. The artifact was improved interactively and incrementally, in a collaborative manner, until the team perceived the artifact as "good enough" for its intended user and problem domain. The activity "test the designed artifact" involved carrying out the actual tests, for instance, examining the artifact in the intended problem domain. The information from the tests was then used in the evaluation activity and compared with the goals set. During the iterations, many features of SMSaúde were changed, removed, or added. During the testing and evaluation of the artifacts, the team listed ideas for improvement, for instance, new requirements for improved versions of the artifact.

The output of this process of evaluation was either artifacts classified as ready and approved by collaborative teams or artifacts that were classified as not accepted. If the artifacts were not accepted they needed to be further designed. Reflections and notifications from the evaluation activity provided additional input for a new iteration.

Figure 3. The process of evaluation of the SMSaúde artifact.



Discussion

Principal Findings

This paper summarizes the processes of design, development, and implementation of a remote management system using mobile technologies to help patients with HIV and TB to improve self-management of their treatment. The system comprises an application layer for the capture and delivery of patient information, including date of next appointment and next date of collecting and taking medication, to a remote server by means of a GSM modem. The server generates personalized appointment reminders, medication reminders, as well as educational and motivational messages and sends them to patients. Health care professionals, technical experts, and an interdisciplinary group of researchers were involved in the design, development, and implementation processes to enhance the utility and functionality of the system.

Our research endeavors to design, develop, and implement a tool to empower patients in self-managing their HIV and TB and in their interactions with health care providers. Mobile phones are available and are practical, low-cost tools that may facilitate and support patient empowerment and involvement in their management of HIV and TB. Our literature study showed that there is evidence that mobile phone text messaging provides an effective communication mechanism between health care providers and patients, provided it is implemented well. It has been shown that mHealth interventions have the potential to improve treatment and motivate patients to adhere to treatment, thus making better use of health care resources [33]. However, a major challenge for health care lies in transforming traditional patient-health care provider relationships in a way that the patient may take a more active and equal role in planning and decision making regarding his/her care and treatment, in line with person-centered approaches [34,35].

Design of a system for treatment of specific diseases like HIV/AIDS and TB, based on mobile phone text message technology, includes careful attention to not only the theoretical underpinning of the strategic intervention and associated content, but also the requirements for optimal design, including how each part of the system has to be placed together. Crucial parts of a successful text messaging intervention include how messages are tailored, how participants may be directed to different content based on their situation, and the intensity of the communication. The system must also include cost-effective mechanisms so as to minimize costs of both technologies involved (including costs for GSM network communication and GSM modems with its data plan) and of sending messages to patients. Other costs include having people entering data frequently.

Although the system was designed specifically for HIV and TB, this development strategy can be generalized to other text messaging-based interventions, maybe with a special focus in settings with limited resources. Certainly, addressing all requirements is important. However, they come with different urgency levels. While, for example, *data* and *connectivity* are basic for making the system work and some agreement on *message content* is crucial to make it at all happen, *privacy and data security* and *system scalability* should be developed with some care. Trust, usefulness, and usability are crucial issues for both patients and professional users, and it is important that features installed also work properly and meet privacy standards. Therefore, it is better to move slowly in making the system more advanced and, at the same time, making sure to have users on board.

Conclusions

This study demonstrated that it is possible to design, develop, and implement an integrated remote patient management system using the mobile phone's text message feature to communicate with patients. The study shows that it is necessary to address the following six different requirements: data collection, telecommunication costs, privacy and data security, the content of text messages, connectivity, and system scalability.

Next Steps

We plan to perform an evaluation of the system, including a satisfaction survey of the health professionals and patients who used it. Additionally, we plan to perform a cost-benefit analysis.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The SMSaúde portal. The table displays outgoing messages with their phone numbers and dates sent.

[JPG File, 395KB - mhealth_v3i1e26_app1.jpg]

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Abbreviations

ARK: Absolute Return for Kids
ART: antiretroviral therapy
CIBS FM&HCM: Institutional Bioethics Committee on Health of Faculty of Medicine and Maputo Central Hospital
DSR: design science research
DSRM: design science research methodology
EMR: electronic medical records
EPTS: electronic patient tracking system
GSM: Global System for Mobile communications
IT: information technology
M-HELP: mobile health examination launched on the phone
PC: personal computer
SMS: short message service
SOC: standard of care
TB: tuberculosis
WSDL: Web services description language
XML: extensible markup language

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Original Paper

Diabetes Text-Message Self-Management Support Program (SMS4BG): A Pilot Study

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Abstract

Background: The increasing prevalence of diabetes and costly long-term complications associated with poor glycemic control are issues facing health services worldwide. Diabetes self-management, with the support of health care providers, is critical for successful outcomes, however, frequent clinical contact is costly. Text messages via short message service (SMS) have the advantage of instant transmission at low cost and, given the ubiquity of mobile phones, may be the ideal platform for the delivery of diabetes self-management support. A tailored text message-based diabetes support intervention called Self-Management Support for Blood Glucose (SMS4BG) was developed. The intervention incorporates prompts around diabetes education, management, and lifestyle factors (healthy eating, exercise, and stress management), as well as blood glucose monitoring reminders, and is tailored to patient preferences and clinical characteristics.

Objective: To determine the usability and acceptability of SMS4BG among adults with poorly controlled diabetes.

Methods: Adults (aged 17 to 69 years) with type 1 (n=12) or type 2 diabetes (n=30), a hemoglobin A1c (HbA1c) over 70 mmol/mol (8.6%), and who owned a mobile phone (n=42) were recruited to take part in a 3-month pilot study of SMS4BG. At registration, participants selected the modules they would like to receive and, where appropriate, the frequency and timing of blood glucose monitoring reminders. Patient satisfaction and perceptions of the usability of the program were obtained via semistructured phone interviews conducted at completion of the pilot study. HbA1c was obtained from patient records at baseline and completion of the pilot study.

Results: Participants received on average 109 messages during the 3-month program with 2 participants withdrawing early from the study. Follow-up interviews were completed with 93% of participants with all reporting SMS4BG to be useful and appropriate to their age and culture. Participants reported a range of perceived positive impacts of SMS4BG on their diabetes and health behaviors. HbA1c results indicated a positive impact of the program on glycemic control with a significant decrease in HbA1c from baseline to follow-up.

Conclusions: A tailored text message-based intervention is both acceptable and useful in supporting self-management in people with poorly controlled diabetes. A randomized controlled trial of longer duration is needed to assess the efficacy and sustainability of SMS4BG.

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KEYWORDS

mHealth; diabetes mellitus; text message; mobile phone; SMS; self-management

Introduction

Globally, diabetes is a significant health issue with increasing incidence worldwide. There is a disproportionate burden of the disease among indigenous peoples internationally [1] and in New Zealand (NZ), where higher disease prevalence is seen in Māori compared with New Zealand Europeans [2]. With the growing incidence and prevalence, there is a subsequent growing burden of caring for those living with the disease. Substantial evidence indicates that good diabetes control provides significant benefit in relation to the reduction of risk of complications [3,4]. Given the costly and debilitating microvascular and macrovascular complications of poorly controlled diabetes, including renal failure, visual impairment, lower limb amputation, heart disease, and stroke, intensive and sustained individual effort is required to achieve optimum control. Given the large impact that individual behaviors have on diabetes control, such as diet, energy expenditure, blood glucose monitoring, medication adherence, and self-adjustment of insulin doses, the standard of diabetes care includes self-management education and support. For those with poor control, education and support needs to extend outside the clinic setting in order to sustain the behaviors needed to manage diabetes in the context of their daily lives. One way to extend self-management support beyond the clinic is through ecological momentary interventions (EMI), which are delivered during a person's daily life providing "real-world" support in "real time" [5]. Mobile phones provide an ideal method for delivering EMI, as they are carried with most people most of the time, thereby maximizing their potential to optimize support for those in need.

Mobile health (mHealth) is the use of mobile devices, including mobile phones, to deliver health services and information [6]. The field of mHealth is growing with increasing support for its use in behavior change and disease management, including smoking cessation, weight loss, cardiac rehabilitation, and diabetes management [7]. Mobile phone ownership and use have continued to increase internationally and in New Zealand [8-10], with high penetration across all groups including hard-to-reach populations. All digital mobile phones provide short message service (SMS), also known as text messaging, with New Zealand having the highest use of SMS by head of population in 2011 compared to other Organisation for Economic Co-operation and Development (OECD) countries [11]. Given the high level of mobile phone ownership and the prolific use of SMS, this mode of communication appears an ideal platform for the delivery of health interventions.

Recent systematic reviews show that the majority of SMS-based behavior change interventions for disease management have positive short-term impacts on behavioral and clinical outcomes [7,12,13]. There is an increasing body of evidence supporting the use of mobile phones and SMS in the management of diabetes, including evidence for these interventions resulting in significant short-term improvements in glycemic control [14,15]. However, although studies to date have shown promising results, there are a lack of theoretically based comprehensive diabetes mHealth interventions [7,16]. Previous research has also highlighted the need to individually tailor messages [5,17-19], as well as to provide people with choices to increase their sense of control over the intervention [20]. To address these previous limitations, we developed and pilot-tested SMS4BG (Self-Management Support for Blood Glucose) a new tailored SMS self-management support program for adults with poorly controlled diabetes in New Zealand.

Methods

Study Design

Overview

A 3-month, nonrandomized pilot study was conducted between July and December 2013. All study documents and procedures were approved by the Health and Disability Ethics Committee (13/NTA/55).

Participants and Recruitment

Eligibility criteria included adults aged 16 to 70 years, a diagnosis of type 1 or type 2 diabetes mellitus, hemoglobin A1c (HbA1c) >70 mmol/mol (8.6%) within the last 12 months, mobile phone ownership, ability to provide informed consent, and ability to read English. An HbA1c result of greater than 70 mmol/mol (8.6%) was utilized as the definition of poorly controlled diabetes in this study, a level associated with increased risk for the development of diabetes complications. Recruitment was carried out across three primary health care practices, two secondary care hospitals, and one community-based organization in Auckland, New Zealand. Clinicians at each site identified potential participants and either enrolled them directly through the study website or referred them to a research assistant to complete registration. Registered participants then received an automated consent text message and were required to reply "Yes" to be enrolled in the program. The program was free to receive but if a participant replied, they were charged NZD $0.20 per message by their network provider. Participants were given a voucher (NZD $20.00) at the conclusion of the study to reimburse them for their time and any costs associated with replying to the messages.

Measures

At the end of the program all participants (including those that withdrew) were asked to complete questions about their

satisfaction with the program, its usefulness and usability, and perceived positive impacts, via a semistructured telephone interview conducted by a research assistant. Engagement with the program was assessed using system-recorded responses to the blood glucose monitoring reminder messages. In addition, participants consented to the research team obtaining their HbA1c test results from their medical records to assess change in HbA1c from baseline to follow-up.

Statistical Analysis

Descriptive statistics were generated for baseline demographic and clinical characteristics, and measures of engagement with the system. Counts and percentages were reported for categorical variables, and means and standard deviations for continuous variables. To determine whether ratings of usefulness differed between ethnic groups and diabetes type, *t* tests were used. Change in HbA1c was calculated using the related-samples Wilcoxon signed-rank test.

Intervention Development

SMS4BG was developed to provide self-management support for adults with poorly controlled diabetes. The content was developed by a multidisciplinary team, led by a health psychologist (RD) and public health physician (RW). The development followed the mHealth Development and Evaluation framework [21], which provides a process to guide the development and testing of mHealth interventions with a focus on implementation, use of behavioral change theory, and involvement of the target population.

The development of the content was informed by a review of the research literature, existing mHealth interventions (targeting diabetes management and related lifestyle behaviors), and current patient resources. The program was informed by two behavior change theories: Social Cognitive Theory [22] and the Common Sense Model [23]. Messages were designed to provide correct perceptions around diabetes and its management and to increase self-efficacy and perceived support for diabetes management. SMS4BG also utilized a number of different behavior change techniques (BCTs) [24] to support behavior change in relation to diabetes management: providing general information linking behavior to health, providing information on consequences, prompting intention formation, prompting barrier identification, providing general encouragement, prompting self-monitoring of behavior, providing feedback on performance, and stress management.

To accommodate personal preferences and clinical characteristics, SMS4BG was made up of modules including a core module that all participants received and additional optional modules. Clinician input determined optional module topics. The core module consisted of 2 messages per week on diabetes education, emotional encouragement, and illness perceptions (available in Māori and non-Māori versions). In addition to the core module, if registered as a smoker, the participant received an additional 1 message per month supporting smoking cessation. Participants could also opt to receive additional modules on topics relevant to diabetes management such as insulin, diet, exercise, stress management, and blood glucose monitoring reminders. A summary of the different SMS4BG modules can be seen in Table 1. There were a total of 180 different messages across all modules with the minimum number of messages a participant could receive being 30 messages over the 3-month period, unless they withdrew early. If the maximum number of modules and blood glucose monitoring reminders were selected, a participant could receive up to 461 messages over the 3-month period. All messages a participant received were unique with the exception of the blood glucose monitoring reminders for which there were 9 different reminder messages that they received.

The SMS4BG program was designed so that text messages were send-only (unidirectional) with the exception of the blood glucose monitoring reminders, which provided the option for participants to reply with their blood glucose test results. In addition to SMS, there was an accompanying website that patients and clinicians could log onto, allowing them to review a graphical display of the participant's blood glucose responses sent into the system. The website also provided administrators with the ability to manage the message content and monitor message delivery. To enhance participant engagement, SMS4BG was personalized with the inclusion of each participant's name in many of the messages. Individuals could also select the frequency and timing of blood glucose monitoring reminder messages—from 1 per week to up to 4 per day.

In New Zealand, there is a higher prevalence of diabetes in Māori in comparison with New Zealand Europeans [2]. To ensure the relevance of SMS4BG to this population, a Māori version of the core module was developed by the study's Māori Advisory Group. The core messages were adapted to incorporate a greater focus on family (whānau), and incorporate key words in the Te Reo Māori language, although messages remained predominately in English.

Once developed, messages were reviewed by diabetes specialists and a selection of messages were pretested by people with diabetes. Feedback from this process was incorporated into the messages before they were finalized and entered into the system for testing. Following development, a pilot study was conducted which set out to assess the usability and acceptability of the text message support program in adults with poorly controlled diabetes.

Table 1. SMS4BG modules.

Module	Description	Participants	Example text message
Core	2 messages per week providing general motivation and support for diabetes management. Available in two versions: (1) Māori, and (2) non-Māori.	All	(1) "SMS4BG: Kia ora. Control of your glucose levels involves eating the right kai, exercise & taking your medication. Your whanau, doctor & nurse can help you." (2) "SMS4BG: There is no quick fix to diabetes but with good management it will have less impact on your life and leave you more time to do the things you enjoy."
Insulin	1 educational text message per week on insulin management for patients receiving insulin.	Available to participants prescribed insulin.	"SMS4BG: Unopened insulin should be kept in the fridge. Don't use insulin that has changed color, lumpy, expired, cracked or leaking, has been frozen or too hot."
Young adult	1 message per week around managing diabetes in the context of work/school and social situations.	Available to participants aged 16-24.	"SMS4BG: It's important not to ignore a hypo. No one likes to be embarrassed, but ignoring a hypo can make you feel worse & can be more embarrassing."
Smoking cessation	1 message per month encouraging participants to consider quitting smoking and providing details of services for support.	All participants who register as smokers.	"SMS4BG: Good management of your diabetes and your future health includes not smoking, call Quitline on 0800 778 778 for support."
Lifestyle behavior	Up to 4 messages per week encouraging participants to set a lifestyle goal and supporting them to work toward this goal. Participants can receive one of these modules for 3 months. The three lifestyle modules are: (1) exercise, (2) healthy eating, and (3) stress and mood.	Available to all participants.	(1) "SMS4BG: Hi [name]. If you are finding it tough to keep up your exercise think about why good management of your diabetes is important to you." (2) "SMS4BG: Healthy eating is an important part of your diabetes treatment and it will help you in controlling your blood glucose levels." (3) "SMS4BG: Make sure you have fun activities scheduled regularly. Doing something enjoyable helps reduce stress & improves mood."
Blood glucose monitoring	Reminders to test blood glucose, sent at a frequency selected by the participant (up to 4 per day), for which they are encouraged to reply by text message with their blood sugar readings.	Available to all participants required to monitor their blood glucose.	"SMS4BG: Hi [name]. Just a reminder it is time to check your blood glucose. Reply with the result." If valid response received, "SMS4BG: Thank you for sending your result."

Results

A total of 44 potential participants were recruited, with 42 participants consenting to participate. Table 2 presents characteristics of the registered participants. Only 2 participants requested to end the program early, both during the third week of their messages. Of the 42 participants enrolled, 3 (7%) were lost to follow-up. Of these 3 participants, 2 could not be contacted, and the remaining participant's phone had been disconnected.

Table 2. Participant characteristics (n=42).

Characteristic		n (%) or mean (SD)
Gender, n (%)		
	Male	20 (48)
Ethnicity, n (%)		
	NZ European	16 (38)
	Māori	15 (36)
	Pacific	3 (7)
	Other	8 (19)
Diabetes type, n (%)		
	Type 2	30 (71)
Recruitment site, n (%)		
	Primary care	22 (52)
	Secondary care	18 (43)
	Other	2 (5)
Age in years, mean (SD)		45.7 (13.1)
HbA1c in mmol/mol, mean (SD)		89 (22)

Participant Engagement

Due to the choice of modules, participants received varying numbers of messages during the 3-month program. Table 3 presents a breakdown of the modules in which the participants were enrolled.

Table 3. Participants' choices of SMS4BG modules (n=42).

Module		n (%)
General		
	Total	42 (100)
	Non-Māori	38 (90)
	Māori	4 (10)
Insulin		15 (36)
Young adult		3 (7)
Smoking cessation		10 (24)
Lifestyle		
	Total	34 (81)
	Exercise	12 (35)
	Healthy eating	12 (35)
	Stress	10 (30)
Blood glucose monitoring reminder messages		
	Total	34 (81)
	1/week	19 (56)
	3/week	4 (12)
	1/day	6 (18)
	2/day	3 (9)
	3/day	1 (3)
	4/day	1 (3)

Participants received on average 109 (range 8 to 437) text messages from the program during the 3-month period, with an average of 13 messages per week. This included on average 63 (range 8 to 93) send-only text messages per participant over the 3-month program. A total of 34 participants out of 42 (81%) opted to receive blood glucose monitoring reminders, receiving on average 58 (range 9 to 353) reminder messages each over the 3-month period. A total of 827 response messages were received from 26 (76%) of the 34 participants registered to receive reminders. Of those who responded to at least one reminder, participants on average responded to 57% of their reminder messages (range 1 to 99%). For those 8 participants that did not reply (8/34, 24%), cost was identified as the leading barrier. Only 4 (12%) of the 34 participants reported accessing their graph online to view their blood glucose results. The most frequently reported barriers were no access to computers or Internet and not responding to the messages, and as a result not having a graph to view.

Patient Satisfaction and Usability

A summary of the results of the follow-up interviews is provided in Table 4. Participants reported high levels of satisfaction with SMS4BG—all (39/39, 100%) reported the program to be useful to some degree, and 97% (38/39) reported they would recommend the program to others with diabetes. When asked to rate how useful the messages were on a scale from 0 (*not at all useful*) to 5 (*extremely useful*), the mean rating was 3.94 (SD 0.98). Higher mean ratings of usefulness were seen in those with type 2 diabetes (4.21, SD 0.75) compared to those with type 1 diabetes (3.17, SD 1.17) (*P*=.004). Although not statistically significant, higher ratings of usefulness were found for Māori (4.13, SD 0.91) compared with New Zealand European (3.68, SD 0.99) (*P*=.23).

All participants were able to identify at least one positive impact of the program. The majority (32/39, 82%) of participants reported that the program had a positive impact on their overall blood glucose control. In addition, 49% (19/39) of all participants interviewed reported a positive impact of SMS4BG on their exercise habits, 59% (23/39) on their diet and eating behavior, and 67% (26/39) on their mood. Of the participants interviewed who received the exercise lifestyle module, 83% (10/12) reported a positive impact of SMS4BG on their exercise habits. Of those interviewed who received the healthy eating module, 82% (9/11) reported a positive impact on their diet and eating behavior. Of those interviewed who received the stress and mood module, 67% (6/9) reported a positive impact on their mood. Of those 10 who were registered as smokers, 3 (30%) participants reported that they had quit smoking during the program.

Suggestions for improvements in the program included making the program longer, allowing for two-way communication with health care professionals through the program, making it free to reply to the messages, allowing for greater choice in the timing of the messages, and greater personalization. Few technical issues were reported—of the 39 participants interviewed, 2 (5%) reported issues accessing their graph, and 8 (21%) participants reported that not having credit/money on the phone account meant they could not reply with their blood glucose test results.

Table 4. Results of the follow-up interviews (n=39).

Question	Response (“yes”), n (%)
Was SMS4BG useful?	39 (100)
Were the messages culturally appropriate?	39 (100)
Were the messages age appropriate?	39 (100)
Do you think SMS4BG has had a positive impact on:	
Your overall BG control?	32 (82)
Your frequency of BG monitoring?	30 (77)
Your diet or eating?	23 (59)
Your exercise?	19 (49)
Your mood?	26 (67)
Your perception of your diabetes?	19 (49)
Your knowledge of diabetes?	16 (41)
Would you recommend SMS4BG to others with diabetes?	38 (97)

Metabolic Control

Baseline HbA1c values were obtained for all participants, but follow-up results were only available for 26 (62%) of the 42 participants. A significant improvement in HbA1c was found from baseline (median 89.50 mmol/mol) to follow-up (median 71.00 mmol/mol, Wilcoxon signed-rank test *P*=.001) for the 26 participants out of 42 (62%) for whom complete data was available.

Discussion

This pilot study has established that SMS4BG is an acceptable and potentially useful tool for adults with poorly controlled diabetes. Perceived positive impacts of the program were

complemented by a significant improvement in glycemic control at follow-up. This aligns with previous text message-based interventions in people with diabetes [14].

Further evidence of the acceptability of SMS4BG was seen in the follow-up interviews, with all participants reporting SMS4BG to be both culturally and age appropriate. Participants ranged in age from 17 to 69 years and over half of the participants were of Māori (15/42, 36%), Pacific (3/42, 7%) or Asian decent (4/42, 10%). This indicates that this type of technology is not limited by demographic characteristics and the text message content was relevant to a wide range of people with poorly controlled type 1 and type 2 diabetes.

Most participants were satisfied with the number and frequency of the messages they received, which may be due to participants being involved in the selection of the modules they received and, therefore, having some degree of control over the number of messages they received.

Although visual feedback was provided in the form of a graph of submitted blood glucose results, this feature was not utilized by the majority of participants. The leading barrier for not accessing the graph was lack of Internet access either at home or on their mobile phones. Previous studies have reported greater improvements in HbA1c with combined mobile and Internet-based interventions compared to studies utilizing mobile intervention alone [14]. Our findings are in contrast to this and highlight that lack of Internet access can reduce participant access to features of the interventions. Other methods for providing feedback should be investigated, such as sending graphs via multimedia messaging service (MMS). Although it was free to take part in the pilot study, the barrier of cost of replying to text messages (NZD $0.20) was identified as preventing a number of participants from responding with their blood glucose results and, therefore, feedback was not available to them. To ensure that SMS4BG is able to be fully utilized by all, removing the cost of reply messaging may be needed if rolled out within a health care setting.

Strengths of the SMS4BG program included that it was theoretically informed, system initiated (ongoing intervention not dependent on participant behaviors), personally tailored, and provided participant choice. Many previous diabetes text messaging programs have had limited reach or were designed specifically for one diabetes type, age group, or single diabetes management behavior. SMS4BG was designed for adults of all ages with both poorly controlled type 1 and type 2 diabetes and provided support for self-management and encouragement in people's everyday lives rather than focusing on specific diabetes-related tasks. In addition, SMS4BG utilized simple technology and, therefore, had less potential for technical issues that have been a limitation in previous mHealth studies.

Another strength of the current study was the inclusion of an indigenous version. With a higher prevalence of diabetes seen in Māori compared to NZ Europeans [2], diabetes interventions need to be both relevant and culturally appropriate to this group. There were two programs that Māori could choose from and although only 4 participants chose to register for the Māori version, no Māori participants withdrew from the program. This acknowledgement of identity may have assisted with retention of the Māori participants. In addition, the inclusion of motivational messages linking diabetes management to family (whānau) aligns with the importance of whānau to the well-being of Māori [25]. Although not significant, the higher ratings of usefulness of SMS4BG by Māori participants compared with New Zealand Europeans warrants further investigation. In addition, future development of the program could incorporate other cultural versions, including one for Pacific peoples.

This study had several limitations, including the absence of a control group and a small sample size. Although positive change in glycemic control was seen without a control group or adequate sample size, this difference must be interpreted with caution. The lack of complete follow-up HbA1c results limits the generalizability of the improved glycemic control results. The target population (poorly controlled) were likely not attending medical appointments as regularly as guidelines state and, therefore, the lack of clinical results could be expected. Future studies could include text messages around the importance of HbA1c tests and reminders to go for tests as a way of potentially overcoming this issue. The pilot study was of short duration and as diabetes is a condition requiring long-term management, longer interventions may be more appropriate. Another limitation was the lack of follow-up to assess whether any effects of SMS4BG were maintained beyond the program itself. A larger and longer-term randomized controlled trial will need to be carried out to establish the efficacy of SMS4BG on self-management behaviors, self-efficacy and clinical outcomes, and its sustainability and cost-effectiveness.

The current study adds to the evidence for the use of mHealth in delivering personally tailored diabetes self-management support and, particularly, the use of text messaging as a medium of delivery. The positive pilot study results indicate that this type of broad reaching EMI could be successful in engaging adults with poorly controlled type 1 or type 2 diabetes and assisting with improved diabetes self-management. Further refinement of SMS4BG is needed based on the pilot study feedback, followed by a larger randomized control trial to determine its efficacy.

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Authors' Contributions

RW, KC, RD, RC, CM, RM, MS, and RH were responsible for the study design and procedures. RD, RW, JS, KC, MS, and AH were responsible for the intervention development. RD, KC, and RW were responsible for data collection. RD, KC, RW, MS, RC, and CM were responsible for the data analysis and interpretation. RD wrote the manuscript. RW, KC, MS, RC, RM (Rinki Murphy), CM, RH, RM (Ralph Maddison), JS, and AH provided critical feedback on the manuscript.

Conflicts of Interest

None declared.

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Abbreviations

BCT: behavior change technique
EMI: ecological momentary interventions
HbA1c: hemoglobin A1c
mHealth: mobile health
MMS: multimedia messaging service
NZ: New Zealand
OECD: Organisation for Economic Co-operation and Development
SMS: short message service
SMS4BG: Self-Management Support for Blood Glucose

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Original Paper

Using a Collaborative Research Approach to Develop an Interdisciplinary Research Agenda for the Study of Mobile Health Interventions for Older Adults

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Abstract

Background: Seniors with chronic diseases are often called on to self-manage their conditions. Mobile health (mHealth) tools may be a useful strategy to help seniors access health information at the point of decision-making, receive real-time feedback and coaching, and monitor health conditions. However, developing successful mHealth interventions for seniors presents many challenges. One of the key challenges is to ensure the scope of possible research questions includes the diverse views of seniors, experts and the stakeholder groups who support seniors as they manage chronic disease.

Objective: Our primary objective was to present a case-study of a collaborative research approach to the development of an interdisciplinary research agenda. Our secondary objectives were to report on the results of a nominal group technique (NGT) approach used generate research questions and to assess the success of including non-academic researchers to enrich the scope, priority, and total number of possible research questions.

Methods: We invited researchers and stakeholders to participate in a full day meeting that included rapid-style presentations by researchers, health care professionals, technology experts, patients and community groups followed by group discussions. An NGT was used to establish group consensus on the following question: In your opinion, what research needs to be done to better understand the effectiveness, usability and design of mobile health apps and devices for older adults?

Results: Overall, the collaborative approach was a very successful strategy to bring together a diverse group of participants with the same end goal. The 32 participants generated 119 items in total. The top three research questions that emerged from the NGT were related to adoption, the need for high quality tools and the digital divide. Strong sub-themes included privacy and security, engagement and design. The NGT also helped us include the perspectives information from non-academic researchers that would not have been captured if the process had been limited to the research team.

Conclusions: Developing ways for patients and other stakeholders to have a voice when it comes to developing patient awareness as related to mHealth may guide future research into engagement, ownership, usability and design. It is our intention that our paper be used and adapted by other researchers to engage small or vulnerable populations often excluded from mHealth research and design.

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KEYWORDS

mHealth; mobile health; nominal group technique; participatory research: collaborative research; older adults; research; seniors

Introduction

mHealth and Older Adults

Mobile technologies (mHealth) are emerging as a way to engage the population in health care. mHealth refers to "...the provision of health services and medical and public health practice via mobile devices, mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices" [1]. For patients and providers alike, mHealth can improve access to information and can also cultivate communication on healthy living and disease management [2]. In 2011, the United States (US) Secretary of Health and Human Services, Kathleen Sebelius described the mHealth innovation as “the biggest technology breakthrough of our time” that will “address our greatest national challenge” [3]. The World Health Organization sees mHealth as a means to improve access to care and reduce professional isolation, especially with isolated populations or rural communities [4].

There is a perception that older adults are late adopters of new technology. However, as of 2013, 59% of American adults aged 65 and over were online, 77% owned a mobile phone, 27% owned a tablet or e-reader, and 18% owned a smartphone [5]. Similar adoption rates have been seen in Canada [6], Britain [7], and Australia [8]. Recent surveys have also found older adults to be particularly interested in mobile tools to help prevent and manage disease [9,10].

Older adults are also high impact users of health care. In Canada, per capita health care spending is five times higher for seniors than for younger adults and this number is growing [11]. In the US, seniors make up 12% of the population and account for a third of all health care spending [12]. For our health care systems to be both efficient and effective in the long-term, our highest impact users must be able to receive care and then implement the recommended treatments in their own lives. And yet, at the moment, a mere half of us are willing or able to adhere to recommended treatments, with the oldest, sickest, poorest, and least literate struggling the most [13-20].

For mHealth to be effective, we need it to be accessible for older adults. Most mHealth research has focused on younger people who provide a poor proxy for the older user [21]. In the face of what we know about the current digital divide, the concentration on existing users rather than high-impact users is also alarming. For example, three in four seniors report needing some help to learn to use a mobile device [5]. As with people who tend to adhere to treatment, those who are online or who own a digital device are far more likely to be physically abled, healthy, educated, and wealthy [5,22] It is not age that prevents adoption so much as the age-related physical and cognitive changes that make it hard or frustrating to use a digital device designed for younger users [23,24]. And yet, despite the difficulty, 79% of seniors who are online feel that “people without Internet access are at a real disadvantage because of all the information they might be missing” [5].

Group Consensus in Collaborative Research

mHealth research is multidisciplinary by necessity. The design, implementation, and evaluation of mHealth tools require expertise in health care, systems design, programming, and business. With so many stakeholders at the table, we need strategies to build consensus across diverse groups. Consensus building-strategies are often used to help group opinions converge [25]. Two popular methods include the Delphi Technique and the Nominal Group Technique (NGT). If done well, both the Delphi and NGT strategies can help groups reach consensus while avoiding the common pitfalls of group dynamics, such as having an ‘expert’ take over or having a small number of participants dominate the discussion.

The Delphi technique is often used to develop clinical practice guidelines. It is particularly suited to helping large, diverse panels of experts reach consensus on the priorities and recommendations while minimizing the influence of individual panellists and the contact among panellists [26-29]. It is a group method that is administered by a leader who assembles a panel of experts, asks questions, synthesizes feedback, and guides the group towards consensus [28]. Unlike traditional survey methods, where the goal is to make generalizations across a population, the Delphi is an iterative process, more like a series of focus groups that leads the participants to a consensus. The goal is to reach an agreement in an area where none previously existed [29]. The Delphi involves several rounds of surveys to gather feedback and interpret expert opinion. It continues until opinions converge. Because the Delphi technique is used to organize conflicting judgements, consensus may not be possible [27].

The NGT is a qualitative method also used for consensus building[30-32]. The NGT can be particularly useful for exploring new and emerging ideas in health care when results need to be prioritized [33,34]. It is an exploratory tool that helps a group generate ideas where the evidence base is limited. As ideas are shared, they are clarified by the group and then ranked. Unlike the Delphi technique, a key feature of the NGT is a face-to-face meeting that gives each participant equal voice in the creation and ranking of ideas [35]. It is well suited to small groups, which need to quickly develop and agree on a list of ideas that can be ranked in order of importance or need. The NGT is also structured enough that it ensures that no single participant dominates the discussion.

When our research team began working together to establish an interdisciplinary research agenda for studying the intersections of mHealth and aging, it was clear that the topic was very complex and evolving. As a team, one of our goals was to understand the perceptions and judgements of both the ‘experts’ and the end users most affected by our research. We chose the NGT over the Delphi method because it allowed us

to involve stakeholders who were deeply invested in health care but who had little interest or expertise in mHealth. In particular, we wanted to have a clear perspective on the needs of high impact users, which often include late and non-adopters of mHealth technologies. Thus, the objective of this paper is to share our experiences using an NGT with interdisciplinary researchers and health care stakeholders to develop an interdisciplinary research agenda for mHealth.

Methods

Overview

To engage our community, we organized an mHealth research event at the University of Waterloo School of Pharmacy that had three purposes: (1) to facilitate trans-disciplinary knowledge exchange among researchers and knowledge users dedicated to mHealth development for older adults; (2) include older users and their community supports in the discussion; and (3) identify research questions using the NGT.

Our sample size was chosen with purpose. It needed to be large enough to cover most opinions and perceptions but not so large as to lose focus on the purpose. We chose our representatives with this same purpose. Achieving full saturation was not the goal of this study; our intention was to get an initial broad sample of the ideas that people who would be developing, using or promoting mHealth apps [36]. Although certain ideas were consistent among the groups, each group identified entirely new suggestions, indicating that a saturation of ideas could not be not reached. Considering that many participants voted for ideas generated by others, it may be worth repeating the event with similar groups in other communities, and to develop a forced-choice inventory based on the most consistently high-ranking ideas that could then be used by larger groups of participants [37].

In planning the research day, we received ethics approval from the University of Waterloo Research Ethics Board (Office of Research Ethics #19064). Following the research day, the researchers reconvened and reviewed the results of the NGT activity and used the NGT methodology to develop the research agenda.

Participants and Recruitment

Meeting participants were recruited from Southwestern Ontario. Our recruitment goal was to include groups that often work on solutions in their own specific context, and rarely collaborate when developing creative solutions. To solicit a broad spectrum of opinions, we recruited participants who either had relationships with the 50-plus community or who were involved in the development of mobile apps. Specifically, we invited researchers in systems design and/or aging, health care providers for older adults, mobile technology professionals, community members living with chronic illness, and disease-specific advocacy organizations. Participants were not required to be experts in mHealth.

We mailed written invitations to 30 potential stakeholder organizations and individuals in May 2013. We followed up with up to three phone calls and recruited 32 participants who represented 18 organizations (Table 1). The participating health professionals were from geriatrics, nursing, physiotherapy, pharmacy, family medicine, and homecare. The patient and advocates represented patients living with diabetes, arthritis, and dementia. The technology professionals included programmers, developers, designers, and trainees.

Table 1. Summary of participants.

Participant Group	Male	Female	Totals
Health Care Professionals	2	7	9
Patients/Advocates	1	4	5
Technology Professionals	5	4	9
Researchers	1	7	8
Total	9	22	32

Workshop Design

To reach the goal of effective stakeholder collaboration, we used three strategies: rapid-style presentations, group discussion, and an NGT (Agenda, Table 2). The meeting began with three sets of 5-in-5 presentations where attendees gave 5 successive presentations lasting 5 minutes each followed by a break. All participants were invited to present their perspective on mHealth including challenges they were facing and questions they had. We limited presentations to 5 minutes to encourage participants to share a high-level overview not an in-depth analysis. Presenters were advised to follow either the Ignite event model and prepare 5 one-minute slides [38] or the Pecha Kucha model and prepare 15-20 slides where each last 15-20 seconds [39]. A 10-minute break was taken after each series of 5 presentations to allow all participants to share any thoughts, ideas, and questions that arose during the presentations. Following the presentations and discussion, we provided a one-hour lunch to encourage networking.

Table 2. Agenda.

Time	Activity
10:00am – 10:30am	Welcome and 5x5 Minute Rapid Presentations (Researchers)
10:30am – 10:40am	Group discussion
10:40am - 11:10am	5x5 Minute Rapid Presentations (Health Providers)
11:10am – 11:20am	Group discussion
11:20am – 11:50 m	5x5 Minute Rapid Presentations (Patients, Technology Professionals)
11:50am – 12:00pm	Group discussion
12:00pm – 1:00pm	Networking Lunch
1:00pm – 2:00pm	Guided Group Discussions (Nominal Group Technique)

Nominal Group Technique

For the second half of the workshop, the NGT method was used to identify potential research questions. Participants were split into three focus groups of 4 to 8 participants according to their background: health care providers, technology professionals, and community stakeholders. Each group followed the same NGT process and was facilitated by a member of the research team. Facilitators began by asking the following question: "In your opinion, what research needs to be done to better understand the effectiveness, usability, and design of mobile health apps and devices for older adults?"

Each facilitator followed a script adapted from a briefing on conducting NGT from the US Centers for Disease Control [38]. We led groups through the following steps: (1) introducing/clarifying the research task; (2) generating ideas silently as individuals and then as a group (on a flip chart); (3) adding, merging, or removing ideas; (4) individually ranking the five most important ideas; (5) reviewing the aggregated rankings as a group; and (6) closing the session [40].

After the initial NGT sessions, we determined that it would be beneficial to hold an additional session with the research team. Researchers across our institution were represented and included the disciplines of engineering, arts, sciences, business, and health. We began the researcher-focused NGT with a brief overview of what had happened during the original NGT sessions, and a very high level discussion of the results of the original NGT sessions.

Data Collection and Analysis

The ideas generated were intended to represent the distinct perspectives of stakeholders and researchers. The purpose of coding was to explore emerging themes, while being mindful that we were examining feedback collected from multiple participants [41-43]. As described by Braun, our thematic analysis included a series of six interconnected stages (familiarization, generating initial codes, searching for themes among codes, defining, naming, and interpreting themes) that enabled us to move back and forth within the data to develop a coherent account of the phenomenon [44]. Afterwards, two researchers (KM, KG) independently coded the generated (original and unedited) ideas and disparities were resolved by discussion. The codes were categorized into themes by one researcher (KM) and verified by a second researcher (KG).

Results

The health professionals identified 32 phrases, the technology professionals identified 29 phrases, community stakeholders identified 19 phrases, and the researchers identified 39 phrases. The top five ranked phrases for each group are listed in Table 3. The themes that emerged as key priorities across all groups included adoption/motivation, privacy/security, need for high quality tools and the digital divide (Figure 1).

Adoption and Motivation referred to the need to design mHealth tools that older adults can use, afford, and adapt for long-term use. It includes designing for people who have age-related impairments and having support in place to help older users learn to use new mHealth tools. Privacy/security refers to creating tools that protect confidentiality across multiple devices and systems while being transparent about who owns and accesses patient data. High quality tools refer to the need for evidence-based systems that provide accurate health information or advice and that are designed to effectively change behaviour. Finally, the digital divide refers to the need for systems that includes patients who would traditionally struggle including those with disabilities, lower income, lower literacy, and limited experience with technology.

As a group, the health care professionals focused on how they could support patients and were the only group that did not rank 'the digital divide' in their top themes. The technology professionals focused more on defining the end-user and on promoting usability for diverse groups. The community stakeholders focused on ways to be inclusive by promoting adoption. Finally, like the community stakeholders, the researcher group was most focused on inclusiveness but also noted the importance of having a quantifiable end-result.

At many points, participants repeatedly emphasized that they were not experts in mHealth and were unsure if their opinions were valid. Many were concerned that their personal experiences with technology did not represent all stakeholders. That said, at the conclusion of the meeting, many participants were deeply interested in the topic and requested online information sources and newsletters. Several participants also noted that mobile and online technologies were at the top of the list for future strategic planning in their organizations.

Figure 1. Top themes organized by group, using the top six phrases from the NGT sessions.

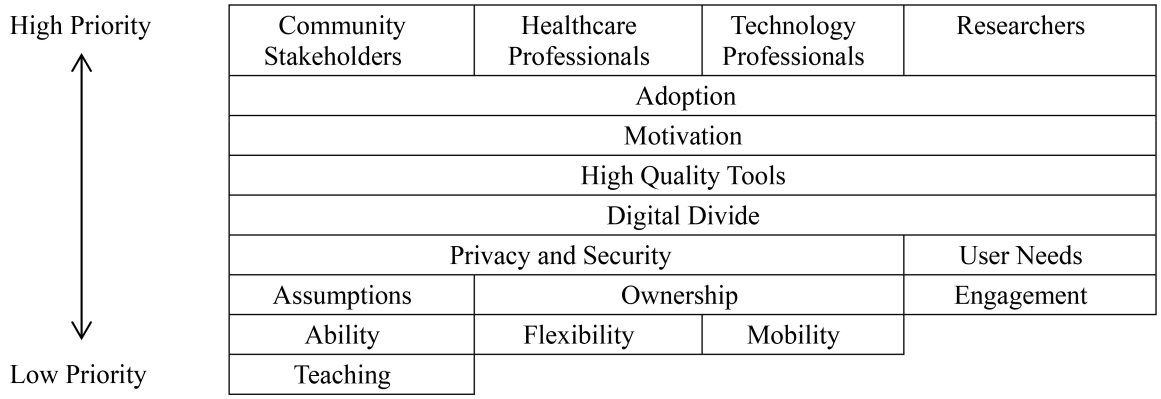

Table 3. Stakeholder perceptions of the research that needs to be done to better understand the effectiveness, usability and design of mHealth for older adults.

Group	Top 5 Phrases by Theme	Votes
Health care providers	Patient generated data: Who will own the data? What should be shared? How should we share? When should we share? What will the patient be willing to share and receive? How do we convert patient data into intelligence for use by both patient/provider?	24
	Flexibility in design: What is the 'right design for long-term use'? Should it be tailored, have task-specific design, use plug and play, have multiple interfaces, use clear, non-technical language? What are the reasons for the failure of current designs? Usability? What are barriers to long-term use?	16
	Support for patients: Should we provide patients with a support system or coach? Is that sustainable? Who receives the data and acts on them?	11
	Check and balance system: How should we provide feedback to patients?	9
	Affordability: How do we design frugally for the lowest common denominator?	7
Technology professionals	Target audience: What is/are the technology usage patterns, gender, ethnicity and personal models of our end users?	23
	Devices: How to provide secure access for multiple devices?	12
	Ease of use: What types of gestures are hard or easy for users?	10
	Digital divide: Who has barriers to mobile technology (e.g., income)?	9
	Archetypal problems in mobile health: Need to be defined	9
Community stakeholders	Motivators: What are the motivators for patients to use or keep using health technology?	9
	Digital divide: Who is left behind by financial and physical limitations?	9
	Teaching new users: How do we best teach new users while avoiding assumptions based on knowledge or education?	8
	Assumptions: How do we avoid making assumptions about users?	7
	Confidentiality & Security: How do we combat fear?	7
Researcher	Digital divide: How do you design motivation for older, less tech savvy populations?	14
	Engagement: How can we employ our knowledge of behavioral psychology to improve user engagement?	12
	Behaviour change: Can mobile devices change behavior (in older adults or health care providers)?	11
	Robust design: How do we track technology development, big data development, and delivery system information to accelerate mHealth opportunities?	9
	Evaluation: What metrics should be used instead of waiting for a longitudinal study?	9

Discussion

Principal Findings

To better understand the effectiveness, usability, and design of mHealth tools for older adults, research should focus on adoption/motivation, privacy/security, defining "quality" and accessibility. While each group had a different perspective, all stakeholders were ultimately focused on end-user engagement and usability. Based on our NGT, the key to mHealth development for older users are to build tools that patients and health care providers can trust (evidence-based, secure) and that are accessible to end users (adaptable, affordable, easy to use).

We found that rapid-style presentations, group discussion and an NGT were simple and useful approaches to identifying a collaborative research agenda. It was also useful for educating and engaging stakeholders who would have been reluctant to partner in mHealth research in the past. Other researchers have had similar experiences using the NGT for consensus building. Giangregorio et al successfully used the NGT approach to identify future research priorities for osteoporosis [45]. Chasens and Olshanskyn used the NGT to prioritize the problems experienced by patients with type 2 diabetes and found that it was a very useful tool for providing a voice to all participants [46]. Further, Carney et al found the NGT helped bridge the gap between researchers and clinicians when looking at the needs of community nurses [47].

We purposely laid out our meeting to give all participants a base of understanding for the topic through the initial discussion in the morning before we ran the NGT sessions. Everyone was given equal time and attention, and we organized the presentations in a way that gave no group authority over another group. In the planning phase, we told every participant they were welcome to create a presentation, but it was not mandatory. Following this, after the planned presentations at the morning meeting, we offered those who did not previously present the opportunity to present, or add their comments to the discussion, and nearly all participants did. All of our participants were very clear to emphasize what they did not know, and we found in every case their contributions to the discussion and the NGT sessions to be invaluable.

One observation that emerged during the NGT activities was that each group was very clear on what they did not know. For example, patients and advocates would repeat the statement "I'm not a programmer or researcher" in different ways throughout the dialogue. A benefit of the NGT is that it minimizes power differentials. In our case, separating our stakeholders into groups gave participants the opportunity to go through the NGT process among a group of people whom they felt they were on equal footing with. This was particularly evident in the patient group, where after one participant made the comment that they did not know about technology, the other participants said they did not know much either. It was also emphasized that we did not want or need them to be experts; rather the purpose was for us to get their ideas and input into future research directions.

Recently, Richardson and Reid outlined several barriers to engaging patients with mHealth that mirrored the concerns of our participants - the most significant being that there is a strong tendency in mHealth apps not to accommodate functional abilities of seniors [48]. The best people to convey the abilities of seniors are seniors themselves. Participants' comments about their discomfort with technology were one of the most valuable pieces of information we gathered. One of the greatest benefits to using the NGT method was that it gave participants the opportunity to offer us valuable insights that they were not aware they had, through providing support for them to give their perspectives and ideas. It also confirmed our idea that discomfort with the topic of technology was a barrier to engagement, which is important to guide both future research directions, as well as awareness to have while building collaborative partnerships between the various groups involved in these discussions.

The Dangers of Focusing on the Divide

The Digital Divide not only refers to the economic ability people have to purchase the technology but also to their ability to understand and use the technology. In our NGT, each group had their own concerns about how the digital divide affected both uptake and continued use of mHealth apps. Regardless of financial or educational constraints, each group at some point thought about and discussed how to best develop an app or tool that could be most accessible to the broadest group of people who may benefit from using it.

In publicly funded health systems such as those in Canada, Britain and Australia, equitable access to health care is considered a human right. Some imagine that the digital divide is a temporary problem that will vanish as physical technologies become cheaper [49,50]. Others caution that unequal access leads not only to political and economic exclusion, but also to social exclusion [51]. However, the risk of linking digital inclusion with social inclusion, and by extension, linking technological progress with social progress, is that we disregard people who have no interest in adopting a new technology, even with technological or financial capacity [52,53]. Wyatt et al suggest that the decision to not use the Internet, and by extension technologies, is a choice, and does not always reflect a disadvantaged position and group non-users in the following way [54,55]: (1) The resisters who have never used the Internet because they do not want to; (2) The rejecters who have stopped using the Internet voluntarily, perhaps because they found it boring or expensive; (3) The excluded who have never had access but would like it; and (4) The expelled who have lost access involuntarily.

In the above list, the first two categories are individuals who have shown agency in their decision whereas the latter two are limited by their own situation. While much of the literature on the digital divide focuses on the generic or ideal user, it will become increasingly important to examine the everyday practices of older adults and how their practices change with the inclusion, or exclusion, of mHealth.

Adoption and Ownership

It is generally accepted that we need to attain positive user attitudes to impact behavior and influence acceptance [56,57].

It is also fairly well accepted that positive user attitudes are important predictors of systems usage, and by extension, success [58,59]. Interestingly, during our research day, neither the health care professional group nor the researcher group touched on the question of who exactly patients considered authorities in terms of information about technology adoption. Van Alstyne et al have noted that "ownership is critical to the success of information systems projects" and related it to "self-interest; owners have a greater vested interest in system's success than nonowners" [60]. This attitude may lead to systems built to support the builders rather than the users [61]. There is little literature on adoption and ownership of mHealth, and the majority of the available literature centers on health technology adoption in organizations. Going outside of the health sphere for information is essentially mandatory, and even then, there is little information available outside of the context of user acceptance.

Strengths and Limitations

Our overall goal was to bring the participants in at the pre-planning stage to ensure that their input informs the entire research cycle. We were also aware that the process may not end up being a fully participatory model, but we wanted to ensure that our research team made a deliberate effort to consider the needs of a very diverse stakeholder group that historically has not worked together collaboratively.

We acknowledge that at the last moment, six attendees from our patients/advocates group had to drop out due to health concerns. Considering that we were inviting adults with complex or serious health conditions, we anticipated that this might be a challenge. While we tried to compensate by inviting a higher proportion of patient groups, it likely limited the patient voices in the NGT. As a result, we made a greater effort to ensure that each patient and advocate in attendance had their opinions heard, and that the patients and advocates completed the NGT in their own group.

The NGT is a strategic and effective means of increasing productivity using focus group methods [62]. Keeping in mind the warning from Delbecq et al that broadly stated or unfocused NGT questions are likely to elicit a variety of responses from persons who have had varied experiences [63], we knew that our questions needed to be framed in a way that helped participants generate information to sufficiently convey their understanding and experiences. Before conducting the NGT, we paid careful attention to the question we would pose to the group. Furthermore, through using the NGT process, we found its depersonalized and highly structured format to be ideal for promoting a respectful, creative and meaningful discussion about personally important issues that we think would have been difficult to achieve with other focus group frameworks. It appeared to be particularly effective at minimizing the perceived hierarchical structures or power differentials among participants because the process allows for individual idea-gathering and generating, and give participants equal voice in the presentation of ideas.

While determining our criteria for recruitment, we particularly wanted to include the patient and patient-advocate voice because they are participants with a perspective that is both broad and specific to older adults. Our targeted community groups reflected this. As patients and patient representatives, they provided us with an opportunity to examine the specific perspectives of users with challenging needs, discuss mHealth efforts already in development by stakeholder groups and their successes, and derive insight into how users were engaging with existing mHealth technologies.

To augment the identification of relevant research questions, health care professionals were also targeted in order to probe the perspective of those providing care to potential users. Integrating an app into daily life requires both the help of the user's health care support system and also an understanding of the additional demands on all of the users to gain buy-in of health support teams. Our perspective was that the patient is not the only knowledge user. mHealth tools that allow users to access health information at the point of decision-making, to receive real-time feedback and coaching and to monitor health conditions, must be equally beneficial or relevant to health care providers.

Although the structured format of the NGT is intended to maximize the greatest number of group responses, certain members may intentionally or unintentionally influence this process by their own agenda. A key goal of all three facilitators was to actively redirect the process toward the defined tasks of the NGT process. However, even when working within the boundaries of the NGT method, we faced challenges facilitating communication among multiple stakeholders. In most groups, one or two participants tried to consistently bring the discussion back to their own perspective or discuss a particular idea at length. Facilitation was necessary to ensure the groups remained on topic and avoided focusing intensely on a single point, particularly when the topic at hand was of personal importance to a participant. It is important to train facilitators properly in NGT, because a level of confidence is required to steer the discussion back to the boundaries of the NGT, particularly when working with invested individuals.

Conclusion

Ultimately, our hope is that this kind of collaborative approach - the Nominal Group Technique - can be used and adapted by other researchers to engage small or vulnerable populations often excluded from mHealth research and design. We believe that the case study experience presented here is transferable for researchers, community organizations, and others with a vested interest in promoting and encouraging mHealth advancements for seniors.

More work is clearly warranted to gather the perspectives of individuals and additional community groups. If we all believe that seniors are active users of mobile technologies and desire to be engaged in their health care programmes, then health care practitioners, technology developers, and other professionals have an obligation to involve them in both decisions about their care and their access to it via mHealth technologies.

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Conflicts of Interest

None declared.

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Abbreviations

NGT: nominal group technique

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Original Paper

Exploring the Far Side of Mobile Health: Information Security and Privacy of Mobile Health Apps on iOS and Android

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Abstract

Background: Mobile health (mHealth) apps aim at providing seamless access to tailored health information technology and have the potential to alleviate global health burdens. Yet, they bear risks to information security and privacy because users need to reveal private, sensitive medical information to redeem certain benefits. Due to the plethora and diversity of available mHealth apps, implications for information security and privacy are unclear and complex.

Objective: The objective of this study was to establish an overview of mHealth apps offered on iOS and Android with a special focus on potential damage to users through information security and privacy infringements.

Methods: We assessed apps available in English and offered in the categories “Medical” and “Health & Fitness” in the iOS and Android App Stores. Based on the information retrievable from the app stores, we established an overview of available mHealth apps, tagged apps to make offered information machine-readable, and clustered the discovered apps to identify and group similar apps. Subsequently, information security and privacy implications were assessed based on health specificity of information available to apps, potential damage through information leaks, potential damage through information manipulation, potential damage through information loss, and potential value of information to third parties.

Results: We discovered 24,405 health-related apps (iOS; 21,953; Android; 2452). Absence or scarceness of ratings for 81.36% (17,860/21,953) of iOS and 76.14% (1867/2452) of Android apps indicates that less than a quarter of mHealth apps are in more or less widespread use. Clustering resulted in 245 distinct clusters, which were consolidated into 12 app archetypes grouping clusters with similar assessments of potential damage through information security and privacy infringements. There were 6426 apps that were excluded during clustering. The majority of apps (95.63%, 17,193/17,979; of apps) pose at least some potential damage through information security and privacy infringements. There were 11.67% (2098/17,979) of apps that scored the highest assessments of potential damages.

Conclusions: Various kinds of mHealth apps collect and offer critical, sensitive, private medical information, calling for a special focus on information security and privacy of mHealth apps. In order to foster user acceptance and trust, appropriate security measures and processes need to be devised and employed so that users can benefit from seamlessly accessible, tailored mHealth apps without exposing themselves to the serious repercussions of information security and privacy infringements.

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KEYWORDS

mobile health; mobile apps; data security; software and application security; patient privacy; health information technology

Introduction

mHealth Apps

Mobile health (mHealth) leverages various wireless technologies to provide health-related information and services on diverse mobile devices and is a promising subset of health information technology (IT) [1-6]. mHealth has the potential to alleviate global health burdens due to rising dissemination of mobile devices, standardized and easy access to cloud or Internet services, and the possibility of affordable global deployment [4,7-9]. mHealth apps target, for instance, prevalent global diseases [10,11] and offer vital health information at an individual as well as population level [12]. On the other hand, users, albeit deeming access to health information and related services beneficial, are concerned with information security and privacy issues, and want to control access to their information [13-15].

Information security and privacy issues impede users' willingness to share information [16,17], and render thus the promising benefits to be reaped from mHealth apps moot, in order to tailor offered information and services to users' needs, mHealth apps require access to relevant personal health information. Thus, mHealth apps will only offer more general services or cannot be used at all if users are not willing to share their health information. Moreover, infringements of information security and privacy lead not only to leakage or manipulation of private, sensitive information, but make also serious consequences like worsened morbidity or death more likely [18].

Mobile Devices for mHealth

Typical mobile devices for mHealth are smartphones and tablets [11], which are characterized by a rapidly rising market penetration and access to a wide range of embedded technology like sensors for audio, video, location, orientation, and acceleration [8,11,19,20]. The main platforms for mobile devices are Google's Android and Apple's iOS [8]. The associated app stores (Apple iTunes, Google Play) [21,22] offer a vast amount of mHealth apps. These mHealth apps provide a variety of functionality requiring access to different kinds of information and supporting users in different ways, for example, support for weight management, tracking of workouts or medication regimens, facilitation of physician patient communication, management of chronic diseases, or implementation of Web-based interventions [23].

Mobile devices and apps have been addressed from various perspectives, for instance, security aspects [24-26], privacy [18,27-29], software engineering [30-32], medical implications [33,34], hardware [19,35], or user implications [20,36,37]. In contrast, pertinent governmental regulations, for example, [38,39], and extant reviews of mHealth apps, for example, [10,11,40-55], focus mostly on functional aspects and utility of apps for specific diseases or health conditions. Information security and privacy of mHealth apps is only scarcely addressed by extant research. With respect to information security and privacy, extant research offers, to the best of our knowledge, neither clear analysis of the peculiarities that distinguish mHealth apps from "common apps" (eg, weather apps or games), nor of the differences distinguishing apps available from each other. In short, understanding of information security and privacy implications of mHealth apps is lacking and hard to grasp due to the diversity and range of mHealth apps available. In order to address this gap, the objective of our research is to establish an overview of mHealth apps offered on iOS and Android, with a special focus on potential damage to users through information security and privacy infringements.

Our research contributes to practice and the knowledge base by shedding light on information security and privacy of mHealth apps. Aside from providing an overview of available mHealth apps, we contribute to the scientific knowledge base by deepening the understanding of information security and privacy of mHealth apps. Instead of treating mHealth apps as a monolithic technology, we focus on the multi-facetted nature of mHealth apps and identify different mHealth app archetypes with respect to information security and privacy. For practical audiences, our work fosters awareness of information security and privacy implications of mHealth apps. Besides substantiating the need for attention to information security and privacy of mHealth apps, our work demonstrates that mHealth apps are of a diverse nature and require tailored attention to information security and privacy. For developers and end users of mHealth apps, the identification of mHealth app archetypes is especially useful to recognize where and understand when attention to information security and privacy is of particular importance. Deepening the understanding of information security and privacy of mHealth apps is an important step toward realization of the promising potential of mHealth apps to transform and improve the health care environment [2].

Methods

App Discovery

We surveyed English language mHealth apps in the official iOS and Android App Stores. App stores organize their offerings in categories (eg, Books, Games, and News). We selected apps from the Medical and Health & Fitness categories, offered in both stores in May 2013. The iOS app store lists all apps by category and offers the desired information in plain hypertext markup language (HTML), enabling us to automatically parse app information to extract data. The Android App Store employs dynamically generated HTML pages so that the HTML texts displayed in the browser do not convey useful information, which is dynamically loaded from an underlying database. Hence, we used a third party open-source interface for retrieving app information [56]. However, Google imposes various constraints on app store access [8,57]; for instance, only a maximum of 500 apps is returned per search request, even if more apps match the query. Our approach for Android app discovery builds search queries based on words from a publicly available English word list [58] appended once with the string "medical" and once with the string "health". Supplemented with missing health-related words and phrases identified during app tagging (see next paragraph), the word list consists of 111,632 distinct words and phrases (see Multimedia Appendices 1 or 2).

Apps that were not available in English, did not have an English description, or were not health-related, despite being offered in the categories Medical or Health & Fitness (eg, apps offering wallpapers), were excluded from further assessment. We employed tagging, that is, assignment of arbitrary terms describing an object to that object, to filter the initially discovered apps (iOS, 32,614; Android, 4632). Instead of assigning tags directly to an app, we assigned tags to corresponding strings in app descriptions. Only tags referring to health-related information collected by apps, health-related app purposes, handling of information, or other health-related app characteristics were used. For example, apps that provide medication-related functionality should be tagged with the tag "Medication". Yet, app descriptions use different wording (eg, medication, pharmaceutical, or drug). Assigning tags to all encountered strings referring to medication reduces the number of redundant tags and establishes a corpus of string tag relationships that facilitates automated tagging of apps. Since extant research offered no clear guidance to determine cut-off points for manual tagging or the number of required tag matches, cut-off points were determined according to the available data in group discussions of the authors. We manually tagged 200 frequently rated apps (100 Health & Fitness, 100 Medical). Based on this initial tag corpus, we employed string matching [59] to automatically tag the remaining apps. With this approach, apps that do not offer English descriptions or health-related functionality are not assigned any or assigned only a small number of tags, because tags are assigned based on English, health-related words. Apps not matched by at least four distinct tags were excluded from further assessment.

App Clustering

Clustering Approach

App tagging created a machine-readable description of app functionality. Since all apps were tagged based on the same tag corpus, apps with similar characteristics are assigned similar tags. We clustered [60] apps based on their tags to aggregate the data and identify the various kinds of apps in our sample. We used a graph—a set of vertices that are connected by a set of edges [61]—to represent the apps and their tag relationships. Vertices represent apps and edges represent tags both vertices have in common.

For identification of clusters, we used a heuristic by Blondel et al [62], called Louvain method, which is based on modularity optimization. Modularity is a measure for cluster quality introduced by Newman and Girvan [63]. Basically, modularity measures the fraction of edges in the graph that connect vertices within the same cluster minus the expected value of connections within a cluster if edges were inserted at random. Hence, a higher modularity value indicates that detected clusters are less random. The Louvain method performed well in comparative analyses of clustering algorithms [64,65], has low runtime so that it breaks our dense app tag graph down into clusters within a feasible amount of time, and does not require a priori determination of the number of clusters to be discovered, which is unfeasible due to the large numbers of apps, tags, and possible combinations. The Louvain method is an agglomerative clustering algorithm [60] that runs in multiple iterations until a maximum of modularity is reached [62]. Required algorithms were implemented in the programming languages PHP and Java. The Java library JGraphT [66] was used to represent graphs. The relational database management system MySQL was used for data management.

Cluster Assessment

Health IT faces various threats, for instance, intentional and unintentional disclosure or manipulation of information through insiders or outsiders, user errors, maintenance errors, software failures, or hardware failures, as well as environmental threats [67-70]. If such threats materialize, users will be in harms' way. Based on extant research on information security and privacy in health care [68,71-79], we assess information security and privacy implications according to five characteristics: (1) health specificity of information available to apps, (2) potential damage through information leaks, (3) potential damage through information manipulation (change), (4) potential damage through information loss, and (5) potential value of information to third parties (Table 1). Cluster assessment is focused on risks specific to mHealth apps. Hence, risks associated with information ordinarily available to apps [24,27], like location information or device identifier, do not contribute to a more grave assessment.

Characteristic 1, health specificity of information available to apps, assesses whether the app has access to medical user information, access to other nonstandard information, or only access to standard information ordinarily available to apps like location information or device identifiers [24,27]. Characteristic 2 assesses the potential damage through information leaks, which can be classified as none, low, or high. Depending on offered functionality, health IT has access to information with low sensitivity like users' height, weight, or common past illnesses and treatments like a cough or broken bones [71,72]. Other health IT offerings have, however, access to information with high sensitivity like abortions, mental illness, sexually transmitted diseases, HIV status, substance abuse, or genetic predispositions to disease [71-73]. Leaks of such information increase the likelihood of potential damage to users through socioeconomic repercussions [74], embarrassment or damage of reputation [68,71-73,75,76], social stigma [75], loss of affection or respect of family members [77], monetary repercussions through medical fraud (billing for treatments never rendered) or medical identity theft (obtainment of medical services with a fake medical identity) [68,73,74], more expensive insurance coverage or problems to obtain insurance coverage [71,72,75,77,78], or lessened employment possibilities [68,71,72,75,77]. Characteristic 3 assesses potential damage through information manipulation (change), possible values are none, low, or high. Potential damage through information manipulation was, for instance, assessed as low for information on eating patterns or past workouts. Manipulation of such information is inconvenient and undesirable, but poses only low potential damage. Potential damage through information manipulation was assessed as high for apps where information manipulation causes greater harm to users. If, for example, erroneous information is added to users' information due to medical fraud, medical identity theft, negligence, malicious intent, or other threats, treatment can be based on

erroneous information [68,73]. In addition, users' quality of care is affected, potential for harm to health or death is increased, and later efforts to obtain medical, life, or disability insurance are impeded [68,73,74,76]. Potential damage through loss of information is assessed with characteristic 4, possible values are none, low, or high. Loss of uncritical information or information that can be restored was assessed as low. Loss of information was assessed as high in cases where, for instance, important information required for users' care is no longer available [71,75,76]. Finally, the potential value of information for third parties is assessed by characteristic 5, possible values are none, low, or high. If apps have access to information valuable to third parties, infringements of information security and privacy are more likely because they are more rewarding for third parties. For mHealth apps that have only access to information commonly available to mobile apps, value was assessed as none. Value was assessed as low for collected information that is not directly useful to third parties, like unspecific information or information not attributable to users. On the other hand, information like insurance policy information, date of birth, or social security numbers is highly valuable to third parties; for instance, to commit medical identity theft or medical fraud [68,71,73]. Further uses of others' private medical information that are not in the best interest of the data subject include the selling of medical information of celebrities [71], better fitting of insurance policies to insurees' risks and selection of insurees [71,78,79], selection of healthy employees [68,71,78,79], or targeted marketing [71,72,78].

Table 1. Cluster assessment characteristics.

#	Name	Definition	Possible values
1	Specificity	Health specificity of information available to apps (eg, phone identifiers, eating habits, disease history)	Standard, nonstandard, medical
2	Leaks	Potential damage through leaks of information (eg, embarrassment, lessened employment prospects)	None, low, high
3	Change	Potential damage through manipulation (change) of information (eg, treatment errors)	None, low, high
4	Loss	Potential damage through loss of information (eg, loss of information important for treatment)	None, low, high
5	Value	Value of information to third parties (eg, medical identity theft, selection of employees)	None, low, high

Assessing Discovered Clusters

There were two researchers that assessed all discovered clusters. To maintain a consistent interpretation of clusters during assessment, each rater annotated each cluster with a short description based on connotation and prevalence of tags assigned to the cluster. These descriptions were verified through comparison to apps contained in the respective cluster. Subsequently, clusters were assessed according to the five characteristics addressing information security and privacy implications. Reliability assessment with Janson's and Olsson's ι, an multivariate extension of Cohen's κ for multiple judges on the same scale [80], led to a "substantial" [81] agreement score of ι=0.71. All remaining differences were resolved by discussion; if necessary, a third researcher was consulted for dispute resolution.

mHealth app archetypes (AT), with respect to information security and privacy are identified by grouping clusters with identical assessments in a final aggregation step. An archetype is "the original pattern or model of which all things of the same type are representations or copies" [82]. Hence, archetypes constitute underlying or core conceptions of objects observed in the real world. Real-world representations of archetypes may, however, materialize in different forms. For example, from an information security and privacy perspective, a medication reminder, as well as a patient interaction app are real-world representations of the same archetype; they both have access to sensitive medical information that should not be leaked to third parties, must remain accurate, and is of value to third parties. Yet, there is only a low demand for data preservation; medication reminders only need to store information until they have reminded users to take their medication, and patient interaction apps only need to store the data until the interaction has happened. Identification of mHealth app archetypes, with respect to information security and privacy, establishes, thus, a graspable overview of the thousands of mHealth apps offered in the app stores. To foster interpretability of app archetypes, identified app archetypes are numbered and additionally characterized by a natural language descriptor. The medication reminder and patient interaction app from the previous example are, for instance, both representations of the archetype AT 11 (Treatment Reminders). Due to the large diversity of possible real-world representations of mHealth app archetypes, it is unfeasible to identify meaningful descriptors capturing all facets of functionality offered by real-world archetype representations. The final descriptors were determined in group discussions of the authors. Hence, the archetype descriptors characterize exemplary functionality of real-world representations to foster archetype interpretability.

Results

Discovered Apps

We discovered a total of 37,246 apps (iOS, 32,614; Android, 4632) in the categories Medical and Health & Fitness (Figure 1 shows this). After automatic tagging, 34.48% of apps (12,841/37,246; iOS, 32.69%, 10,661/32,614; Android, 47.06%, 2180/4632) were excluded from further assessment. The ratio of iOS mHealth apps to Android mHealth apps is 8.95 (21,953 to 2452).

In both stores, users rate apps on 5-star integer rating scales, ranging from 1 to 5 stars. Mean rating scores of rated iOS and Android mHealth apps are 3.1 (median 3, SD 1.01) and 3.7

(median 3.92, SD 1.08), respectively. Figures 2 and 3 illustrate app ratings and rating counts in more detail. There are 81.36% (17,860/21,953) of iOS and 76.14% (1867/2452) of Android apps that have been rated less than 10 times. There are 75.76% (16,631/21,953) of iOS and 42.37% (1039/2452) of Android apps that have not been rated. There are 1.38% (302/21,953) of iOS and 1.55% (38/2452) of Android apps that have been rated more than 1000 times. There are 39.36% (2095/5322) of rated iOS apps that are rated four stars or more and 27.85% (1482/5322) of rated iOS apps are rated two stars or less. On Android, 64.83% (916/1413) of rated apps are rated four stars or more and 14.23% (201/1413) of rated apps are rated two stars or less. As illustrated in Figure 2, Android mHealth apps are rated higher than iOS mHealth apps (Mann Whitney U(6733)=2,592,190; P<.001; r=0.31; 95% CI 0.99997-0.99998). App category has no significant influence on app rating (iOS, Mann Whitney U(5320)=3,516,696; P=.92; r=0.002; Android, Mann Whitney U(1411)=203,559.5; P=.13; r=0.05).

For Android apps, rating count and download count are strongly positively correlated (Spearman ρ=0.89, n=2452, P<.001), indicating that rating count is a good proxy for download count (Figure 4 shows this).

Figure 1. Flow chart of apps selection.

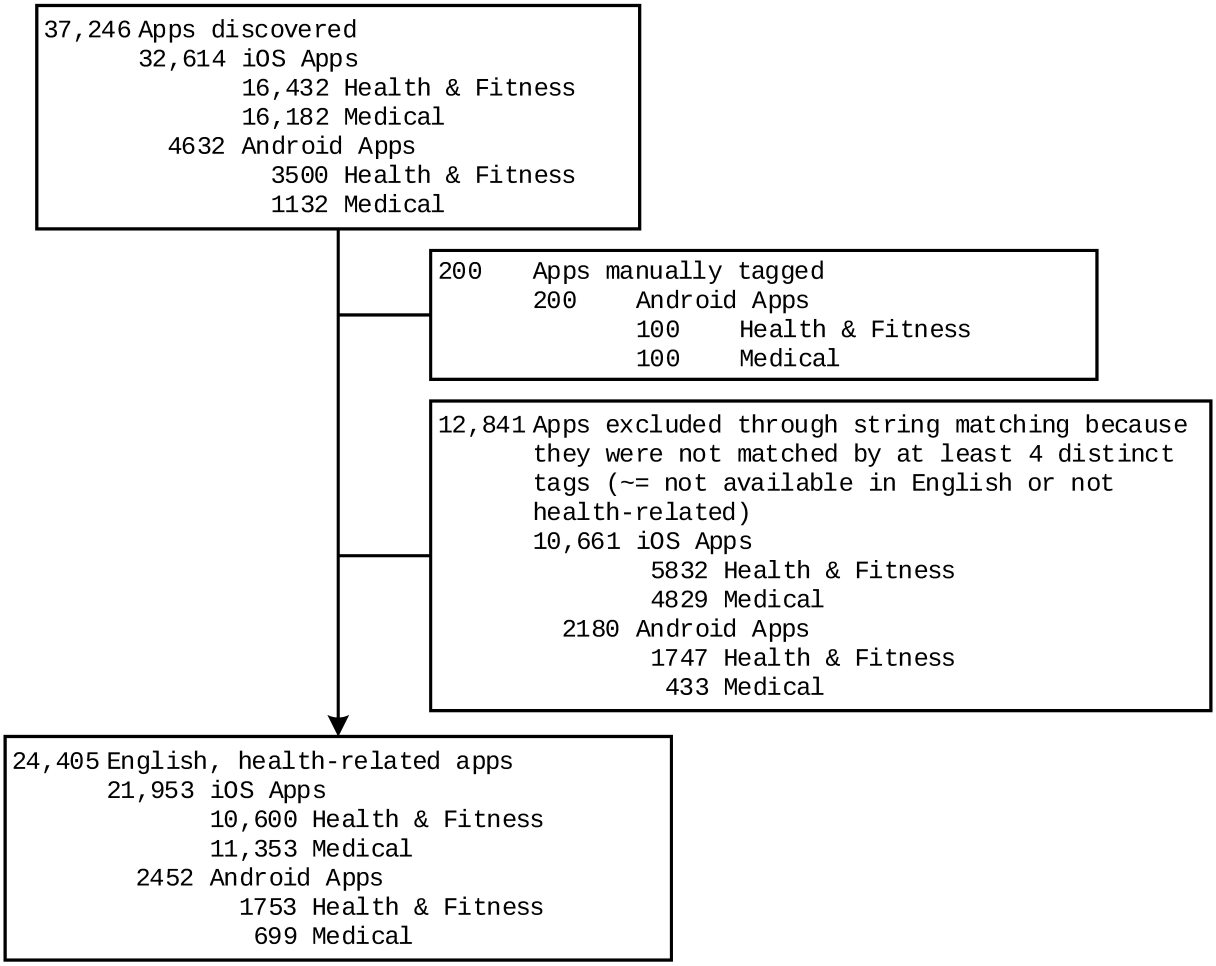


Figure 2. Rating count of mHealth apps by store. Number of ratings increases from left to right.

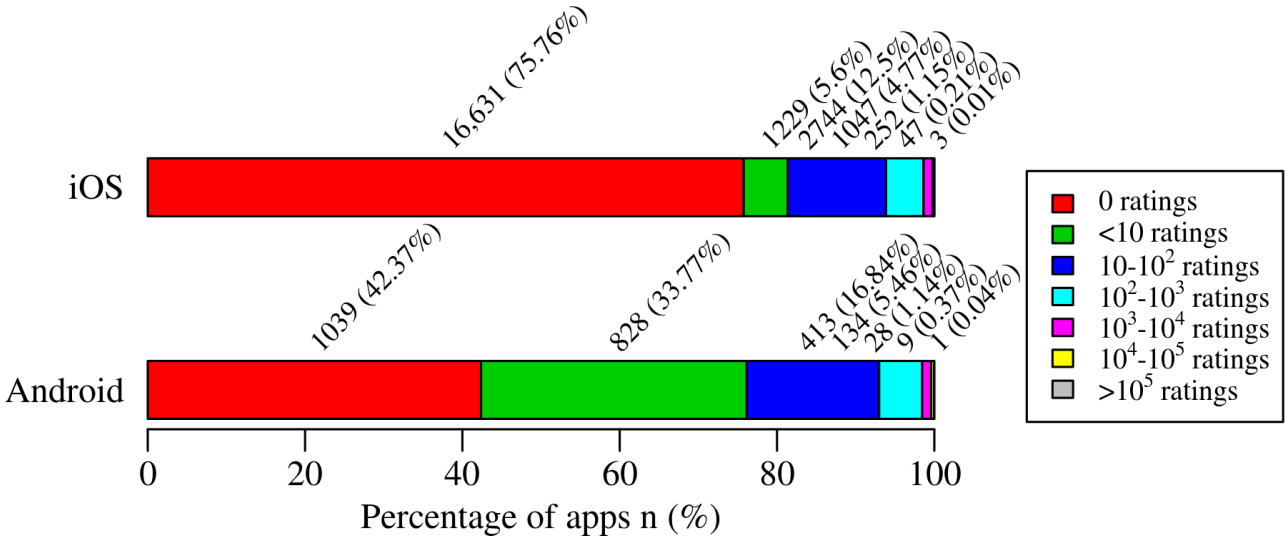


Figure 3. Rating of rated mHealth apps by store.

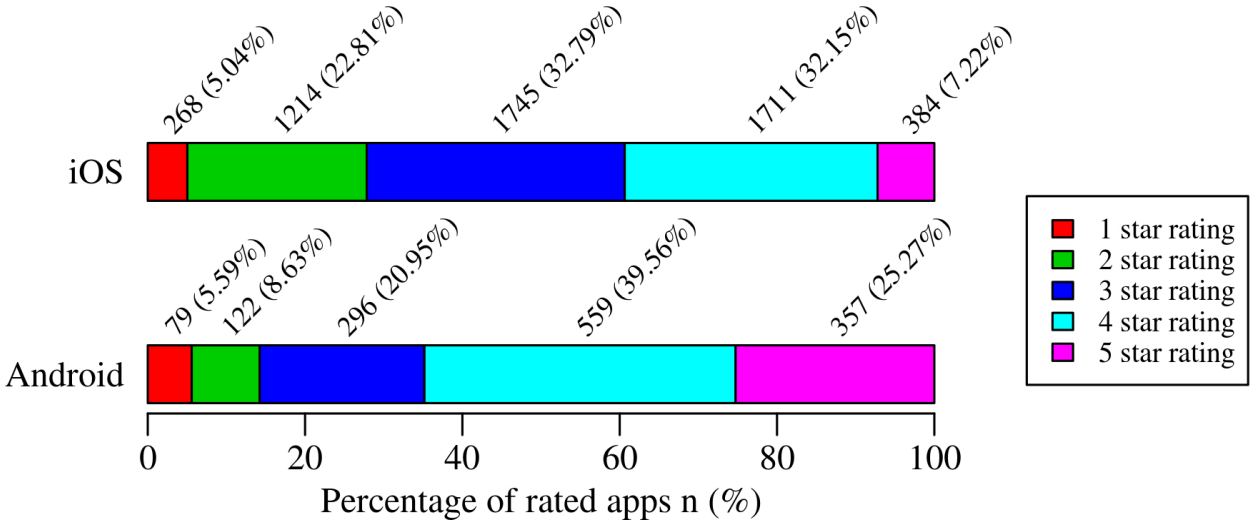
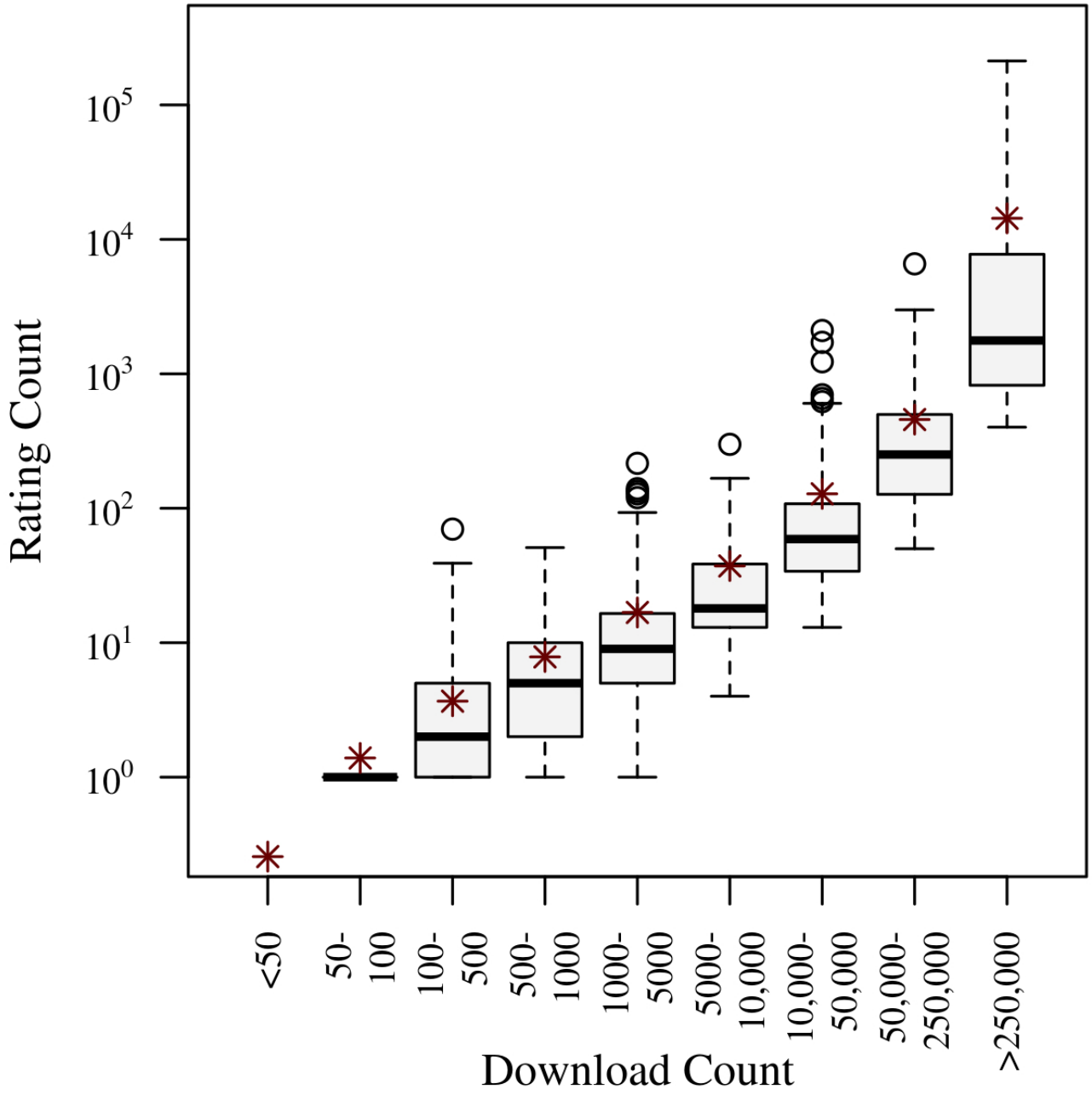


Figure 4. Boxplot of Android app rating count (log-scaled) and download count. Mean values are indicated with asterisks.



App Clustering

Application of the Louvain method [62] grouped the 24,405 apps applicable for clustering into 245 distinct clusters with a modularity score of 0.47, which indicates a good division of the graph [63,83]. Discovered clusters have a mean size of 99.6 apps (minimum 2; maximum 910; median 90; SD 113.6). There are 28.6% (70/245) of clusters containing 26.33% (6426/24,405) of apps that conveyed no information relevant to our research scope and were excluded from further assessment. Some clusters are, for instance, too ambiguous because contained apps match mainly a single tag (eg, “Pain” or “Care Giver”) that is uninformative on its own with respect to our research scope. Cluster assessment, according to the five characteristics, led to further consolidation of the 175 informative clusters into 12 app archetypes, grouping clusters with identical characteristic assessments. The 12 app archetypes have a mean size of 14.6 clusters (minimum 3; maximum 58; median 8; SD 4.6) and 1498.25 apps (minimum 60; maximum 5603; median 615; SD 506.18). Figure 5 shows the clustering process.

Table 2 provides an overview of the cluster assessments with respect to health specificity of information, potential damage through leaks, manipulation, loss of information, and value of collected information to third parties. Medical information is available to apps in 33.7% (59/175) of clusters. There are 16.0% (28/175) of clusters that have access to information not available to ordinary apps [24,27], and apps in 50.3% (88/175) of clusters do not have access to more information than ordinary apps. Apps in 73.7% (129/175) of clusters have no or low potential damage through leaks of information. There are 39.4% (69/175) of clusters that are comprised of apps with high potential damage through manipulation of information. There is no potential damage through loss of information in 67.4% (118/175) of clusters. There are 77.7% (136/175) of clusters that consist of

apps that have only access to information with no or low value for third parties.

Table 2. Cluster assessments with respect to the five information security and privacy characteristics.

		Clusters n (%)[a] N=175	Apps n (%)[a] N=17,979
Specificity [b]			
	Standard[c]	88 (50.3)	8463 (47.07)
	Nonstandard[d]	28 (16.0)	4818 (26.80)
	Medical[e]	59 (33.7)	4698 (26.13)
Leaks [f]			
	None	88 (50.3)	8463 (47.07)
	Low	41 (23.4)	5388 (29.97)
	High	46 (26.3)	4128 (22.96)
Change [g]			
	None	9 (5.1)	786 (4.37)
	Low	97 (55.4)	11,641 (64.75)
	High	69 (39.4)	5552 (30.88)
Loss [h]			
	None	118 (67.4)	10,049 (55.89)
	Low	32 (18.3)	5832 (32.44)
	High	25 (14.3)	2098 (11.67)
Value [i]			
	None	88 (50.3)	8463 (47.07)
	Low	48 (27.4)	6108 (33.97)
	High	39 (22.3)	3408 (18.96)

[a] Uninformative clusters are not included in percentages

[b] Health specificity of information available to apps

[c] Apps only have access to information ordinarily available to apps, for example, phone identifiers or location information

[d] Apps have access to information not ordinarily available to apps, but no access to medical information, for example, workout history or eating habits

[e] Apps have access to medical information, for example, disease history or health insurance information

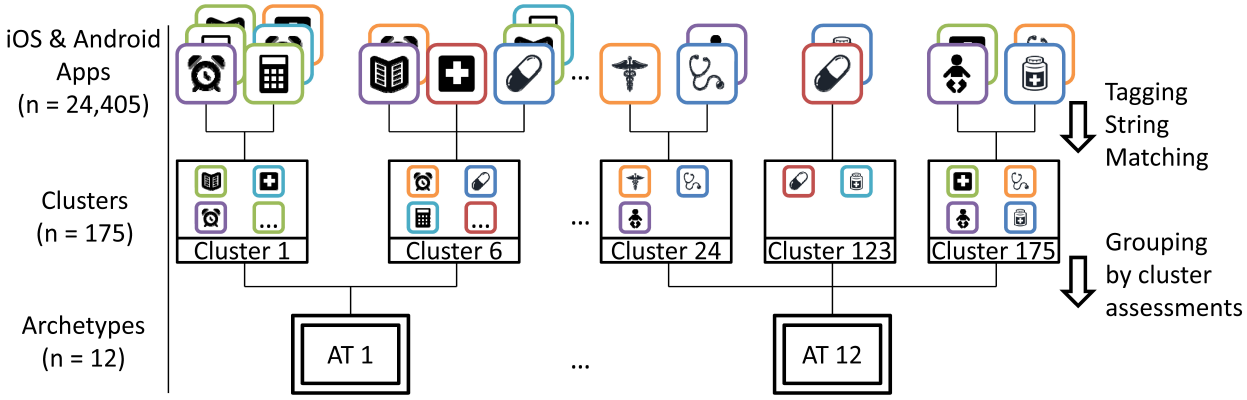
[f] Potential damage through leaks of information, for example, embarrassment, lessened employment possibilities

[g] Potential damage through manipulation, change, of information, for example, treatment based on erroneous information

[h] Potential damage through loss of information, for example, loss of information important for treatment

[i] Value of information to third parties, for example, medical identity theft, selection of employees

Figure 5. Outline of clustering process (AT = archetype).



App Archetypes

Archetype descriptors and examples for functionality offered by apps of the different app archetypes are listed in Table 3. Table 4 illustrates the twelve discovered app archetypes with distinct value combinations according to the five characteristics. AT 1 (Casual Tools) represents 5.1% (9/175) of clusters and 4.37% (786/17,979) of apps. Apps of AT 1 only have access to information also available to ordinary apps and provide no critical functionality, so that their use cannot cause more damage than the use of any other app. Apps of AT 1 offer mostly generic information and are only marginally health-related. AT 2 (Common Knowledge Providers) is the archetype with the most representations in our sample (33.1%, 58/175 of clusters; 31.16%, 5603/17,979 of apps). Apps of AT 2 also have no access to other information than ordinary apps, so that there is no damage through leaks or loss of information. Apps of AT 2 have low potential damage through manipulation of information. More critical information is provided by apps of AT 3 (Treatment Guides), which provide information directly relevant for (self-)treatment or intended to guide users in emergency situations. Information provided by apps of AT 3 needs to be correct to serve as reliable foundation for (self-)treatment decisions; accidental or malicious provision of erroneous information promotes wrong or counterproductive treatment decisions. AT 3 represents 12.0% (21/175) of clusters and 11.54% (2074/17,979) of apps. AT 4 and AT 5 (Fitness Ad-Hoc Tools and Fitness Trackers; 16.0%, 28/175 of clusters; 26.80%, 4818/17,979 of apps) have access to more information than ordinary apps. Yet, they do not collect medical information, so that there is at most low potential damage because collected information is not sensitive, not crucial for provision of medical services, not important for future endeavors, and not valuable to third parties. The remaining seven app archetypes collect medical information (33.7%, 59/175 of clusters; 26.13%, 4698/17,979 of apps). AT 6 (Treatment Support Tools) is the only app archetype that collects medical information and has low potential damage through leaks of information. AT 6 represents calculators and tools for medical professionals or tools offering very specific functionality, so that collected information is either not attributable to patients or not informative. Hence, there is only low potential damage through leaks of information and low value of information to third parties. AT 3 (Treatment Guides), AT 6 (Treatment Support Tools), AT 10 (Health Monitors), AT 11 (Treatment Reminders), and AT 12 (Health Records) offer functionality directly relevant for treatment or decision making so that there is high potential damage through information manipulation. There are four app archetypes, AT 8 (State of Health Tests), AT 10 (Health Monitors), AT 11 (Treatment Reminders), and AT 12 (Health Records) that collect medical information detailed enough to be of high value to third parties (eg, blood test results, medication histories, or health records). While the other app archetypes do not require long storage times of collected information, apps of AT 12 (Health Records) collect medical information relevant for future decision making (eg, disease management tools, medication history, or health records), so that potential damage through loss of information is high. Since apps of AT 12 also tend to collect very detailed, personal information, potential damage through leaks or manipulation and value of information to third parties is high as well.

Table 3. Exemplary functionality of apps represented by the AT.

Archetype	Descriptor	Exemplary kinds of contained apps
AT 1	Casual Tools	Life improvement guides; mosquito repellents; brain fitness trainer
AT 2	Common Knowledge Providers	Information provision for education; alarm clocks; fitness guides
AT 3	Treatment Guides	First aid guides; home remedy guides; medication guides
AT 4	Fitness Ad-Hoc Tools	Diet calculators; weight control calculators; fitness calculators
AT 5	Fitness Trackers	Workout tracker; smoking cessation tools; diet tracker
AT 6	Treatment Support Tools	Diabetes calculators; dosage calculators; diagnosis support tools
AT 7	Intimate Ad-Hoc Tools	Fertility calculators; pregnancy calculators; physician finder
AT 8	State of Health Tests	Acuity tests; color vision tests; blood alcohol calculators
AT 9	Intimate Trackers	Menstruation, intercourse, fertility, and pregnancy tracker
AT 10	Health Monitors	Heart rate monitors; disease counseling; tools for blood test analysis
AT 11	Treatment Reminders	Medication reminder; patient interaction and communities
AT 12	Health Records	Health/emergency records; disease management tools; medication tracker

Table 4. AT with respective assessments of the five information security and privacy characteristics and contained clusters and apps.

AT	Specificity[a]	Leaks[e]	Change[f]	Loss[g]	Value[h]	Clusters n (%)[i] N=175	Apps n (%)[i] N=17,979
1	Standard[b]	None	None	None	None	9 (5.1)	786 (4.37)
2	Standard	None	Low	None	None	58 (33.1)	5603 (31.16)
3	Standard	None	High	None	None	21 (12.0)	2074 (11.54)
4	Nonstandard[c]	Low	Low	None	Low	7 (4.0)	216 (1.20)
5	Nonstandard	Low	Low	Low	Low	21 (12.0)	4602 (25.60)
6	Medical[d]	Low	High	None	Low	13 (7.4)	570 (3.17)
7	Medical	High	Low	None	Low	3 (1.7)	60 (0.33)
8	Medical	High	Low	None	High	4 (2.3)	500 (2.78)
9	Medical	High	Low	Low	Low	4 (2.3)	660 (3.67)
10	Medical	High	High	None	High	3 (1.7)	240 (1.33)
11	Medical	High	High	Low	High	7 (4.0)	570 (3.17)
12	Medical	High	High	High	High	25 (14.3)	2098 (11.67)

[a] Health specificity of information available to apps

[b] Apps only have access to information ordinarily available to apps, for example, phone identifiers or location information

[c] Apps have access to information not ordinarily available to apps, but no access to medical information, for example, workout history or eating habits

[d] Apps have access to medical information, for example, disease history or health insurance information

[e] Potential damage through leaks of information, for example, embarrassment, lessened employment possibilities

[f] Potential damage through manipulation, change, of information, for example, treatment based on erroneous information

[g] Potential damage through loss of information, for example, loss of information important for treatment

[h] Value of information to third parties, for example, medical identity theft, selection of employees

[i] Uninformative clusters are not included in percentages

Discussion

Principal Results

Discovered Apps

Since their inception in 2008, the iOS and Android App Stores underwent a rapid development. After a few years, the app portfolios of both stores encompass hundreds of thousands of apps [8,29,57], which include thousands of mHealth apps. However, absence or scarceness of ratings for 81.36% (17,860/21,953) of iOS and 76.14% (1867/2452) of Android apps indicates that over three quarters of mHealth apps are not in widespread use. A fraction of users who download apps provide ratings [15,84]. Hence, apps less often rated are likely

to be less often used than more often rated apps. An explanation for this is the increased visibility of better-rated apps [85], apps with higher and more ratings are more prominently displayed in app stores and thus more likely to be discovered by potential users. More ratings make the resulting app assessment also more reliable, which attracts more users. Furthermore, many apps offer similar or competing functionality (eg, calculation of the body mass index, tracking of workouts, or prediction of date of birth), so that only a few first-movers, heavily promoted apps, or high quality apps will gain a large user base. App ratings indicate that most users are not dissatisfied with rated apps, 72.15% (3840/5322) of iOS and 85.77% (1212/1413) of Android apps are rated average or above. Another impediment for more widespread use of mHealth apps might be users' concerns about information security and privacy implications [15]. Our cluster analysis of mHealth apps sheds some light on the potential damage through information security and privacy infringements.

App Clustering

Since mHealth apps usually offer functionality related to users' health, it is not a surprising finding that information security and privacy infringements cause potential damage for the majority of apps (94.9%, 166/175 of clusters; 95.63%, 17,193/17,979 of apps). mHealth apps offer, however, diverse functionality so that potential for damage through information security and privacy infringements differs. Manipulation of information is a threat common to most mHealth apps (94.9%, 166/175 of clusters; 95.63%, 17,193/17,979 of apps). Even apps that do not collect any medical information, like AT 2 (Common Knowledge Providers) or AT 3 (Treatment Guides), must ensure that information they provide is correct and stays correct because, at least some, users will act on offered information and base (self)treatment decisions on provided information. Apps offering information or functionality directly relevant for treatment or care must especially ensure that offered information is not accidentally or maliciously manipulated. mHealth apps that only provide information have, however, no information security and privacy implications through leaks or loss of collected information since no information is collected. About one half of the apps in our sample (50.3%, 88/175 of clusters; 47.07%, 8463/17,979 of apps) only provide information. Such apps are probably the most "pleasant" apps when it comes to protecting information security and privacy since no user-collected information must be protected. Thus, providers can focus on protection of integrity of information in rest and during transport, as well as offering accurate information from the onset. Still, extant research shows that information provided by some apps does not concur with current evidence and recommendations or is even contradicting [49,51].

There are 33.7% (59/175) of clusters and 26.13% (4698/17,979) of apps that have access to medical user information. All of these apps have high potential damage through information security and privacy infringements in at least one characteristic. Some apps, for example, AT 6 (Treatment Support Tools) do not collect detailed information or information attributable to users and do not retain entered information, so that there is no potential damage through loss of information, low potential damage through leaks of information, and low value of information for third parties. Yet, they serve as foundation for treatment decisions (eg, appropriate medication dosage), so that there is high potential damage through manipulation of information. Other apps collect information users want to keep private, for example, AT 9 (Intimate Trackers), so that there is high potential damage through leaks of information, but collected information is not directly relevant for treatment or state of health, so that the other characteristics pose only low potential damage. Potential damage of other apps, for example, AT 12 (Health Records) was rated with the most critical assessment in all five characteristics since contained information is sensitive and must be kept private, has to be accurate and accessible to inform treatment decisions, and allows for misuse motivated by financial gain. Consequentially, there is no one-size-fits-all approach for ensuring information security and privacy of mHealth apps. mHealth apps offer different functionality so that they are also subject to different threats. Accordingly, measures for protection of information security and privacy must be tailored to the app to be protected [70].

Our identification of the twelve mHealth app archetypes elucidates information security and privacy of mHealth apps, instead of a hazy collection comprised of the thousands of mHealth apps available in the app stores, the archetypes constitute a lucid, descriptive collection of twelve mHealth app archetypes with different information security and privacy characteristics. Future research can build on the archetypes, for instance, to prioritize information security and privacy requirements with respect to app type, devise collections of security measures ensuring sound protection of information security and privacy, analyze user perceptions of information security and privacy with respect to different kinds of apps, or to further theory and methodology for app development that takes information security and privacy implications into account. For example, potential damage through information security and privacy infringements would obviously be reduced if apps that mainly provide information did not store any user information and focused rather on secure interoperability with specialized storage apps. An overview of app archetypes with respect to information security is also helpful for practical audiences. Associating an mHealth app of interest with the respective archetype improves, for instance, the understanding of perks and perils associated with app use. The overview of the archetypes alone is useful to foster user comprehension and awareness of information security and privacy implications of mHealth app use. In order to continuously benefit from mHealth apps, users must be able to make informed decisions about mHealth app adoption and use.

The apps with the most serious assessment of potential damage through information security and privacy infractions (AT 12, Health Records; 14.3%, 25/175 of clusters; 11.67%, 2098/17,979 of apps) may also offer the most benefits to users [2]. AT 12 represents all the different facets of health records and disease management tools [86-89], which collect detailed health information, allowing them to offer functionality tailored to users' needs and individual peculiarities or to provide other apps with the information required for tailoring offered functionality. Apps of AT 12 could rise to central hubs in the emerging mHealth environment if interoperability issues are solved [12,90] and information security and privacy is

sufficiently addressed so that users can safely trust apps of AT 12 to protect their information [14,91,92].

It is noteworthy that some threats are common to all kinds of mHealth apps, even those without any data collection. Users' behavior, or the sole fact that a guide for stress relief or fighting depression, a support tool for hypertension, or an app providing information on cancer, chronic diseases, infertility, or incontinence, is installed on a device reveals sensitive, private, or embarrassing information [93]. In the end, it is up to users which apps they use and what information they intend to share. To support users in this decision, it is important that they are sensitized to the risks associated with sharing private, sensitive, medical information [16,94] and offered means to gauge, configure, and control information security and privacy practices of mHealth apps [95,96]. Moreover, app stores need to establish processes that ensure protection of information security and privacy prior to making apps publicly accessible, at least, for apps with high potential damage and value to third parties. App developers and providers need to implement appropriate security measures to protect information security and privacy. While ease of app development, free access to helpful apps, and fast dissemination of innovations is desirable, it is imperative that these do not come at the price of lacking information security and privacy. Last, but not least, experienced users, researchers, and further independent entities need to contribute as well by identifying malicious and harmful apps, publishing their findings, and eliminating sources of harm and malice.

Limitations

Since we established a broad overview of available mHealth apps and assessed all discovered apps fitting our selection criteria, it was unfeasible to install and test all apps, so that we focused on the information provided in app stores. This is, however, a common approach, for example, [8,40,51,52], which allowed us to analyze a large sample of over 30,000 apps. Moreover, we cannot ascertain how many of the English apps available on the Android App Store we discovered because the app store offers no complete listing of available apps and search results are limited to 500 apps. Extant reviews of apps in all categories offered in the Android App Store report around 20,000 apps offered in the categories Medial and Health & Fitness. However, these reviews collected apps independent of language and did not assess whether the apps actually offer functionality fitting the categories Medical or Health & Fitness. Our diverse wordlist, comprised of 111,632 distinct words and phrases (see Multimedia Appendices 1 or 2), introduced diversity to search queries and led to the discovery of a wide array of apps, while avoiding bias towards specific types of apps. Creation of search strings based on English words favored discovery of apps offered in English. While this may have reduced the number of discovered Android apps, it suits our research approach and objectives because apps not available in English were excluded from further assessment. Nevertheless, the reported difference in number of apps available on iOS and Android should be treated with care. For now, the iOS and Android App Stores offer far more apps than any other app store [8]. The dominant position of iOS and Android supports our focus on the iOS and Android App Store.

Conclusions

The iOS and Android App Stores offer a wide selection of mHealth apps. Analysis of rating counts indicates, however, that less than a quarter of available apps are in more or less widespread use. An issue impeding app dissemination might be users' information security and privacy concerns [15]. Our cluster analysis shows that most mHealth apps require access to sensitive personal information or offer other services potentially impacting users' treatment or state of health, which increases the potential damage through information security and privacy infringements. The diversity of mHealth apps prevents, however, a one-size-fits-all approach to ensuring information security and privacy of mHealth apps. To address arising challenges, app providers, developers, stores, as well as users, must be sensitized to potential threats and further research and development efforts are required to facilitate protection from information security and privacy infringements. It would be undesirable to diminish or undermine the promising potential of mHealth apps to transform and improve the health care environment [2] through lacking attention to information security and privacy.

Acknowledgments

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Authors' Contributions

AS, SS, and TD conceived of the project. AS, FG, and TD wrote the manuscript. FG, SS, and TD conducted data acquisition and analysis. TD performed the statistical analyses. SS and TD implemented required custom software.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Word list used for construction of search queries for Android app discovery.

[CSV File, 1MB - mhealth_v3i1e8_app1.csv]

Multimedia Appendix 2

Word list used for construction of search queries for Android app discovery (alternate version in Microsoft Word format with new lines as seperator).

[DOC File, 3MB - mhealth_v3i1e8_app2.doc]

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Abbreviations

AT: app archetype
HTML: Hyper Text Markup Language

IT: information technology
mHealth: mobile health

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Review

Finding a Depression App: A Review and Content Analysis of the Depression App Marketplace

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Abstract

Background: Depression is highly prevalent and causes considerable suffering and disease burden despite the existence of wide-ranging treatment options. Mobile phone apps offer the potential to help close this treatment gap by confronting key barriers to accessing support for depression.

Objectives: Our goal was to identify and characterize the different types of mobile phone depression apps available in the marketplace.

Methods: A search for depression apps was conducted on the app stores of the five major mobile phone platforms: Android, iPhone, BlackBerry, Nokia, and Windows. Apps were included if they focused on depression and were available to people who self-identify as having depression. Data were extracted from the app descriptions found in the app stores.

Results: Of the 1054 apps identified by the search strategy, nearly one-quarter (23.0%, 243/1054) unique depression apps met the inclusion criteria. Over one-quarter (27.7%, 210/758) of the excluded apps failed to mention depression in the title or description. Two-thirds of the apps had as their main purpose providing therapeutic treatment (33.7%, 82/243) or psychoeducation (32.1%, 78/243). The other main purpose categories were medical assessment (16.9%, 41/243), symptom management (8.2%, 20/243), and supportive resources (1.6%, 4/243). A majority of the apps failed to sufficiently describe their organizational affiliation (65.0%, 158/243) and content source (61.7%, 150/243). There was a significant relationship (χ^2_5=50.5, P<.001) between the main purpose of the app and the reporting of content source, with most medical assessment apps reporting their content source (80.5%, 33/41). A fifth of the apps featured an e-book (20.6%, 50/243), audio therapy (16.9%, 41/243), or screening (16.9%, 41/243) function. Most apps had a dynamic user interface (72.4%, 176/243) and used text as the main type of media (51.9%, 126/243), and over a third (14.4%, 35/243) incorporated more than one form of media.

Conclusion: Without guidance, finding an appropriate depression app may be challenging, as the search results yielded non-depression–specific apps to depression apps at a 3:1 ratio. Inadequate reporting of organization affiliation and content source increases the difficulty of assessing the credibility and reliability of the app. While certification and vetting initiatives are underway, this study demonstrates the need for standardized reporting in app stores to help consumers select appropriate tools, particularly among those classified as medical devices.

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KEYWORDS

mobile apps; depression; health information; consumer; mental health

Introduction

Depression is a serious, common, and recurring disorder linked to diminished functioning, quality of life, medical morbidity, and mortality [1]. There has been a 37.5% increase in health life years lost to depression over the past two decades [2]. Depression was the third-leading cause of global burden of disease in 2004 and the leading cause of burden of disease in high- and middle-income countries. It is projected to be the leading cause globally in 2030 [3]. While effective treatments for depression are available, they are underused. Barriers to treatment include geography, socioeconomic status, system capacity, treatment costs (direct and indirect), low mental health literacy, cultural beliefs, and stigma [4,5]. A 2010 study found that 75% of primary care patients with depression in urban areas could identify more than one structural, psychological, cultural, or emotional barrier to accessing behavioral treatments. The rate was substantially higher in rural areas [6].

Information and communication technologies (ICTs) hold tremendous promise to expand the reach of quality mental health care [7] and close the treatment gap for depression. A meta-analysis [8] examining the effectiveness and acceptability of computer-based therapy for anxiety and depressive disorders found that computer-based therapy showed superiority in outcome over the control groups with substantial effect sizes. The study also found that adherence and satisfaction were good, suggesting acceptability. These findings were echoed in other meta-analysis studies of computer-based treatments for depression [9,10]. With the ever-increasing ubiquity and sophistication of ICTs, namely the evolution to mobile devices (ie, smartphones, tablets, and phone tablets or "phablets"), there is potential to further expand the reach of mental health treatment through mobile health (or mHealth). The emergence of a commercial marketplace of software for mobile devices (or apps) has given users the ability to personalize their devices to cater to their health and informational needs by purchasing or downloading apps at their convenience [11]. These apps can help support a variety of useful tasks such as self-assessment, symptom monitoring, psychoeducation, psychological therapy, and psychotherapy skills training [12].

Many consider apps as an opportunity to increase patient access to evidence-based mental health (and addictions) treatments [13-17]; however, many apps fail to incorporate evidence-based practices, health behavior theory, or clinical expertise [17-19] into the design of the app. For instance, smoking cessation apps are found to have low adherence to evidence-based practices [20,21] and insufficiently incorporate behavioral theory [22]. A study on addiction recovery apps found that only six of the 52 app developers had clinical experience or used academic or clinical advisors in the development of apps; additionally, none of the app store descriptions mention any evaluation of the apps [23]. The lack of reported evaluations is also seen in scientific literature, as the current body of evidence is marginal in comparison to the number of mental health apps available. In 2013, there were only 32 published articles on depression apps in comparison to the 1536 available in the marketplace [24]. A 2013 systematic review [14] found only four studies (3 randomized controlled trials and 1 pre-post) evaluating three different depression apps. Two apps demonstrated a significant reduction in depression [25,26]; however, none of the apps were publicly available at the time of that review.

The discrepancy between availability and evaluation is problematic because many of these products will continue to be marketed with unfounded claims of health improvement to attract health consumers [27-29]. To better understand what types of apps are offered to those seeking support for depression, this study aimed to identify the mHealth offerings in the mobile app marketplace and characterize the information provided to health consumers in the app store descriptions. This study asked the following research questions: (1) What mobile apps are available for people in treatment for depression, as well as for their families, including informal caregivers? (2) What are the commercial characteristics of depression apps? (3) What are the main purposes of depression apps? and (4) How do depression apps claim to support users in the store description?

Methods

Overview

We used a systematic review and content analysis approach based on a study by Bender et al [30] to guide the collection and characterization of available depression apps. The review was carried out on the five major app stores: Apple (iTunes), Android (Google Play), BlackBerry (AppWorld), Nokia/Symbian (Ovi), and Windows Mobile (Marketplace). On March 5, 2013, we entered the keyword "depression" into the search field on each of the four marketplace websites. The Apple apps were accessed through the iTunes interface using the same search term. The search term was applied across all store categories in the five instances. The two reviewers (MJL and NS) recorded the links and the titles of apps found in the search yield. Based on their availability, one reviewer (NS) compiled apps found in iTunes and the other (MJL) focused on the remaining app stores. For the eligibility assessment of the apps, the entire inventory was split into two equal samples for independent review.

Selection Criteria

Apps were organized as either "potentially relevant" or "not relevant" based on the app title, store description, and available screenshots. Apps were categorized as "potentially relevant" and included in the final analysis if they met three criteria: (1) the term "depression" was in the title or store description, (2) the app targeted health consumers (ie, those who self-identify as needing support for depression, including family or caregivers), rather than health care professionals, and (3) the app had an English-language interface or English translation (if in another language).

Apps were excluded from the study if they did not provide sufficient information, did not have a clear focus on depression,

used the term depression in an unrelated context (eg, the Great Depression), used the term depression as a keyword in a list of unrelated items or as background information, and were duplicates appearing in multiple markets or for other devices (ie, optimized for tablets). The duplicate that provided the most information for data extraction was retained based on the following hierarchy (most to least information): Google Play, iTunes, AppWorld, Ovi, and Marketplace.

After independent screening for relevance, the 2 reviewers exchanged a random selection of 5% (104 apps) of their search yields to verify eligibility. Interrater reliability (IRR) of the random samples, as determined by Cohen's kappa (kappa=.77, P<.001), was statistically significant. According to Landis and Koch's guidelines [31], the score indicated that there was a "substantial agreement" between the 2 reviewers. Because the IRR exceeded the pre-determined minimum kappa threshold of .7, independent reviews of the whole sample were not required. Disagreements found in the exchanged sample were resolved by consensus.

Data Extraction and Coding

Information was extracted from the store descriptions of the apps for the following variables: commercial information (ie, year of release/update, cost, developer name, audience, downloads), organizational affiliation, content source, main purpose, user interface, media type, and popularity (ie, rating, number of raters, number of comments). The 2 reviewers (MJL and NS) collectively and iteratively developed a preliminary coding scheme by analyzing the content of 20.5% (108/528) of randomly selected "potentially relevant" apps. The coding for the main purpose variable used the Luxton et al [17] classification of mental health app (ie, self-assessment, symptom monitoring, psychoeducation, psychological therapy, psychotherapeutic skills training) as the foundation for development. An IRR test of 20.4% (22/108) of this pilot sample was conducted to evaluate understanding and application of the codes. The results were all significant (P<.001), yielding "almost perfect" agreement for exclusion (kappa=1.00), affiliation (kappa=.91), content source (kappa=1.00), and user interface (kappa=.91). There was "substantial agreement" for main purpose (kappa=.77) and "moderate agreement" for media type (kappa=.49) [31]. The discrepancies in coding for the multimedia variable were discussed, and problem areas were identified and resolved. The final coding scheme is outlined in Table 1.

The remaining sample was divided for data extraction based on odd and even numbering to ensure that the reviewers had equal proportions of apps from each marketplace. After independent review, 20% (combined 41 apps) of each reviewer's sample was randomly selected, exchanged, and coded to assess IRR. The results were all significant (P<.001) with "almost perfect agreement" for affiliation (kappa=.89) and main purpose (kappa=.83), and "substantial agreement" for user interface (kappa=.74). There was also "substantial agreement" for media type (kappa=.68); however, the low kappa (kappa<.70) required the reviewers to examine and understand the discrepancies in coding and correct the coding within each of their respective samples. This process was also applied to content source (kappa=.53). Flagged apps were collectively reviewed for inclusion and then coded. Because the exclusion criteria became more nuanced during this process, apps that were labeled not relevant were also collectively reviewed and coded if they were considered relevant.

Table 1. Final codebook for content analysis.

Variable	Code	Description
Organizational affiliation	UNI	UNIVERSITY: Produced in affiliation with a university or other academic institution
	MEDC	MEDICAL CENTER: Produced in affiliation with a medical institution
	GOVT	GOVERNMENT: Produced in affiliation with a government institution
	INST	INSTITUTION: An explicit association (ie, foundation, center, NGO, church)
	OTHER	OTHER: There is a clear but unclassifiable affiliation (eg, LLC, LLP, Inc.), not .com
	INSUFF	INSUFFICIENT: The affiliation cannot be confirmed by available info
Content source	EXP	EXPERT: Developed by/with an accredited medical professional (eg, Dr., LCSW)
	EXT	EXTERNAL SOURCE: From specific external source (eg, BDI, DSM, Bible) but not "based on" or inspired by a theory/practice (eg, cognitive behavioral therapy)
	LAY	LAYPERSON: Source identified but no credential mentioned. Non-medical expertise clearly indicated by detailed bio or qualifier (eg, years of experience)
	PLE	PERSON LIVED EXPERIENCE: Indication that app is developed by people with lived experience
	INSUFF	INSUFFICIENT: No direct information provided about origin of intervention
Audience	ADULT	ADULT: Adult or high maturity, age 18+
	YADULT	YOUNG ADULT: Medium maturity, age 12+
	YOUTH	YOUTH: Low maturity, age 9+
	ALL	ALL: "Everyone," age 4+, "general," no rating
Main purpose	PE	PSYCHOEDUCATION: Educational material that includes books or guides, news or journal articles, commentaries/opinions, tips, and lessons
	MA	MEDICAL ASSESSMENT: Allows users to screen, diagnose, assess risk, determine treatment
	SM	SYMPTOM MANAGEMENT: Allows users to track symptoms – only for mood diaries
	SR	SUPPORTIVE RESOURCES: Provides referrals for help or connects users with support. May include the use of forums
	TT	THERAPEUTIC TREATMENT: Provides therapy and includes functions that support relaxation (eg, hypnosis, binaural beats); meditation, spiritual faith-based solutions; holistic therapy (eg, diet, exercise, nutrition, lifestyle, cannabis); and positive affirmation
	MULTI	MULTIPLE PURPOSES: Use only if indistinguishable overlap of categories
User interface	INFO	INFORMATION ONLY: Static user interface that provides minimal interaction (eg, e-book). The only interactions available are for settings or navigation
	TOOL	TOOL: Dynamic user interface that provides an interactive component to app (ie, games, social media consultation) or allows users to input data
Media type	AUD	AUDIO: Audio only (with supporting background images/text)
	TXT	TEXT ONLY: Text only (with supporting background images) – eg, e-book
	PIC	PICTORIAL: Pictures only (eg, wallpaper)
	VID	VIDEO: Video only
	VIS	VISUAL: Animations or graphics or charts (ie, no audio or video)
	MULTI	MULTIMEDIA: Used more than one of the categories above
	INSUFF	INSUFFICIENT: Not enough information to determine types of media used

Data Analysis

Cohen's kappa and descriptive statistics were computed using SPSS version 20. Chi-square tests of independence examined the relationship between the variables data source, user interface and multimedia, and the main purpose of the app. Statistical significance was set at $P<.05$. The option to collapse the values within a variable to fulfill the expected cell frequency assumptions of chi-square tests was explored if the research team viewed it as a logical transformation.

Results

General Characteristics

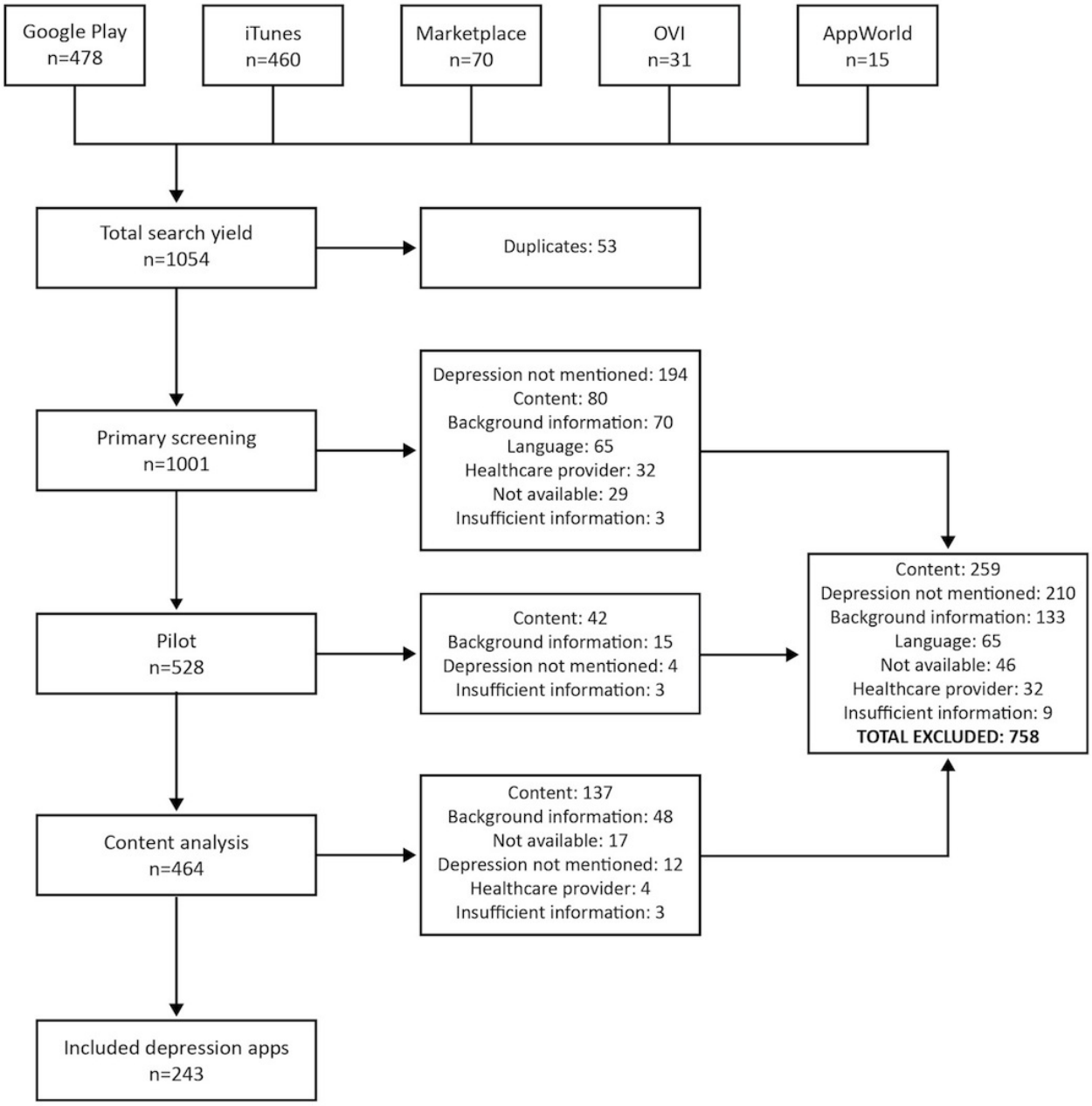
The initial search yielded 1054 apps, of which 53 were excluded as duplicates (31 were available in two stores, eight in three

stores, two in four stores, and one in all stores). Of the remaining apps, 243 met the inclusion criteria. Figure 1 shows the exclusion of apps at the various stages of the study. See Multimedia Appendix 1 for a list of the included apps.

Windows (4.5%, 11/243), Nokia (2.5%, 6/243), and BlackBerry (2.5%, 6/243) accounted for less than 10% of the included sample, as the majority of apps were from the Google (53.5%, 130/243) and Apple (37.0%, 90/243) marketplaces. The apps spanned 32 different store categories, with 79.9% (194/243) of the apps found under four categories: health and fitness (41.2%, 100/243), medical (17.3%, 42/243), lifestyle (14.4%, 35/243), and books (7.0%, 17/243). Six (2.5%, 6/243) apps had no categorization. The average price for paid apps (152/243; 62.6%) was CAN $3.15 and ranged from $0.99 to $15.99. The majority of paid apps (73.7%, 112/152) were sold for less than $4.99, with the mode price of $0.99 (18.9%, 46/243).

Only the release date was provided by the iTunes store, whereas Google Play, BlackBerry, and Windows provided dates of the last app update. Nokia did not provide this information. The earliest date reported by the app stores was 2009 (3.7%, 9/243). Two-thirds (66.0%, 156/237) of the apps were released or updated in 2012 (36.2%, 88/243) and the first quarter of 2013 (28.0%; 68/243). Google Play was the only market that reported the number of installs (ie, downloaded and installed on an Android mobile device) and was reported in ranges; 40 apps (30.8%, 40/130) were installed less than 50 times. The most frequent ranges of installation were 100-500 and 1000-5000, each registering 16.9% (22/130) of the sample. One app (0.4%, 1/243) was installed in the 1 million to 5 million range, and four apps fell into the 100,000 to 500,000 range.

Figure 1. Flow diagram illustrating the exclusion of apps at various stages of the study.



Developers and Affiliations

There were 190 developers in the sample, with 35 accounting for multiple apps. Of this group, 27 developers created two apps, three developed three apps, and four developed four apps. The top developer, MOZ, created nine apps. Only 5.3% (10/190) of the developers were either medical centers (1.0%, 2/190), universities (1.0%, 2/190), and institutions (3.2%, 6/190). A total of 56 developers indicated that they were a commercial developer (eg, LLC, LLP, Inc.), while 124 developers did not provide sufficient information about their affiliation.

Depression Apps Ratings

Of the 113 rated apps (46.5%, 113/243), there was an average of 37.2 raters (95% CI 21.6-52.81) per app. One app had 583 raters. The average rating (out of five stars) was 3.5 stars (95% CI 3.3-3.7). There was an average of 5.9 comments per rated app (95% CI 4.2-7.7), with a range from zero to 56 comments.

Overall Picture of Depression Apps

Over 80% of the apps had the main purpose of providing therapeutic treatment (33.7%, 82/243), psychoeducation (32.1%, 78/243), or medical assessment (16.9%, 21/243). Apps with multiple purposes accounted for 7.4% (18/243) of the sample. Only 38.3% (93/243) of the apps reported the content source in sufficient detail and mainly cited an external (17.7%, 42/243) or expert (14.0%, 30/243) source. The majority (72.4%, 176/243) featured a dynamic user interface. Over half of the apps were text-only (51.9%, 126/243), while 14.4% (35/243) used multiple forms of media. Table 2 summarizes the distribution of apps across the different variables.

The chi-square tests of independence yielded significant results ($P<.001$); however, the expected cell count assumption was violated in all cases. Two variables, affiliation and content source, were collapsed into binary variables. The chi-square analysis for affiliation (ie, sufficiently or insufficiently reported) and main purpose showed that there was no relationship between the two variables ($\chi^2_5=8.8$, $P=.12$). The content source variable (ie, sufficiently or insufficiently reported) showed a significant ($\chi^2_5=50.5$, $P<.01$) association between the main purpose of the app and the reporting of the source. An ad hoc analysis was conducted between media type and user interface, which yielded a significant relationship between the two variables ($\chi^2_4=46.3$, $P<.01$).

Table 2. Distribution of depression apps by variable and main purpose.

Variable and Value	Main purpose, n (%)[a]						
	TT	PE	MA	SM	SR	MP	Total
Overall[b]	82 (33.7)	78 (32.1)	41 (16.9)	20 (8.2)	4 (1.6)	18 (7.4)	243
Affiliation [c]							
Reported [b] **85 (35.0)**							
Institution	1 (1.2)	2 (2.6)		1 (5.0)	3 (75.0)		7 (2.9)
Academic			1 (2.4)		1 (25.0)		2 (0.8)
Medical center	1 (1.2)		1 (2.4)				2 (0.8)
Other	27 (32.9)	21 (26.9)	14 (34.1)	6 (30.0)		6 (33.3)	74 (30.5)
Insufficient information	53 (64.6)	55 (70.5)	25 (61.0)	13 (65.0)		12 (66.6)	158 (65.0)
Content source [c]							
Reported 93 (38.3)							
External	8 (9.8)	6 (7.7)	21 (26.9)	1 (5.0)	1 (25.0)	5 (27.8)	42 (17.3)
Expert	3 (3.7)	10 (12.8)	11 (26.8)			6 (33.3)	30 (12.3)
Patient lived experience		7 (9.0)	1 (2.4)	2 (10.0)		1 (5.6)	11 (4.5)
Layperson	9 (11.0)	1 (1.3)					10 (4.1)
Insufficient information	62 (75.6)	54 (69.2)	8 (19.5)	17 (85.0)	3 (75.0)	6 (33.3)	150 (61.7)
User interface							
Tool (dynamic)	75 (91.5)	18 (23.1)	41 (100.0)	20 (100.0)	4 (100.0)	18 (100.0)	176 (72.4)
Information only (static)	7 (8.5)	60 (76.9)					67 (27.6)
Media type [d]							
Text only	17 (20.7)	61 (78.2)	35 (85.4)	4 (20.0)	2 (50.0)	7 38.9)	126 (51.9)
Audio only	36 (43.9)	3 (3.8)					39 (16.0)
Multimedia	16 (19.5)	9 (11.5)	1 (2.4)	3 (15.0)	2 (50.0)	4 (22.2)	35 (14.4)
Visual	8 (9.8)	4 (5.1)	4 (9.8)	11 (55.0)		7 (38.9)	34 (14.0)
Pictorial	5 (6.1)			1 (5.0)			6 (2.5)
Insufficient information		1 (1.3)	1 (2.4)	1 (5.0)			3 (1.2)

[a]Calculated as percentage within main purpose category; TT=therapeutic treatment, PE=psychoeducation, MA=medical assessment, SM=symptom management, SR=supportive resources, MP=multiple purposes.

[b]Total was calculated as percentage within the whole sample (N=243).

[c]The denoted variables were collapsed into binary categories for chi-square analysis.

[d]None of the apps were video based.

Characterization of Apps by Main Purpose

Therapeutic Treatment

Audio (44%, 36/82) was the most frequently used media for therapeutic treatment apps, which accounted for 92% (36/39) of audio apps found in the entire sample. Similarly, therapeutic treatment apps most frequently used multimedia, which represented 46% (16/35) of multimedia apps in the entire sample. Half (41/82) of the therapeutic treatment apps supported audio therapy in the form of hypnosis (n=14), brainwave entrainment (n=23), music therapy (n=3), or nature sounds (n=1). Five of the audio therapy apps included other types of media. One hypnosis app used visual media only. Nine of the 11 relaxation therapy apps reported layperson as the source, which accounts for 90% (9/10) of the layperson-sourced apps in the sample. Other types of therapy included spiritual/faith-based (n=10), entertainment (n=10), positive affirmation (n=7), behavior training (n=7), and light/visual (n=3). Two apps provided exercise-based therapy consisting of breathing techniques and yoga. One app focused on diet and one provided activity suggestions. There were ten apps that provided cognitive behavioral therapy and were classified under the multipurpose category.

Psychoeducation

The psychoeducation category of apps predominantly used a static (ie, read-only) interface (n=60) and represented 90.0% (60/67) of the static interface apps in the sample. The most frequently used media was the text-only category (n=61) and represented roughly half of all text-only apps (48.4%; 61/126) in the entire sample. Fifty psychoeducation apps were general e-books about depression, of which two were fiction and seven were reference manuals (ie, medication library), 12 apps provided tips or advice on how to overcome depression, and 11 apps provided education through learning modules or lessons. Five apps provided a collection of resources such as news and journal articles. The psychoeducation category had the greatest number of apps based on patient lived experience (n=7). Five of these were general e-books, one provided tips, and one provided lessons.

Medical Assessment

Of the medical assessment apps, 33 (81%; 33/41) reported the content source, which is the highest proportion and number of sourced apps within a main purpose category. External sources were reported 21 times and used 11 different questionnaires. The most frequently used questionnaire was the Patient Health Questionnaire (PHQ-9) [32], used in eight apps. The Beck Depression Inventory 2 [33], Geriatric Depression Scale [34], and M3 Questionnaire [35] were all used twice. The Automatic Thoughts Questionnaire [36], Center for Epidemiology Studies Depression Scale [37], Edinburgh Postnatal Depression Scale (EPDS) [38], Goldberg Depression Questionnaire [39], Quick Inventory of Depressive Symptomology Questionnaire [40], and Zung Self-Rating Depression Scale (SDS) [41] were each used once. The Psychological Tests App contained multiple depression questionnaires. The 11 expert-sourced apps did not provide a specific questionnaire but mentioned in the description that a medical professional (ie, physician or psychologist) developed the app or that the questionnaire was used in practice. One app contained a questionnaire based on patient lived experience. With the exception of five apps, all the apps were text-only.

Symptom Management

Only 15% (3/20) of symptom management apps reported the content source, the lowest proportion of all the main purpose categories. Over half of the symptom management apps used visual media (55%; 11/20). Nine apps allowed users to track their moods and eight tracked lifestyle factors (eg, mood, sleep, diet, medication, exercise). Two apps allowed users to keep a journal, and one app used a checklist system.

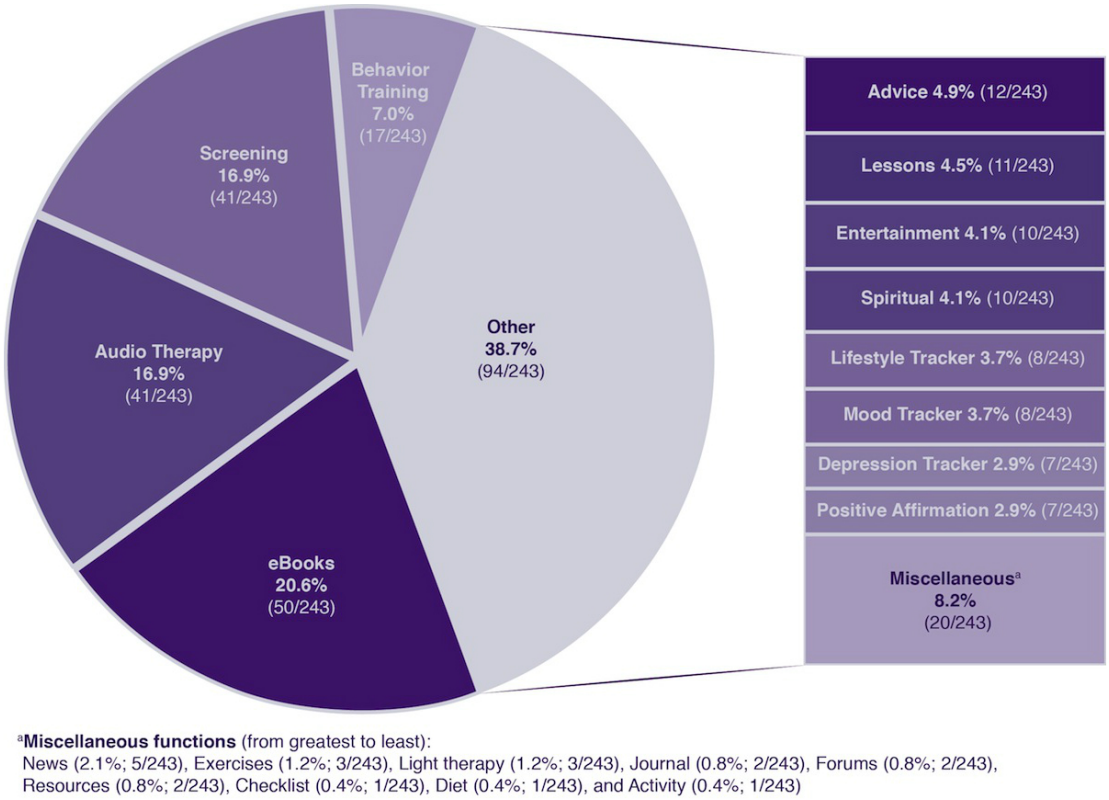
Supportive Resources

Half of the apps (50%; 2/4) were text-only, while the other half were multimedia. One app reported the content source and cited an external source. Two apps provided resources (online and offline) and references for help. The other two apps connected users to a community via online forums.

Multipurpose

Two-thirds (67%; 12/18) of the multipurpose apps reported the source, with almost all citing an expert (n=6) or external (n=5) source. All the apps used text (n=7) or visual (n=7) as the primary media. Four apps were multimedia, and 17 apps (94%; 17/18) used a combination of medical assessment and symptom management. Ten of these apps specifically focused on cognitive behavioral therapy (CBT), while seven used a questionnaire and allowed users to track depression over time. The questionnaires consisted of PHQ-9 (n=2) [32], EDPS (n=1) [38], and SDS (n=1) [41]. One app used a proprietary questionnaire (Treatment Depression Inventory). Two apps did not specify the questionnaire. One app provided therapeutic treatment through meditation exercises and also provided psychoeducation about the exercises and CBT. Figure 2 presents a summary and distribution of the different app functions.

Figure 2. Distribution of depression apps by function.



Discussion

Principal Findings

This review found that depression apps provided support on five different dimensions: therapeutic treatment, psychoeducation, medical assessment, and supportive resources. Through the iterative development of this typology and understanding of the available commercial information, the results provided some insights into the user experience of those seeking depression support through apps. Similar to a recent study by Martinez-Perez et al [24], this study found that depression app seekers need to filter through 400+ apps in either the Google Play or iTunes marketplace. In context of the one million app milestone announcements by both Google and Apple in 2013 [42,43], this number may suggest that the app marketplace has entered a phase of "overload" or "diseconomies of scale", where the large quantity of apps available makes it difficult for users to find the right one [44,45]. The apps excluded from this study indicate that metadata may play a role in this phenomenon. Vendors may leverage the use of metadata or the keyword "depression" to increase exposure of their non-depression apps in the depression app search results. For example, one-fifth of the search yield made no mention of depression anywhere in the app title or store description. One-quarter of the search yield was excluded because the word depression was mentioned only in a "laundry list" of keywords in the app's description, not in the title. Many of these apps were white-labeled (ie, essentially identical but marketed for different purposes or under different developer names) and were evident by the identical store descriptions (see Figure 3). White labeling was primarily observed for e-book and audio therapy apps. Last, although some apps made reference to depression, their main purpose was to address a different condition (eg, weight loss or acne apps may describe how being obese or having acne may lead to depression).

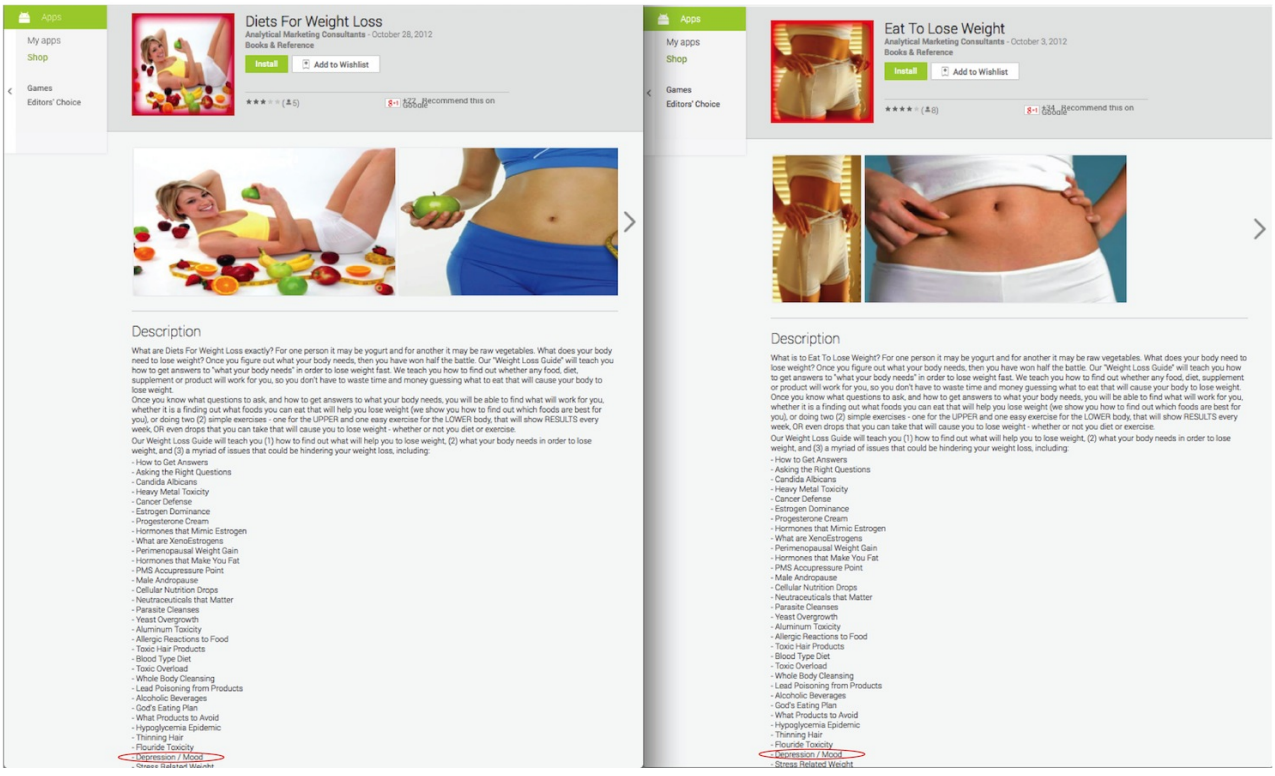
Of the apps included in the study, there were three times more text-only apps than any other media category; furthermore, almost all the text-only apps with static interfaces were found in the psychoeducation app category. The reviewers found that these apps, based on screenshots and descriptions, were rudimentary in function and minimal in design. The proliferation of these apps may be a result of the low barrier to entry into the marketplace in the form of prerequisite resources and skills, thereby allowing those with minimal programming skills and resources to develop and publish their own apps [46]. This finding could explain why only one-third of the 190 unique developers adequately described or indicated their affiliation and the proportionately low number of apps from formal institutions. Furthermore, only a third of the app store descriptions reported content sources. Many other app reviews [18-23,30,47-51] have also found that the app development process often failed to involve health care professionals or academics and to include content aligned with clinical guidelines or behavior change theories or techniques. The majority of these apps were categorized under the main purposes of psychoeducation and therapeutic treatment.

The lack of apps that incorporate authoritative sources remains problematic. It has been estimated that one in five of paid apps claim to treat or cure medical ailments [28]. Similar to the potential shortcomings of information found on the Internet, the information or therapies provided by apps may be incomplete or based on insufficient scientific evidence. This presents a

potential health hazard for consumers who interpret this information incorrectly or try inappropriate treatments [52]. For example, reading about a disease may increase health anxiety, reinforce hypochondriasis, cause unnecessary concerns, or lead people to purchase harmful drugs or engage in risky health behaviors [53]. These harms, however, are often a cautionary claim, as most research on the utility of online health information has focused on the quality of information rather than its effects [54,55]. Only a few studies actually reported instances of harm [56]. This gap between evidence-based recommendations and app functionality continues to be a common theme across different health conditions [20,21,47,51,57-59]. Public attention has turned to these "snake oil" apps, prompted by a US Federal Trade Commission settlement involving two app developers who falsely cited a study from the *British Medical Journal of Dermatology* in their claims that the colored display screens featured in their apps could cure acne [60]. The proceedings were founded on the premise of false advertising rather than public safety [61]. This case has led to a call for the US Food and Drug Administration (FDA) to regulate mobile medical apps; however, there is debate about the appropriateness of this measure [62]. In September 2013, the FDA issued guidance for developers of apps that perform as medical devices, defined as apps that diagnose or treat disease whereby malfunctions can carry significant risks of harm [63].

Based on the app store categories used in this study, 42 apps were defined as medical; however, this category included apps that are considered innocuous, such as those that help patients organize their health information or look up information about treatments [64]. Perhaps these apps would be better suited for other categories, such as health and fitness, lifestyle, and books, where more than half of the included apps were found. Apps found in these non-medical categories are considered low risk as long as they do not provide specific treatments or treatment suggestions. They may provide benefits to the patient, such as those associated with using a mood tracker to maintain a symptom diary [65]. To help users navigate the app marketplace, Happtique (a subsidiary company of the Greater New York Hospital Association) developed standards for an app certification program in early 2013. Unfortunately, these efforts were brought to a halt when an audit found that 2 of the 19 Happtique-certified apps had privacy issues [66]. There are other initiatives to help curate apps, such as the iMedicalApps website; however, it is a tremendous task to benchmark. Policing the quality of apps is a near-impossible endeavor that is reminiscent of the early days of appraising online health information [67]. Deshpande and Jadad have found that past initiatives to assess the quality of online health information or tools had limited success and recommend that efforts be hedged towards an open, distributed, and collaborative approach similar to Wikipedia [68].

Figure 3. An example of white labeling where the apps have the same description but are labeled as different apps. The word depression (circled in red) is only one in a list of unrelated terms and is an example of how such lists allow non-depression apps to enter the search.



Evaluation

The most common function of depression apps provides users with information about depression through an e-book modality. Despite the potential to translate books or bibliotherapeutic guides, only 13 of the 50 e-books cited a content source. The majority of these books were self-help guides, often with titles that claimed they would help users overcome depression. Examples include "Beat Depression", "Defeat Depression", and

"Stomping Out Depression". While these non-sourced books do pose the potential to distribute erroneous or biased information to people seeking help, the Google dataset shows that two-thirds of these apps are installed less than 100 times and indicates that users do exercise some discretion before purchasing or installing apps. Nettleton et al [69] suggested that users are able to make reasonable assessments of health information in the context of other health information seeking practices to complement their formal care. This behavior extends to mobile phone apps: one qualitative study found that the reputation and legitimacy of sources factor into the use of an app [70]. For example, an e-book app that cited the US National Institutes of Health was downloaded within the 10,000 installs range. While promising, this finding could be confounded by the application's free status. The "Anxiety and Depression" and "Audio Book Anxiety and Depression" e-book apps, which were in the install ranges of 10,000 and 100,000, were also free. One study suggested that consumers exercise more caution when having to purchase apps than when downloading them for free due to the burden of price [71]. The same study also showed that ranking, customer ratings, and content size affect downloading when the app is free. Consumers depend more on their own information and experiences rather than on rankings or ratings when the app requires payment. They closely consider low ratings, including complaints, not mean score when they have to pay [71]. The relationship between price, affiliation, source, downloads, and satisfaction via ratings and comments could be a potential area to explore in future studies.

Medical assessment was the only app category with a high rate of reporting content source. All of these apps were screening tools that allowed users to self-diagnose for depression. There is an absence of published data investigating the impact of patient self-diagnosis using apps or the Internet; however, some studies have identified false positive assessments as a potential source of harm [53,72-74]. Despite this shortcoming, medical assessment apps could help to address some systemic barriers to diagnosing depression in primary care [75]. Depression is often under-detected in the health care system, and the practice of routine screening is a contentious and unresolved issue [76]. Medical assessment apps may help to bridge this gap by assisting individuals in identifying mental health issues, thereby providing the impetus to approach and engage their health care providers. Clarke and Yarborough described this effect as a lowering of threshold of entry-level mental health services so that it extends the reach of care to people who do not seek traditional treatment for depression [5].

Audio therapy apps may have a similar potential to that of medical assessment apps [77,78]. This study found that half of therapeutic treatment used audio therapy and is consistent with a recent report that found that 43% of therapeutic apps used audio for treatment [28]. The effectiveness of audio therapy, regardless of mode of delivery, is not fully understood and is often under scrutiny [47,79-81]. There are many gaps in knowledge regarding the psychological effects of brainwave entrainment and hypnosis on depression [82,83]. Systematic reviews [81] and meta-analysis [84] of existing research have found mixed results on the effectiveness of these types of interventions. A similar review of a hypnosis app found on iTunes reported that none of the 407 identified apps were tested for efficacy or were based on evidence [47]; however, the study did not discuss potential harms associated with using non-evidence-based, non-evaluated apps. The authors do caution against "self-described professional titles", as certification could easily be purchased online. They also warn that certification does not mean that the individual was adequately trained.

The fourth most prevalent function of depression apps was offering behavior training or therapy, with most apps focusing on CBT. Internet-based CBT (ICBT) has shown to be an effective treatment for depression [85], with the magnitude of effects depending on level of support and content of the intervention [86]. ICBT is considered to be well suited for delivery through an app because it would offer users the convenience of recording and tracking their moods and context in real time, as well as accessing psychoeducational materials [87]. Two-thirds of the CBT apps identified in this study had multiple purposes, which often included tracking, screening, and providing psychoeducation. In practice, one study demonstrated the feasibility of app-based CBT in treating depression, with clinical improvement in the patients [26]. This app was captured in the sample and provided a very brief description mentioning the CBT program and its affiliation with a hospital; however, the raters felt it did not provide sufficient information about the intervention source. This shortcoming underscores the importance for app developers to follow a standardized reporting system to advertise the credibility of apps and to prevent empirically tested apps from going unnoticed. Similarly, it might be necessary to develop a framework that could protect both app developers and users from harm, particularly from liability associated with cases of preventable suicide.

Limitations

While the development of regulations and certification standards for assessing the quality of apps is underway, this study used the information available in the app store description (ie, developer affiliation and content source) to understand how depression apps are advertised to health consumers seeking depression apps. The information provided about affiliation and content source was accepted prima facie based on the developed inclusion criteria. The high percentage of insufficient reporting of affiliation may be an overestimation, since the developer websites were not examined to corroborate their status. Similarly, the reported content sources were not further examined. It is acknowledged that the apps themselves may contain more information and that not downloading and testing the apps is a limitation of this study. The lack of physical testing mirrors the actual user experience when making the decision to download apps [48], where the information provided in the description may serve as an initial proxy measure for quality before downloading and trialing an app. It also underscores the need for a standardized app store description reporting system for vendors to refer or adhere to. With over 190 unique developers identified in our eligible sample and many more in the initial sample, consumers may not have the time to view all the developer websites to verify their affiliations. Requiring vendors to outline their affiliations, evidence base, or content

source could provide potential users with enough contexts to assess the credibility of the app.

A second limitation lies in the possibility that many of the apps excluded from this study because they were not depression specific could potentially be useful for people with depression. ICBT apps are prime examples of potentially useful non-depression-specific apps. ICBT is regarded as a well-established treatment for depression, panic disorder, and social phobia, but it is also an option for 25 other clinical disorders. While ICBT apps could be the prototypical depression app [26,88], non-depression ICBT apps were excluded to maintain consistency in assessing the relevance of other apps that provided an intervention (eg, binaural beats [81], yoga [89], spirituality [90]) where a case could be made for their inclusion. To prevent confirmation biases from entering the sample, it was decided that the app was required to be specific to depression to be eligible.

This study represents a snapshot of depression apps found in Canadian app stores in March of 2013. This may be a limitation in three ways. First, the landscape of the depression market will have changed at the time of submission of this publication. Second, the findings from this study may not be representative of all the depression apps available on the global market because certain apps may be localized or licensed only to specific countries. The study by Martinez-Perez et al in Spain found over 1537 depression apps available on the five major platforms. In comparison, the current review yielded 1001 unique apps, with a large part of the discrepancy attributed to Google Play app count. Moreover, a sample of Android apps may be missing because this study was conducted just prior to the Amazon announcement [91] of expanding access to its Android app store outside of the United States to Canada and 200 other countries. A quick search of the Android app store using the search term “depression” yielded 123 apps. Because development standards vary from different app stores, future content analysis studies should consider including the Amazon marketplace to understand its contributions to the app marketplace. Last, frameworks such the Self-Certification Model for Mobile Medical Apps by Health on the Net Foundation (HON) [92] and App Synopsis [93] became available shortly after the data extraction phase concluded (mid-2013). These models provide some important parameters that were not covered in this study (eg, data requisition and management, advertising policy, justification of claims). However, this study demonstrates that most apps would fare poorly against the aforementioned standards and delineates the need for such reporting approaches to be disseminated to mHealth developers to bring the information presented to health consumers to an acceptable level.

Conclusions

This study found that finding an appropriate depression app may be challenging due to the large quantity available. The search results yielded non–depression-specific apps to depression apps at a ratio of 3:1. Over one-quarter of the apps excluded from the study failed to even mention depression in their description or title and exemplify the role of metadata in populating the search results. The lack of reporting of organizational affiliation and content source brings the credibility into question. Whether the content is evidence-based is a whole other issue. This lack of information was most common among symptom management apps, followed by therapeutic treatment and psychoeducation apps. Only medical assessment apps, many of which were based on well-established depression questionnaires, adequately described their sources. As the app phenomenon and health consumerism continue to grow, the user’s ability to find a reliable and credible app may become increasingly difficult. While efforts are underway to populate the marketplace with certifications and professional vetting, this study delineates the need for standards in reporting and for a framework to enable people with depression or other conditions to use proxy measures to assess the legitimacy of apps.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

List of included apps (N=243).

[PDF File (Adobe PDF File), 338KB - mhealth_v3i1e16_app1.pdf]

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Abbreviations

CBT: cognitive behavioral therapy
EPDS: Edinburgh Postnatal Depression Scale
ICBT: Internet-based cognitive behavioral therapy
ICT: information and communication technologies
IRR: interrater reliability
PHQ-9: Patient Health Questionnaire
SDS: Zung Self-Rating Depression Scale

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Original Paper

mHealthApps: A Repository and Database of Mobile Health Apps

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Abstract

Background: The market of mobile health (mHealth) apps has rapidly evolved in the past decade. With more than 100,000 mHealth apps currently available, there is no centralized resource that collects information on these health-related apps for researchers in this field to effectively evaluate the strength and weakness of these apps.

Objective: The objective of this study was to create a centralized mHealth app repository. We expect the analysis of information in this repository to provide insights for future mHealth research developments.

Methods: We focused on apps from the two most established app stores, the Apple App Store and the Google Play Store. We extracted detailed information of each health-related app from these two app stores via our python crawling program, and then stored the information in both a user-friendly array format and a standard JavaScript Object Notation (JSON) format.

Results: We have developed a centralized resource that provides detailed information of more than 60,000 health-related apps from the Apple App Store and the Google Play Store. Using this information resource, we analyzed thousands of apps systematically and provide an overview of the trends for mHealth apps.

Conclusions: This unique database allows the meta-analysis of health-related apps and provides guidance for research designs of future apps in the mHealth field.

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KEYWORDS

mobile healtlh; app repository; app database

Introduction

With the constant expansion of mobile health (mHealth) in the past few years, the market of mobile apps related to health is rapidly evolving, making countless new mobile technologies potentially available to the health care system. According to a new report (May 2014) generated by the Research2Guidance firm [1], there are more than 100,000 apps falling into the health, fitness, or medical categories, which doubles the market size of that in two and a half years ago. Recently, there have been a number of studies in the field, including the development of a mHealth behavior change system [2], the creation of a food database [3], and a collaborative effort aiming to integrate apps platform, research data repository, and patient summarization [4]. However, there is still a lack of systematic research on the impact of the mHealth apps on health outcomes.

Currently, most research in this field often investigates the apps individually, either by searching the apps from app stores, or by manually installing each individual app on smartphones or tablets one by one [5-8] to get the detailed information of each app. For example, Chomutare et al manually installed 488 diabetes related apps to review their features [5]. Sama et al manually installed around 400 apps to evaluate existing mHealth app tools [6]. Due to the difference in health conditions and app specialization, Tomlinson et al suggested an open mHealth architecture-based platform to facilitate scalable and sustainable health information systems [7]. While the app stores provide a wealth of information including the prices and customer reviews

for apps [9], there is not a centralized resource that collects information of all health-related apps for researchers to systematically evaluate the apps regarding their effectiveness and health outcome. In this study, we aim to obtain a comprehensive view on the mHealth apps by creating an app repository. We expect the analysis of apps in this repository can provide insights for future mHealth research developments.

Methods

Repository Based on the Apple App Store

Since the Apple App Store (AppStore) is the major representative in the market, we first created an app repository based on all the health related apps from the AppStore. The list of apps was crawled from the Apple iTunes Web pages [10], including the pages for the Health & Fitness [11] and the Medical [12] subcategories. Then using our own crawling program, we extracted detailed information of each app via the iTunes Search app program interface (API) [13]. We noticed the results from our data extraction step are in the JavaScript Object Notation (JSON) [14] format. For the convenience of researchers, we transferred the files from JSON format to tab-delimited text files encoded with "utf8mb4" (flat files with array format), so that researchers can directly import these files to Excel or another program for ease of analysis. In the text files, each row corresponds to an app with 39 features, including the app unique identity (ID), app name, description, user rating count, average user rating, etc. Table 1 lists all the 39 features along with their annotations.

Repository Based on the Google Play Store

Since the Google Play Store (GooglePlay) is now the biggest app store in the market, we also created an app repository based on the information of all popular health-related apps from the GooglePlay. The list of apps was crawled from the GooglePlay Web pages [15], including the pages for the HEALTH_AND_FITNESS [16] and MEDCIAL [17]. We then extracted the detailed information of each popular app using the python HyperText Markup Language parsing tool via the Google Play Search API. For researchers' convenience, we provided both the JSON format and tab-delimited text files as well. In the text files, each row corresponds to an app with 27 features (Table 2), including the app unique ID, app name, description, user rating count, average user rating, etc. Files in both formats (JSON and tab-delimited) can be obtained from the repository website [18].

Table 1. The list of 39 features for each app in the AppStore.

Feature	Annotation
trackId	Unique app ID
artistId	Developer ID
artistName	Name of the developer
artistViewUrl	The URL for the developer
artworkUrl100	The URL for the artwork in 100*100 pixels
artworkUrl512	The URL for the artwork in 512*512 pixels
artworkUrl60	The URL for the artwork in 60*60 pixels
averageUserRating	Average of user ratings
averageUserRatingForCurrentVersion	Average of user ratings for current version
bundleId	Bundle ID
contentAdvisoryRating	Content ratings by content advisor
currency	Currency
description	Description of the app
features	Features
fileSizeBytes	File size in bytes
formattedPrice	Price in currency format
genreIds	Categories IDs
genres	Categories
ipadScreenshotUrls	The URLs for the iPad screenshot
isGameCenterEnabled	Whether it is game center enabled
kind	The kind of content
languageCodesISO2A	Language codes ISO2A
price	Price
primaryGenreId	Primary category ID
primaryGenreName	Primary category name
releaseDate	Release date
releaseNotes	Release notes
screenshotUrls	The URLs for screenshot
sellerName	Seller name
sellerUrl	The URL for the seller
supportedDevices	Supported devices
trackCensoredName	Name (censored)
trackContentRating	Content rating
trackName	App name
trackViewUrl	The URL for the app
userRatingCount	The number of user ratings
userRatingCountForCurrentVersion	The number of user ratings for current version
version	Version number
wrapperType	The name of object

Table 2. The list of 27 features for each app in the GooglePlay.

Features	Annotation
trackId	Unique app ID
artworkUrl	The URL for the artwork
averageUserRating	Average of user ratings
badge	Developer badge
category	Category
contentRating	Content rating
description	Description of the app
developerEmail	Developer email address
developerId	Developer ID
developerName	Name of the developer
developerPrivacy	The link to the developer privacy notation
developerWebsite	Developer website
fileSize	File size
formattedPrice	Price in currency format
inAppPurchase	Whether it is in app purchase or not
installs	Number of installations
price	Price
releaseNotes	Release notes
requiresAndroid	Android OS requirement
screenshotUrls	The URLs for screenshot
screenshotVideoUrls	The URLs for video screenshot
trackName	App name
trackViewUrl	The URL for the app
updated	Update date
userRatingCount	The number of user ratings
userRatingCountDistribution	The numbers of ratings with 5, 4, 3, 2, or 1 stars
version	Version number

Results

Apps From Apple App Store

In the US market, there are 74,211 apps listed in the Apple iTunes Health & Fitness and Medical subcategories as of December 4, 2014. By removing duplicated entries, we obtained 62,621 totally unique apps in these two subcategories. We note the category of each app is defined by the app's owner (developer or seller) and approved by Apple's customer service, so the app categorization was done in the server side (API) and was used directly as our app selection criteria. The primary categories of some apps are neither Health & Fitness nor Medical, but others, such as Lifestyle, Education, Sports, Food & Drink, or Games. To reduce the ambiguity, we only included the 47,883 apps with either Health & Fitness or Medical as their primary category in our app repository. In addition to the US market, this repository contains the information of mHealth apps from the AppStore distributed in four other countries with the most established Internet markets [19]: (1) China (CN), (2) Japan (JP), (3) Brazil (BR), and (4) Russia (RU). There are 27,157 and 21,607 unique apps in the categories of Health & Fitness and Medical from the top five countries of the AppStore, respectively, leading to 48,764 totally unique health-related apps from the top five countries. In both categories, there are slightly more apps available in the United States than in any of the other four countries (Table 3). Overall, more than 98.19% (47,883/48,764) of these unique apps are available in the United States.

Table 3. The number of apps in different stores and regions.

Store_region_category	Apps[a]	Free apps	% of free apps	Sum of user ratings[b]	Sum of user ratings (free)[c]	% of user ratings (free apps)
AppStore_BR_Health&Fitness	25,931	16,761	65	79,738	60,924	76
AppStore_BR_Medical	20,047	13,313	66	24,169	18,074	75
AppStore_CN_Health&Fitness	25,845	16,732	65	164,314	137,011	83
AppStore_CN_Medical	19,857	13,173	66	14,765	12,128	82
AppStore_JP_Health&Fitness	25,962	16,809	65	204,012	141,292	69
AppStore_JP_Medical	19,961	13,250	66	21,008	16,426	78
AppStore_RU_Health&Fitness	25,926	16,774	65	139,488	96,348	69
AppStore_RU_Medical	19,912	13,198	66	19,736	15,679	79
AppStore_US_Health&Fitness	26,762	17,521	65	3,596,338	2,877,808	80
AppStore_US_Medical	21,121	14,357	68	866,582	671,408	77
AppStore_Top5Regions_Health&Fitness	27,157	17,813	66	4,183,890	3,313,383	79
AppStore_Top5Regions_Medical	21,607	14,729	68	946,260	733,715	78
GooglePlay_US_Health&Fitness	6894	5155	75	10,921,244	10,446,157	96
GooglePlay_US_Medical	5378	3180	59	900,476	852,068	95

[a] Apps, the total number of apps in each specified combination of store, region, and category.

[b] Sum of user ratings, the total number of ratings received from app users.

[c] Sum of user ratings, free, the total number of ratings received for free apps.

Apps From Google Play Store

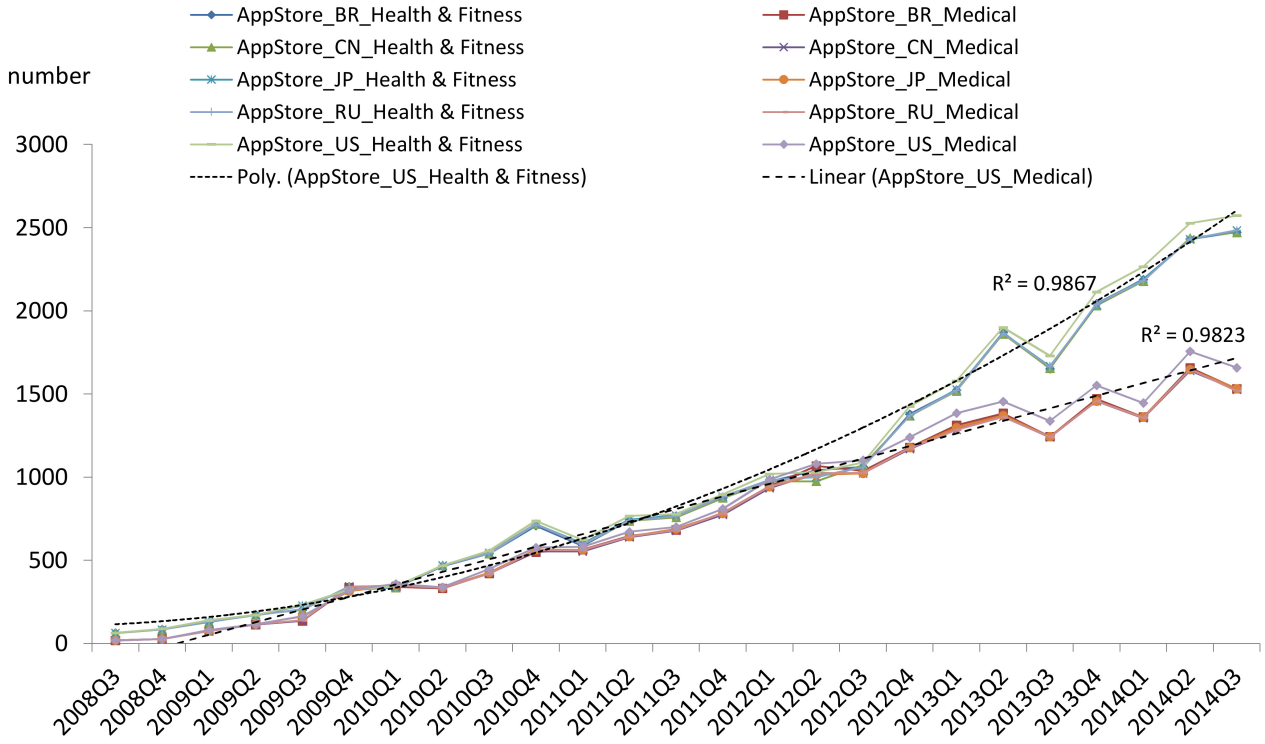
The repository also contains information of the most popular apps from the GooglePlay in the United States. For the GooglePlay, the Web pages only list the most popular or the newest released apps in each category based on their release dates and daily user usage. Since the GooglePlay Web pages are updated daily, to get a comprehensive list of all the apps, we collected the app IDs available on the GooglePlay with our crawling program every day from July 24 to December 6, 2014, and combined the results to get a list of 14,817 unique app IDs. We then excluded the inactive apps that are no longer available on the GooglePlay. In addition, as we did for the AppStore, we also excluded the apps with their primary category other than HEALTH_AND_FITNESS or MEDICAL. Finally, we obtained a list of 12,272 totally unique apps, including 6894 and 5378 apps in the subcategories of HEALTH_AND_FITNESS and MEDICAL, respectively. Table 3 gives the total number of apps and the total number of user ratings received in each category. Considering the fact that the GooglePlay apps in our repository are among the most popular ones, and GooglePlay represents the biggest app store now, it is not surprising to see that the number of user ratings received for the Health & Fitness apps in GooglePlay is more than two times higher than the sum of user ratings collected from the top five countries for the AppStore apps in the same category.

Price Factors and App Release Trend

According to Table 3, we can deduce that the average number of user ratings received per app in the Health & Fitness category is significantly higher than that in the Medical category, regardless of app stores. Because the number of user ratings reflects the popularity of the app, this comparison result indicates apps in the Health & Fitness category are more popular than those in the Medical category. We further investigated the effect of app prices on their popularity among users. Overall, a majority of mHealth apps are free, especially in the GooglePlay, as high as 74.78% (5155/6894) of apps in the category of Health& Fitness are free apps. Based on Table 3, we can see that the average number of user ratings per free app is always higher than that for a nonfree app. In addition, if we use the average number of user ratings per app as a measure for app popularity, the significantly high percentage of user ratings provided by GooglePlay free app users (95.57%, 11,298,225/11,821,720) suggests the GooglePlay users prefer free apps, compared to the AppStore users.

Based on the release date information of each app included in our repository, we can analyze the trend of mHealth apps available in the AppStore. We plotted the number of apps released in each quarter since the third quarter of 2008 (Figure 1 shows this). From this figure, we can see that the apps in the Health & Fitness category show a quadratic growth (R^2 = 0.9867), while the apps in the Medical category demonstrate a linear growth (R^2 = 0.9823). The patterns in the top five countries are similar for both the Health & Fitness and Medical subcategories. The GooglePlay doesn't contain the released date information of apps; instead, only the updated date information is available. More than 76.57% (9397/12,272) of the apps were updated in the last two quarters. Therefore, the trend for apps in GooglePlay was not analyzed in this study.

Figure 1. The trend of the number of released mHealth apps in the Apple App Store (AppStore). 2008Q3: third quarter of year 2008. BR: Brazil; CN: China; JP: Japan; RU: Russia; US: United States.



Discussion

The mHealth App Repository

The mHealthApps repository allows us to analyze thousands of apps in the market systematically and efficiently, and can be utilized to provide an overview of the trends for mHealth apps. The repository is scheduled to be updated quarterly. Detailed information of all these apps can be freely requested from the repository website [18], but will be restricted for personal and noncommercial use only. A unique feature of our repository is that it provides a new dimension of information of apps, such as the user behavior, which is neglected by many other studies in the field. The user behavior data, including the average user rating, the number of user ratings received per app, and the distribution of user ratings in the five-star rating system are based on millions of mHealth apps users worldwide, and have been tested on the real market. The repository also contains other information, such as the price, the released/updated date, and the app descriptions, which can be used for further business marketing, activity analysis, detail subcategories decomposition, and so on.

Limitations

It is noted that our study has some limitations. First, the category of each app is submitted by the app's owner and approved by the app store. Therefore, the accuracy of app categorization is beyond our control. Additional strategy based on nature language processing would be necessary to ensure all the apps included in our repository are health-related. Second, we only retrieved mHealth apps from the two most established system platforms, the iOS (AppStore) and the Android (GooglePlay), there are also apps from other platforms, such as the Windows Phone Store [20] and the BlackBerry World [21]. Third, our repository is limited in the regions the information was extracted from. For the AppStore, we only extracted apps information from the top 5 regions according to the market size, which neglects information from other well developed countries such as Australia and European countries (different stores are separated by different languages), as well as from fast developing regions such as Africa and India. For the Android platform, we only extracted apps information from the GooglePlay US store, due to the complex Android markets in other countries. For example, in China, the major Android stores include Baidu Shouji Zhushou [22], Tencent Yingyongbao [23], and 360 Shouji Zhushou [24], while the GooglePlay is not among the major Android stores. Fourth, the number of apps from the GooglePlay is limited due to the availability of apps on the GooglePlay website, which only lists up to 600 of the most popular apps every day. Our repository is based on the lists of apps accumulated between July 24 and December 6, 2014. In spite of these limitations, we expect this mHealth app repository will not only serve as a centralized information resource for researchers to perform meta-analysis on current apps, but also provide guidance for future research designs in the mHealth field.

Acknowledgments

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Authors' Contributions

WX and YL conceived of the idea and wrote the paper. WX performed the derivations, implemented the algorithm, and prepared the data.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Zip flat file with array format for AppStore Health & Fitness apps in United States.

[GZ File, 25MB - mhealth_v3i1e28_app1.gz]

Multimedia Appendix 2

Zip flat file with array format for AppStore Health & Fitness apps in China.

[GZ File, 24MB - mhealth_v3i1e28_app2.gz]

Multimedia Appendix 3

Zip flat file with array format for AppStore Health & Fitness apps in Japan.

[GZ File, 25MB - mhealth_v3i1e28_app3.gz]

Multimedia Appendix 4

Zip flat file with array format for AppStore Health & Fitness apps in Brazil.

[GZ File, 24MB - mhealth_v3i1e28_app4.gz]

Multimedia Appendix 5

Zip flat file with array format for AppStore Health & Fitness apps in Russia.

[GZ File, 25MB - mhealth_v3i1e28_app5.gz]

Multimedia Appendix 6

Zip flat file with array format for AppStore Medical apps in United States.

[GZ File, 19MB - mhealth_v3i1e28_app6.gz]

Multimedia Appendix 7

Zip flat file with array format for AppStore Medical apps in China.

[GZ File, 18MB - mhealth_v3i1e28_app7.gz]

Multimedia Appendix 8

Zip flat file with array format for AppStore Medical apps in Japan.

[GZ File, 19MB - mhealth_v3i1e28_app8.gz]

Multimedia Appendix 9

Zip flat file with array format for AppStore Medical apps in Brazil.

[GZ File, 19MB - mhealth_v3i1e28_app9.gz]

Multimedia Appendix 10

Zip flat file with array format for AppStore Medical apps in Russia.

[GZ File, 19MB - mhealth_v3i1e28_app10.gz]

Multimedia Appendix 11

Zip flat file with array format for GooglePlay Health & Fitness apps in United States.

[GZ File, 6MB - mhealth_v3i1e28_app11.gz]

Multimedia Appendix 12

Zip flat file with array format for GooglePlay Medical apps in United States.

[GZ File, 4MB - mhealth_v3i1e28_app12.gz]

Multimedia Appendix 13

Disclaimer.

[TXT File, 802B - mhealth_v3i1e28_app13.txt]

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Abbreviations

API: app program interface
apps: apps
AppStore: Apple App Store
BR: Brazil
CN: China
GooglePlay: Google Play Store
ID: identity
JP: Japan
JSON: JavaScript Object Notation
mHealth: mobile health
RU: Russia

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Original Paper

Mobile App Rating Scale: A New Tool for Assessing the Quality of Health Mobile Apps

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Abstract

Background: The use of mobile apps for health and well being promotion has grown exponentially in recent years. Yet, there is currently no app-quality assessment tool beyond “star”-ratings.

Objective: The objective of this study was to develop a reliable, multidimensional measure for trialling, classifying, and rating the quality of mobile health apps.

Methods: A literature search was conducted to identify articles containing explicit Web or app quality rating criteria published between January 2000 and January 2013. Existing criteria for the assessment of app quality were categorized by an expert panel to develop the new Mobile App Rating Scale (MARS) subscales, items, descriptors, and anchors. There were sixty well being apps that were randomly selected using an iTunes search for MARS rating. There were ten that were used to pilot the rating procedure, and the remaining 50 provided data on interrater reliability.

Results: There were 372 explicit criteria for assessing Web or app quality that were extracted from 25 published papers, conference proceedings, and Internet resources. There were five broad categories of criteria that were identified including four objective quality scales: engagement, functionality, aesthetics, and information quality; and one subjective quality scale; which were refined into the 23-item MARS. The MARS demonstrated excellent internal consistency (alpha = .90) and interrater reliability intraclass correlation coefficient (ICC = .79).

Conclusions: The MARS is a simple, objective, and reliable tool for classifying and assessing the quality of mobile health apps. It can also be used to provide a checklist for the design and development of new high quality health apps.

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KEYWORDS

well being; mental health; e-health; mobile health (mhealth); mobile application; assessment; rating; scale development

Introduction

Global Smart Phone App Usage

The use of mobile apps for health and well being promotion has grown exponentially in recent years [1]. Between 2013 and 2014 the global use of smart phones increased by 406 million, reaching 1.82 billion devices (up 5% in a year), and Internet usage via mobile devices has increased by 81% in one year [2]. There were 13.4 billion apps that were downloaded in the first quarter of 2013 [3], with projected figures of 102 billion for the whole year [4]. The portability of smart phones provides access to health information and interventions at any time in any context. The capabilities (eg, sensors) of smart phones can also enhance the delivery of these health resources.

Given the rapid proliferation of smart phone apps, it is increasingly difficult for users, health professionals, and researchers to readily identify and assess high quality apps [5]. Little information on the quality of apps is available, beyond the star ratings published on retailers' Web pages, and app reviews are subjective by nature and may come from suspicious sources [6]. Selecting apps on the basis of popularity yields little or no meaningful information on app quality [7].

Much of the published literature focuses on technical aspects of websites, presented mostly in the form of checklists, which do not assess the quality of these features [8-10]. Website quality can be described as a function of: (1) *content*, (2) *appearance and multimedia*, (3) *navigation*, (4) *structure and design*, and (5) *uniqueness* [11]. A synthesis of website evaluation criteria conducted by Kim et al [12] shortlisted 165 evaluation criteria, grouped in 13 groups (eg, *design and aesthetics*, *ease of use*). However, 33 criteria were unable to be grouped and were coded as "miscellaneous", highlighting the complexity of the task. While many website criteria may be applicable to mobile apps, there is a need to consider whether a specific quality rating scale may be needed for apps.

Attempts to develop mobile health (mHealth) evaluation criteria are often too general, complex, or specific to a particular health domain. Handel [13] reviewed 35 health and well being mobile apps based on user ratings of: (1) *ease of use*, (2) *reliability*, (3) *quality*, (4) *scope of information*, and (5) *aesthetics*. While these criteria may cover important aspects of quality, no rationale for these specific criteria was provided. Khoja et al [14] described the development of a matrix of evaluation criteria, divided into seven themes for each of the four stages of an app's life-cycle: (1) *development*, (2) *implementation*, (3) *integration*, and (4) *sustained operation*. While this matrix provides comprehensive criteria for rating app quality, the complex and time-consuming nature of the evaluation scheme would be difficult to apply in routine practice and research. Furthermore, the matrix omits any evaluation of the visual *aesthetics* of the app as a criterion.

Guidelines for evaluating the usability of mHealth apps were also compiled by the Health Care Information and Management Systems Society (HIMSS) [15]. These guidelines use a "Strongly agree" to "Strongly disagree" Likert scale to rate each criterion, which does not provide an indication of their quality. Strong agreement that a criterion is met (ie, clarity in whether a feature is present) is not necessarily equivalent to meeting the criterion to a high degree. While the HIMSS criteria were extensive, and included usability criteria for rating *efficiency*, *effectiveness*, *user satisfaction*, and *platform optimization*, no criteria for rating *information quality* were included. This is problematic, as failure to evaluate the accuracy and appropriateness of the health information contained in mHealth apps could compromise user health and safety [16].

A reliable and objective instrument is needed to rate the degree that mHealth apps satisfy quality criteria. This scale should be easy to understand and use with minimal training. This scale will initially be used by researchers, but may later be made available to app developers and health professionals, pending further research.

Objectives

The objective of this study is to develop a reliable, multidimensional scale for classifying and rating the quality of mobile health apps.

Methods

Mobile App Rating Scale Development

A comprehensive literature search was conducted to identify articles containing explicit Web- or app-related quality rating criteria. English-language papers from January 2000 through January 2013 were retrieved from PsycINFO, ProQuest, EBSCOhost, IEEE Xplore, Web of Science, and ScienceDirect. The search terms were, "mobile" AND "app*" OR "web*" PAIRED WITH "quality" OR "criteria" OR "assess*" OR "evaluat*".

Three key websites, including the EU's Usability Sciences [17], Nielsen Norman Group's user experience (UX) criteria, and HIMSS were searched for relevant information. References of retrieved articles were also hand-searched. Professional research manuals, unpublished manuscripts, and conference proceedings were also explored for additional quality criteria. After initial screening of title and abstract, only studies that reported quality assessment criteria for apps or Web content were included.

Website and app assessment criteria identified in previous research were extracted. Criteria irrelevant to mobile content and duplicates were removed. An advisory team of psychologists, interaction and interface designers and developers, and professionals involved in the development of mHealth apps worked together to classify assessment criteria into categories and subcategories, and develop the scale items and descriptors. Additional items assessing the app's description in the Internet store and its evidence base were added. Corrections were made until agreement between all panel members was reached.

Mobile App Rating Scale Testing on Mental Health Apps

A systematic search of the Apple iTunes store was conducted on September 19, 2013, following the PRISMA guidelines for systematic literature reviews [18]. An exhaustive list of mental-health related mobile apps was created. The following search terms were employed, "Mindfulness" OR "Depression"

OR “Wellbeing” OR “Well-being” OR “Mental Health” OR “Anger” OR “CBT” OR “Stress” OR “Distress” OR “Anxiety”.

App inclusion criteria were: (1) English language; (2) free of charge; (3) availability in the Australian iTunes store; and (4) from iTunes categories, “Health & Fitness”, “Lifestyle”, “Medical”, “Productivity”, “Music”, “Education”, and “Utilities”. The category inclusion criteria were based on careful scrutiny of the titles and types of apps present in those categories.

There were 60 apps that were randomly selected using a randomization website [19]. The first ten were used for training and piloting purposes. There were two expert raters: (1) a research officer with a Research Masters in Psychology and two years’ experience in mobile app development, and (2) a PhD candidate with a Masters degree in Applied Psychology and over nine years information technology experience, that trialled each of the first 10 apps for a minimum of 10 minutes and then independently rated their quality using the Mobile App Rating Scale (MARS). The raters convened to compare ratings and address ambiguities in the scale content until consensus was reached. The MARS was revised based on that experience, and the remaining 50 mental health and well being related apps were trialled and independently rated. A minimum sample size of 41 is required to establish whether the true interrater reliability lies within .15 of a sample observation of .80, with 87% assurance (based on 10,000 simulation runs) [20]. The sample size of 50, therefore, provides substantial confidence in the estimation of the interrater reliability in the current study. Data were analyzed with SPSS version 21 (SPSS Inc, Chicago, IL, USA). The internal consistency of the MARS quality subscales and total quality score was calculated using Cronbach alpha. This indicates the degree (correlations) to which items measuring the same general construct produce similar scores. Interrater reliability of the MARS subscales and total score was determined by the intraclass correlation coefficient (ICC) [21]. This statistic allows for the appropriate calculation of weighted values of rater agreement and accounts for proximity, rather than equality of ratings. A two-way mixed effects, average measures model with absolute agreement was utilized [22]. The concurrent validity of the MARS total score was examined in relation to the Apple iTunes App Store average star rating for each app (collected from the Apple iTunes App Store on September 19, 2013).

Results

Mobile App Rating Scale Development

The search strategy yielded 25 publications, including peer-reviewed journal articles (n=14), conference proceedings (n=8), and Internet resources (n=3) containing explicit mobile or Web-related quality criteria. The complete list of utilized resources is available with this article (see Multimedia Appendix 1, papers, publications, and materials used for MARS criteria selection). A total of 427 criteria were extracted, 56 were removed as duplicates, and 22 were deemed irrelevant to apps. The remaining 349 criteria were grouped into six categories by the expert panel, one relating to app *classification*, four categories on objective app qualities (*engagement*, *functionality*, *aesthetics*, and *information quality*), and one on *subjective app quality* (see Table 1), through an iterative approach.

Table 1. Number of criteria for evaluation of mHealth app quality identified in the literature search.

Criterion category	Frequency, N=349	(%)
App classification, confidentiality, security, registration, community, affiliation	12	(3.4)
Aesthetics, graphics, layout, visual appeal	52	(14.8)
Engagement, entertainment, customization, interactivity, fit to target group, etc	66	(18.9)
Functionality, performance, navigation, gestural design, ease of use	90	(25.8)
Information, quality, quantity, visual information, credibility, goals, description	113	(32.4)
Subjective quality, worth recommending, stimulates repeat use, overall satisfaction rating	16	(4.6)

Classification Category

The *classification* category collected descriptive information on the app (eg, price, platform, rating) as well as its technical aspects (eg, log-in, password-protection, sharing capabilities). Additional sections collect information on the target age group of the app (if relevant), as well as information on what aspects of health (including physical health, mental health, well-being) the app targets. These domains may be adapted to include/exclude specific content areas as needed.

The app quality criteria were clustered within the *engagement*, *functionality*, *aesthetics*, *information quality*, and *subjective quality* categories, to develop 23 subcategories from which the 23 individual MARS items were developed. Each MARS item used a 5-point scale (1-Inadequate, 2-Poor, 3-Acceptable, 4-Good, 5-Excellent), descriptors for these rating anchors were written for each item. In cases where an item may not be applicable for all apps, an option of Not applicable was included. The expert panel scrutinized the MARS items and rating descriptor terminology to ensure appropriate and consistent language was used throughout the scale.

Calculating the mean scores of the e*ngagement*, *functionality*, *aesthetics*, and *information quality* objective subscales, and an overall mean app quality total score is how the MARS is scored. Mean scores instead of total scores are used because an item can be rated as Not applicable. Additionally, mean scores are used to provide quality ratings corresponding to the familiar format of star ratings. The *subjective quality* items can be scored separately as individual items, or a mean *subjective quality*

score. The MARS *app classification* section is for descriptive purposes only.

Mobile App Rating Scale Testing

A total of 1533 apps were retrieved from the iTunes search. All duplicate, non-English, and paid apps were removed. Apps from the categories "games"; "books"; "business"; "catalog"; "entertainment"; "finance"; "navigation"; "news"; "social networking"; and "travel" were also removed. Remaining apps were screened by title. The app store descriptions of apps with unclear titles were reviewed prior to exclusion. App titles with the words "magazine", "mother", "mum", "job", "festival", "massage", "shop", or "conference", as well as company ads and Web apps were also excluded, as they were linked to irrelevant content. There were sixty of the remaining 405 apps that were randomly selected for rating with the MARS (Figure 1 shows this).

On attempting to rate the initial ten apps, it was found that one was faulty and could not be rated. MARS ratings of the remaining nine apps indicated the scale had a high level of internal consistency (Cronbach alpha = .78) and fair interrater reliability (2-way mixed ICC = .57, 95% CI 0.41-0.69). The Not applicable option was removed from items within the *engagement* category, as this feature was considered to be an important and universal component of all high-quality apps. The meaning of *visual information* was clarified and the item rephrased. The stated or inferred age target of "young people" was defined as app users age 16-25. The descriptor of *goals* was clarified to read; *Does the app have specific, measurable, and achievable goals (specified in app store description or within the app itself)?*; to help distinguish it from the item *accuracy of app description*, which often relates to the app's goals. On the *information* subscale, raters found it difficult to determine when lack of information within an app should be rated as Not applicable or as a flaw; this item was therefore revised to require that information be rated unless the apps were purely for entertainment. The final version of the MARS is provided with this article (see Multimedia Appendix 2, Mobile App Rating Scale).

Independent ratings on the overall MARS total score of the remaining 50 mental health and well being apps demonstrated an excellent level of interrater reliability (2-way mixed ICC = .79, 95% CI 0.75-0.83). The MARS total score had excellent internal consistency (Cronbach alpha = .90) and was highly correlated with the MARS star rating item (#23), $r(50) = .89$, $P<.001$. Internal consistencies of the MARS subscales were also very high (Cronbach alpha = .80-.89, median .85), and their interrater reliabilities were fair to excellent (ICC = .50-.80, median .65). Detailed item and subscale statistics are presented in Table 2. A full list of the apps, which were trialled and rated, using the MARS, as well as their mean objective and subjective app quality scores is provided with this article (see Multimedia Appendix 3, Mobile Apps Used for MARS Evaluation).

Only 15 of the 50 mental health and well being apps extracted from the iTunes App Store had received the five user ratings required for a star rating to be displayed. These apps showed a moderate correlation between the iTunes star rating and the total MARS score ($r(15) = .55$, $P<.05$).

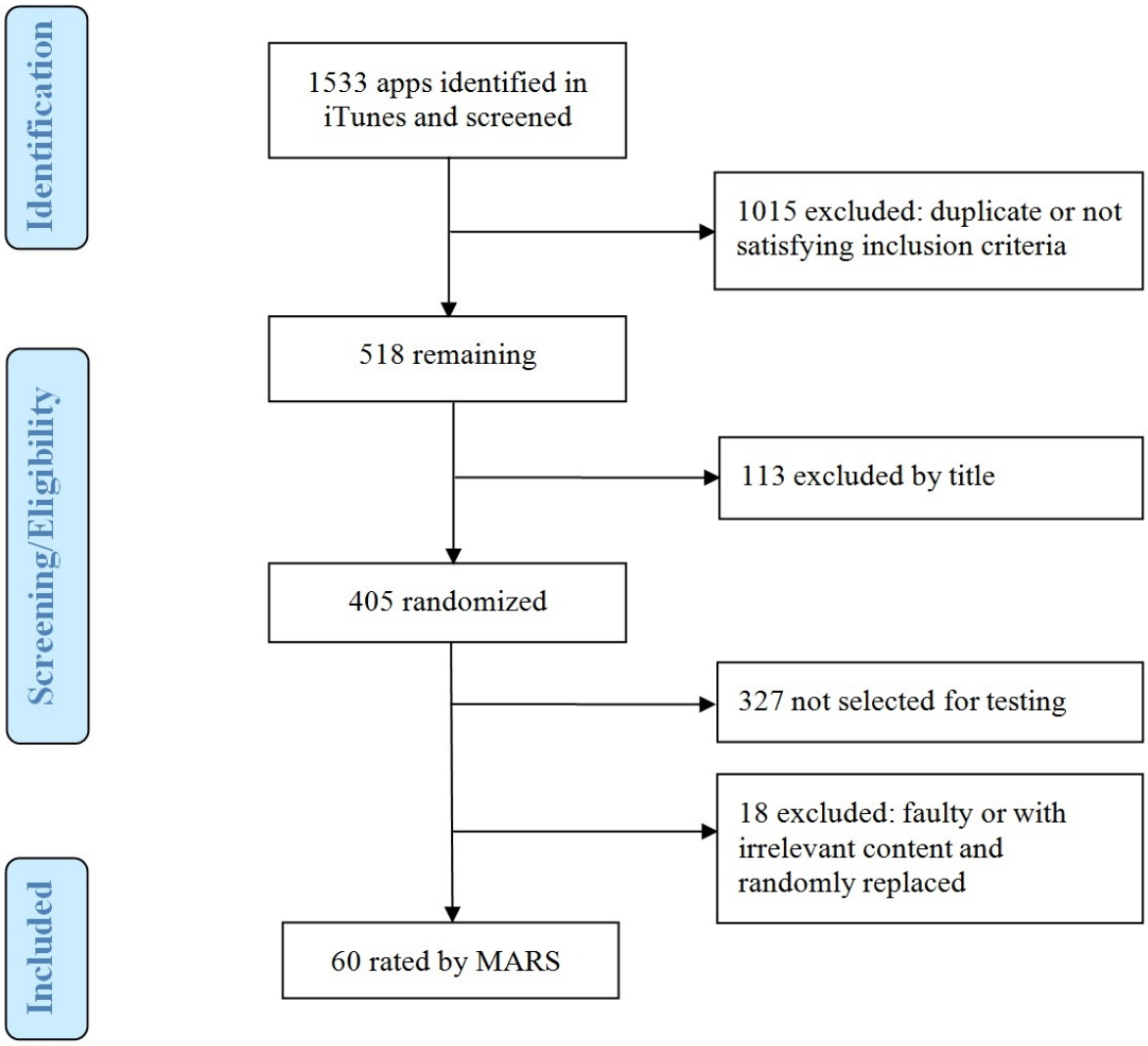
Table 2. Interrater reliability and internal consistency of the MARS items and subscale scores, and corrected item-total correlations and descriptive statistics of items, based on independent ratings of 50 mental health and well being apps.

#	Subscale/item	Corrected item-total correlation	Mean	SD
Engagement alpha = 0.89, ICC = 0.80 (95% CI 0.73-0.85)				
1	Entertainment	.63	2.49	1.24
2	Interest	.69	2.52	1.20
3	Customization	.60	2.27	1.15
4	Interactivity	.65	2.70	1.22
5	Target group	.61	3.41	0.93
Functionality alpha = 0.80, ICC = 0.50 (95% CI 0.33-0.62)				
6	Performance	.42	4.00	0.93
7	Ease of use	.29	3.93	0.87
8	Navigation	.48	4.00	0.94
9	Gestural design	.48	4.10	0.79
Aesthetics alpha = 0.86, ICC = 0.61 (95% CI 0.46-0.72)				
10	Layout	.56	3.91	0.87
11	Graphics	.61	3.41	0.92
12	Visual appeal: How good does the app look?	.60	3.14	0.91
Information alpha = 0.81, ICC = 0.79 (95% CI 0.71-0.84)				
13	Accuracy of app description	.67	3.66	1.03
14	Goals	.70	3.43	1.10
15	Quality of information	.47	3.18	1.46
16	Quantity of information	.58	2.87	1.54
17	Visual information	.39	1.35	1.89
18	Credibility	.46	2.79	0.95
19	Evidence base[a]	-	-	-
Subjective quality alpha = 0.93, ICC = 0.83 (95% CI 0.75-0.88) [b]				
20	Would you recommend this app?	.84	2.31	1.17
21	How many times do you think you would use this app?	.82	2.46	1.12
22	Would you pay for this app?	.63	1.31	0.60
23	What is your overall star rating of the app?	.89	2.69	1.06

[a] Item 19 “Evidence base” was excluded from all calculations, as it currently contains no measurable data.

[b] The *Subjective quality* subscale was excluded from the total MARS ICC calculation.

Figure 1. Flow diagram of the process utilized to identify apps for piloting the Mobile App Rating Scale (MARS).



Discussion

Principal Results

The MARS is the first mHealth app quality rating tool, to our knowledge, to provide a multidimensional measure of the app quality indicators of *engagement*, *functionality*, *aesthetics*, and *information quality*, as well as app *subjective quality*. These app quality indicators were extracted from previous research across the UX, technical, human-computer interaction, and mHealth literature, but had not previously been combined in a singular framework. Previous attempts to develop mobile app evaluation criteria have been too technical or specific to a particular health domain. They have also not been developed and piloted in a systematic manner using an expert panel of health professionals, designers, and developers of health Web and mobile apps. In contrast, the MARS is an easy-to-use (with appropriate training), simple, objective, reliable, and widely applicable measure of app quality, developed by an expert multidisciplinary team. Although the generalizability of the MARS is yet to be tested, the scale can be modified to measure the quality of nonhealth related apps. The MARS total mean score describes the overall quality of an app, while the mean *engagement*, *functionality*, *aesthetics*, and *information quality* subscale scores can be used to describe its specific strengths and weaknesses.

The use of objective MARS item anchors and the high level of interrater reliability obtained in the current study should allow health practitioners and researchers to use the scale with confidence. Both the app quality total score and four app-quality subscales had high internal consistency, indicating that the MARS provides raters with a reliable indicator of overall app quality, as well as the quality of app *engagement*, *functionality*, *aesthetics*, and *information quality*. The exclusion of the *subjective quality* subscale from the overall mean app quality score, due to its subjective nature, strengthens the objectivity of the MARS as a measure of app quality. Nevertheless, the high correlation between the MARS quality total score and its overall star rating provides a further indication that it is capturing perceived overall quality. It should be noted that the MARS overall star rating is likely to be influenced by the prior completion of the 19 MARS app quality items. Nevertheless, the iTunes App Store star ratings available on 15 of the 50 mental health apps rated were only moderately correlated with the MARS total score. This was unsurprising; given the variable criteria likely to be used by different raters, the subjective nature of these ratings, and the lack of reliability of the iTunes star

ratings, as has been highlighted in previous research [6]. In addition, the MARS overall star rating score was only moderately correlated with the iTunes App Store star rating. The MARS star rating is likely to provide a more reliable measure of overall app quality, as it is rated following completion of the entire MARS, and is therefore informed by the preceding items.

It is recommended that MARS raters complete a training exercise before commencing use. Training slides are available from the corresponding author. If multiple MARS raters are utilized, it is recommended that raters develop a shared understanding of the target group for the apps, clarify the meaning of any MARS items they find ambiguous, and determine if all MARS items and subscales are relevant to the specific health area of interest. App-quality ratings should be piloted and reviewed until an appropriate level of interrater reliability or consensus ratings are reached. The MARS also assumes that raters have undertaken a detailed exploration of the app's content and functionalities.

Due to the generic nature of the mHealth app quality indicators included in the MARS, it is recommended that a number of "App-Specific" items are added to obtain information on the perceived impact of the app on the user's knowledge, attitudes, and intentions related to the target health behavior (see *App Specific* section of the MARS).

For convenience, the MARS was piloted on iPhone, rather than Android apps. Since initial testing, however, the scale has been applied to multiple Android apps and no compatibility issues were encountered. However, future research should explore the reliability of the scale with Android apps.

Limitations

While the original search strategy to identify app-quality rating criteria was conducted using guidelines for a systematic review, few peer-reviewed journal articles were identified. As a result, the search strategy was expanded to include conference proceedings and Internet resources, which may not have been as extensively peer reviewed. Suggested guidelines for scale-development were followed [23], whereby a qualitative analysis of existing research was conducted to extract app-quality criteria and then develop app-quality categories, subcategories, MARS items, and their anchor ratings via a thematic review and expert panel ratings. Despite these efforts, and the corrections made after piloting the scale, two MARS items on the *functionality* subscale (*ease of use* and *navigation*) achieved only moderate levels of interrater reliability (ICC = .50). These items have been revised and are being tested.

Researchers are yet to test the impact of the mental health apps included in this study. As a result, the MARS item *evidence base* was not rated for any of the apps in the current study and its performance has not been tested. It is hoped that as the evidence base for health apps develops, the applicability of this MARS item will be tested.

Future Research

Future research is required to determine the suitability and reliability of the MARS across multiple health and other app domains, as well as its applicability in the sphere of app development. The association of the app quality total and subscale scores with the concepts of user experience, quality of experience, and quality of service requires further investigation. Future refinements of MARS terminology and additional items are likely to be required, as the functionality of mobile apps progresses. It is hoped the current version of the MARS provides mHealth app-developers with a checklist of criteria for ensuring the design of high-quality apps.

The MARS could also be utilized to provide quantitative information on the quality of medical apps as part of recent medical app peer-review initiatives, such as that launched by JMIR mHealth and uHealth [24].

With some modification, the MARS may also inform the development and quality rating of health-related websites. While the MARS was designed to be utilized by experts in the mHealth field, a simpler version of the scale, "MARS-app user", based on the original MARS, was developed in consultation with youth agencies and young people for the purposes of obtaining user feedback on app quality and satisfaction. The MARS-app user version is currently being piloted. It is available upon request from the corresponding author.

Future research is also required to determine how to best evaluate the safety of mHealth apps in terms of the quality of the health information contained in the apps and the privacy and security of user information [16,25]. Su [25] recently suggested that assessment of the security and integrity of mHealth apps should include exploration of open-source developer codes for potential malicious functions.

Conclusions

The MARS provides a multidimensional, reliable, and flexible app-quality rating scale for researchers, developers, and health-professionals. Current results suggest that the MARS is a reliable measure of health app quality, provided raters are sufficiently and appropriately trained.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Papers, publications, and materials used for MARS criteria selection.

[PDF File (Adobe PDF File), 83KB - mhealth_v3i1e27_app1.pdf]

Multimedia Appendix 2

Mobile App Rating Scale.

[PDF File (Adobe PDF File), 259KB - mhealth_v3i1e27_app2.pdf]

Multimedia Appendix 3

Mobile Apps Used for MARS Evaluation.

[PDF File (Adobe PDF File), 65KB - mhealth_v3i1e27_app3.pdf]

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Abbreviations

CBT: cognitive behavioral therapy
HIMSS: Health Care Information and Management Systems Society
ICC: intraclass correlation coefficient
MARS: Mobile App Rating Scale
mHealth: mobile health
UX: user experience
Young and Well CRC: Young and Well Cooperative Research Centre

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Original Paper

Apps Seeking Theories: Results of a Study on the Use of Health Behavior Change Theories in Cancer Survivorship Mobile Apps

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Abstract

Background: Thousands of mobile health apps are now available for use on mobile phones for a variety of uses and conditions, including cancer survivorship. Many of these apps appear to deliver health behavior interventions but may fail to consider design considerations based in human computer interface and health behavior change theories.

Objective: This study is designed to assess the presence of and manner in which health behavior change and health communication theories are applied in mobile phone cancer survivorship apps.

Methods: The research team selected a set of criteria-based health apps for mobile phones and assessed each app using qualitative coding methods to assess the application of health behavior change and communication theories. Each app was assessed using a coding derived from the taxonomy of 26 health behavior change techniques by Abraham and Michie with a few important changes based on the characteristics of mHealth apps that are specific to information processing and human computer interaction such as control theory and feedback systems.

Results: A total of 68 mobile phone apps and games built on the iOS and Android platforms were coded, with 65 being unique. Using a Cohen's kappa analysis statistic, the inter-rater reliability for the iOS apps was 86.1 (P<.001) and for the Android apps, 77.4 (P<.001). For the most part, the scores for inclusion of theory-based health behavior change characteristics in the iOS platform cancer survivorship apps were consistently higher than those of the Android platform apps. For personalization and tailoring, 67% of the iOS apps (24/36) had these elements as compared to 38% of the Android apps (12/32). In the area of prompting for intention formation, 67% of the iOS apps (34/36) indicated these elements as compared to 16% (5/32) of the Android apps.

Conclusions: Mobile apps are rapidly emerging as a way to deliver health behavior change interventions that can be tailored or personalized for individuals. As these apps and games continue to evolve and include interactive and adaptive sensors and other forms of dynamic feedback, their content and interventional elements need to be grounded in human computer interface design and health behavior and communication theory and practice.

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KEYWORDS

mobile apps; health behavior; survivorship; health promotion; eHealth; mobile health

Introduction

> *We tend to overestimate the effect of a technology in the short run and underestimate the effect in the long run.* [Roy Amara, leader at the Institute for the Future]

Background

The use of mobile phones has shifted from voice and text only to the Internet accessibility of smartphones. In this shift, a large market of mobile software apps has emerged. As of May 2014, the United States had 345.2 million mobile subscribers [1]. This is more than one mobile subscription per person, based on US population estimates of 313.9 million [2]. According to the Pew Internet and American Life Surveys, 91% of US adults own a cell phone and 60% use their phone to access the Internet [3].

Mobile technology, smartphones, and tablets provide anytime anywhere access to health information, health promotion, and behavioral interventions. Use of mobile technology for health-seeking information is high, with 31% of smartphone owners using the device to search for health information [3]. Personal mobile apps are a critical component of mHealth, providing educational resources, decision-making tools, psychosocial communication, and social support.

For the growing population of cancer survivors, who experience differing needs in terms of medical care, psychosocial support, and practical needs of daily living, mHealth apps have the potential to provide access to information and health behavior interventions that are low cost, easy to access, and personalized to their specific needs. Increasingly, socially disadvantaged populations including racial/ethnic minorities, those with lower incomes, and elderly persons use mobile phones as their primary or only connection to the Internet [4,5]. While sparse, studies such as those by Bender et al are beginning to explore the efficacy and potential of mobile app interventions [5]. With relation to disease-specific apps, previous reviews have coded cancer apps to examine which apps were scientifically/clinically based or evidence-based or on the basis of the app's purpose and content such as awareness, cancer treatment information, fundraising, or early detection [6-8]. To date, none of the research on mHealth cancer apps has systematically assessed the extent to which cancer survivorship apps, as health behavioral interventions, are theory-based.

Study Aims

A sophisticated taxonomy of health behavior theories and behavior change frameworks developed by Abraham and Michie was later refined as a system to code Internet interventions associated with health behavior by Webb et al [9-11]. Our review further adapts that taxonomy to mHealth interventions for cancer survivorship and investigates if and how behavior change theories, some of which form the groundwork for human computer interactions and cognitive psychology, are being used. By doing so, we begin to answer two important theoretical and applied questions: "To what extent are apps for health promotion and disease prevention based on health behavior and communication theories and frameworks?" and "How can mHealth cancer survivorship apps be designed differently to be more effective health behavior change interventions?"

As a secondary aim, we considered the comparison of the degree to which the health behavior and communication theories appear to be taken into consideration based on the type of mobile platform (ie, iOS compared to Android) the apps used.

Methods

Overview

In preparation for this research and a number of other health communication and mobile app projects, we worked closely with over 30 cancer survivors from various racial, ethnic, age, and sociodemographic groups. We considered a cancer survivor to be any person who has been diagnosed with cancer from the time of diagnosis through the balance of life.

Prior to and during this research, we consistently received feedback on their informational needs and preferences in the use of mobile apps. In this study, we used such qualitative input in the formative stage. In November 2013, we conducted a computerized search for mHealth cancer survivorship apps on the Apple App Store for iPhone and iPad apps and on Google Play for Android apps. We explored other mobile app markets including those for Nokia, Microsoft, and Blackberry smartphones but found no cancer apps that met our criteria of being more than badges or skins. As a result of this preliminary analysis, we limited our search to native apps—software apps that must be installed on a device such as a smartphone, iPad, or table—available either for the iOS or Android platform or both. The apps could have elements or portions linked to websites or cloud-based servers, including assessments, videos, PDFs, or other linked materials, but the user interface must be initiated on the smartphone or tablet.

Inclusion and Exclusion Criteria

Mobile app searches were conducted on Google Play and the Apple App Store using the search terms cancer + survivor, cancer + survivorship, cancer + care, cancer + treatment, and cancer + management.

Web-based searches for mobile apps were also made on Google, Bing, and Yahoo, as these are among the top search engines used in English. Search terms included cancer + mobile web, cancer survivorship + mobile web, and cancer survivorship app.

Textbox 1. Inclusion criteria for survivorship apps

Inclusion criteria

- Includes specific mention of cancer care, treatment, survivorship, or cancer survivors

  Mention can be made in the description found on the app store, in the website listing, or in the table of contents of the app or its navigation terms/icons
- Applicable to one or more cancer types or cancer care

  Includes functionality and services for all cancers, information for one or more types of cancers, or information specifically addressing the late effects of cancer survivorship as a condition
- Designed for patients and survivors

  Can also include information for caregivers and providers
- Free and available for public download and use

  Input from cancer survivors suggested a reluctance to pay for apps based on the availability of free educational and instructional resources
- Offers some level of interaction for health behavior change

Textbox 2. Exclusion criteria for survivorship apps.

Exclusion criteria

- Designed for research studies only
- Relevant only to patients and survivors of a specific institution or cancer center (branding of a cancer center in an app was considered allowable)
- Designed solely for use by providers
- Paid apps
- Mobile phone screen skins or badges
- Fundraising only apps
- Glossaries and mobile versions of periodicals and websites

Study Design

The taxonomy for behavior change techniques used in this research study was derived from a taxonomy of 26 health behavior change techniques (HBCTs) by Abraham and Michie with a few important changes based on the characteristics of mHealth apps [9-11]. The mHealth app taxonomy was limited to 15 HBCTs with each described by one or more health behavior or communication theories. An additional area of HBCTs included in the mHealth taxonomy but not found in the taxonomy of Abraham and Michie and the works by Webb et al is tailored health communications (THC) [9-11]. As indicated by Rimmer and Kreuter, THCs are important elements of health communication and persuasion and may promote action through increased relevance and motivation to process information actively [12].

The theoretical models and frameworks initially used by Abraham and Michie and Michie et al [9,11] and Webb et al [10] that were included in the mHealth survivorship app taxonomy are as follows: elaboration likelihood model (ELM) (Petty and Cacioppo), social cognitive theory (SCogT) (Bandura), information-motivation-behavioral skills model (IMB) (Fisher and Fisher), control theory (CT) (Carver and Scheier), and operant conditioning (OC) (Skinner). Also used were theories related to the impact of social support on health behaviors (SS) (Cohen) and social comparison (SC) (Festinger) and theory of planned behavior (Ajzen) [12-19].

Statistical Analysis

A coding manual was developed specifically for use in coding the mHealth apps for cancer survivorship (Multimedia Appendix 1) based on the work of Michie et al, *A Taxonomy of Behavior Change Techniques Used in Interventions* [9]. A coding guide (Table 1) drawn from the mHealth cancer survivorship taxonomy of HBCTs and theories was developed, analyzed, and tested by the coders DVD, KF, JP. The team tested and trained with the coding guide using three apps that existed both on iOS and Android mobile platforms that were not specifically related to cancer. These apps were not included in the research assessment.

Master lists of identified iOS and Android apps were developed collectively by the coders for use in downloading the apps to their smartphones and tablets. Two coders were assigned to each type of app platform, and each coder independently loaded the apps that met the eligibility criteria onto one or more mobile devices. The coding rubric used a score of 1 to indicate that the HBCT was present and 0 to indicate that the HBCT was absent. Based on two raters for each app, total possible scores for the platforms are 72 for iOS apps (36 apps times 2 raters) and 64 (32 apps times 2 raters) for the Android apps. Several apps were not working and could not be loaded and a few crashed consistently, thus preventing coding. The only major difference in coding approach was related to coding of games, and that issue was easily resolved by consensus.

Table 1. mHealth cancer survivorship taxonomy for coding.

Behavior Change Techniques	Theory Basis	Definition
Personalized	THC[a], SCogT[b], ELM[c]	Rimer and Kreuter define personalization and tailoring as a process for creating individualized communications by gathering and assessing personal data, (ie, logging in with personal information)
Tailoring (macro/meso/micro)	THC, ELM	Macro occurs at the group level; meso is determined by individual needs of user but is not highly specific; micro is very specific to the user
Health behavior linkage	IMB[d]	General information about linkage of individual behavior and health (ie, benefits of good nutrition and physical activity)
Action/behavior consequences	TRA[e], TPB[f], SCogT,IMB	Information about potential benefits and costs of action or inaction in relation to health and well-being (ie, stop smoking)
Intention formation	TRA, TPB, SCogT, IMB	Encourage the person to take an action or decide on a goal to improve treatment response or survivorship
Provide instruction	SCogT	Show or tell the user how to perform a behavior (ie, asking your doctor questions)
Provide materials for education	SCogT	Provide information or educational materials about cancer care and survivorship
Goal setting	CT[g]	Prompt specific goal setting (ie, walk 5 miles daily)
Self-efficacy	SCogT	Aid user in recognizing skills or education developed
Feedback on performance	CT	Scores, tests, game results
Persuasion (general/targeted)	OC[h]	Messages to strengthen self-efficacy/control beliefs
Social influence: information on peer behavior (passive)	SCogT	Facilitate user access to information on how others have changed behavior or addressed challenges (nonexpert)
Opportunity for social comparison (active)	SS[i]/SC[j]	Facilitate active user engagement in social media for sharing and comparison
Mobilize social norms (exposure to important others)	SS/SC	Provide user exposure to expert opinions and information

[a]THC, tailored health communication model
[b]SCogT, social cognitive theory
[c]ELM, elaboration likelihood model
[d]IMB, information-motivation-behavioral skills model
[e]TRA, theory of reasoned action
[f]TBP, theory of planned behavior
[g]CT, control theory
[h]OC, operant conditioning
[i]SS, social support
[j]SC, social comparison

Results

Ratings for Health Behavior Techniques

A search of the mHealth cancer survivorship apps yielded a total of 104 potentially relevant apps that appeared to meet the selection criteria. After removing the paid apps (N=7) and those that crashed or would not open (N=29), there were 68 apps that were coded. A flow diagram showing the numbers, source, and refinement of the apps identified for coding is shown in Figure 1.

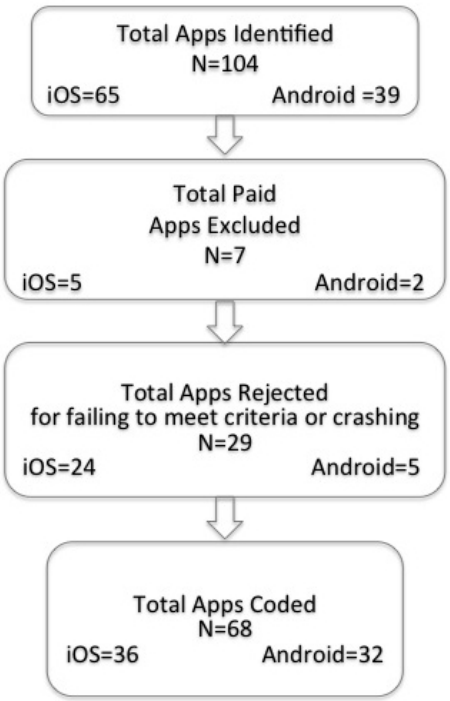
There were three apps that were available on both the Apple App Store and Google Play, and both teams coded these apps. Seven of the Android cancer apps were configured as games, as were four iOS games. A total of 68 unpaid apps were coded and 65 of these were unique. Using a Cohen's kappa analysis statistic, the inter-rater reliability for the iOS apps was .86 (P<.001) and for the Android apps it was .77 (P<.001). Table 2 shows the results of the teams' scorings of the HBCT for both Android and iOS platforms.

In considering our secondary aim of comparing platforms, we found that the iOS cancer survivorship apps received higher scores across nearly all of the HBCT areas. Additionally, the iOS apps appeared to have greater functionality and appeared to include more of the HBCTs overall, per app, than the Android apps.

Table 2. Rating totals for health behavior change techniques. Each item was scored as 1=present or 0=not present. Total possible scores for each platform are 72 (2×36) for iOS apps and 64 (2×32) for Android apps based on the use of two raters for each type of app.

Techniques/Characteristics	iOS HBCT Scores (N=36)	Android HBCT Scores (N=32)
Personalization	48	24
Tailoring, macro	45	15
Tailoring, meso	8	6
Tailoring, micro	11	4
Health behavior linkage	32	32
Action/behavior consequences	21	2
Prompt for intention formation	48	10
Provide instruction	54	10
Provide materials for education	28	12
Prompt for specific goals	10	14
Review of goal activity	2	2
Self-monitoring of goals	24	13
Feedback/evaluation of goals	18	16
General persuasion	25	2
Tailored persuasion	10	0
Social influence (passive)	17	0
Social influence (active)	18	8
Social norms—opportunity for comparison to important others	8	1

Figure 1. Android and iOS app selection flow chart.



Percentages of Health Behavior Change by Category

The percentage of HBCTs for each category of both the iOS and the Android platforms is shown in Table 3. A discussion of the percentages and interpretation of the results is found in the section following Table 3.

Table 3. Category and platform percentages for health behavior characteristics. Each item was scored as 1=present or 0=not present.

Technique/Characteristic	iOS Platform, % (N=36)	Android Platform, % (N=32)	Total for Both Platforms, %
Personalization	67	38	53
Tailoring, macro	63	23	44
Tailoring, meso	11	9	10
Tailoring, micro	15	6	11
Health behavior linkage	44	50	47
Action/behavior consequences	29	3	11
Prompt for intention formation	67	16	25
Provide instruction	75	16	32
Provide materials for education	39	19	30
Prompt for specific goals	14	22	18
Review of goal activity	3	3	3
Self-monitoring of goals	33	20	27
Feedback/evaluation of goals	25	25	25
General persuasion	35	3	20
Tailored persuasion	14	0	7
Social influence (passive)	24	0	13
Social influence (active)	25	0	19
Social norms—opportunity for comparison to important others	11	2	6

Personalization in the apps includes requiring that the user log in with a username and password and was present in 67% of the iOS apps (48/72) and 38% (24/64) of the Android apps. For most of the apps, personalization enabled access to selected parts of the app and also allowed data to be entered and maintained on the app's server rather than being stored on the phone, thus providing adequate security for sensitive health information. Several apps requested specific information about the user's type of cancer and then provided meso- or micro-level tailoring regarding concerns such as types of treatment and late effects. Macro-tailoring was the most commonly found technique with 63% (45/72) for iOS and 23% (15/64) for Android. An example of personalization (Figure 2), with both macro- and meso-level tailoring, is found in the *Cancer Side Effects Helper* app developed by PearlPoint Cancer Support. The app allows users to identify the side effects they may be experiencing (eg, fatigue, dry mouth, nausea). Once a user selects a side effect, the app provides education and health behavior linkages and may also suggest specific goals or actions to reduce the identified side effect.

Scoring on health behavior linkages was indicative of the app providing basic information about cancer care and survivorship, including diagnosis, treatment, and/or availability of resources for clinical or non-clinical purposes. Based on the high scores for this HBCT on both iOS and Android apps, it appears that most of the apps, 94% (64/68), provide a basic level of health behavior information.

iOS apps had much higher scores for action/behavior consequences at 29% (21/72) as compared to the Android platform apps at 3% (19/64). Scoring for this category indicates that the app provides information or feedback on health behavior changes suggested or stimulated by the app.

The prompt for intention formation HBCT was coded as positive if the app included suggestions for general behavior or for formulating desired outcomes of a behavior for healthy survivorship (eg, maintain a healthy weight, exercise daily, stop smoking, and consider medication). The scoring of the apps indicated that iOS apps at 67% (48/72) included this technique more frequently than Android apps at 16% (10/64). This HBCT concerns the user's intent to do something and is different from taking the step to set a goal or initiate an action. Such behavioral intention is a critical motivational factor in determining whether a person actually adopts a behavior, as discussed by Ajzen [17]. An example of prompting for intent formation can be found in the *AYA Healthy Survivorship* app, an iOS app, shown in Figure 3.

The iOS app *Lymphedema Tracker*, shown in Figure 4, provides instruction on how to measure a survivor's arm to set a baseline and do ongoing measurements to track lymphedema. Following the trend, a greater percentage of the iOS apps (54/72, 75%) provided instruction on this HBCT as compared to the Android apps (10/64, 16%).

A significantly greater percentage of the iOS apps (28/72, 39%) demonstrated the provide materials for education HBCT when compared to the Android platform apps (12/64, 19%). To be

coded as positive, the material on the app had to be directly related to showing or telling the user ways to facilitate a specific health behavior change. An example of education specific to managing fatigue, a common concern for survivors and in post-treatment, is found in the iOS app *My Cancer Manager* from the Cancer Support Community (Figure 5). The app educates patients on the activity of tracking their fatigue and also instructs them to consider sharing information with a provider if the score stays persistently high. Overall the app scores for this HBCT were low at 39% (28/72) for the iOS apps and 19% (12/64) for the Android apps.

The presence of activities or information across both iOS and Android platform apps for goal-setting activities (eg, prompts for specific goals, review of goals, self-monitoring of goals, and feedback or evaluation of goals) was low overall. Examples in the area of self-monitoring of goals were suggestions found in several apps for the survivor to record brief notes or keep a diary or journal to record behaviors and actions related to health behaviors. Examples found among the apps included journals or tracking tools for pain and distress monitoring, as well as suggestions for practicing meditation. Among the iOS apps, these categories ranged from a low of 3% (2/72) for reviews of goal activity to a high of 33% (24/72) for self-monitoring of goals. Similarly, but lower still, the Android apps ranged from a low of 3% (2/64) to a high of 25% (16/64). These low scores included activities in the mHealth cancer survivor game apps for engaging in a first-person shooter cancer-destroying activity with goals for hitting targets. The user generally received feedback on scores for numbers of strikes or targets acquired. Other apps prompted goal setting via use of guided imagery suggesting that the user focus energy and concentration on specific body parts or processes affected by cancer.

The delivery of personalized or tailored messages designed to strengthen efficacy/control beliefs related to the initiation or execution of health behavior change has been heralded as an area of promise for mHealth apps. The use of mHealth persuasion in cancer survivorship apps includes activities or signaling for new beliefs and or new information. Scores in this area were low for both general and targeted persuasion. As an example, Figure 6 shows use of general persuasion that can be found in the *AYA Healthy Survivorship* iOS app that allows the user to elect to receive a "health tip of the day." The highest scores were found among the iOS apps, with a low for targeted persuasion of 14% (10/72) and a high of 35% (25/72) for general persuasion. Persuasion barely registered as an HBCT area on the Android apps with a low of zero for tailored persuasion and 3% (2/64) for general persuasion.

Social influence is an area of HBCT techniques that would appear to be a strong opportunity area for mHealth apps in cancer survivorship, given the easy access to mobile communities including Twitter, Facebook, YouTube, and numerous other cancer-related blog and social networking sites. The presence of passive social influence, where the app provides stories, anecdotes, interviews, or case histories about what other cancer survivors have done or experienced was, again, unexpectedly low. For the iOS apps, only 24% (17/72) offered access to such stories and Android apps had no scores for this HBCT. Active social influence, wherein a survivor might be invited to participate in a group or peer discussion and relay activities about their own, also was relatively low with a score of 25% (18/72) for iOS and 0 for the Android apps.

The apps were examined for examples of mobilization of social norms in which the user would be exposed to the social norms of important others in relation to a healthy survivorship activity or health behavior change. Important others could include a valued and trusted expert such as a health care professional or a celebrity cancer survivor advocate. One of the apps that uses this HBCT most effectively is the *Cancer.net* app (Figure 8), which supports RSS feeds on the app linking users to physicians and important role models. Cancer.Net was developed by the American Society of Clinical Oncology and is offered on both the iOS and Android platforms.

Cancer.net also provides the user with links for brief videos of well-respected cancer researchers and clinicians on a range of topics, including HBCTs. While this is an area of HBCT that offers easy access on mHealth apps, few of the apps reviewed in the study incorporated this potentially important element. Scores for these apps were 11% (8/72) for iOS apps and 2% (1/64) for Android apps. The evidence base for considering highly interactive mobile games and interactive game-like elements for guided imagery in apps is very limited. The potential applications of health behavior change theories in the design of game and game-like interventions are significant, ranging from elements of personalization and tailoring for scoring to goal setting, tracking and feedback, and potentially powerful elements of social interaction among game participants.

Figure 2. My PearlPoint app.

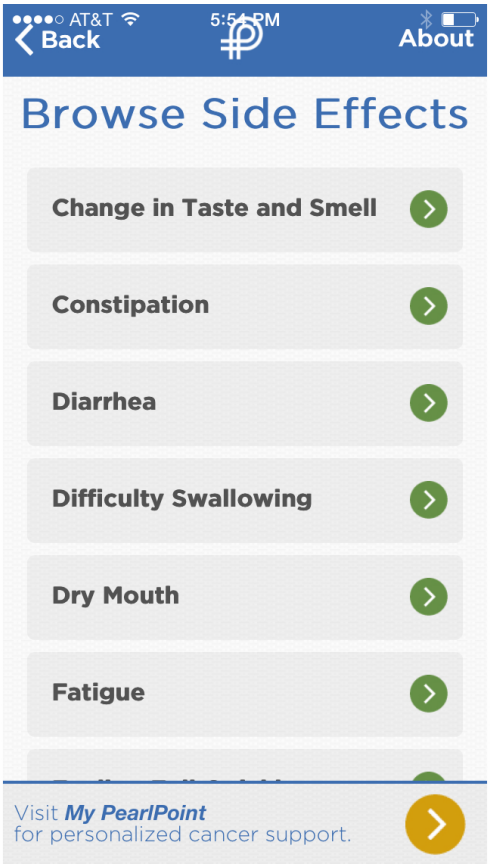


Figure 3. AYA Healthy Survivorship app: intent formation.

Figure 4. Lymphedema Tracker app.

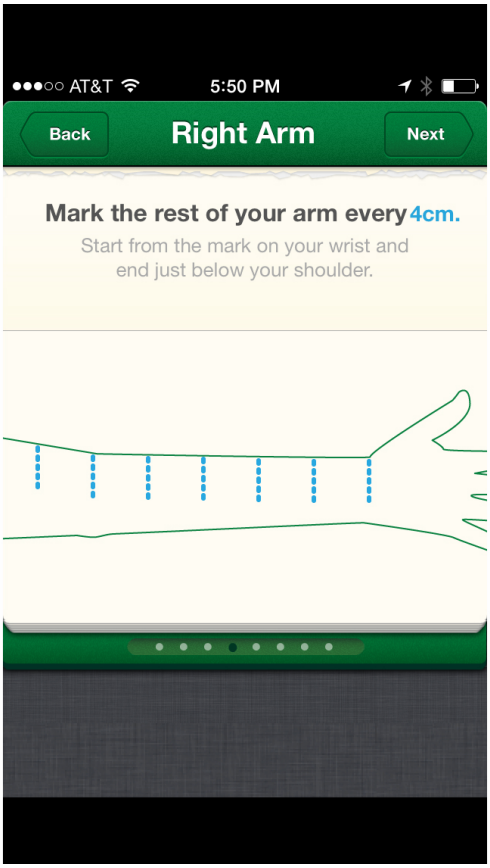


Figure 5. My Cancer Manager app.

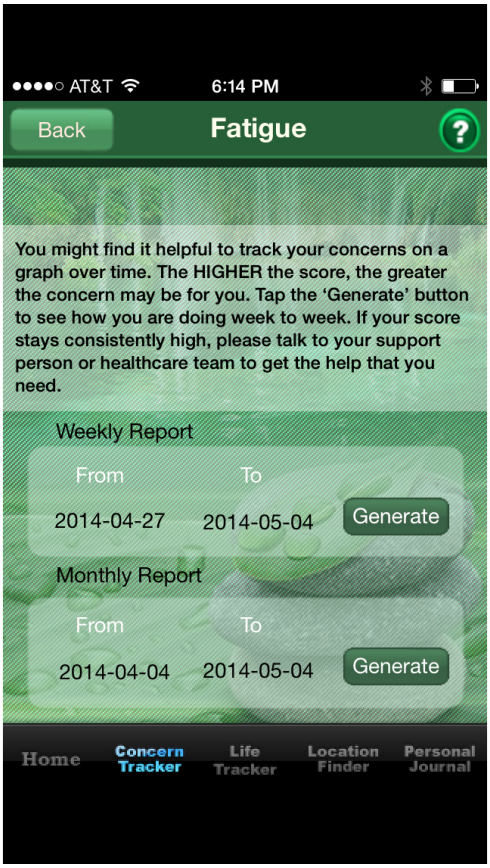


Figure 6. AYA Healthy Survivorship app: daily tip.

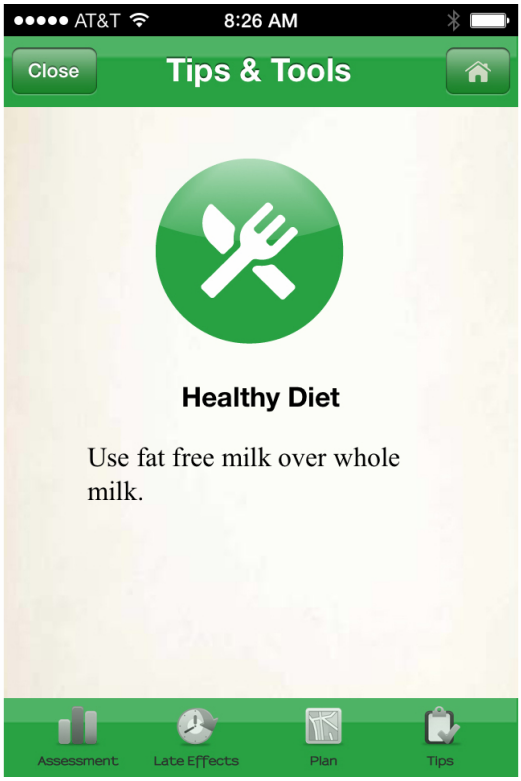
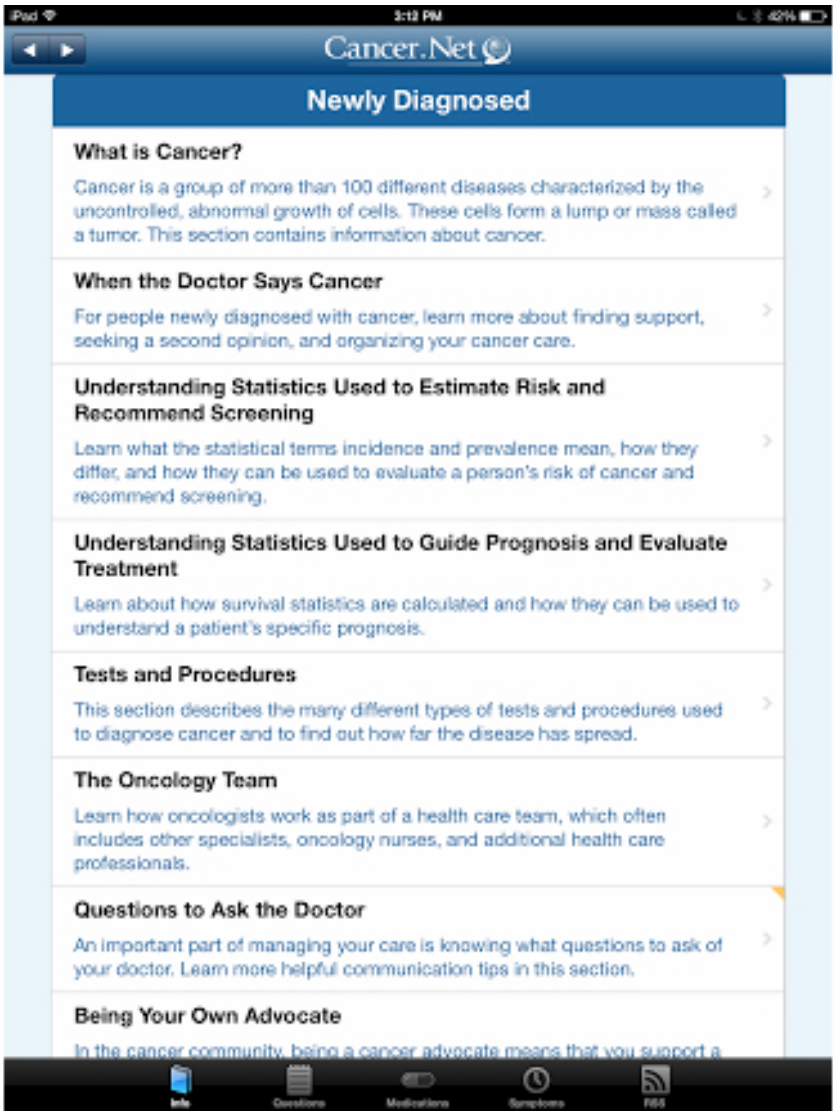


Figure 8. Re-Mission 2: Nanobot's Revenge app.

Games for Cancer Survivorship

Our team was initially optimistic about the inclusion and rating of the four iOS and Android mHealth games and interactive apps for cancer survivorship. App names such as *Cancer Fighter, Whip Cancer,* and *Play to Cure* promised much but delivered little as HBCT interventions. Few of the interactive or game apps provided even basic education or information for HBCTs. Rather, the user was launched into series of images and audio effects with opportunities to score by shooting down images on the mobile screen but offered little or no explanation about what might be of benefit to the cancer survivor. An exception was found in *Re-Mission2: Nanobot's Revenge* (Figure 7), a project of HopeLab that initiates the shooter game by explaining that the user is the Nanobot and the goal is to "fire targeted treatment at growing cancer and prevent it from escaping into the blood stream."

Figure 7. ASCO's Cancer.Net app.



Discussion

Principal Findings

A primary aim of this study was to analyze the linkage of HBCT interventions in cancer survivorship mHealth apps to theories and models that are used to predict health behavior change and communications, including those that are specific to information processing and human computer interaction such as control theory and feedback systems. The mHealth apps in this study varied greatly in how they ranked in the use of theoretical elements of health behavior change. This study's findings are consistent with prior research that asserts that mHealth interventions could benefit from increased use of behavior and communications theories in their design [10-16,20,21]. In reviewing the HBCT scores for the apps, three theories/models appeared to be most influential: SCogT, THC, and CT. However, with no explicit discussion regarding the design or development of the apps reviewed in this study, it is not clear if these theories were intentionally applied or that the design deliberately reflected a theoretical approach. Moreover, the HBCT elements were just barely present in the game apps, which made up 16% (11/68) of all coded apps.

The mHealth cancer survivorship apps that appeared to be firmly based in HBCT theory were similar in that they offered multiple types of HBCTs, required personalization and some degree of tailoring, were highly interactive, included some type of

questions or assessments, suggested goals and actions, and provided social engagement and the mobilization of social norms. Most of these examples were either developed by cancer advocacy groups, clinical associations, or academic researchers, which suggests that the information provided was more likely to be based in evidence and clinical research and health behavior theory. Examples include (1) Livestrong *Cancer Guide and Tracker* app, available only for iPad (see Figure 9); (2) *Cancer.net*, developed by the American Society of Clinical Oncology, available on iOS and Android platforms (see Figure 8) and also offers a Web-based version and one that is translated into Spanish; (3) *AYA Healthy Survivorship*, an iOS app, developed for Adolescent and Young Adult (AYA) survivors by Texas A&M School of Public Health with late effects guidelines provided by the Children's Oncology Group (see Figures 4 and 6); and (4) *My Cancer Manager* developed by the Cancer Support Community and available only as an iOS app (see Figure 5).

An area of HBCT that demonstrated weak results in the coding of the mHealth apps considered in this study but one that bears additional research consideration is the theoretical realm of social influence and social media. Cancer survivors are strongly influenced by their social ties and connections with others, and social networks can have important effects on survivor health and wellbeing [4,8,22].

Figure 9. Livestrong Cancer Guide and Tracker app.

Strengths and Limitations of This Study

The strength of this study is based in its reliance on the prior work of Abraham, Webb and Michie in defining the taxonomy and coding of behavior change techniques used in interventions and their basis in theory [9-11]. This research on mHealth cancer survivorship apps had certain limitations. The initial search and selection of cancer survivorship apps was restricted to the commercial descriptions of apps available for Microsoft, Nokia, Blackberry, Apple, and Android phones. Based on that review and the application of our criteria, we narrowed our search to the Apple App Store and Google Play. Based on input from a variety of cancer survivors, we included only unpaid apps, although we did examine the paid apps to see if they appeared to include greater HBCT in their design. They did not. The search results for this study were dependent on the terms included in the search strategy and the functionality of the search engines used. We attempted to overcome the search limitation by choosing common terms and combinations of terms, including those we found in literature reviews of cancer care and cancer survivorship. We considered only apps that were in English. Moreover, we only considered apps that were focused on cancer and included the word cancer in the title or the description. It is possible that we missed apps that include cancer care and survivorship in addition to other chronic diseases.

Future Directions in App Development

Clearly, the taxonomy provided in this research for mHealth cancer apps is not exhaustive, and additional theories and models across different behavioral change techniques should be defined. As the more highly rated apps in our study offered multiple HBCT techniques, it may be beneficial to design a study that takes into account the interaction across multiple HBCT aspects. It may also be helpful to explore the differences in use, HBCT efficacy, and persistence on the device for single purpose apps for specific survivorship concerns in comparison to apps that offer multiple types of HBCT elements. Research and exploration into the theories and models relevant to interactive apps, mobile games, and the use of sensors in mHealth is timely and needed.

An article by Tomlinson et al further articulates concerns about both the lack of evidence and theory in mHealth and how theory, when referenced, is actually applied. Tomlinson's article addresses use of mHealth primarily in lesser-developed and under- resourced countries but raises concerns about level of evidence and generalizability of mHealth apps [23]. A World Health Organization report by Kay and associates that tracked over 500 mHealth pilot studies reported that very little is known about likely uptake, best strategies for engagement, efficacy, or effectiveness of these initiatives [24]. Kay and colleagues' review of mHealth interventions suggests that the apps they reviewed lacked both theoretical foundations and evidence sufficient to support an evidence-based scale-up. The most recent systematic review on mHealth for health behavior change by Free et al was not able to identify the theoretical basis for the research studies reviewed [22]. Both reviews confirm that there is mixed evidence for the effectiveness of health intervention delivery to health care consumers using mobile technologies. Moreover, both reviews' conclusions highlighted the need for additional high-quality controlled trials of mHealth apps. These findings regarding the potential for use of theory support a call for mHealth intervention designers to reflect more deeply and extensively on the application of theoretical models and frameworks in the design and development of mobile HBCT apps.

Conclusions

The study provides a framework for future research and contributes to the emerging science of mHealth interventions for behavior change. The findings suggest a strong rationale for investing the time and diligence into more rigorous theory-based mHealth interventions that may incorporate, as did the apps reviewed, multiple levels and types of health behavior change strategies and techniques. Similarly, our results reinforce the need for carefully constructed studies to measure the effect and impact of mHealth interventions.

Our findings contribute to behavioral health literature and health policy initiatives by demonstrating that mHealth intervention design needs stronger theoretical and evidence-based underpinning. The field of research on mHealth interventions for behavior change is rapidly shifting with new technologies and systems for sensors, big data analytics, and opportunities for more patient-centric health care. The integration of apps with mobile hardware, including sensors, and electronic medical records is rapidly emerging as evidenced by the ongoing announcements of such integrated solutions. While the promise of interoperability of apps, sensors, and clinical data will soon be a reality, what is missing is the understanding of how this will translate into benefits to users with chronic medical conditions, such as cancer survivors. What is also missing is how, where, and when clinicians will access and use this data to educate, inform, and offer improved opportunities for health and wellness to their patients.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Survivorship App Coding Manual.

[PDF File (Adobe PDF File), 23KB - mhealth_v3i1e31_app1.pdf]

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Abbreviations

CT: control theory
ELM: elaboration likelihood model
HBCT: health behavior change techniques
IMB: information-motivation-behavioral skills model
OC: operant conditioning
SC: social comparison
SS: social support
SCogT: social cognitive theory
THC: tailored health communications

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Original Paper

Don't Forget the Doctor: Gastroenterologists' Preferences on the Development of mHealth Tools for Inflammatory Bowel Disease

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Abstract

Background: Inflammatory bowel disease (IBD) encompasses a number of disorders of the gastrointestinal tract. Treatment for IBD is lifelong and complex, and the majority of IBD patients seek information on the Internet. However, research has found existing digital resources to be of questionable quality and that patients find content lacking. Gastroenterologists are frontline sources of information for North American IBD patients, but their opinions and preferences for digital content, design, and utility have not been investigated. The purpose of this study is to systematically explore gastroenterologists' perceptions of, and design preferences for, mHealth tools.

Objective: Our goal was to critically assess these issues and elicit expert feedback by seeking consensus with Canadian gastroenterologists.

Methods: Using a qualitative approach, a closed meeting with 7 gastroenterologists was audio recorded and field notes taken. To synthesize results, an anonymous questionnaire was collected at the end of the session. Participant-led discussion themes included methodological approaches to non-adherence, concordance, patient-centricity, and attributes of digital tools that would be actively supported and promoted.

Results: Survey results indicated that 4 of the 7 gastroenterologists had experienced patients bringing digital resources to a visit, but 5 found digital patient resources to be inaccurate or irrelevant. All participants agreed that digital tools were of increasing importance and could be leveraged to aid in consultations and save time. When asked to assess digital attributes that they would be confident to refer patients to, all seven indicated that the inclusion of evidence-based facts were of greatest importance. Patient peer-support networks were deemed an asset but only if closely monitored by experts. When asked about interventions, nearly all (6/7) preferred tools that addressed a mix of compliance and concordance, and only one supported the development of tools that focused on compliance. Participants confirmed that they would actively refer patients and other physicians to digital resources. However, while a number of digital IBD tools exist, gastroenterologists would be reluctant to endorse them.

Conclusions: Gastroenterologists appear eager to use digital resources that they believe benefit the physician-patient relationship, but despite the trend of patient-centric tools that focus on concordance (shared decision making and enlightened communication between patients and their health care providers), they would prefer digital tools that highlight compliance (patient following orders). This concordance gap highlights an issue of disparity in digital health: patients may not use tools that physicians promote, and physicians may not endorse tools that patients will use. Further research investigating the concordance gap, and tensions between physician preferences and patient needs, is required.

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KEYWORDS

mHealth; adherence; concordance; compliance; shared decision making; therapeutic alliance; gastroenterology; IBD; ulcerative colitis

Introduction

Background

Inflammatory bowel disease (IBD) encompasses a number of disorders of the gastrointestinal tract, which are usually classified as Crohn's disease (CD) or ulcerative colitis (UC). IBD is widespread, and it is estimated that as many as 2.2 million Europeans and 1.4 million Americans suffer from IBD [1]. With approximately 0.7% of the Canadian population diagnosed with the disease, Canada has one of the highest rates of IBD in the world [2,3].

Environmental, genetic, and intestinal microbial factors contribute to the chronic nature of the disease, which requires continuous medical treatment and frequent outpatient visits. However, effective treatment is available [4-6], and patients who do not take their medication have a five-fold risk of relapse than those who are adherent [7]. Despite the availability of treatment, there have been increases in hospitalizations for IBD, with significant economic costs [8,9], yet specific factors related to non-adherence in immunology are largely unknown [10].

As in other conditions, medication non-adherence in IBD is often noted as a cause of relapse and increased health care burden. For example, while adherence resulted in shorter hospital length of stay and lower inpatient costs among CD patients in one study [11], another discovered that when compared to adherent UC patients, those who were non-adherent incurred twice the inpatient costs and significantly higher health care costs [12].

As treatment for IBD is lifelong and variable, accurate patient education is critical. A recent survey found that the majority of IBD patients seek information on the Internet, but that information is of questionable quality [13]. In another US-based IBD clinic, it was found that over half of patients used the Internet to gather information, and Web-based resources ranked closely behind obtaining information from patients' gastroenterologists [14]. A third study found that the quality of websites containing information on IBD varied widely, with most material being too difficult for patients to comprehend [15].

IBD experts generally agree that digital tools are a major resource for patients, but it is difficult for patients to determine which sites are accurate. While some resources may assist physicians, others may promote dangerous misunderstandings and misconceptions [16].

Successful digital tools require needs assessment of not only patients, but physicians who "prescribe" them. Achieving expert support and collaboration will be required to meet all stakeholder needs, and tool design needs to be strategic and based on theory. Design factors from the perspective of prescribing physicians have yet to be explored, and this paper is the first step in addressing that gap.

Terminology and Definitions

Lack of medication adherence is a well-known, systemic issue in health care. However, despite decades of research into non-adherence, terminology describing the common phenomenon of patients not taking medication as directed remains inconsistent [17,18]. To complicate the matter, there is no consensual standard for what constitutes adherence or non-adherence, even within serious conditions [19]. For clarity, adherence definitions reported in recent immunology research are reproduced here.

Medication Adherence

Patients are generally considered adherent if they take >80% of their prescribed dose regimen (prescribed time and dose) [7,17,20]. Studies estimate that in IBD, non-adherence rates vary from 40-60% [21-24]; however, some studies have shown non-adherence to be as high as 72% [20,25]. Following dose regimen is the responsibility of the patient, and the vast majority of IBD literature largely describes medication adherence as inadequate.

Unintentional and Intentional Non-Adherence

Medication non-adherence is generally defined as "intentional" or "unintentional" [26-28]; however, "voluntary" or "involuntary" is also referred to in the literature. Intentional non-adherence occurs when patients purposely do not take their medication. Examples are patients taking a drug holiday, purposefully avoiding side effects, lack of perceived need or benefit, or avoidance of other factors. Unintentional non-adherence occurs when patients do not take their medication due to forgetfulness, poor comprehension, cost, inconvenience, or other factors attributed to busy lifestyles, work, or family commitments. Especially in IBD where treatment is complex, a patient's relationship with medicine is often based on their individual beliefs and behaviors [29].

Compliance

The terms "adherence" and "compliance" are often interchanged, however, they are very different constructs. Patients are compliant if they follow their doctor's orders and act in accordance with dosing regimen [30]. Compliance is generally regarded as a negative term as it implies a paternalistic relationship, submission to authority, and a situation where the patient is a passive observer with no control [31].

Concordance

"Concordance" is the newly accepted term replacing adherence and compliance. Concordance implies shared decision making and enlightened communication between patients and their health care providers, leading to an agreed treatment protocol [32].

Patient-Centric Models of Care

A patient-centric model of care is a holistic approach that focuses on patients' feelings about being ill, their ideas about what is wrong with them, the impact on their daily functioning, and expectations of treatment [33,34]. Shared decision making is an important part of the patient-centric model; however, medication concordance and prescribing occurs only after health professionals have a thorough understanding of environmental determinants surrounding the patient [35]. Calibration of medication can occur only in follow-up appointments where issues like dose regimen, side effects, and other issues can be empirically explored. Research indicates that digital applications can be designed to enable concordance among physicians, patients, and families to ensure that procedures and decisions follow individual patient need [36].

IBD and Digital Treatment Programs

Compared to other chronic conditions, limited research has been conducted on IBD treatment through the Internet or mobile phone [37]. A reason for this may be attributed to the complexity and variability of the disease.

The majority of Web-based research has focused on irritable bowel syndrome (IBS). Several randomized controlled trials on IBS Web programs have shown effectiveness [38-40], however, IBS is a far less severe disorder that does not cause inflammation, ulcers, or other permanent damage to the bowel [41].

To date, two digital interventions for IBD have shown some promise. The first is an American intervention, which used a laptop and a device (Home Telemanagement Device). At 6-month follow-up, improvements in quality of life (QoL) and patient knowledge were found [42], but at 1-year follow-up the intervention proved to be ineffective [43].

The second, a European program (Constant Care) has shown promise for UC patients in Denmark and Ireland. At 1-year follow-up, there were noted improvements in QoL, patient knowledge, and decreased number of acute and routine visits [44]. However, the program is multifaceted and requires intensive participation by a number of stakeholders. Offering the program on a population level may require a reshaping of the health care system for IBD patients both legally and economically [45], and it is unknown if the program would work in a North American setting.

Objectives

Gastroenterologists are the most common sources of information for IBD patients in North America [19]. The opinions and preferences of gastroenterologists on the utility of digital resources have not been examined, especially in a Canadian context.

To critically assess these issues and elicit feedback from experts, consensus was sought in a closed meeting among 7 Canadian gastroenterologists. The session included addressing past experiences with digital resources designed to improve medication adherence, attributes of digital tools that could benefit the physician-patient relationship, and the completion of a 12-item questionnaire (see Multimedia Appendix 1).

As the gastroenterologists in the study hold teaching positions, their insights and preferences are regularly disseminated to practitioners. Given the relatively small population of Canada, the gastroenterologists in this study have the potential to impact the gastroenterological community. As such, research questions were specifically formulated to investigate their specific views and needs:

RQ1. For the field of gastroenterology, what methodological approach to adherence should be used in the creation of digital devices?

RQ2. What attributes of digital tools will be supported by gastroenterologists?

RQ3. To create value in daily practice, how should digital tools be positioned to gastroenterologists, family physicians, and other professional stakeholders?

Methods

In November 2013, 7 Canadian gastroenterologists participated in a 1-day Scientific Advisory Board meeting in Toronto, Ontario, which was sponsored by Ferring Pharmaceuticals Inc. (Canada). Discussion largely focused on medication non-adherence in Canadian IBD patients. Gastroenterologists were paid an honorarium for their participation, were made aware that the discussion was recorded and were advised that anonymized results may be used in an academic study.

The gastroenterology community in Canada is quite small; in 2007, it consisted of approximately 550 practicing gastroenterologists or internists [46]. As 5-8 participants are generally considered sufficient for an exploratory study with a homogeneous group [47-49], this convenience sample was a rare opportunity to collect insights from subject-matter experts in significant leadership positions.

Although gastroenterologists received a meeting agenda, the three research questions were not disclosed, as a primary concern was that their disclosure would shift discussions toward intervention design. The intention of the focus group was to allow gastroenterologists to freely explore, among each other, their perceptions of existing digital tools and how efficacious tools could be positioned. The discussion was also used as a means to position questionnaire content.

Facilitators strategically introduced links between non-adherence and digital tools several times during the meeting, and audio transcripts recorded discussions. At the onset of the meeting, gastroenterologists were advised that an anonymous follow-up questionnaire would be disseminated, and results would be collected, analyzed, and disseminated.

The questionnaire was based on existing peer-reviewed studies where survey instruments were designed to assess the impact of digital health information on the patient-physician relationship [50-52]. The 12-item questionnaire focused on medication non-adherence (three items plus one open-ended question) and perceived patient use of digital resources and physician need (seven items plus one open-ended question).

The Consolidated Criteria for Reporting Qualitative Research (COREQ) was used to describe the focus group process (Multimedia Appendix 2) [10]. Descriptive statistics were analyzed in SPSS version 19 for Mac.

Results

Themes

Themes emerging from gastroenterologists' discussions centered on the pervasiveness of non-adherence, how shared decision making should be positioned, and the thematic nature of digital tools that can assist in communicating with patients (see Table 1).

Methodological Approach to Addressing Non-Adherence With Patients

In the questionnaire, gastroenterologists were asked to rate the impact of non-adherence on a scale of 1-9, with 1 being not a factor and 9 being extremely important. Almost all (6/7) indicated that non-adherence was a barrier to treatment, with a median score of 6. On the questionnaire, one gastroenterologist noted that medication non-adherence was not a barrier in active disease, and another that non-adherence is higher in rectal therapies, especially enemas.

The 7 gastroenterologists were asked if voluntary or involuntary non-adherence was more challenging to address, or if both were weighed equally; 2 gastroenterologists indicated voluntary, 3 indicated involuntary, and 2 weighed both types of non-adherence as equally challenging to address.

When asked about patient interventions, almost all (6/7) would prefer digital tools that addressed a mix of compliance and concordance, and only one gastroenterologist supported the development of tools that focused on compliance. No gastroenterologists endorsed tools that only centered on concordance.

In the discussion, gastroenterologists expressed the difference between results in randomized controlled trials (RCT) and real-world settings, with compliance rates much higher in RCTs than in actual practice. Denial, or patients not accepting the diagnosis of IBD, was also identified as an issue.

Gastroenterologists noted that digital tools might be used only by patients who are already adherent, and those who are non-adherent may also be non-adherent with digital tool usage. Gastroenterologists were also forthright and generally agreed that patient focus groups could provide unique insights in digital tool criteria that gastroenterologists were not in a position to offer.

Assessment of Existing Digital Tools

Over half of the gastroenterologists (4/7) reported that patients brought digital resources to a visit; 5 found them to be inaccurate and irrelevant, but 4 regularly refer their patients to specific resources.

Gastroenterologists generally agreed that what is missing is a respectable digital resource that is fact-based but not overly commercial. A gap identified is the apparent lack of peer-to-peer support tools that have been successfully utilized in other conditions, and that this type of interaction could be especially beneficial for younger people. However, this type of resource would need to be moderated by experts or other health care professionals with specific knowledge in the field.

Table 1. Gastroenterologist opinions on non-adherence, shared decision making, and digital assets.

Theme	Research question	Representative quotations
Non-adherence and shared decision making	RQ1	Patients don't really care about full remission. They care about going from 20 to five bowel movements a day.
	RQ2, RQ3	That's the problem. Everyone is compliant in the study [Randomized Controlled Trials]. You need real world data [which can be collected through digital tool usage data].
	RQ1	I think IBD takes a long time to get to grips with. If you have a heart attack, you can deal with it right away mentally. IBD in my practice takes months or years to accommodate and really understand. Young males are the worst. They take a decade to deal.
	RQ1	I think we should be concentrating equally on what the patient wants: a response as much as a remission rate. That's going to give you a different set of numbers.
	RQ3	Gastroenterologist 1: Another factor with the younger patient is the rapport with the physician. That's extremely important. How they connect. In other words, education for the physicians. Gastroenterologist 2: How do you achieve that in seven minutes?
	RQ2, RQ3	This is a huge thing [digital tools targeting non-adherence in IBD]. This is very, very ambitious. What's to say that patients who have adherence problems aren't going to have problems adhering to the [digital] program? It will always come back to the physician…you say you're trying to offload the physician so there's less work. But you're talking about motivating the patient to become adherent, but that has to come via some sort of interaction. And usually, the best sort of interaction is in the physician's office. If patients are going to be involved in this, then I think physicians have to be involved.
	RQ2, RQ3	I think also what you haven't done as yet is that you need to have multiple patient focus groups to get their insight and to select people who would meet your non-adherent patient criteria. If you can ask them and get their feedback, they will provide data and insight that we [gastroenterologists] can't offer…
Digital solutions for IBD		...tools are important. I'm more and more convinced that effective visual tools are the way to get them [patients] to do what you want, with me having to do less verbiage.
	RQ3, RQ1	It's been done [Internet sites for IBD]. People have tried this…focusing on lifestyle modification. It looks good and when you think about it…but no one actually does [uses the program]. So I know from experience: I don't actually use this great site!
	RQ3	We have all these disparate [Internet] tools, some bad—some great, that we don't use. I don't know how to bring those together in a better format.
	RQ3	I'm trying to teach them [patients] how to use it [enemas]. That's why I'm using the YouTube video. If you take someone who's 20, and say "here take this enema", it spills on their sheets, it's messy, it's painful…A good cartoon, showing how to lay down, how to put a towel under yourself in case it leaks, and so on…that's where practical things would be really valuable.
	RQ2, RQ3	I think you need to show that it's a respectable site, and not commercial. There's a plethora of info out there; you don't want to just repeat it. We have sites already; you go on with a DIN number...and you navigate through that. Ideally, it would be best to go through a third party...You know you're going to the right place.
	RQ1, RQ3	Gastroenterologist 1: What percentage of your patients spend time on the Internet? Gastroenterologist 2: 60% Gastroenterologist 3: I'd say 80%. They don't want to have the disease. They don't want IBD. The 20 year olds are wanting to ignore the disease. Gastroenterologist 4: They think you're wrong. They don't think they have it [IBD]. Gastroenterologist 1: It used to be a small number. Now it's almost everybody. ...if you start something like this [community-based digital tool], and you get everybody on board and excited, and the program peters out a year down the line, you have to be certain that you can keep the commitment. I think you're on the right track [with digital tools targeting non-adherence]. The apps are so incredibly important these days...I equate it to this: if the patients have access to all that information, the challenge is how to keep that alive. How does that not fizzle out? A lot of sites have had a big fanfare, only to fizzle out. About peer-to-peer support, there's always something lacking in young people and their ability to interact with peers with similar circumstances…that can work two ways, a crowd mentality can turn against you. Still, it's something that's never quite been there for IBD patients. I think we've [gastroenterologists] underutilized other health care professionals, like nurses, who could actually dialogue [on the Internet] with patients and could answer some of those ongoing questions and be that mother/father person on the site who is giving them that right information. We just don't utilize that.

Characteristics of Digital Tools: Content Type, Endorsement

All 7 gastroenterologists indicated that digital resources could benefit the physician-patient relationship, and 4 found that current digital resources did not increase their workload and patient misconceptions.

Gastroenterologists were asked which attributes of digital tools would increase their comfort level in regards to patient referral. All of them indicated that the inclusion of evidence-based facts was of extreme importance. None endorsed the inclusion of standardized text, and 4 wished to see patient-centric tools (see Table 2).

The 7 gastroenterologists were also asked to consider the importance of the source of the digital tool: 4 indicated that professional association or non-profit agency endorsement was important, and only 2 noted that publishing results from interventions was important. The one respondent who answered "other" indicated in the development of digital tools, endorsement by gastroenterologists was important.

A discussion ensued regarding patient Internet access. While one gastroenterologist felt that 60% of patients spent time on the Internet, another believed that the number was close to 80%, and a third remarked, "now it's almost everybody".

Gastroenterologists generally agreed that digital tools were important and could simultaneously help patients, aid in consultation, and save time. While a number of IBD digital resources exist, none has yet synthesized patient and expert need. Helpful resources may include practical information presented in visual format, such as videos explaining how to properly administer enemas. However, content would need to be continually refreshed and updated. See Table 3 for the summarized responses to our research questions.

Table 2. Gastroenterologist responses to survey question (N=7).

Question: If you were comfortable referring patients to a digital tool, which attributes would you support (select all that apply)?	Recommended, % (n)
Standardized test (eg, product monographs)	0 (0)
Patient-centric tools	57 (4)
Professional association or non-profit agency endorsement	57 (4)
Evidence-based facts	100 (7)
Published within the literature	29 (2)
Other	14 (1)

Table 3. Answers to research questions.

Research question	Answer
What methodological approach to adherence should be used in the creation of digital devices that will be used by gastroenterologists?	A mix of compliance and concordance, weighted toward compliance.
What attributes of digital tools will be supported by gastroenterologists?	Evidence-based facts and patient-centric tools. Endorsement by professional associations would be a benefit.
To create value in daily practice, how should digital tools be positioned to gastroenterologists, family physicians and other professional stakeholders?	Gastroenterologists will refer patients to tools that clearly explain IBD, how it effects patients differently, and the importance of medication maintenance.

Discussion

Principal Findings

Based on the qualitative approach and questionnaire results, specific content themes and design strategies emerged.

A Concordance Gap

Six gastroenterologists preferred tools that contained a mix of both compliance and concordance, and one supported interventions that focused on compliance. Given the general trend toward patient-centricity and shared decision making in medicine, it may be surprising to see that none of the gastroenterologists endorsed the creation of digital interventions that focus on concordance.

However, this focus on compliance may not be surprising when considering complexity of IBD, the variability in an individual's course of disease, and the fact that IBD cannot be cured. In IBD, diversions from prescribed dose regimen will most likely result in disease flare. Given that IBD is a disabling condition, patients may confuse feeling better with remission, so consistency of physician recommended dose regimen is most likely key to maintaining healthy outcomes.

The Root of Non-Adherence

The impact of non-adherence and the need for compliance can be seen in other data. For example, the questionnaire asked gastroenterologists to rate how much of a barrier to treatment non-adherence was on a scale of 1-9 (with 1 being not a factor and 9 being extremely important), and the median score was 6. As one gastroenterologist notes, medication non-adherence is not a barrier in active disease. In the discussion, barriers such as denial and inability to administer medication (enemas, especially among young adults) was seen as a greater challenge.

From questionnaire data, voluntary and involuntary non-adherence are equally important and digital interventions need to focus on both. Further research may explore whether voluntary or involuntary non-adherence is prevalent in different demographics or specific stages of disease.

Shared Decision Making

All gastroenterologists supported digital tools that benefit the physician-patient relationship (the Therapeutic Alliance) through shared decision making. This may contradict their focus on compliance, which is a paternalistic approach. However, from discussions it becomes clear that a main cause of non-adherence is rooted in negative patient beliefs and issues such as denial and embarrassment. As such, traditional tools such as diaries and medication trackers, which have not proven successful for gastroenterologists or their patients, are not a priority.

Information Gap

The theme of non-adherence and patient beliefs is also reflected in gastroenterologists identifying the need for evidence-based tools that do not contain standardized text (eg, medical themed). Clearly, IBD is a personal disease and digital content should not be overly formal. However, in the questionnaire patient-centricity was only somewhat important (4/7). Such heterogeneous results can be difficult to interpret or draw broad conclusions. In discussions, gastroenterologists did note that patient focus groups could provide data and insights that gastroenterologists could not provide.

Current State of Digital Tools

As mentioned previously, current research indicates that the vast amount of IBD information on the Internet is questionable and too complex for the average patient [13-15]. This was confirmed in our study. Most digital information brought to the gastroenterologists by patients was seen as inaccurate (5/7). However, 4 gastroenterologists regularly refer their patients to specific resources and as mentioned previously, all believe that digital resources have the potential to improve the physician-patient relationship.

Future Directions

Based on the insights from this Canadian study, current digital interventions in IBD are not meeting professional needs. Clearly, patients can benefit from learning the importance of adherence during all phases of disease, and the information must be presented in a clear, evidence-based format free from standard medical jargon.

Gastroenterologists appear to welcome the opportunity to refer patients to resources that promote dialogue that can facilitate shared decision making, provided that patients are provided with information that clearly outlines consequences related to medication non-adherence.

Strengths and Limitations

The opportunity to engage with top Canadian gastroenterologists in a setting where facilitators encourage the free flow of ideas, personal experiences, and idea generation is rare. To our knowledge, this is the first study where a cohort of top Canadian gastroenterologists systematically explored their perceptions of, and needs for, digital tools.

The qualitative approach and the introduction of digital tools and adherence at specific intervals throughout the meeting formulated an environment where the research questions were indirectly addressed. The use of the brief 12-item questionnaire at the end of the session was also strategic as it was designed to seek individual gastroenterologist opinion after engagement with peers, and not a consensus. The questionnaire (Multimedia Appendix 1) is not IBD specific and can be used to explore the views of experts in other conditions.

All 7 gastroenterologists were Canadian academics and practitioners and represented several provinces and research centers. Results and outcomes are uniquely Canadian and may not be applicable to other geographic areas. For example, Canada's Medicare system is provincially administered, and approximately 70% is publically funded while 30% comes from private sources [53]. Results from the American and Danish/Irish interventions described earlier may not be replicable in a Canadian setting, and digital interventions may need to be specifically developed for different health care settings and funding systems.

Conclusions

According to Canadian gastroenterologists, they are eager to use digital resources that benefit the physician-patient relationship; however, current resources are largely inaccurate and unreliable.

Based on insights generated from the qualitative session and results from the questionnaire, gastroenterologists would prefer digital tools that focus on the importance of medication compliance and address both voluntary and involuntary non-adherence. Tools should be evidence-based, but patient-centric in that content is comprehensive and written in plain language (see Table 3).

Despite the trend of patient-centric tools that focus on concordance, gastroenterologists in this study would prefer digital tools that highlight compliance.

While this study gives insights into the needs and preferences of Canadian gastroenterologists, it does not address the needs and preferences of IBD patients. The results highlight the issue of disparity in digital health: patients may not use tools that physicians promote, and physicians may not endorse tools that patients need.

If digital tools are to be used, they need to be embraced by patients, their physicians, gastroenterologists, family members, and other health care stakeholders. Further research investigating concordance, and the digital gap between physician preferences and patient needs, is required.

Conflicts of Interest

This study was commissioned by Ferring Pharmaceuticals Canada, which manufactures Pentasa, a 5-ASA medication used in the treatment of IBD. Mr van Mierlo and Ms Fournier are employees of Evolution Health Systems Inc., a research and development organization that develops digital tools designed to increase medication and treatment adherence. Dr Fedorak is a member of Ferring Pharmaceutical's Advisory Board.

Multimedia Appendix 1

Gastroenterologist survey.

[PDF File (Adobe PDF File), 8KB - mhealth_v3i1e5_app1.pdf]

Multimedia Appendix 2

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist.

[PDF File (Adobe PDF File), 8KB - mhealth_v3i1e5_app2.pdf]

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Abbreviations

IBD: inflammatory bowel disease
QoL: quality of life
RCT: randomized controlled trial

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Original Paper

Diet App Use by Sports Dietitians: A Survey in Five Countries

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Abstract

Background: Despite the hundreds of diet apps available for use on smartphones (mobile phones), no studies have examined their use as tools for dietary assessment and tracking in sports nutrition.

Objective: The aim is to examine the prevalence and perceptions of using smartphone diet apps for dietary assessment and tracking among sports dietitians.

Methods: A cross-sectional online survey to examine the use and perception of diet apps was developed and distributed to sports dietitians in Australia, Canada, New Zealand, the United Kingdom, and the United States (US).

Results: The overall response rate from the 1709 sports dietitians invited to participate was 10.3% (n=180). diet apps were used by 32.4% (57/176) of sports dietitians to assess and track the dietary intake of athletes. Sports dietitians from the US were more likely to use smartphone diet apps than sports dietitians from other countries (OR=5.61, 95% CI 1.84-17.08, *P*=.002). Sports dietitians used 28 different diet apps, with 56% (32/57) choosing MyFitnessPal. Overall, sports dietitians held a positive perception of smartphone diet apps, with the majority of respondents viewing diet apps as “better” (25/53, 47%) or “equivalent” (22/53, 41%) when compared with traditional dietary assessment methods.

Conclusions: Nearly one-third of sports dietitians used mobile phone diet apps in sports nutrition practice, and viewed them as useful in helping to assess and track the dietary intake of athletes.

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KEYWORDS

nutritional requirements; nutrition assessment; dietary self-monitoring; mobile apps; questionnaire; telemedicine; sports nutritional sciences

Introduction

Dietitians are experts in nutrition and work in all sectors of health [1]. Sports dietitians advise athletes on appropriate and effective nutrition for health, physical activity, and athletic performance [2]. Sports nutrition is prescriptive, with nutrition recommendations set as grams of macronutrients (such as protein, carbohydrates, and fat) per day based on an athlete’s characteristics [2]. This makes sports nutrition a field that benefits from the quantitative assessment of energy and nutrient intakes.

A core practice of sports dietitians is to assess dietary intake by examining the composition and adequacy of food and nutrients usually consumed by an athlete. However, accurate dietary assessment using traditional methods (such as a diet record recorded with pen and paper) is challenging as people tend to misreport the type and amount of food consumed, either because of memory lapse, social desirability bias, incorrect estimation of portion size, or lack of knowledge of the content of meals.

Additionally, people may alter their usual food and fluid intake to ease recording [3-5]. Furthermore, traditional methods require dietitians to convert food intake to nutrient intake, which can be labour-intensive and prone to error [6].

Sports dietitians also ask athletes to track or monitor their dietary intake after implementing nutrition advice, in order to evaluate the effect and adherence to prescribed dietary recommendations [7]. Interestingly, an additional benefit of tracking dietary intake is that this behavior may increase an athlete's adherence to nutrition recommendations, as dietary self-monitoring has been shown to result in greater achievement of nutrition and body composition goals [8-11].

The emergence of smartphone (mobile phone) technology and diet apps has expanded the tools available to sports dietitians to assess and track dietary intake. Diet apps on smartphones allow recording of food intake, which is instantly converted to nutrient intake and compared with calculated nutrition goals. Nutrition goals are calculated based on a diet app user's sex, weight, weight goals, and activity level. Food entries and weight progress can be shared with a dietitian in real time [12].

Studies examining the validity of diet apps on personal digital assistants (PDAs) have shown them to be as valid as traditional dietary assessment methods [13,14], however whether this also applies to use on smartphones is not well established. To date, only one study has examined the validity of a data-based smartphone diet app, and found that the diet app correlated highly with 24-hour recalls (a traditional dietary assessment method) for estimating group means of energy and macronutrient intakes, but showed wide limits of agreement with individual energy intakes [15]. These results suggest that the specific diet app tested may not be valid for assessing individual dietary intake, however whether this apply to other diet apps is untested.

Regardless of their uncertain validity, smartphone diet apps have become prolific in app stores [12] and popular among people seeking dietetic advice [16]. Despite their popularity, no studies have examined their use as tools for dietary assessing and tracking in sports nutrition. Therefore, we conducted an international survey with the aim of examining prevalence and perception of using smartphone diet apps for dietary assessment and tracking among sports dietitians.

Methods

Overview

A cross-sectional online survey to assess smartphone diet app use in sports dietetics was developed and distributed electronically between June 22 and November 11, 2012, to sports dietitians in Australia, Canada, New Zealand, the United Kingdom (UK), and the United States (US). We selected English-speaking countries that had known sports dietetic associations. An administrator from each dietetic association sent a series of emails to their members to invite them to participate in our survey. We chose to survey registered sports dietitians, as their registration guarantees academic and professional qualification in nutrition [1,17]. Ethical approval was obtained from the University of Otago Ethics Committee.

Survey Design and Administration

Survey questions were initially developed by reviewing the literature on technological advancements in dietary assessment and tracking, and by pilot interviews of two registered sports dietitians, conducted in March 2012. Semi-structured interviews lasted one hour each and included the following topics: methods of dietary assessment and tracking in sports dietetics, barriers in assessing and tracking dietary intake of athletes, and benefits and limitations of using smartphone diet apps. The interviews were recorded (with Philips Voice Tracer digital recorder lfh0622), transcribed, and analyzed.

The resulting questionnaire (Multimedia Appendix 1) asked sports dietitians about their use of smartphone diet apps in assessing and tracking dietary intake of athletes, dietary assessment and nutrition intervention in sports dietetics, and demographic information. The questionnaire was refined based on recommendations from survey design best practices [18-21], and from pretesting with a convenience sample of seven people, consisting of a sports dietitian, a clinical dietitian, a sports nutritionist, a clinical psychologist, a biostatistician, and two second-year Master of Dietetics students. The purpose of pretesting was to determine whether the questionnaire was clear, concise, and user-friendly. Amendments included: changing "tick all that apply" questions to forced-choice, dichotomous questions (eg, yes or no); reordering questions to ensure that the most important questions were asked at the start of the survey; adjusting wording to increase comprehension; and adding multiple-choice answers to cover a wider range of possible responses.

Skip logic, which is also known as "adaptive questioning", was employed to direct respondents through different paths in the questionnaire based on their answers. The questionnaire included a total of 27 questions. Depending on the respondent's answers, the number of questions presented ranged from 13 to 26. Of the questions, 9 required an answer before the respondent could proceed to the next page. The questionnaire was 11 pages, with 1 to 8 questions per page. Question order was not randomized because of the use of skip logic. However, answer choices for multiple-choice questions were randomized or flipped [19]. The questionnaire was set to only allow one response per computer using secure sockets layer data encryption, which limited responses based on Internet protocol addresses. Respondents were able to review their answers prior to submitting the questionnaire with the use of a "previous" button. Respondents were permitted as much time as they required to complete the questionnaire, but they could not re-enter the questionnaire after it was exited.

The questionnaire took 5-15 minutes to complete, depending on the paths taken through the questionnaire. A progress bar appeared on every page, which displayed the percentage of the questionnaire that was complete. A 'thank you' page was automatically displayed upon completion of the questionnaire. A separate collector was set up for each dietetic association that consisted of customized weblinks, identifying the dietetic membership of respondents. Administrators of each dietetic association sent their members an invitation email with a link to the questionnaire. Reminder emails were sent to all

respondents one and two weeks after the initial email was distributed, following the Dillman's Tailored Design Method [19]. Respondents had four weeks to complete the questionnaire.

Respondents who completed the questionnaire could submit their email addresses to receive a factsheet about using smartphone diet apps in sports dietetics practice, a background paper on dietary tracking with smartphones, and results from the study. Email addresses were collected with a second questionnaire, which was hyperlinked to the end of the primary questionnaire (*"click here to enter your email address"*). The primary questionnaire remained anonymous, as it was not associated with the second questionnaire.

Statistical Analysis

Results from both complete and incomplete questionnaires were included in the final analysis. Response rate was calculated as the number of first question respondents, divided by the number of invited respondents. Completion rate was calculated as the number of last page respondents, divided by the number of first page respondents. Data was analyzed using Stata version 12 (StataCorp LP, College Station, TX, USA). Descriptive statistics were used to describe attitudes and current practices of sports dietitians (including frequency counts and cross-tabulations). Associations were examined using Fisher's exact test, as cell counts were frequently less than five. All statistical comparisons were 2-tailed, and $P<.05$ was considered statistically significant. No weighting scheme was used. Text responses were analyzed qualitatively and coded. Responses to open-ended questions about the benefits and limitations of diet apps were clustered into common themes and paired with representative quotes from respondents.

Results

Response

The overall response rate from the 1709 sports dietitians invited to participate was 10.3% (n=180). Of the 180 respondents who began the questionnaire, 90.0% (n=162) completed it. Four respondents were excluded from analysis because they were dietetic students and were not yet working. The results presented include both complete and incomplete questionnaires, yielding 176 responses.

Respondents

The plurality of respondents were Australian or Canadian, in the age range of 30-39 years, and had been practicing sports nutrition for 6 to 10 years (Table 1). Responding sports dietitians most frequently advised clients performing endurance type sports: running (63/158, 39.9%), triathlon or multisport (53/158, 33.5%), and cycling (31/158, 19.6%).

Table 1. Demographics of survey respondents.

Characteristic (N)[a]	N	%
Country (N=174)		
Australia	54	30.7
Canada	54	30.7
United States	39	22.2
United Kingdom	17	9.7
New Zealand	10	5.7
Age (N=162)		
21-29	40	24.7
30-39	55	34.0
40-49	36	22.2
50-59	22	13.6
60 or older	9	5.6
Years Practicing (N=161)		
0-1	14	8.7
1-5	22	13.7
6-10	54	33.5
11-15	36	22.4
16-20	16	9.9
More than 20	16	9.9
Other (part-time)	3	1.9

[a] Results reflect the proportion of respondents who answered each question.

Smartphone Diet App Usage

For this section all results refer to the subset of participating sports dietitians who use diet apps in their clinical practice (n=57) and are referred to as *diet app users.*

Smartphone diet apps were used by 32.4% (57/176) of sports dietitians to help them assess and track the dietary intake of athletes. The age of the sports dietitian was not associated with diet app use (logistic regression $P>.05$). The country of residence of the sports dietitian was significantly associated with diet app use, with dietitians from the US more likely to use diet apps (odds ratio=5.61, 95% CI 1.84-17.08, $P=.002$). This translated to 56% of US sports dietitians using diet apps versus 25% for the other countries combined (Figure 1).

Overall, diet app users utilized 28 different smartphone diet apps when counseling clients. MyFitnessPal was overwhelmingly the most popular diet app, used by 56% (32/57) of diet app users (Figure 2). In the previous three months 19/53 (36%) diet app users had recommended diet apps to 5 or less clients, 12/53 (23%) had recommended diet apps to 6-10 clients, 7/53 (13%) had recommended diet apps to 11-15 clients, 3/53 (6%) had recommended diet apps to 15-20 clients, and 12/53 (23%) had recommended diet apps to 20 or more clients.

Figure 1. Diet app use by sports dietitian's country of residence.

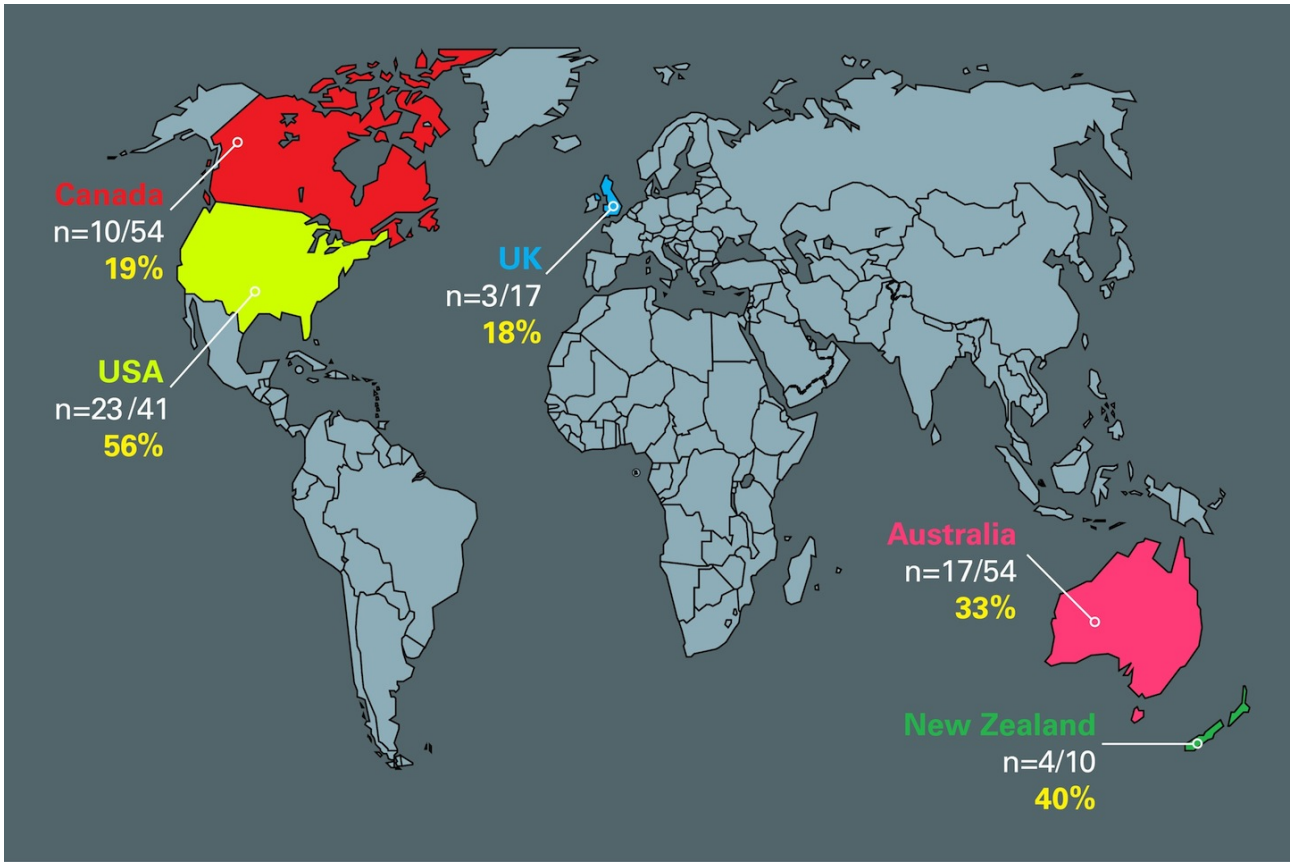
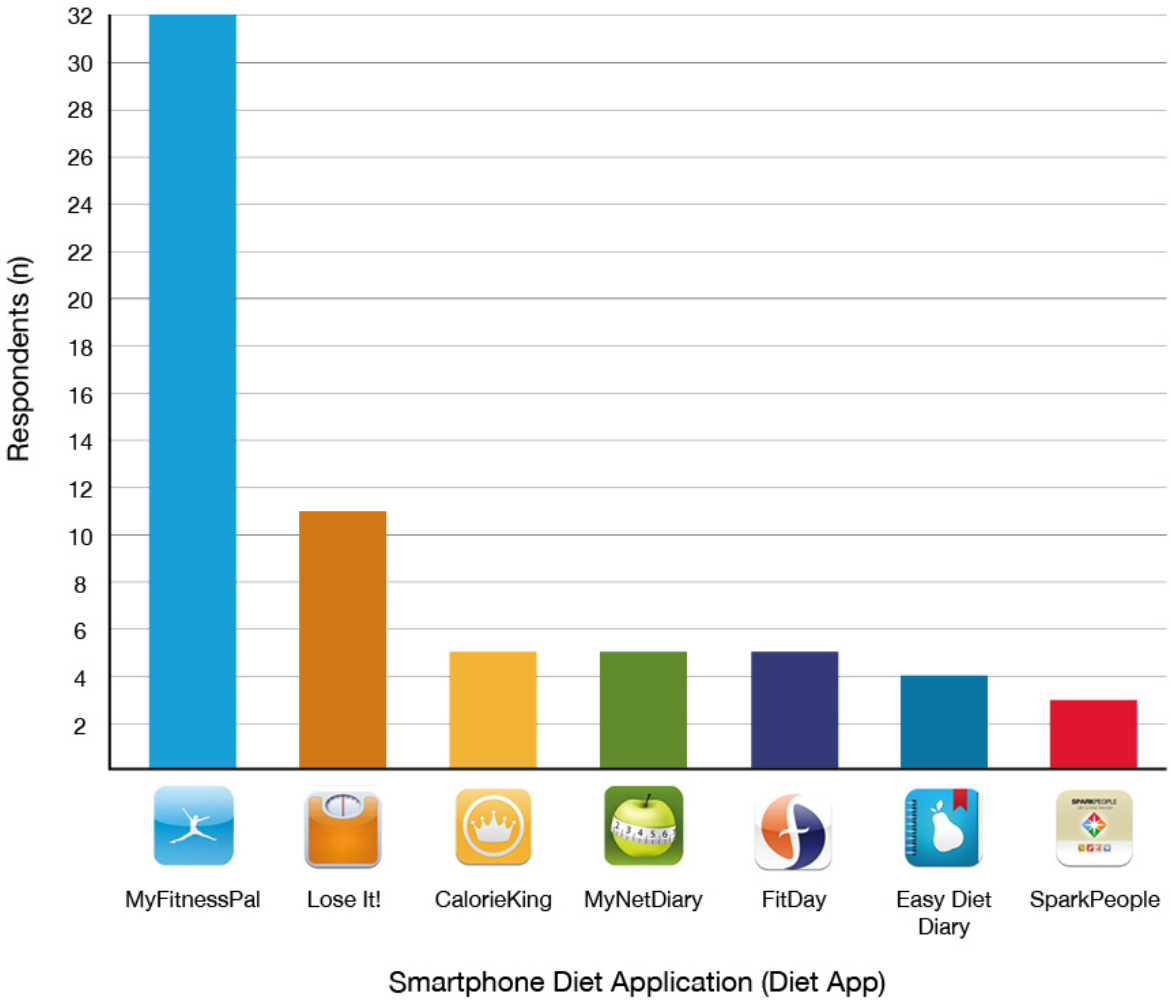


Figure 2. "Which smartphone diet application(s) do you use?" N=57.



Perception of Diet Apps

Respondents rated the effectiveness of diet apps in assisting with dietary assessment (Figure 3). Sports dietitians rated diet apps as "very effective" for their clients assessing their own diet more often than for themselves (as sports dietitians) assessing the diet of their clients. No respondents stated that diet apps were "not at all effective". The majority of diet app users viewed diet apps as "better" (25/53, 47%) or "equivalent" (22/53, 42%) compared with traditional dietary assessment methods, such as a diet record or diet history recorded on paper. Only 6/53 (11%) of app users rated the diet app "worse" compared with traditional dietary assessment methods.

Of the diet app users, 95% (54/57) reported limitations and benefits of using diet apps in clinical practice. The most commonly perceived limitations of diet apps were problems with the nutrient database, incorrect portion size selection by the client, and incorrect food selection by the client (Table 2). The most commonly perceived benefits of diet apps were their ubiquity, convenience, and ease of use (Table 3).

Table 2. "What are the limitations of using smartphone diet apps?" (N=54)[a].

Theme	n	%	Example of Comments
Nutrient database is inaccurate, missing foods, not country-specific	22	41	"Poor, incomplete databases with no monitoring of foods that are added by users for accuracy" "Food products are not on database (but can be added)" "Some don't contain many sports foods" "Many overseas versions and not always using foods common in New Zealand" "Lack of Canadian foods and restaurants [in the nutrient database]"
Incorrect portion size selection	12	22	"Inaccuracies in reporting portions of foods" "The patient must know portions"
Incorrect food selection	10	19	"The clients must know the differences between foods and how they were prepared" "Inaccuracies in reporting types of foods"
Client does not own smartphone	7	13	"Not all clients have smartphones" "Older or less affluent clients lack access or skills with technology"
Requires client to be tech savvy	7	13	"Difficult to use for those that are not tech savvy" "I have clients that are not as familiar with using applications" "Requires skills to use apps"
Difficulty transferring data from app to dietitian's reports	7	13	"Getting the information off the app onto a record system that the dietitian can keep" "Getting access to the information from a client's phone" "Transferring the results"

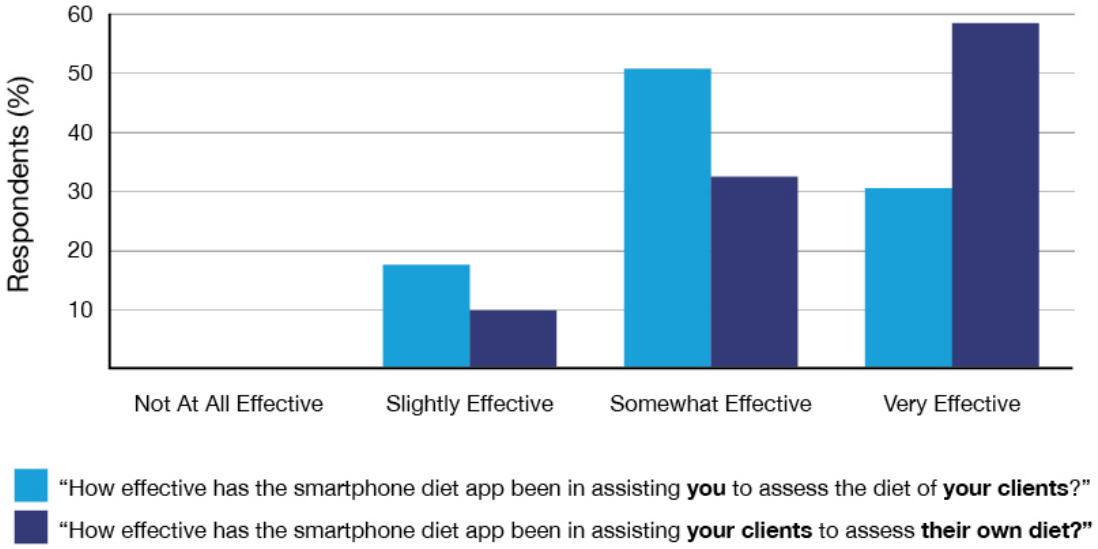
[a]Questions were open-ended.

Table 3. "What are the benefits of using smartphone diet apps?" (N=54)[b].

Theme	n	%	Example of comments
Ubiquitous	27	50	"Most people have a smartphone and use it constantly" "Clients ALWAYS have their phone with them anyways" "Easy access for client to record, so decreases forgetting"
Convenient	14	26	"More convenient than pen and paper record" "It is more convenient so I find my clients are more likely to consistently track" "Convenient for client to enter diet records and for me to see them"
Easy to use	12	22	"They are extremely fast and easy to use encouraging adherence" "Ease of recording for athlete"
Enter foods as they are eaten	11	20	"Clients can record food as they go. Less risk of forgetting" "Clients can use it throughout their day, less likely to forget foods they have eaten"
Instant feedback	10	19	"Immediate feedback" "Instant results" "Provides feedback to the client quickly"
Increases awareness of nutrition	8	15	"Creates awareness of calories in and out" "Effects of overconsumption of treats seen very dramatically, leading to moderation" "An education tool" "Increased awareness of food composition for clients"
Accurate	7	13	"Possibly more accurate as they can record as they go and not embarrassing to be seen to be writing down food intake as everyone is on phones these days" "People can enter items in real time, which I believe improves accuracy of the diet record" "Likely more honest about the foods they have eaten"

[b]Questions were open-ended.

Figure 3. Perceived effectiveness of smartphone diet apps in assessing dietary intake (N=53).



Discussion

Principal Results

The present study is, to our knowledge, the first to survey sports dietitians about their use and perceptions of smartphone diet apps in sports nutrition practice. We found that one in three sports dietitians used smartphone diet apps to assess and track the dietary intake of athletes. This prevalence is comparable to a recent study by Lieffers et al [22] that surveyed Canadian dietitians from all disciplines and found that 40.5% of respondents had recommended diet apps to clients.

In our study, MyFitnessPal was the most popular diet app, which is consistent with finding from Lieffers et al [22]. As far as we know, there are no commercially available apps designed specifically for sports nutrition. Sports dietitians and athletes are required to use general diet apps instead, which are often designed for weight loss [23]. This presents an interesting gap in the app market as sports nutrition has particular requirements that could be highlighted in an app, specifically: the timing of food intake (especially before, during, and after exercise); the use of sports foods/drinks and ergogenic supplements (eg, tracking the amount of caffeine consumed); energy balance, including signs of low energy availability (eg, loss of menstrual function); and the ability to easily manipulate nutrient goals based on training and competition (eg, carbohydrate loading, rehydration, recovery nutrition, etc) [7].

Sports dietitians in our survey believed that the ubiquity of diet apps may increase the accuracy of dietary assessment/tracking. The immediate entry of records after eating would reduce reliance on memory, which is notoriously problematic in traditional dietary assessment methods [5]. While using PDAs to record meals does not eliminate erroneous food entry [24], further research is needed on diet apps to gauge accuracy and immediacy of diet recording after meals. Concern about accuracy of diet apps was evident in our survey, where accuracy of the nutrient database and incorrect food entry by athletes were the main reported limitations of diet apps, and is in agreement results from Lieffers et al [22]. This highlights the need for further studies to validate commercially available diet apps for dietary assessment and tracking, particularly among athletes.

In the present survey, sports dietitians had a positive perception of diet apps in helping them to assess/track dietary intake, which was in agreement with Lieffers et al [22] who similarly found that reported benefits included convenience and ease of use. If diet apps can be further validated, they offer potential benefits of easier and faster dietary tracking with tools like barcode scanners to log packaged foods [12]. Indeed, recently Wharton et al [25] found greater adherence to dietary tracking with a commercially available diet app (Lose It!) compared with pen and paper.

Limitations

Our survey was disseminated in English-speaking, developed countries, which may limit the generalizability of our findings. The survey was sent out on different dates to the five participating countries, due to factors outside of our control.

For instance, dietetic associations emailed their members at varying frequencies (eg, weekly, fortnightly, or monthly), which influenced when the survey invitation was distributed. Future studies should explore alternative ways of distributing surveys that are independent of administrators - perhaps using social media to disseminate the survey [26,27].

The overall response rate is lower than we desired, however it is similar or greater to electronic surveys of dietitians in participating countries [22,28-30]. The survey distribution period overlapped with the London 2012 Olympic Games, which may have contributed to the low response rate, especially in the UK. Dietitians who use smartphone diet apps may have been more inclined to answer the survey, leading to a possible non-response bias that may have overestimated diet app use [5,31]. However, we made an effort to encourage all potential participants through multiple reminders via email.

We were unable to distinguish whether respondents used diet apps for dietary assessment or dietary tracking. Future surveys should differentiate between these two possible roles of diet apps, as certain apps may be better suited to one of these two tasks. In this study, all of the most commonly used diet apps compare actual nutrient intake to goal recommendations, which may make them prone to social desirability bias as overt nutrition recommendations can encourage people to report that they consume foods inline with known recommendations [32]. Therefore, currently available diet apps may be most suited to *track* dietary intake in order to increase adherence to nutrition recommendations rather than to accurately *assess* dietary intake. Lastly, we did not survey athletes who use diet apps, which would have provided an interesting comparison group. Future studies should investigate the prevalence and perception of diet app use among athletes, especially as a way to record their dietary intake to share with their consulting sports dietitian.

Conclusions

We found that one-third of sports dietitians used smartphone diet apps with athletes. Sports dietitians who used diet apps had a positive perception of them, and viewed diet apps as useful in helping to assess and track the dietary intake of athletes. We expect that more sports dietitians will use diet apps as smartphone adoption continues to increase and diet app software is refined. Software developers have an opportunity to address the limitations of currently available diet apps and enhance the benefits cited by the sports dietitians in this study. Future research should continue to survey dietitians from all disciplines on their use of smartphone diet apps to examine usage and best practice in dietary assessment and tracking. Finally, there is clearly a need to validate commercially available diet apps, so that dietitians can be confident in recommending their use for dietary assessment and tracking.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Study questionnaire.

[PDF File (Adobe PDF File), 357KB - mhealth_v3i1e7_app1.pdf]

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Abbreviations

PDA: personal digital assistant

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Original Paper

Internet Use and Access Among Pregnant Women via Computer and Mobile Phone: Implications for Delivery of Perinatal Care

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Abstract

Background: The use of Internet-based behavioral programs may be an efficient, flexible method to enhance prenatal care and improve pregnancy outcomes. There are few data about access to, and use of, the Internet via computers and mobile phones among pregnant women.

Objective: We describe pregnant women's access to, and use of, computers, mobile phones, and computer technologies (eg, Internet, blogs, chat rooms) in a southern United States population. We describe the willingness of pregnant women to participate in Internet-supported weight-loss interventions delivered via computers or mobile phones.

Methods: We conducted a cross-sectional survey among 100 pregnant women at a tertiary referral center ultrasound clinic in the southeast United States. Data were analyzed using Stata version 10 (StataCorp) and R (R Core Team 2013). Means and frequency procedures were used to describe demographic characteristics, access to computers and mobile phones, and use of specific Internet modalities. Chi-square testing was used to determine whether there were differences in technology access and Internet modality use according to age, race/ethnicity, income, or children in the home. The Fisher's exact test was used to describe preferences to participate in Internet-based postpartum weight-loss interventions via computer versus mobile phone. Logistic regression was used to determine demographic characteristics associated with these preferences.

Results: The study sample was 61.0% white, 26.0% black, 6.0% Hispanic, and 7.0% Asian with a mean age of 31.0 (SD 5.1). Most participants had access to a computer (89/100, 89.0%) or mobile phone (88/100, 88.0%) for at least 8 hours per week. Access remained high (>74%) across age groups, racial/ethnic groups, income levels, and number of children in the home. Internet/Web (94/100, 94.0%), email (90/100, 90.0%), and Facebook (50/100, 50.0%) were the most commonly used Internet technologies. Women aged less than 30 years were more likely to report use of Twitter and chat rooms compared to women 30 years of age or older. Of the participants, 82.0% (82/100) were fairly willing or very willing to participate in postpartum lifestyle intervention. Of the participants, 83.0% (83/100) were fairly willing or very willing to participate in an Internet intervention delivered via computer, while only 49.0% (49/100) were fairly willing or very willing to do so via mobile phone technology. Older women and women with children tended to be less likely to desire a mobile phone-based program.

Conclusions: There is broad access and use of computer and mobile phone technology among southern US pregnant women with varied demographic characteristics. Pregnant women are willing to participate in Internet-supported perinatal interventions. Our findings can inform the development of computer- and mobile phone-based approaches for the delivery of clinical and educational interventions.

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KEYWORDS

pregnancy; postpartum period; Internet; mobile phone; health behavior; risk reduction behavior

Introduction

Recent data from the Pew Research Center suggest that access to the Internet is growing rapidly across all segments of the US adult population [1]. Internet-based clinical interventions have grown in popularity [2] and have been used successfully for weight loss [3-5], diabetes management [6,7], physical activity [8,9], and tobacco cessation [10]. There are currently over 61 million women of childbearing age in the United States [11]. The preconception, pregnancy, and postpartum periods are critical teachable moments in the lives of young women, providing opportunities to implement interventions to promote maternal and infant health [12]. As such, Internet-based educational and clinical interventions may be particularly useful to women leading up to, during, and immediately after pregnancy [13].

Pregnant women in Europe report excellent access to Internet-based interventions [14,15]. Pregnant women in the US are thought to have broad access to the Internet, however, there is little published data exploring pregnant women's access to Internet technologies in the US. Additionally, there is a paucity of data regarding Internet access among pregnant women of different racial/ethnic groups, socioeconomic status, or specific geographical region. Huberty et al, for example, described the use of the Internet by pregnant and postpartum women in a Midwestern US population [16]. However, only Internet-using women were included in the online sampling method, and the population was comprised predominately (70%) of non-Hispanic white women. Because of racial/ethnic differences and the variability of Internet availability within geographical areas, targeted assessment of access to, and use of, specific Internet-based technologies among vulnerable populations, including pregnant women, can assist providers in developing programs to broaden the delivery of health care services. Clinicians, researchers, and policy makers can use this information to develop prenatal and postnatal behavioral interventions that effectively employ Internet-based technologies, tailored to the needs of their target patient populations.

In response to the absence of data on pregnant women, particularly pregnant women living in Central North Carolina, we endeavored to assess women's access to the Internet using computers and mobile phones and their use of various computer and mobile phone technologies. The prevalence of overweight and obesity among pregnant women at our institutions is about 60%. As such, we also aimed to describe the willingness of pregnant women to participate in an Internet-based, weight-loss intervention delivered via computer or mobile phone.

Methods

Study Setting and Sample

We conducted a written, in-person survey among a convenience sample of pregnant women presenting for obstetrical ultrasound at a university-based, tertiary care center in Central North Carolina between March 1, 2011 and May 31, 2011. The ultrasound unit provides care to a racially and socioeconomically diverse group of pregnant women from hospital-based clinics at the university and 14 health departments in the surrounding area. Approximately 300 women per month are referred for ultrasound evaluation. Women were eligible to participate if they were 18 years of age or older and able to provide written informed consent in English. We excluded women presenting for genetic counseling and women with a nonviable pregnancy or a pregnancy complicated by a fetal anomaly. We aimed for a sample size of 100 women based on the assumption of 80% power to detect a 10% difference in our main outcome, which was willingness to participate in a behavioral intervention program via Internet on the computer versus on a mobile phone. The Institutional Review Board of the University of North Carolina approved the study.

Survey Instrument

The Institute of Medicine access to care model was used as a framework for the study. A questionnaire was developed to examine women's access to computers and mobile phones according to predisposing (ie, age, race/ethnicity), enabling (ie, income, number of children in the home), and clinical (ie, gestational age) factors [17]. A brief survey was developed following a review of published articles on Internet use among pregnant women. The survey was initially reviewed by 10 pregnant women attending our university-based prenatal clinics. Based on the feedback provided, we made minor edits to the wording of several questions for clarity. The final version consisted of eight items on access to, and use of, computers, mobile phones, and Internet and social media tools, as well as preferences for the delivery of a postpartum weight-loss intervention and demographic information. Each participant was asked the following questions (see Multimedia Appendix 1 for the full survey):

1. "Do you have access to a home phone with Internet? (Yes/No)"

2. "Do you have access to a mobile phone with Internet? (Yes/No)"

3. "Do you have access to a computer for at least 8 hours per week (at home, at work, or in a public setting such as your local library)? (Yes/No)"

4. "How often do you use the following Internet programs (Internet/Web, email, Facebook, blogs, Twitter, chat rooms, Skype) on your computer? (Not at all, Not very often, Often, Very often)"

5. "How often do you use these items (Internet/Web, email, Facebook, blogs, Twitter, chat rooms) on your cell phone? (Not at all, Not very often, Often, Very often)"

6. "How willing are you to participate in a postpartum weight-loss program? (Not at all willing, Not very willing, Fairly willing, Very willing)"

7. "How willing are you to participate in an Internet-based postpartum weight-loss program delivered via the computer? (Not at all willing, Not very willing, Fairly willing, Very willing)"

8. "How willing are you to participate in an Internet-based postpartum weight-loss program on your cell phone? (Not at all willing, Not very willing, Fairly willing, Very willing)"

Procedure

Women were approached consecutively by trained research staff to ascertain their interest in participating in the study as they presented for their ultrasound appointment. If women expressed an interest, they were escorted to a private conference room within the ultrasound unit where they were screened for eligibility. If they were deemed eligible, informed consent was obtained and they were officially enrolled in the study. The average time to complete the survey was 10 minutes. The research staff reviewed each survey for completeness in the presence of the participant. Participants who completed the survey received a US $10 gift card. Data were entered into a master spreadsheet by a study staff member. As part of our quality control protocol, a second staff member conducted an audit of the data each month to ensure correct entries. There were no missing data.

Data Analysis

Maternal demographic and clinical characteristics were summarized using means and standard deviations for continuous variables and numbers with proportions for categorical variables. The proportion of participants with access to computers and mobile phones across predisposing (ie, age, race/ethnicity), enabling (ie, income, number of children in the home), and clinical (ie, gestational age) factors was assessed using chi-square statistics. Given the performance of four tests and following the Bonferroni correction for multiple testing [18], results were considered statistically significant if $P<.013$ (.05 divided by three). For analyses stratified by race/ethnicity, we recategorized African American, Asian, and Hispanic women into one category, termed *nonwhite*, due to small numbers.

Willingness to participate in the various types of interventions was defined as those who answered *fairly willing* or *very willing* and was compared to the number who answered *not at all willing* or *not very willing*. Willingness to participate in a postpartum weight-loss intervention across sociodemographic groups was assessed using Fisher's exact test. The *P* values were corrected for multiple testing with a Benjamini-Hochberg correction [19]. To determine which demographic characteristics were associated with women's willingness to participate in computer-based or mobile phone-based weight-loss interventions, we first performed univariate logistic regression. The models looked at willingness to participate in interventions via computer and mobile phone according to age (continuous), race/ethnicity (nonwhite versus white), income level (≥US $25,000 versus <US $25,000), and number of children in the home (one or more versus none). We then included all the above variables in a multiple logistic regression model to determine if any were predictive of increased willingness to participate in an Internet intervention by computer or by mobile phone. Again, based on a Bonferroni correction [18], results were considered statistically significant if the *P* value was <.006. Analyses were conducted using Stata version 10 statistical software (StataCorp) and R (R Core Team 2013).

Results

Overview

Of the 120 women approached, 110 (91.7%) were eligible for the study and 100 (83.3%) agreed to participate. Of those approached, 10 out of 120 (8.3%) women were not eligible to participate in the study due to a nonviable pregnancy (9/120, 7.5%) or pregnancy complicated by a fetal anomaly (1/120, 0.8%). Of those approached, 10 out of 120 (8.3%) women declined to participate due to a lack of time to complete the survey. The study sample represents approximately 10% of the patients presenting to the ultrasound unit during the 3-month study period.

Characteristics of the Study Sample

The mean age of participants was 31.0 (SD 5.1) years (see Table 1) with a range of 22 to 44 years. Of the participants, 61.0% (61/100) were white, 26.0% (26/100) were African American, 7.0% (7/100) were Asian, and 6.0% (6/100) were Hispanic. Of the participants, 45.0% (45/100) reported a yearly household income of more than US $50,000. Median gestational age at the time of the survey was 26.0 weeks ± 9.2 with a range of 7 to 41 weeks. Most participants (64/100, 64.0%) had one or more children in the home. See Table 1 for further demographic information.

Table 1. Selected sociodemographic and clinical characteristics of study participants (n=100).

Characteristics		mean (SD), n (%), or median (range)
Age in years, mean (SD)		31.0 (5.1)
Race/ethnicity, n (%)		
	White	61 (61.0)
	African American	26 (26.0)
	Asian	7 (7.0)
	Hispanic	6 (6.0)
Yearly household income, n (%)		
	≤US $25,000	28 (28.0)
	US $25,001-$50,000	27 (27.0)
	>US $50,000	45 (45.0)
Number of children in the home, median (range)		1.2 (0-5)
Gestational age in weeks, median (range)		26.0 (7-41)

Computer and Mobile Phone Internet Access

Most participants reported access to computers (89/100, 89.0%) and mobile phones (88/100, 88.0%). White women were more likely to report access to both computers and mobile phones compared to nonwhite women (*P*=.007, see Table 2). There were no statistically significant differences in access to computers or mobile phones by age.

Women with one or more children in the home reported slightly less access to both mobile phones and computers than those with no children in the home, but this difference was not statistically significant (*P*=.07)—94.0% (94/100) versus 81.0% (81/100), respectively (see Table 3). There were no statistically significant differences in access to computers or mobile phones by income or by number of children in the home.

Table 2. Self-reported computer and mobile phone Internet access among pregnant women stratified by age and race (n=100).

Internet variables	Total (n=100)	Age in years		*P* value	Race		*P* value
		<30 (n=37)	≥30 (n=63)		White (n=61)	Nonwhite (n=39)	
Access to computer with Internet, n (%)	89 (89.0)	32 (86)	57 (90)	.5	57 (93)	32 (82)	.04
Access to mobile phone with Internet, n (%)	88 (88.0)	33 (89)	55 (87)	.8	57 (93)	31 (79)	.08
Access to both computer and mobile phone, n (%)	86 (86.0)	32 (86)	54 (86)	.9	57 (93)	29 (74)	.007

Table 3. Self-reported computer and mobile phone Internet access among pregnant women stratified by income and number of children in the home.

Internet variables	Total (n=100)	Annual income			*P* value	Number children in the home		*P* value
		≤US $25,000 (n=28)	US $25,000-$50,000 (n=27)	>US $50,000 (n=45)		None (n=36)	One or more (n=64)	
Access to computer with Internet, n (%)	89 (89.0)	25 (89)	24 (89)	40 (89)	.998	34 (94)	55 (86)	.20
Access to mobile phone with Internet, n (%)	88 (88.0)	24 (86)	25 (93)	39 (87)	.70	34 (94)	54 (84)	.15
Access to both computer and mobile phone, n (%)	86 (86.0)	23 (82)	24 (89)	39 (87)	.80	34 (94)	52 (81)	.07

Willingness to Participate in an Online Postpartum Weight-Loss Intervention

Of the women surveyed, 82.0% (82/100) were *very willing* or *fairly willing* to participate in an online weight-loss intervention program after delivery. Bivariate analysis did not show any statistically significant differences in the willingness versus nonwillingness to participate in an online intervention by age, race, or income categories. Women with no children in the home were more likely to be *very willing* or *fairly willing* to participate in a postpartum program compared to women with one or more children in the home (*P*=.07)—93.0% (93/100) versus 77.0%

(77/100), respectively. When asked whether they were willing to participate in a postpartum Internet-based intervention delivered via mobile phone or computer, women were significantly more willing to participate via computer (83/100, 83.0%) compared to by mobile phone (49/100, 49.0%) (*P*<.001).

Willingness to Engage in an Online Intervention via Computer or Mobile Phone

To explore the individual contributions of demographic factors on willingness to participate in a computer-based or mobile phone-based intervention, we developed separate logistic regression models for each modality (Table 4). In both bivariate and adjusted analyses, there were no statistically significant findings. Women of different ages, races, income levels, and number of children at home were similarly willing to participate in computer-based or mobile phone-based interventions.

Table 4. Association of demographic characteristics of pregnant women *very willing* and *fairly willing* to participate in an online weight-loss intervention delivered via computer or mobile phone.

Variables	Computer-based intervention					Mobile phone-based intervention				
	n (%)	Regression coefficient (log OR[a])	Crude OR (95% CI)	Adjusted OR (95% CI)	*P* value	n (%)	Regression coefficient (log OR)	Crude OR (95% CI)	Adjusted OR (95% CI)	*P* value
Age range in years [b,c], n (%)										
21-25 (n=16)	14 (88)	1.5	1.0 (0.9-1.1)	1.0 (0.9-1.1)	.86	14 (88)	2.4	0.9 (0.9-1.0)	0.9 (0.8-1.0)	.08
26-30 (n=34)	28 (82)					14 (41)				
31-35 (n=27)	20 (74)					10 (37)				
36-40 (n=21)	20 (95)					10 (48)				
41-45 (n=2)	1 (50)					1 (50)				
Race/ethnicity, n (%)										
White (n=61)	49 (80)	Ref[d]	Ref	Ref		29 (48)	Ref	Ref	Ref	
Nonwhite (n=39)	34 (87)	1.9	0.6 (0.2-1.8)	0.6 (0.2-1.9)	.35	20 (51)	0.1	0.9 (0.4-1.9)	0.7 (0.3-1.8)	.48
Income, n (%)										
<US $25,000 (n=28)	22 (79)	Ref	Ref	Ref		13 (46)	Ref	Ref	Ref	
≥US $25,000 (n=72)	61 (85)	1.6	1.0 (0.5-1.8)	1.0 (0.5-2.2)	.91	36 (50)	-0.1	1.0 (0.7-1.7)	1.3 (0.7-2.3)	.44
Children at home, n (%)										
None (n=36)	31 (86)	Ref	Ref	Ref		23 (64)	Ref	Ref	Ref	
One or more (n=64)	52 (81)	1.8	0.7 (0.2-2.2)	0.7 (0.2-2.2)	.49	26 (41)	0.6	0.4 (0.2-0.9)	0.4 (0.2-1.1)	.07

[a]odds ratio (OD).

[b]Reference variable is 21 years old.

[c]Age is a continuous variable but selected intervals are presented here.

[d]Reference (Ref) variable.

Use of Internet Technologies

The majority of participants reported that they *often*, or *very often*, used the Internet (94/100, 94.0%), email (90/100, 90.0%), and Facebook (59/100, 59.0%) through a computer. While the use of specific technologies among sociodemographic groups was not significantly different, there were several important trends noted. In an analysis stratified by age, women under 30

years of age were more likely to report the use of Twitter and chat rooms compared to women 30 years and older (Table 5). Nonwhite women were more likely to report using a computer to access Facebook (26/39, 67%) or chat rooms (5/39, 13%) compared to their white counterparts—54% (33/61) and 5% (3/61), respectively. While the Internet/Web, email, and Facebook were commonly accessed through computers, a smaller proportion of women reported they *often* or *very often* used these technologies via mobile phone—49.0% (49/100), 43.0% (43/100), and 36.0% (36/100), respectively. Women aged 30 and older were less likely to report the use of Facebook *often* or *very often* via mobile phone compared to women under age 30.

Table 5. Number of pregnant women reporting the use of Internet technologies as *very often* and *often* on computers or mobile phones by age and race.

Internet variables	Age in years		Race		Total (n=100)
	<30 (n=37)	≥30 (n=63)	White (n=61)	Nonwhite (n=39)	
Internet program used *very often* or *often* with computers, n (%)					
Internet/Web	34 (92)	60 (95)	59 (97)	35 (90)	94 (94.0)
Email	31 (84)	59 (94)	56 (92)	34 (87)	90 (90.0)
Facebook	22 (60)	37 (59)	33(54)	26 (67)	59 (59.0)
Blogs	9 (24)	14 (22)	17 (28)	6 (15)	23 (23.0)
Twitter	6 (16)	5 (8)	7 (12)	4 (10)	11 (11.0)
Chat rooms	4 (11)	4 (6)	3 (5)	5 (13)	8 (8.0)
Skype	2 (5)	10 (16)	7 (12)	5 (13)	12 (12.0)
Internet program used *very often* or *often* with mobile phones, n (%)					
Internet/Web	20 (54)	29 (46)	28 (46)	21 (54)	49 (49.0)
Email	14 (38)	29 (46)	26 (43)	17 (44)	43 (23.0)
Facebook	18 (49)	18 (29)	17 (28)	19 (49)	36 (36.0)
Blogs	5 (14)	1 (2)	3 (5)	3 (8)	6 (6.0)
Twitter	4 (11)	4 (6)	5 (8)	3 (8)	8 (8.0)
Chat rooms	1 (3)	1 (2)	1 (2)	1 (3)	2 (2.0)

Women with one or more children in the home were less likely to report the use of the Internet via computer compared to women with no children in the home. Women with one or more children in the home reported less use of a mobile phone to access email, Facebook, and other technologies compared to women with no children in the home. The lowest-income women were less likely to access most Internet technologies via computer and mobile phone than women in higher-income levels, as seen in Table 6.

Table 6. Number of pregnant women reporting the use of Internet technologies *very often* or *often* on computers or mobile phones by income and number of children in the home.

Internet variables	Annual household income			Number children in the home		Total (n=100)
	<US $25,000 (n=28)	US S25,000-$50,000 (n=27)	>US $50,000 (n=45)	None (n=36)	One or more (n=64)	
Internet program used *very often* or *often* with computers, n (%)						
Internet/Web	24 (86)	26 (96)	44 (98)	59 (97)	35 (88)	94 (94.0)
Email	23 (82)	24 (89)	43 (96)	56 (92)	34 (87)	90 (90.0)
Facebook	17 (60)	18 (67)	24 (53)	33 (54)	26 (67)	59 (59.0)
Blogs	3 (11)	9 (33)	11 (24)	17 (28)	6 (15)	23 (23.0)
Twitter	2 (7)	4 (15)	5 (11)	7 (12)	4 (10)	11 (11.0)
Chat rooms	4 (14)	3 (11)	1 (2)	3 (5)	5 (13)	8 (8.0)
Skype	1 (4)	7(2)	9 (20)	7 (12)	5 (13)	12 (12.0)
Internet program used *very often* or *often* with mobile phones, n (%)						
Internet/Web	12 (43)	15 (56)	22 (49)	24 (67)	21 (54)	49 (49.0)
Email	8 (29)	11 (41)	24 (53)	18 (50)	17 (44)	43 (43.0)
Facebook	10 (36)	12 (44)	14 (31)	16 (44)	19 (49)	36 (36.0)
Blogs	1 (4)	1 (4)	4 (9)	11 (4)	3 (8)	6 (6.0)
Twitter	2 (7)	3 (11)	3 (7)	5 (14)	3 (8)	8 (8.0)
Chat rooms	1 (4)	0 (0)	1 (2)	1 (3)	1 (3)	2 (2.0)

Discussion

Principal Findings

Investigations among nonpregnant, adult populations suggest that behavioral interventions delivered through computers and mobile phones are effective [4-10]. Some groups of pregnant women frequently access health information via the Internet and may do so in lieu of conversations with health care providers [16,20]. Text4Baby is an example of a mobile phone educational campaign accessed by thousands of pregnant women across the US [21,22]. At least one small trial of an Internet-based intervention with pregnant women improved compliance with medical therapy and physical activity [9]. Health care providers and researchers are interested in scalable computer-based or mHealth interventions for larger populations of pregnant women, but more information about access to, and use of, Internet technologies among pregnant women is needed.

Pregnant women in our study reported broad access to the Internet through computers and mobile phones and use of a variety of Internet technologies, including Internet/Web browsers, email, and Facebook. Although nonwhite women and women with one or more children in the home may have less access to the Internet than white women with no children at home, access to, and use of, the Internet was quite high across all groups. Less access by nonwhite women and women with children in the home may be due, in part, to financial restraints or competing demands on time [23].

The majority of women in the study sample were willing to participate in an Internet-based behavioral intervention via computer (83/100, 83.0%), but not as willing to participate via mobile phone (49/100, 49.0%). A recent US study found that 50% of the pregnant women surveyed used the Internet to access health information. However, the survey was administered online and may not be generalizable to larger groups of women [16]. Although other studies have found that pregnant women use the Internet to access pregnancy and childbirth-related information, guidance on physical activity, and newborn health, the data are largely limited to Caucasian women and international populations [14,15,24,25]. It may be that women use mobile phones to access specific screening or treatment information, but may not be as willing to use mobile phones for ongoing weight-management interventions. We did not ascertain the extent to which women used computers or mobile phones to gather health information in the current study. Future studies that examine women's access and use of the Internet will need to explore what types of information women are searching for when using computers or mobile phones.

In our study, willingness to participate in a mobile phone intervention was not dependent on age, race, income level, or having a child at home. Some trends were noted which may be important to investigate in a larger sample. Younger women and women with no children at home tended to be more willing to participate in a mobile phone-based intervention. Our findings support the development of Internet-based clinical and educational interventions for expectant mothers. Developing mHealth programs or interventions that can be delivered through computer-based technologies may promote better uptake based

on individual patient preferences. For example, only 8% of Dutch pregnant women used an email-based intervention [26]. Additionally, further work is needed to better understand the influence of other children in the home on less access to the Internet and, possibly, lower willingness to engage in computer- or mobile phone-based interventions.

The broad access and use of the Internet by women in our sample is similar to rates reported by a 2011 Pew Research Center report [27,28]. In the Pew report, minority women reported slightly lower access to the Internet compared to their white women counterparts (73% versus 94%, respectively). Our findings differ from the Pew study in that we did not find substantially less access to the Internet among lower-income women compared to higher-income women. This difference may be due to the younger age range of our sample of study participants compared with the national sample used in the Pew study. Our findings suggest less of a "digital divide" based on income levels in younger, reproductive-age women. These findings further emphasize the need for targeted studies to better describe access to, and use of, the Internet and other computer technologies in different patient groups (eg, pregnant women) and geographical areas (eg, Central North Carolina).

Limitations

Our study has several limitations that deserve attention. First, our descriptive study includes a relatively small sample size. Therefore, there is limited power to detect differences between sociodemographic groups. We found some small differences in access between white and nonwhite women and also between women with and without children at home. The survey was investigator developed and, therefore, had not been extensively tested prior to its use. Our data also relies on self-reporting. However, given the nature and setting of the survey, it is unlikely that women were biased in their responses. Also, we did not provide specific information on the weight-loss intervention, so participants may have responded differently if they had been given additional information. Another limitation is that our survey does not explore women's health information-seeking behavior on the Internet. Access to Internet technologies and use of such technologies is not the same as using such technologies for health applications. For example, in a recent study of Internet users in the US, adults of lower socioeconomic status were less likely to use the Internet for health information seeking specifically [29]. However, use of the Internet specifically for health information seeking is not a prerequisite to participating in an Internet-based behavioral intervention. It is also not a known indicator of uptake of such interventions.

Because our study was conducted in one tertiary care center, it can be argued that the findings have limited generalizability. However, we recruited women referred for ultrasound examination from a wide range of community settings and economic backgrounds. Nevertheless, these findings should be confirmed in a larger sample of women living in a diverse community and receiving care in multiple tertiary care settings.

Conclusions

This study represents a first step in characterizing access to the Internet among a diverse group of pregnant women in the United States. Larger scale studies across geographical regions are needed to better inform and tailor the development of Web-based interventions to take advantage of this critical period in a woman's lifespan. Integrating Web-based educational interventions into pregnancy and the postpartum periods may lead to improved maternal and newborn outcomes through improved access and education. Such interventions could change the current paradigm of perinatal care, giving clinicians an opportunity to provide ongoing care to pregnant women between prenatal visits [9]. Internet-based interventions to improve clinical care of pregnant women should also be considered. For example, Internet-based interventions might include feedback and communication between patients and providers about a variety of prenatal disease conditions, screening tests, and shared decision making. Our findings suggest broad access to the Internet through computers and mobile phones for pregnant women across multiple demographic strata. Also, our findings suggest that interventions designed to be delivered using contemporary technologies should be accessible via computers or mobile phones and able to be scaled to meet the needs and preferences of women based on age, race, and the presence of other children in the home that may influence access and sustainable use of the Internet.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Patient questionnaire.

[PDF File (Adobe PDF File), 40KB - mhealth_v3i1e25_app1.pdf]

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Abbreviations

OD: odds ratio

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Original Paper

Using a Mobile App for Monitoring Post-Operative Quality of Recovery of Patients at Home: A Feasibility Study

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Abstract

Background: Mobile apps are being viewed as a new solution for post-operative monitoring of surgical patients. Mobile phone monitoring of patients in the post-operative period can allow expedited discharge and may allow early detection of complications.

Objective: The objective of the current study was to assess the feasibility of using a mobile app for the monitoring of post-operative quality of recovery at home following surgery in an ambulatory setting.

Methods: We enrolled 65 consecutive patients (n=33, breast reconstruction surgery; n=32, orthopedic surgery) and asked them to use a mobile phone daily to complete a validated quality of recovery scale (QoR-9) and take photographs of the surgical site for the first 30 days post-op. Surgeons were asked to review patient-entered data on each patient in their roster daily. A semistructured questionnaire was administered to patients and surgeons to assess satisfaction and feasibility of the mobile device.

Results: All 65 patients completed the study. The mean number of logins was 23.9 (range 7-30) for the breast patients and 19.3 (range 5-30) for the orthopedic patients. The mean number of logins was higher in the first 14 days compared to the 15-30 days post-op for both breast patients (13.4 vs 10.5; $P<.001$) and for the orthopedic patients (13.4 vs 6.0; $P<.001$). The mean score for overall satisfaction with using the mobile device was 3.9 for breast patients and 3.7 for orthopedic patients (scored from 1 (poor) to 4 (excellent)). Surgeons reported on the easy-to-navigate design, the portability to monitor patients outside of hospital, and the ability of the technology to improve time efficiency.

Conclusions: The use of mobile apps for monitoring the quality of recovery in post-operative patients at home was feasible and acceptable to patients and surgeons in the current study. Future large scale studies in varying patient populations are required.

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KEYWORDS

outpatient; recovery; care; post-operative; smartphone; technology; mobile

Introduction

There is a growing body of evidence that supports the use of mobile apps in health care interventions [1]. These include the use of apps for smoking cessation [2], other behavior change programs such as exercise and weight management [3,4], and self-management of long-term conditions such as diabetes [5]. Text messaging is being used to provide health education [6], to issue reminders for appointments [7], and to improve the efficiency of health systems overall [8,9]. However, there is relatively little research on the feasibility or effectiveness of downloadable apps or software for mobile phones (specifically smartphones) for the remote monitoring of patients following surgery [10]. Surgical populations differ from previous groups monitored with mobile phone technology but are highly appropriate in that they have a homogenous set of standard indicators of what constitutes quality of recovery, common touch points regarding care professionals and hospitals, and have a limited recovery period [11].

Modern ambulatory surgical units are performing more complex surgical procedures due to new approaches in pain control, the introduction of techniques that reduce the peri-operative stress response, and the use of minimally invasive surgical techniques [11].

The first 30 days following surgery have been identified as a major focus area in health care [12,13]. The majority of post-operative complications develop during this time period [13]. In addition, during this 30-day post-op period, many of the unexpected visits to the emergency department and re-admissions to hospital occur. These unexpected visits and re-admissions to hospital cost the health care systems in North America billions of dollars annually [13]. Modern surgical initiatives such as expedited discharge and fast-tracking programs require appropriate methodology to monitor and maintain quality of recovery while the patients recover at home [14,15].

Mobile phone monitoring of patients in the post-operative period may not only allow faster discharge of patients from hospital but also shed insight into the patient's experience while at home and provide a mechanism for the early detection of developing complications. In addition, there would be numerous benefits for surgeons and care providers in having the ability to monitor patients remotely as well as potential time saved in replacing face-to-face visits with virtual visits.

We performed a feasibility study to determine if mobile apps can be used to monitor a patient's recovery at home during the immediate post-operative period.

Methods

Overview

This prospective cohort study was conducted with ambulatory care patients undergoing breast reconstruction (breast) or orthopedic arthroscopic anterior cruciate ligament repair (ACL) surgery. The pilot study began in October 2011. All patients registered for breast reconstruction and orthopedic surgery were screened for inclusion in the study until the desired number of participants was obtained (minimum 60 patients—30 breast reconstruction and 30 orthopedic surgery). Patients were selected based on three inclusion criteria: (1) ages 18-75, (2) non-smoker status (in breast reconstruction patients as there is a high complication rate in smokers), and (3) ability to communicate in English. Patients were excluded from the study if they suffered from chronic pain or psychiatric disturbances, took narcotic (morphine-like) medication for pain on a regular basis, or had an allergy to local anesthetics or morphine-like medications. All patients received an information sheet discussing the purpose of the study and had the opportunity to discuss the process with the study coordinator. After written consent was obtained by the study coordinator, each patient met with the coordinator for approximately 30-45 minutes before their surgery to learn how to use the mobile device and review the different indicators they would be asked to answer on the mobile device each day. Patients were also shown how to take a picture of their surgical wound site using the mobile device.

Prior to discharge, patients were given either a smartphone or a tablet with half of each study arm receiving one or the other. Software was provided by QoC Health Inc (Toronto), devices were provided by Samsung, and network time was provided by Rogers Communications. Patients practiced taking photos with the study coordinator to ensure they understood how to take pictures with the device. In addition to the one-on-one consultation with the study coordinator, each participant was provided with an education booklet with details on how to use the mobile app device and answer questions regarding security and confidentiality. The education booklet also included illustrations on how to frame the body and angle the camera to take pictures. These parameters were based on the most effective view required by surgeons to assess the wound site. Study participants continued to have their regularly scheduled face-to-face post-operative visits with the surgeon in keeping with normal care processes.

The three participating surgeons used a mobile interface or desktop computer to access patient data. Scores on question items that fell outside the normal range of defined parameters were immediately flagged in the database for quick viewing. Being flagged meant that the app sensed an extreme on the value scale as a response. The app would alert the surgeon by sending a "flag" to the surgeon (care provider). In addition, the app would report the list of patients on the roster so that the "flagged" patient would be at the top of the list and be highlighted in red. The surgeon could then phone the patient to enquire why the extreme score had been registered. The app updated every 5 minutes. Results and flags were reviewed, and if needed, patients were contacted by the surgeon and/or nurse. Daily photographs were reviewed by surgeons to assess the recovery of the surgical site and wound and to determine if healing was progressing normally and without complications.

Four sets of data were gathered for this study including (1) data from the mobile app that was entered by patients in the pilot study while recovering at home, (2) post-recovery follow-up feedback surveys with patients, (3) post-recovery interviews with patients, and (4) post-pilot feedback surveys with participating surgeons.

Mobile App Data

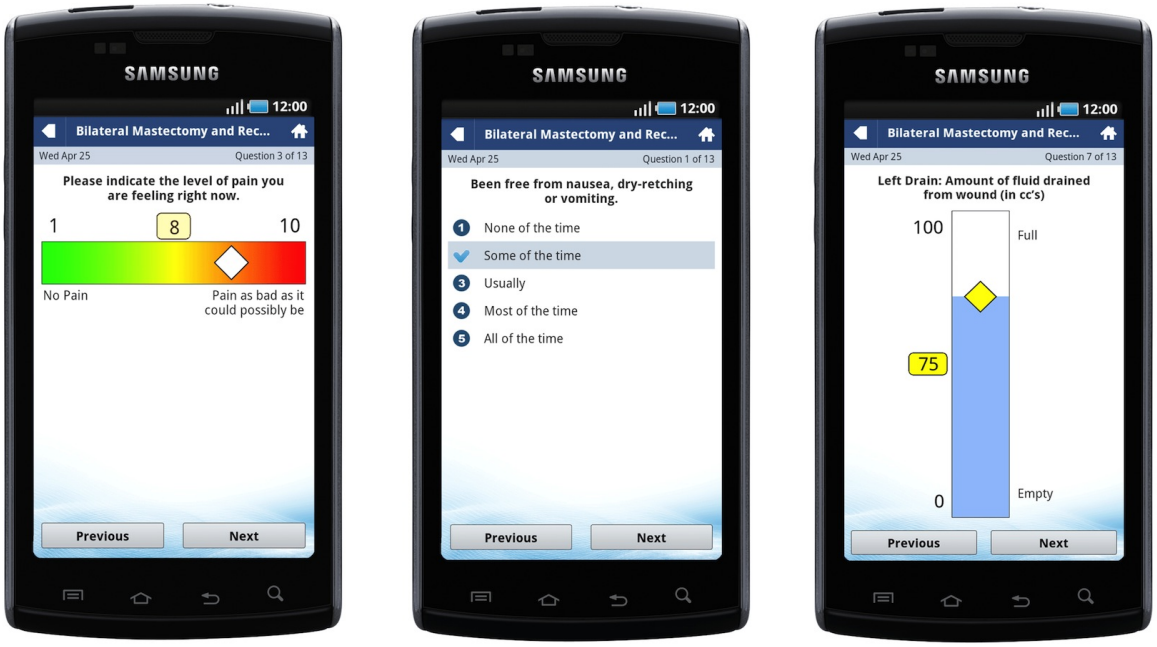
The mobile app recovery indicators included a visual analogue scale (VAS) for pain and Likert questions from the Quality of Recovery (QoR-9) questionnaire. The QoR-9 is an earlier version of the Quality of Recovery (QoR-40) questionnaire, which has been extensively utilized and validated to assess the quality of life of patients after surgery [14]. The QoR-40 is composed of 40 items organized into six dimensions: emotional state, physical comfort, psychological support, physical independence, pain, and a global score [14]. Despite the comprehensiveness of the QoR-40, the feasibility of using this questionnaire as a daily self-administered assessment tool is limited due to survey length. In consideration of time and the frequency of conducting the assessments, the QoR-9 is much more appropriate for the purpose of daily remote monitoring and provides insight into patient quality of recovery and outcomes of care. In this study, all nine questions from the QoR-9 served as indicators; however, one item ("been able to pass urine and no trouble with bowel movements") was split into two question items addressing urine function and bowel function separately. Reporting began from the day of discharge up to a period of 6 weeks dependent on patient recovery time for each procedure. The patients were asked to complete the app survey once per day at the outset but not reminded in any way. At the outset, we asked the patients to answer the survey in the morning when they took their first set of pain medications. This was in an attempt to standardize the responses.

Table 1 lists the indicators on the mobiles devices for breast reconstruction and orthopedic patients in the pilot, in addition to the scores that elicited a "flag" for the surgeons. Being flagged meant that the app sensed an extreme on the value scale as a response. The app would alert the surgeon by sending a "flag" to the surgeon (care provider). In addition, the app would list the patients on the roster so that the "flagged" patient would be at the top of the list and be highlighted in red. The surgeon could then phone the patient to enquire why the extreme score had been registered. The app updated every 5 minutes. Figure 1 depicts the screenshots and provides an example of the indicators as viewed on the mobile devices.

Table 1. List of indicators on the mobile device.

Type	Question	Scale	Flag
Anxiety	How anxious (worried, nervous) do you feel?	1-not at all anxious, 2-a little anxious, 3-moderately anxious, 4-very anxious, 5-extremely anxious	4 & 5
Pain	Please indicate the level of pain you are feeling right now.	Visual Analogue Scale 1-10	5-10
Drain (breast)	Amount of fluid drained from wound (in cc's)	1-100 cc's sliding scale (one drain per breast and side of abdomen)	50-100
QoR	Had a feeling of general well being	1-all of the time, 2-most of the time, 3-usually, 4-some of the time, 5-none of the time	4 & 5
QoR	Had support from others	1-all of the time, 2-most of the time, 3-usually, 4-some of the time, 5-none of the time	4 & 5
QoR	Been able to understand instructions and advice. Not being confused	1-all of the time, 2-most of the time, 3-usually, 4-some of the time, 5-none of the time	4 & 5
QoR	Been able to look after personal toilet and hygiene unaided	1-all of the time, 2-most of the time, 3-usually, 4-some of the time, 5-none of the time	4 & 5
QoR	Been able to pass urine	1-all of the time, 2-most of the time, 3-usually, 4-some of the time, 5-none of the time	4 & 5
QoR	Had normal bowel function	1-all of the time, 2-most of the time, 3-usually, 4-some of the time, 5-none of the time	4 & 5
QoR	Been able to breathe easily	1-all of the time, 2-most of the time, 3-usually, 4-some of the time, 5-none of the time	4 & 5
QoR	Been free from headache, backache or muscle pains	1-all of the time, 2-most of the time, 3-usually, 4-some of the time, 5-none of the time	4 & 5
QoR	Been free from nausea, dry-retching, or vomiting	1-all of the time, 2-most of the time, 3-usually, 4-some of the time, 5-none of the time	4 & 5
QoR	Been free from experiencing severe pain or constant moderate pain	1-all of the time, 2-most of the time, 3-usually, 4-some of the time, 5-none of the time	4 & 5
Mobility (ortho)	How difficult is it to stand on your leg?	1-not at all difficult, 2-slightly difficult, 3-moderately difficult, 4-very difficult, 5-extremely difficult	4 & 5
Mobility (ortho)	How difficult is it to walk on your leg?	1-not at all difficult, 2-slightly difficult, 3-moderately difficult, 4-very difficult, 5-extremely difficult	4 & 5
Mobility (ortho)	How difficult is it to go up and down stairs?	1-not at all difficult, 2-slightly difficult, 3-moderately difficult, 4-very difficult, 5-extremely difficult	4 & 5
Picture	Take a photograph of your procedure site. You can add several photos.	N/A	N/A

Figure 1. Examples of the touch screen interface of the patient portal, including the visual analogue pain scale, an example of the QoR 9 question on postoperative nausea, and the visual analogue scale for fluid in the postoperative surgical drains.



Post-Recovery Follow-Up Survey for Patients

During the second follow-up visit to the surgeon, the mobile device was returned and patients were invited to fill in a post-recovery survey evaluating their recovery as well as their experience using the mobile device. The survey contained 33 questions including the same nine recovery indicators as the mobile app as well as questions pertaining to anxiety, desire to contact health care professionals, satisfaction with quality of care, satisfaction with the mobile device, and the patients' willingness to pay for the app in the future. The study coordinator was available while patients filled in the survey to provide clarification when required and answer patient questions about the study. In the event the patient was unable to complete the survey without assistance, the survey was read aloud by the coordinator and completed in a structured interview manner.

Post-Recovery Interview With Patients

Patients in the study were also invited to participate in a study evaluation interview. The interview focused on the patient recovery experience using the mobile device, user-friendliness of the mobile device and app, and suggestions for improvement.

Post-Pilot Surveys With Participating Surgeons

After the study was complete, the 3 participating surgeons were asked to fill out a post-pilot survey with 13 open-ended questions evaluating their post-operative recovery experience using the QoC Health technology platform. This survey included questions on overall experience, user-friendliness of the portal, changes that could improve the app and portal, potential impact on care and reduction of patient post-op visits, and potential for the solution to identify complications.

Ethical Considerations

Women's College Hospital Research Ethics Board approval for the pilot study was granted in July 2011. As there was no change in the current medical standard of care, there was no risk to patients by participating in the study. No patient was discharged from the hospital unless they met the standard discharge criteria applied to all patients, and all standard practices of post-surgical care were followed.

Patient Confidentiality

To ensure patient confidentiality, all hard copies of the data (ie, surveys and interview notes) were stored in locked filing cabinets in the investigator's office at Women's College Hospital with access restricted. All patients were coded, so that identifiers were absent from survey and interview data. Data sheets containing subject identifiers as well as subject identifications numbers were stored separately from data sheets containing subject identification numbers only. No identifiers were or will be included on any hard copy data sheets that link with health information (ie, only identification numbers are used), and password-protected databases are used.

Pictures of patients were related to the surgical site only, and no patient identifiers were used. By using managed devices (patients were given a mobile phone), a "locked down" subscriber identity module (SIM) card was used. The photographs were kept on a secure internal file folder and not available for viewing in the "Gallery" aspect of the mobile phone apps.

Health Canada was consulted as to whether this monitoring concept on a mobile phone would be considered a classification of "medical device". Because it is not diagnostic and is

essentially “monitoring stored forward” data, it is not considered a “device”.

Canadian Medical Protective Agency was also consulted in regards to medical legal liability and the participating surgeons. Their only stipulation was that of maintaining standards of privacy and security of patient data.

Data Security on a Mobile Platform

Patient data collected using the mobile app is double encrypted on the server and the phone. Designed from the “ground up” to ensure security and privacy, the app conforms to leading health care audit and interoperability standards including the Personal Health Protection Act, Health Level Seven International (HL7), Information Technology Infrastructure Library (ITIL), and Statement on Auditing Standards No. 70 (SAS70). Multiple layers of encryption, including resting state advanced encryption standard (AES) encryption, in transmission content encryption using unique per patient public/private key pairs, and in transmission transport layer security/secure sockets layer (TLS/SSL) protocol encryption were applied to maintain the highest level of patient confidentiality as possible. Modern infrastructure design leveraging distributed infrastructure as a service (IaaS) and cloud computing services (SaaS) for seamless accessibility, redundancy, and scalability were also utilized.

Analysis

Both quantitative and qualitative analyses were performed. Descriptive statistics were generated for demographic variables. Overall satisfaction with use of mobile device was scored from 1 (poor) to 4 (excellent), and means were generated. Frequencies were generated for categorical variables. Qualitative information from the evaluation survey and interviews were assessed for common themes.

Results

Demographics

A total of 38 breast patients were approached for participation, and 33 (87%) consented to participate. A total of 40 orthopedic patients seeking arthroscopic anterior cruciate ligament reconstruction were approached, and 32 (80%) consented to participate. Reasons for not participating included ineligibility (n=2), surgery cancellations (n=3), inability to provide a device due to timing of surgery (n=3), and patient preference not to participate (n=5). We enrolled 65 patients in the study, and Table 2 shows a summary of the demographic data for both orthopedic and breast patients. All of the patients completed the study protocol.

Table 2. Patient demographic information.

Characteristics	n (%)
Breast reconstruction (n=33)	
Gender	
Male	0 (0)
Female	33 (100)
Age in years	
Mean age	48
Age range	32-68
Orthopedic-arthroscopic anterior cruciate ligament reconstruction (n=32)	
Gender	
Male	18 (56)
Female	14 (44)
Age in years	
Mean age	33
Age range	21-55

Mobile App Data

The program was downloaded on to a standard device (mobile phones and tablets) and loaned to the patient for the period of the 30-day pilot. Few technical issues arose during the pilot. In total, there were ten technical inquiries from the 65 patients during the pilot. All of these inquiries related to the patient attempting to access the Internet for personal use on the managed device. All devices and connections worked well throughout the study and were returned on the final follow-up visit.

Patients were asked to log in daily to complete the QoR-9 (data not presented here). The mean number of logins over the 30-day study period was 23.9 (range 7-30) for the breast patients and 19.3 (range 5-30) for the orthopedic patients. The mean number of logins was higher in the first 14 days post-op compared to the 15-30 days post-op for both breast patients (13.4 vs 10.5; $P<.001$) and for the orthopedic patients (13.4 vs 6.0; $P<.001$). The mobile app aggregate response profile data to post surgery quality of recovery indicator questions (QoR 9 modified) is available in Multimedia Appendix 1.

Patients were also asked to upload photographs of the surgical site on a daily basis. Over the 30-day period, 2087 photos were uploaded by the breast patients and 1201 by the orthopedic patients. The mean number of photos uploaded by breast patients was 63 photos (range 11-181) each over the 30-day period, and for orthopedic patients was 38 photos (range 13-160) (P=.003). Overall, 82% (range 33%-100%) of the breast patients uploaded at least one photo per day, and 58% (range 30%-100%) of the orthopedic patients uploaded at least one photo per day (P<.001).

Two potential surgical complications were detected through surgeon viewing of the photographs. Figure 2 shows one of the breast reconstruction patients who was identified with increasing erythema at day 12 post-op. One orthopedic patient was also identified with increased erythema at 5 days post-op. There were no patients who presented clinically with complications that were not identified through monitoring of the mobile phones.

Figure 2. Patient-entered pictures showing left breast of a breast reconstruction patient following insertion of a tissue expander, where the surgeon identified an increasing erythema at 10 days post-op. The sequence of pictures and dates are shown. The patient was placed on antibiotics (over the phone) on Dec. 28th and the erythema starts to recede. The camera quality on most mobile phones is capable of detecting subtle changes in skin tone.

Post-Recovery Follow-Up Survey for Patients and Post-Recovery Interview

Most of the patients (82%, 53/65) completed the follow-up survey on study completion: 31 breast patients (94%) and 22 orthopedic patients (69%). On a scale from 1 (poor) to 4 (excellent), the mean score for overall satisfaction with using the mobile handheld device was 3.9 for breast patients and 3.7 for orthopedic patients. Most of the patients (87%, 46/53) rated overall satisfaction as excellent, and very few rated it as good (9%, 5/53), fair (4%, 2/53), and poor (0). All patients responded that they would be willing to use the handheld device during a future post-op period.

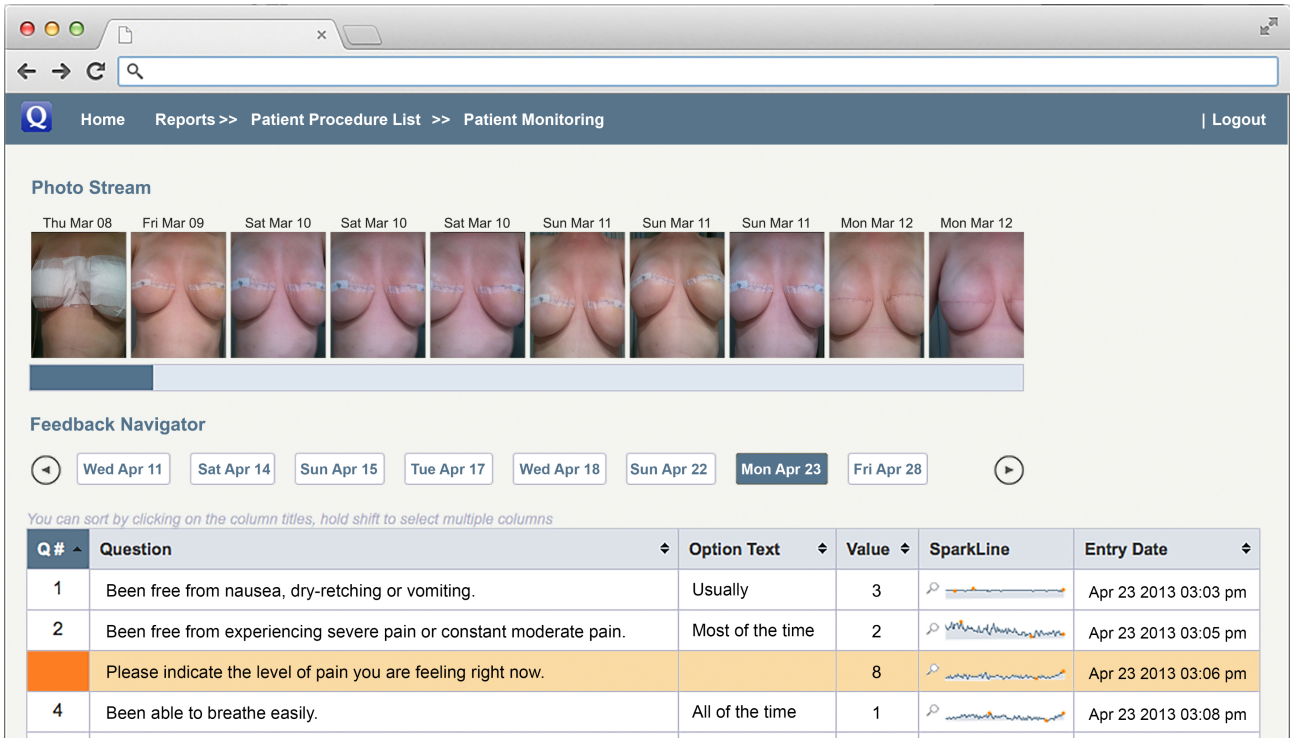
Surgeon Follow-up

All three participating surgeons completed the follow-up. Each surgeon followed a mean of 22 patients using the platform. All of the surgeons responded that the platform was user-friendly and intuitive. Specific aspects that enhanced the experience included the easy-to-navigate design, the portability to monitor patients outside of hospital perimeter, and the ability of the technology to improve time efficiency. Surgeons and other care providers reported on the depth of the information that was available in identifying the patient's recovery trends. New data and insight were apparent in the comparison of the photographic sequence of the surgical site and in the profile of the patient's recovery. Concerns raised by one surgeon focused on how much additional time would be required by care providers to monitor multiple recovering patients on an ongoing basis. A second

point identified the fact that currently (in Canada's health care system), there is no remuneration code for such activity. Figure 3 depicts an example of the surgeon's dashboard.

Follow-up visits for patients enrolled in the pilot were scheduled in the usual pattern for each surgeon. When asked whether the surgeons would feel comfortable canceling a follow-up visit if they saw patients were recovering well through the Web portal, all surgeons indicated they would consider canceling the 6-week follow-up for orthopedic surgeries or the first or second follow-up visit for breast-reconstruction surgeries. For canceled follow-up appointments, the orthopedic surgeons indicated that replacing the in-person consultation with a phone call was not an efficient option, and they considered phone calls to be an outdated mode of communication. Rather, surgeons were willing to send an electronic confirmation with personalized feedback to the patients who were progressing well and had their follow-up canceled.

Figure 3. Surgeon's dashboard: The surgeon or care provider can view the patient's quality of recovery all on one screen. The photos show the patient's "selfies" of the surgical site with the date. The QoR-9 questions are listed with the responses. Question #3 is highlighted red because of the abnormally high pain score entered by the patient. The "spark line" represents every score as a point of data on that particular indicator since the start of the monitoring. The pictures can be enlarged by tapping on them.



Discussion

Principal Findings

Physicians and patients who carry mobile phones are being introduced to the advantage and convenience of "mobile health", or mHealth. However, there is relatively little research on the feasibility or effectiveness of downloadable apps or software for mobile phones (specifically smartphones) for the remote monitoring of patients following surgery [10].

This study provides evidence that the use of mobile app monitoring with breast reconstruction and orthopedic surgery patients is feasible and acceptable to patients and surgeons.

Patient adherence in using mobile app technology has been demonstrated previously in chronic conditions [16]. However, this pilot study has demonstrated that adherence is also high in acute post-operative patients discharged from hospital within 24 hours after surgery. Patients were asked to log on to the device on a daily basis for 30 days post-operatively. Patient adherence was high; on average, in the first 15 days post-op, patients logged on to the device 13.4 times. This decreased considerably in days 16-30. Logan et al have also reported that adherence also decreases over time in hypertensive patients using mobile devices for blood pressure monitoring [16]. However, with post-operative patients it may be directly related to the type of questions asked of the patients. During the 30 post-operative days, the questions were based primarily on a survey of the patient's immediate post-op recovery and therefore became less relevant as the weeks passed. A modified questionnaire incorporating different questions relating to features of daily activity (ability of the patient to independently get dressed or return to work) may be more relevant in weeks 3 of a 30-day recovery profile.

Patient satisfaction was very high in this pilot study of breast reconstruction and orthopedic surgery patients. On a scale from 1 (poor) to 4 (excellent), the mean score for overall satisfaction with using the mobile handheld device was 3.9 for breast patients and 3.7 for orthopedic patients. Furthermore, 46 of the 53 patients (87%) rated overall satisfaction as excellent, and all would be willing to use this monitoring in the post-operative period. This patient data supports the acceptance of this type of mobile monitoring. These findings are consistent with other studies evaluating the acceptance of the use of mobile technology in other medical conditions including hypertension,

congestive heart failure, and diabetes [16-19]. Generally, it has been reported that patients have an overall positive attitude towards mobile technology [20].

In addition to feasibility of patients using the device, we have also demonstrated the feasibility of surgeons monitoring post-operative patients. Through the platform, the surgeons had a first-time view of daily patient recovery between discharge from hospital and the first follow-up visit through the use of the quality of recovery data and photographs. Observing the incisions in sequence allowed for a new type of indicator assessment for surgeons and an opportunity for intervening in the early development of post-operative infections. The resolution and quality of cameras available on most mobile phones are now capable of detecting subtle color changes in skin tone. As a result, complications were observed in real-time and allowed for the identification of complications prior to scheduled follow-up visits. Furthermore, there were no complications identified at follow-up visits that had not been identified using the mobile phone monitoring. The use of photographic imaging using mobile phones in post-operative monitoring of microvascular free tissue transplantations has previously been examined in post-operative patients; Engel et al [21] used a prospective study to compare the accuracy rate in detecting complications using mobile phone photographic assessments compared to in-person examinations. They reported that the remote mobile phone photography assessment had a comparable accuracy rate, and importantly, had a shorter response time compared with an in-person visit. In the post-operative period, it is critical that complications be identified promptly and treated.

Our research and that of others, demonstrates that mobile phone monitoring using photographs for post-operative patients is feasible for patients and effective at detecting complications for surgeons. Consequently, in our study, surgeons identified that with the mobile monitoring they would feel comfortable reducing post-operative follow-up visits if patients were using mobile monitoring. Other modalities of telemedicine, including Skype, have previously been shown to decrease the number of unscheduled post-operative visits in patients with total joint arthroplasty [22]. The reduction in the number of post-operative visits has financial implications. We have previously reported that mobile app follow-up care is cost-effective from a societal and health care system perspective [23].

The most common issues raised in regards to using mobile apps in health care are privacy and data security, funding, a lack of good examples of the efficacy and cost effectiveness in practice, and the need for more high-quality research [1]. With appropriate attention to privacy and security, these concerns can be addressed in a comprehensive manner. Given the fact that this may be considered “new data”, one must be aware of who owns the data and where the data should go in regards to patient care. In this study, we assumed the data to belong to the patient and a copy of the results, in accordance with the Review of Ethics Board for the Women’s College Hospital Research Institute, were sent to the patient’s hospital chart.

Limitations

There are limitations to the current study. Information regarding the patient’s race, ethnicity, or socioeconomic status was not collected. The study sample was relatively young and as a result may have been more comfortable with technology. In addition, the sample of surgeons was small. Further large-scale studies are required to ensure generalizability of the results. Furthermore, it will be important to evaluate the cost-effectiveness of using this type of technology, and further studies are planned to elucidate the cost and efficiency details with greater clarity.

Conclusions

This study sets the stage for future studies of this nature in different patient populations, both acute and chronic. This type of at-home monitoring using mobile technology appears to be feasible and acceptable for breast reconstruction and orthopedic surgery patients. Future studies can leverage this initial proof of concept and explore in more detail the use of patient-reported recovery information and mobile technology. The results of this pilot study provide a possible solution that supports the current shift in health care from inpatient care to ambulatory care and increased emphasis on recovery in the home.

Conflicts of Interest

Authors Semple and Sharpe hold shares in QoC Health Inc. As part of the Review of Ethics process at Women’s College Hospital, all data from this study and this manuscript have been reviewed by an independent Conflict of Interest Committee.

Multimedia Appendix 1

Mobile App Aggregate Response Profile data to Post Surgery Quality of Recovery Indicator questions (QoR 9 modified). Two post surgical populations Breast Reconstruction and Orthopedic (ACL repair).

[PDF File (Adobe PDF File), 170KB - mhealth_v3i1e18_app1.pdf]

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Abbreviations

AES: advanced encryption standard
HL7: Health Level Seven International
IaaS: infrastructure as a service
ITIL: Information Technology Infrastructure Library
QoR-9: Quality of Recovery questionnaire
SaaS: cloud computing services

SAS70: Statement on Auditing Standards No. 70
SIM card: international mobile subscriber identity
TLS/SSL: transmission transport layer security/secure sockets layer
VAS Scale: Visual Analogue Scale

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Original Paper

A Mobile Cloud-Based Parkinson's Disease Assessment System for Home-Based Monitoring

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Abstract

Background: Parkinson's disease (PD) is the most prevalent movement disorder of the central nervous system, and affects more than 6.3 million people in the world. The characteristic motor features include tremor, bradykinesia, rigidity, and impaired postural stability. Current therapy based on augmentation or replacement of dopamine is designed to improve patients' motor performance but often leads to levodopa-induced adverse effects, such as dyskinesia and motor fluctuation. Clinicians must regularly monitor patients in order to identify these effects and other declines in motor function as soon as possible. Current clinical assessment for Parkinson's is subjective and mostly conducted by brief observations made during patient visits. Changes in patients' motor function between visits are hard to track and clinicians are not able to make the most informed decisions about the course of therapy without frequent visits. Frequent clinic visits increase the physical and economic burden on patients and their families.

Objective: In this project, we sought to design, develop, and evaluate a prototype mobile cloud-based mHealth app, "PD Dr", which collects quantitative and objective information about PD and would enable home-based assessment and monitoring of major PD symptoms.

Methods: We designed and developed a mobile app on the Android platform to collect PD-related motion data using the smartphone 3D accelerometer and to send the data to a cloud service for storage, data processing, and PD symptoms severity estimation. To evaluate this system, data from the system were collected from 40 patients with PD and compared with experts' rating on standardized rating scales.

Results: The evaluation showed that PD Dr could effectively capture important motion features that differentiate PD severity and identify critical symptoms. For hand resting tremor detection, the sensitivity was .77 and accuracy was .82. For gait difficulty detection, the sensitivity was .89 and accuracy was .81. In PD severity estimation, the captured motion features also demonstrated strong correlation with PD severity stage, hand resting tremor severity, and gait difficulty. The system is simple to use, user friendly, and economically affordable.

Conclusions: The key contribution of this study was building a mobile PD assessment and monitoring system to extend current PD assessment based in the clinic setting to the home-based environment. The results of this study proved feasibility and a promising future for utilizing mobile technology in PD management.

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KEYWORDS

mHealth; Smartphone; Mobile App; Cloud application; Parkinson's Disease; Home based monitoring; Telemedicine; Decision marking; Tremor; Gait difficulty

Introduction

Parkinson's disease (PD) is a progressive neurodegenerative disorder that affects more than 1 million US residents and about 3% of the population over the age of 65 in the world [1,2]. PD can cause significant physical and mental impairment and decreased quality of life [3]. When PD becomes clinically overt, tremor, bradykinesia, rigidity, and impaired postural stability are the four cardinal motor signs [4]. Patients may also suffer from shuffling of gait, freezing of gait, and dystonia [5]. Current PD management requires regular assessment and close monitoring of symptoms in order to adjust medication dosage and frequency, especially when motor complications of therapy appear. Assessment is generally conducted using brief observations by the physician during a patient visit. Assessment in this clinical setting is subjective and it is difficult to keep track of decline and improvement of symptoms between clinic visits [6]. Closer monitoring of PD symptoms has the potential to permit more informed decisions about therapy. Achieving closer monitoring with more frequent clinic visits increases the physical and economic burden for PD patients and their families [7].

Given the characteristics of Parkinson's disease and its challenges on disease management, designing ambulatory tools for remote monitoring of PD patients has also attracted a lot of attention recently [8-13]. The eddy-current detector, commercial portable multichannel recorder, and wearable sensor have been used to measure hand tremor [14-16]. In a recent study, Rodriguez-Molinero et al used a portable inertial sensor to detect motor fluctuations (on-off) in PD patients, and the result showed very high sensitivity and specificity [17]. In terms of gait, there are three primary measurements of gait: (1) force-based measurement, (2) angular rate measurement, and (3) accelerometer measurement [18]. Several accelerometer-based measurement systems for ambulatory monitoring of gait-related symptoms in PD have been reported in freezing of gait detection, posture and walking speed estimation, and fall risk estimation [3,19-21]. Salarian et al used body-attached gyroscopes to estimate gait features and physical activities related to PD. However, their study did not report any result about how to use the estimated features to detect and estimate PD severity [22,23]. Patel et al, in Harvard medical school, used wearable accelerometers to evaluate motor complications on persons with PD, and attempted to predicate the clinicians' estimates of disease symptoms severity [8,24,25]. But their approach needed patients to attach several sensors at different locations and also required a separate control module to transmit and store data. The requirement of these extra settings puts an additional burden on users and decreases the usability of the system.

With the rapid development of sensor technology, cloud computing, and ubiquitous access to the Internet from mobile devices, eHealth and mobile health have spurred the development of telemedical systems that monitor vital signs and physiological signals, including electrocardiograms and electromyography, with several being marketed [8,26-28]. With the integrated sensors in modern smartphones becoming more powerful and cheaper, the feasibility and accuracy of using smartphones to measure various movement-related metrics have attracted a lot of research interest. Fontecha et al recently reported using tri-axels accelerometers in smartphones to assess frailty in elderly people [29]. Liddle et al used the global positioning system (GPS) sensor in smartphones to evaluate lifespace of people with PD [30]. Galan-Mercant et al utilized the accelerometer and gyroscope to measure sit-to-stand posture transition in elderly persons [31]. Recently, Apple unveiled its plan to embark on health care by releasing HealthKit APIs in iOS 8 in June 2014. These provide efficient tools and an interface for developers to develop apps to access, manage, and transfer information about health and well-being with a wearable device. With these technology evolutions, it is feasible and very promising to extend PD monitoring from intermittent clinic-based assessment to the home-based environment by leveraging current mobile device and powerful cloud computing.

In this project, we designed, developed, and evaluated a mobile cloud-based app, "PD Dr", for Parkinson's disease home-based monitoring and assessment. PD Dr assesses users' motor performance by capturing motion data using the embedded 3D accelerometer of a smartphone, identifying key symptoms, and estimating symptom severity based on this captured data. In this paper, we first describe system architecture, design, and development. We then present the initial test results. We end by discussing design considerations, potential limitations, and future directions.

Methods

System Description and Architecture

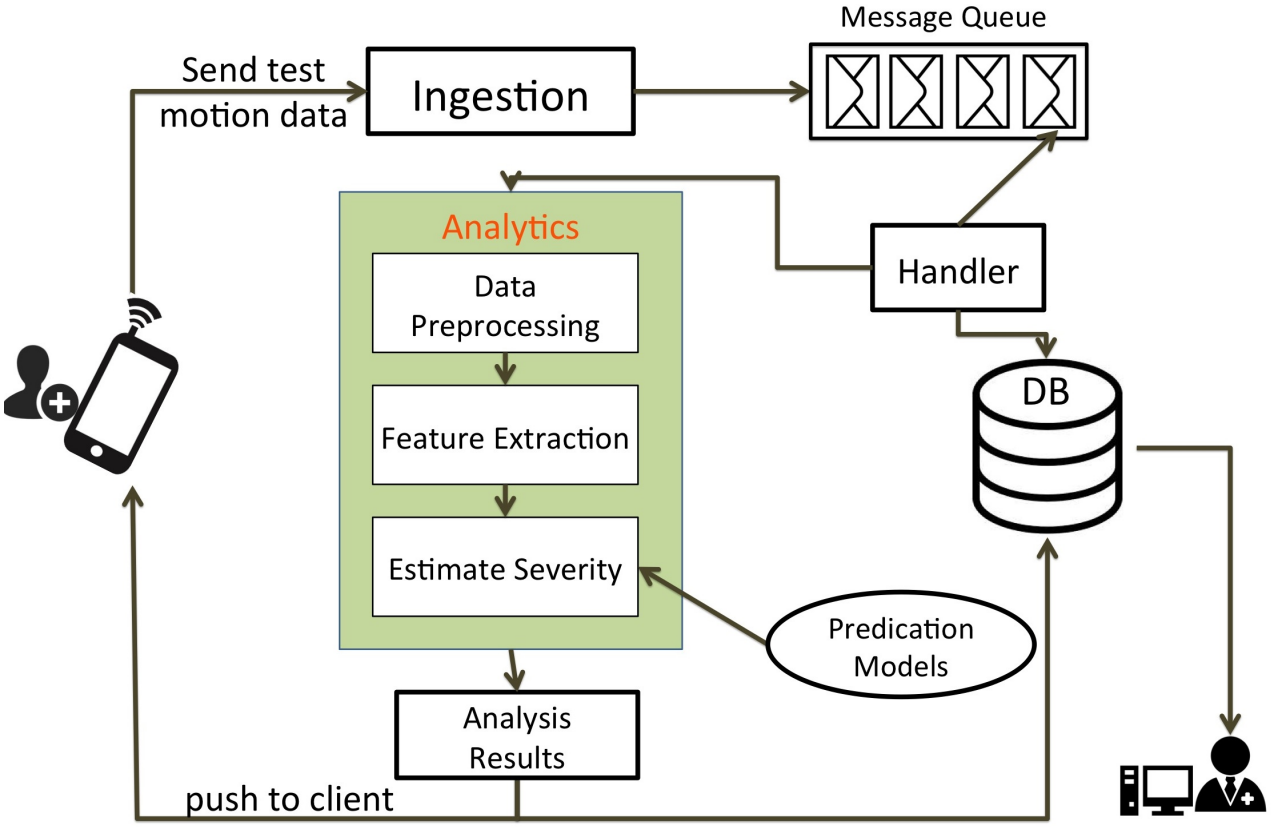
PD Dr is a mobile cloud app that utilizes the 3D accelerometer in a smartphone to collect data on hand tremor and walking motion, and utilize high computing performance and cloud service storage to analyze disease severity and monitor disease progression. The system is composed of two parts: a mobile app on a smartphone for motion data collection and user interaction, and a cloud service that processes the motion data and stores results. Patients use the client app to test their own performance, send the motion data to a cloud service, and receive evaluation results back from the cloud. Figure 1 displays the overall system architecture and data flow.

The mobile app on the smartphone captures patients' movement accelerations while they conduct a motor performance task. The smartphone is mounted on the back of the hand or ankle of the patient with a strap, and instructions on screen guide them through the motor performance task. Data captured by the 3D accelerometer embedded in the smartphone are temporarily stored locally on the device. Once a task is finished, captured motion data and metadata are sent to a cloud service. The cloud application processes received data through a data pipeline that estimates disease severity and the estimate is sent back as a

report to the patient's smartphone. All motion data and analysis results are stored in a cloud database that is used for tracking disease history.

In PD Dr, users' privacy and data security are assured at three levels: at the mobile app level, the data transmission level, and the data storage level. In the mobile app, user log-in is required in order to perform the test and browse test history. All application data stored on the local mobile device are encrypted; the data are deleted from the device after sending to the cloud server. The mobile app does not store or display any patient identity information, in accordance with Health Insurance Portability and Accountability Act (HIPAA) regulations. At the data transmission level, data are encrypted and transmitted through secure hypertext transfer protocol (https). At the server level, data are stored in the database in encrypted format and only an authorized database administrator has access.

Figure 1. System architecture and data communication flow.



Motor Performance Test Design

PD Dr measures motion in three motor performance tasks: hand resting tremor, walking, and turning. Selection of these three tasks was based on previous studies that found a strong association of the three motor performances with PD severity. Hand resting tremor is a typical symptom that is found in most early stage PD patients [32]. A strong association exists between PD lower body motor disabilities and walking/turning performance [33]. Table 1 provides a detailed explanation of the motor tasks. Figure 2 depicts the mount positions of the smartphone in the hand resting tremor, walking, and turning tasks.

Table 1. Designed motor performance test on PD Dr app.

Test name	Test description	Captured data description
Hand tremor	User attaches the smartphone to the back of the hand and leaves the hand hanging for 20 seconds.	Translational acceleration rate at X, Y, and Z directions and angular acceleration rate at pitch, roll, and yaw directions.
Walking	User attaches the smartphone to the ankle of one leg and walks 25 feet.	Translational acceleration rate at X, Y, and Z directions and rotation matrix of smartphone with time change.
Turning	User attaches the smartphone to the pivot leg in turning 360°.	Angular acceleration rate at pitch, roll, and yaw directions with time change.

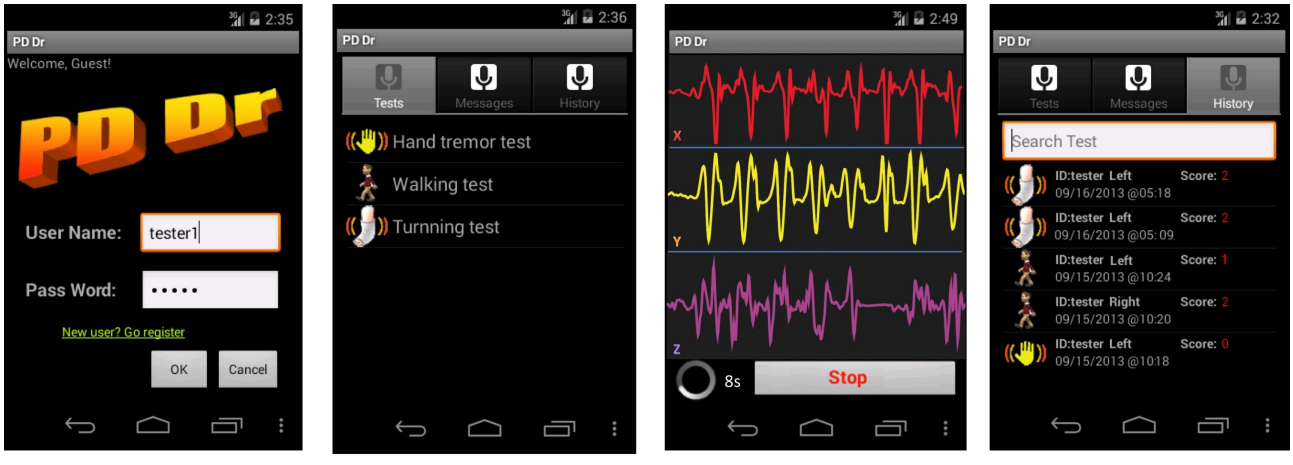
Figure 2. Smartphone and motor test application in hand tremor test (A) and walking & turning test (B).

Mobile App: Data Acquisition and Communication

The client mobile app was developed on the Android 4.0 platform. The sampling rate of the accelerometer was set to 100 Hz. Since hand tremor acceleration is lower than 20 Hz [34,35], and walking and turning acceleration is between 2~5 Hz [36], 100 Hz sampling rate is sufficient to capture PD-related motion features. Because the device might not have Internet access in certain conditions, an internal relational database SQLite was utilized as temporary local data storage to store captured motion data. To accommodate situations where neither a wireless network nor mobile phone network is available, acquired motion data can be temporarily stored in the internal database and then sent to the server side when a network is available. All data was marshaled into XML format and then encrypted using Advanced Encryption Standard (AES) algorithm for transmitting to the cloud server through the Internet [37].

The mobile app is made up of four function modules, shown in Figure 3. The first module is user log-in and account verification. Users must first log in with their credentials to perform the tests. See Figure 3 (A). The second module, the motor performance test module, lists the three tests for user selection. See Figure 3 (B). After the user selects a test, the test view appears and displays step-by-step instructions on how to conduct the test. As the user performs the test, captured motion data are displayed on the smartphone screen in real time; the data are saved on the smartphone once the test is completed, as shown in Figure 3 (C). The third module is a communication module, which integrates with short message service (SMS) and email. Users can send questions or receive medical recommendations from the medical care facility server. The fourth module is the test history management module. It is composed of a list view and search field. Users can browse test history chronologically or search a specific test. Once a target test record is found, the user can click on a test record to review details, send it to a server, or delete it from the smartphone. See Figure 3 (D).

Figure 3. Screenshots of PD Dr app: (A) User account log-in, (B) Motor test list, (C) Data collection during test, and (D) Test history and evaluation result.



Cloud Service: Data Processing and Decision Making

The cloud service is composed of three components: (1) a data processing pipeline, (2) disease severity predictive models, and (3) database storage. The framework of server side components is depicted in Figure 4. Motion data are first received by the ingestion module in encrypted XML. For each received test record, the data ingestion module decrypts and parses out the raw motion data and associated metadata, which consists of sampling rate, time duration, date, test type and user ID. The ingestion module then puts the test record into a message queue for asynchronized handlers to process. Each asynchronized handler pulls a message from the message queue, then sends the data to the database, where it is analyzed through the data processing pipeline. The main reason to use a message queue and asynchronized handler to process data is to increase system scalability and decouple the system components. The data processing pipeline executes a series signal processing steps and data analysis steps. The pipeline first filters out noise through low pass filter and then calibrates acceleration to zero baseline.This is followed by analytics to extract PD-related motion features using several signal processing and motion pattern extraction algorithms that were introduced in previous studies [38-40]. Tables 2 and 3 provide a detailed description of extracted motion features for hand resting tremor, walking, and turning. The extracted motion features are then fed into a decision support module that uses the information to estimate disease severity based on Part III of the Unified Parkinson's Disease Rating Scale (UPDRS) and disease stage using the Hoehn&Yahr scores [41]. All of the cloud components, including the motion ingestion module and data processing pipeline, were home-developed using Java programming language and were built on the Spring web framework.

The decision support module was designed to detect critical movement disability symptoms and to estimate PD severity. In this prototype, the decision support module could provide severity estimation of hand resting tremor and gait difficulty, as well as PD disease stage estimation. We utilized a subset of data mining techniques to assess whether hand resting tremor and gait difficulty are characterized by specific patterns and to estimate disease severity from the hand resting tremor motion features and gait features respectively. Input features for hand resting tremor and gait difficulty were extracted motion features, as described in Tables 2 and 3. The motion features of hand resting tremor were selected based on previous study results on characteristics of resting tremor, as well as experts' opinions [34,35,42]. Two binary classification models were trained using Support Vector Machine (SVM), to detect gait difficulty and hand resting tremor [43,44]. For estimating symptom severity, we built three regression models to estimate disease stage (Hoehn&Yahr score from 1-5), hand resting tremor UPDRS score, and gait difficulty UPDRS score, using the Lasso regression approach [41,45,46].

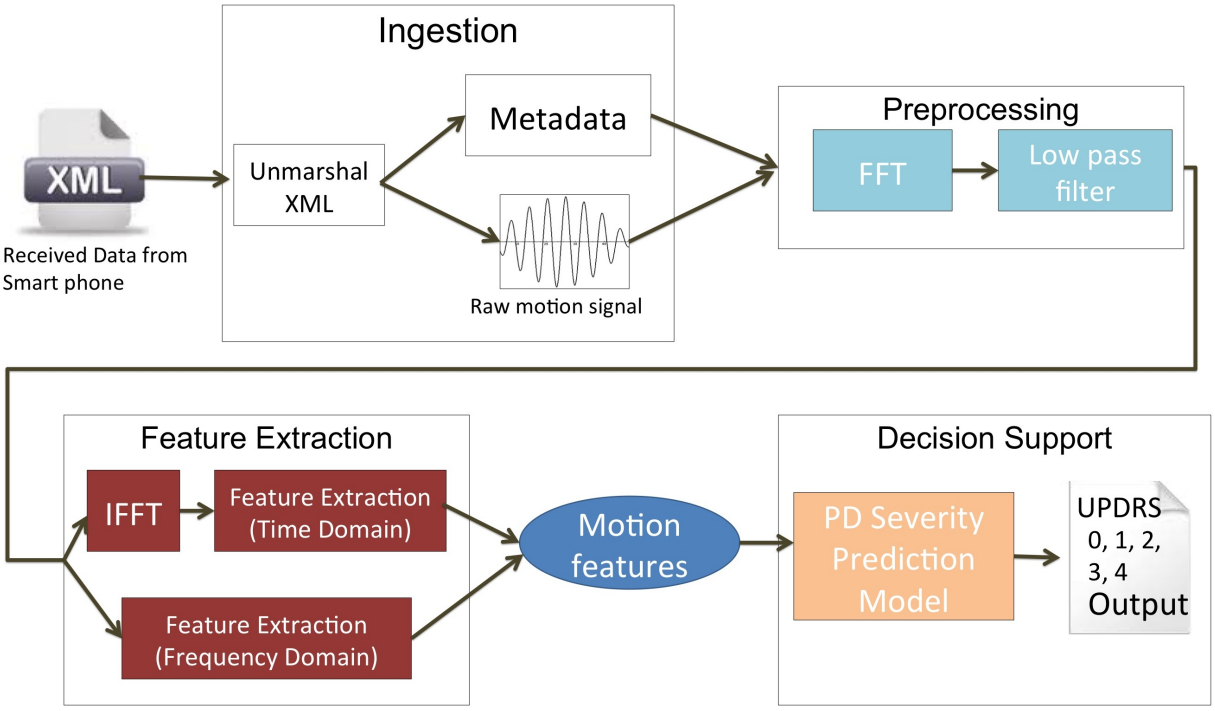
Table 2. Extracted hand resting tremor motion features.

Tremor features	Description
PF4_6	The power of the motion data between 4 and 6 Hz.
%PF4_6	Fraction of power of motion data between 4 and 6 Hz.
PR	Power ratio of the motion data in 3.5~15 Hz to 0.15~3.5 Hz frequency components
PF0_20	The total power of motion data from 0~20 Hz
PEAK_POWER	The peak power value of hand resting tremor motion data.
AVG_ACC	The average acceleration of motion of hand resting tremor.

Table 3. Extracted gait motion features.

Gait features		Description
Walking Straight Task		
	CT (s)	Average gait cycle time.
	SL (m)	Average stride length.
	SP (m/s)	Average walking speed.
	AVG_ACC (m/s^2)	Average acceleration during walking.
Turning 360 ^{o}		
	NUM_TURN	The number of steps used to finish turning 360^{o}.
	TURN_SP	The speed of turning 360^{o}, calculated by 360^{o} / time.

Figure 4. Cloud data processing pipeline.



System Evaluation

PD Dr was tested and evaluated by recruiting patients with PD to use this system. The involvement of PD patients in the project was approved by the St. Joseph's Hospital and Medical Center (SJHMC) Institutional Review Board. Patients who received UPDRS-based evaluations as part of their regular clinic visits were invited to participate in this study, except mentally incompetent individuals and those with conditions that increased their vulnerability. The study instructions and consent forms were given to patients and explained by the principal investigator. If patients agreed to participate in this study, they signed the consent forms, which were collected by the principal investigator before testing. Participation was voluntary and participants could withdraw at any time during the study. We recruited 40 patients with a diagnosis of PD who had motor symptoms from among outpatients seen in the Muhammad Ali Parkinson Center. Hand resting tremor, walking, and turning motion data were collected through PD Dr. Two movement disorder experts also evaluated the severity of PD symptoms and disease stages of these 40 test subjects. Their expert ratings and evaluation of disease stage were treated as ground truth in training the prediction models used in decision support module. Collected motion data were analyzed and validated against the experts' evaluation of disease severity.

Results

Test Subject Description

Table 4 shows the general characteristics of the 40 PD patients in this study. Among these 40 patients, 5 were female and 35 were male. Ages of the participants ranged from 44 to 84 years, and the average age was 68.5 years old (SD 9.5). Among all subjects, 16 were in early disease stage (disease duration less than 6 years), and 24 subjects were in late disease stage (disease duration more than 6 years). The average Hoehn&Yahr stage was 2.4 (SD 0.8). There were 6 subjects at stage 1, 13 subjects at stage 2, 12 subjects at stage 3, and 9 subjects at stage 4. No subjects at stage 5 were recruited in this study. Among these 40 subjects, 9 subjects had freezing of gait (FoG), 11 subjects had gait difficulty other than FoG, 19 subjects had postural instability, and 5 subjects reported having falls on a weekly basis.

Table 4. Patients' general characteristics and UPDRS[a] scores (N=40).

		Mean (SD) or number	Range	Median (Q1-3)
Age (years)		68.5 (9.5)	44-84	70 (63-74)
Disease duration (years)		6.6 (4.0)	0-19	6 (4-8)
Hoehn&Yahr stage		2.4 (0.8)	1-4	2 (2-3)
Presence of motor related disabilities (Yes/No)				
	Bradykinesia	10/30	N/A	N/A
	Freezing of gait (FoG)	9/31	N/A	N/A
	Gait difficulty	11/29	N/A	N/A
	Postural stability problem	19/21	N/A	N/A
	Falls	5/35	N/A	N/A

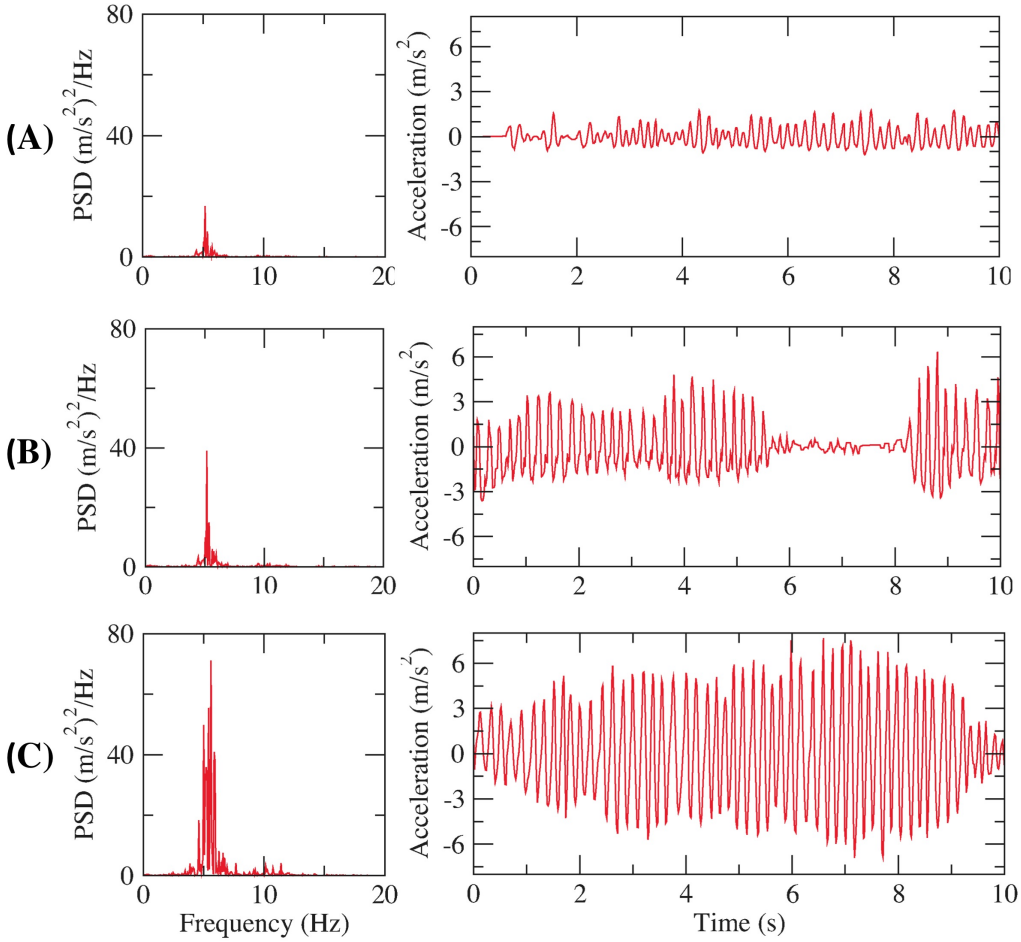
[a]UPDRS: Unified Parkinson's Disease Rating Scale

Hand Resting Tremor

Collected hand resting tremor motion data were analyzed and compared between subjects with different disease severities. Figure 5 shows hand resting tremor motion data for three subjects with UPDRS tremor score (UPDRS III Item 20) ranging from 1~3, which maps to mild, moderate, and severe. Power spectrum density (PSD) plots are shown in the left column, and corresponding accelerations are shown in the right column. The patient with mild hand tremor, Figure 5 (A), shows average acceleration of hand motion of 0.47 m/s^2. The PSD plot shows power spectrum mainly dominated around 5 Hz and the peak power was 16.8 $(m/s^2)^2/Hz$. For the patient with intermediate hand tremor, Figure 5 (B), the peak acceleration was at 6.3 m/s^2, and peak PSD was at 39.01 $(m/s^2)^2/Hz$. The patient at intermediate severity shows intermittent hand tremor, with average acceleration at 1.7 m/s^2 when hand tremor appears. Figure 5 (C) shows the motion data of a patient with severe hand resting tremor. It can be observed that continuous large acceleration of tremor movement appeared at 3~5 m/s^2, with peak PSD at 71.2 $(m/s^2)^2/Hz$.

From the above comparison, the results show that acceleration of hand tremor from PD Dr can demonstrate distinct quantitative characteristics according to change of severity. Moreover, our results are congruent with the observation rest tremor in PD predominates in 4~6 Hz [34]. The acceleration and PSD analyses demonstrate that hand tremor motion data collected from PD Dr can effectively capture motion features to characterize tremor, and provide a quantitative measurement for hand resting tremor.

Figure 5. Acceleration waveform and power spectrum density (PSD) plot of hand resting tremor of different severity: (A) Mild hand resting tremor, (B) Moderate hand resting tremor, and (C) Severe hand resting tremor.



Gait Difficulty

Over the course of PD, motor impairment in the lower body can substantially impair walking, balance, and postural stability, putting patients at risk for falling. PD Dr captures lower body movement from measurements of 3D acceleration of the ankle during walking and turning, as shown in Figure 6. Sample gait motion data from four test subjects with UPDRS gait score (UPDRS III Item 29) at 0, 1, 2, and 3 (according to ascending of severity) respectively, are shown in Figures 7-10. Figure 7 shows the gait acceleration waveform from a subject with UPDRS gait score of 0, with no gait difficulty observed. The gait profile exhibits the repetitive pattern of gait cycles: each gait cycle is composed of a swing phase and a stance phrase. Peak acceleration in each gait cycle generally remains consistent. Positive peak acceleration is up to 8 m/s^2, and the negative peak acceleration is up to 12 m/s^2. As severity of gait impairment increases, gait patterns in each cycle become more volatile and peak accelerations decrease substantially. In Figure 8, from a subject with UPDRS gait score of 1, repeating gait cycles can still be observed and the acceleration in each gait cycle is still stable. However, the peak acceleration decreases substantially to less than 5 m/s^2. When UPDRS gait difficulty increases to 2, shown in Figure 9, regular gait patterns disappear. The duration of gait cycles shows large variation, and the swing and stance phases become obscure. Accelerations of ankle movement also show large fluctuations. Figure 10 shows the data from a test subject who was diagnosed with FoG. It can be seen that the gait cycle is discontinuous, and there is a long gap from 3.6 s to 5.3 s, and from 6.2 s to 8.2 s; during those two periods, the test subject was unable to move.

To further evaluate the performance of PD Dr in capturing key motion characteristics of PD symptoms, gait cycle time (CT), stride length (SL), walking speed (SP), and average acceleration (ACC) of all 40 PD patients were extracted. These four features were compared between patients without gait difficulty (UPDRS gait difficulty score <2) and patients with gait difficulty (UPDRS gait difficulty score ≥2). The statistical significance of differences between these two groups was tested based on the *t* test. Table 5 shows the result of this analysis. Average gait cycle time (CT) of patients without gait difficulty is 1.1 s (SD 0.32), smaller than the average gait cycle time 1.22 s (SD 0.49) of patients having gait difficulty. The stride length and walking speed of patients without gait difficulty are significantly larger than patients with gait difficulty. The average acceleration of walking is 5.2 m/s^2 (SD 1.1) for patients without gait difficulty, and 3.6 m/s^2 (SD 1.7) for patients with gait difficulty. There were statistically significant differences between the two groups for SL (*P*=.035), SP (*P*=.026), and AVG_ACC (*P*=.038). In turning, the number of steps to complete turning 360° (NUM_TURN) and turning speed (TURN_SP) were compared

between the two groups. Patients without gait difficulty needed 3.1 (SD 0.9) steps for turning a full circle, and their average turning speed was 79.1 degree/s (SD 8.49). For the group of patients with gait difficulty, 5.4 steps (SD 1.1) were needed and turning speed was 53.7 degree/s (SD 6.98). The differences of these two turning features are also statistically significant (*P*=.042 for NUM_TURN and *P*=.039 for TURN_SP).

Figure 6. The mount position of the smartphone in walking and turning task.

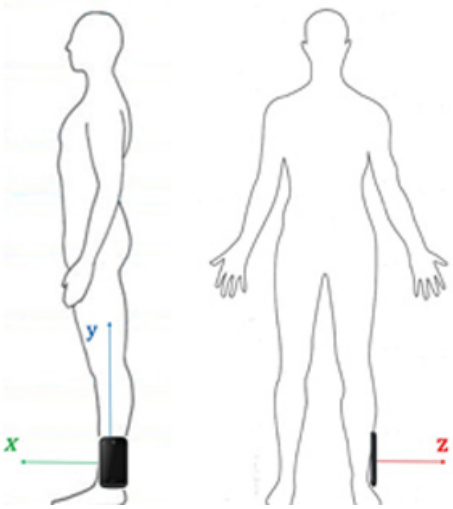


Table 5. Extracted motion features from walking and turning tests (results are divided into two groups, UPDRS[a]gait score <2 and UPDRS gait score ≥2.)

Gait features		UPDRS gait score <2	UPDRS gait score ≥2	*P* value
		Mean (SD)		
Walking straight				
	CT(s)[b]	1.1 (0.32)	1.22 (0.49)	.076
	SL(m)[c]	1.26 (0.17)	1.07 (0.29)	.035[h]
	SP(m/s)[d]	1.15 (0.20)	0.87 (0.28)	.026[h]
	AVG_ACC(m/s^2)[e]	5.2 (1.1)	3.6 (1.7)	.038[h]
Turning 360 ^{o}				
	NUM_TURN[f]	3.1 (0.9)	5.4 (1.1)	.042[h]
	TURN_SP(degree/s)[g]	79.1 (8.49)	53.7 (6.98)	.039[h]

[a]UPDRS: Unified Parkinson's Disease Rating Scale.

[b]CT: gait cycle time.

[c]SL: stride length.

[d]SP: walking speed.

[e]ACC: average acceleration.

[f]NUM_TURN: the number of step used to finish turning 360^{o}.

[g]TURN_SP: the speed of turning 360^{o}, calculated by 360^{o} / time.

[h]Significance (α=.05).

Figure 7. Acceleration in walking, Unified Parkinson's Disease Rating Scale (UPDRS) gait score = 0.

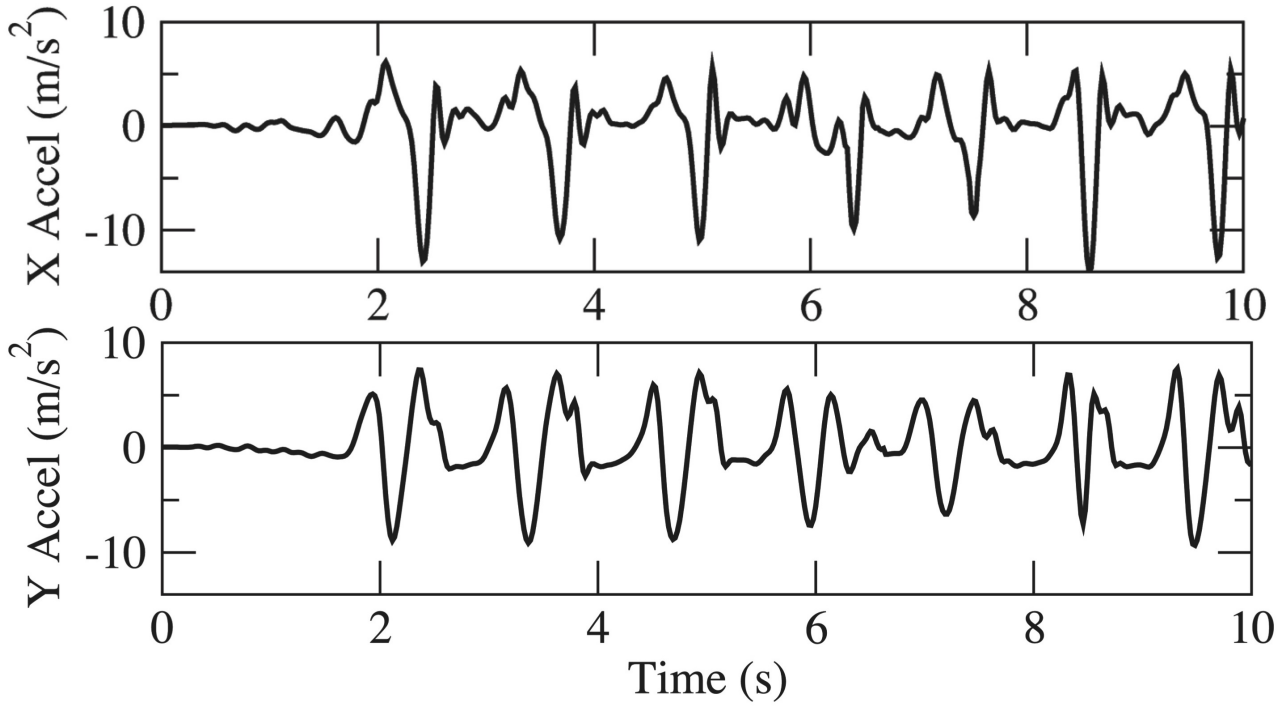


Figure 8. Acceleration in walking, Unified Parkinson's Disease Rating Scale (UPDRS) gait score = 1.

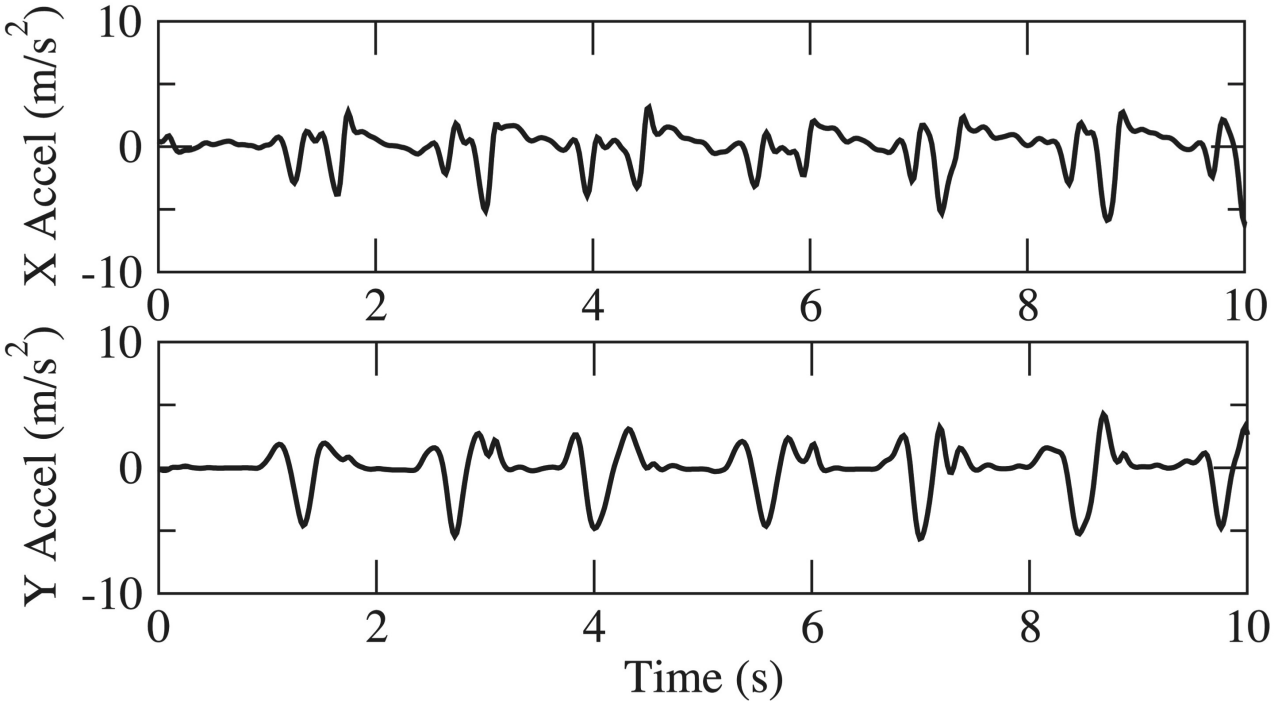


Figure 9. Acceleration in walking, Unified Parkinson's Disease Rating Scale (UPDRS) gait score = 2.

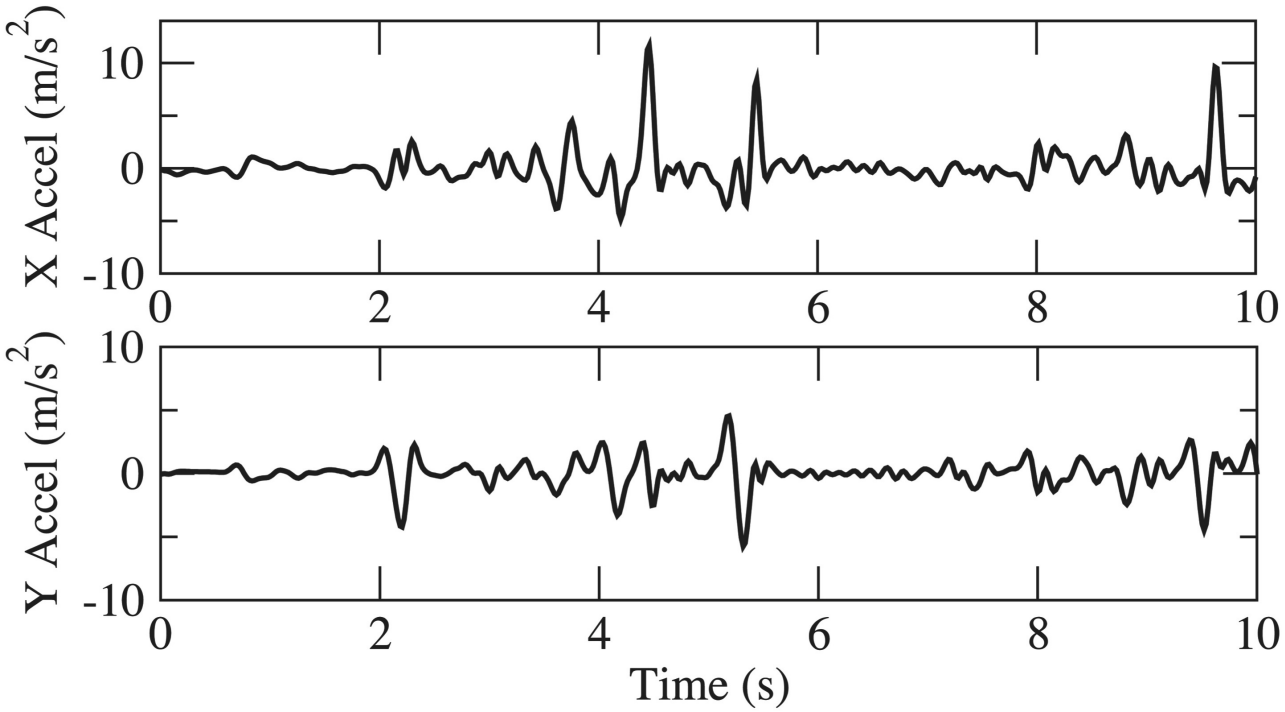
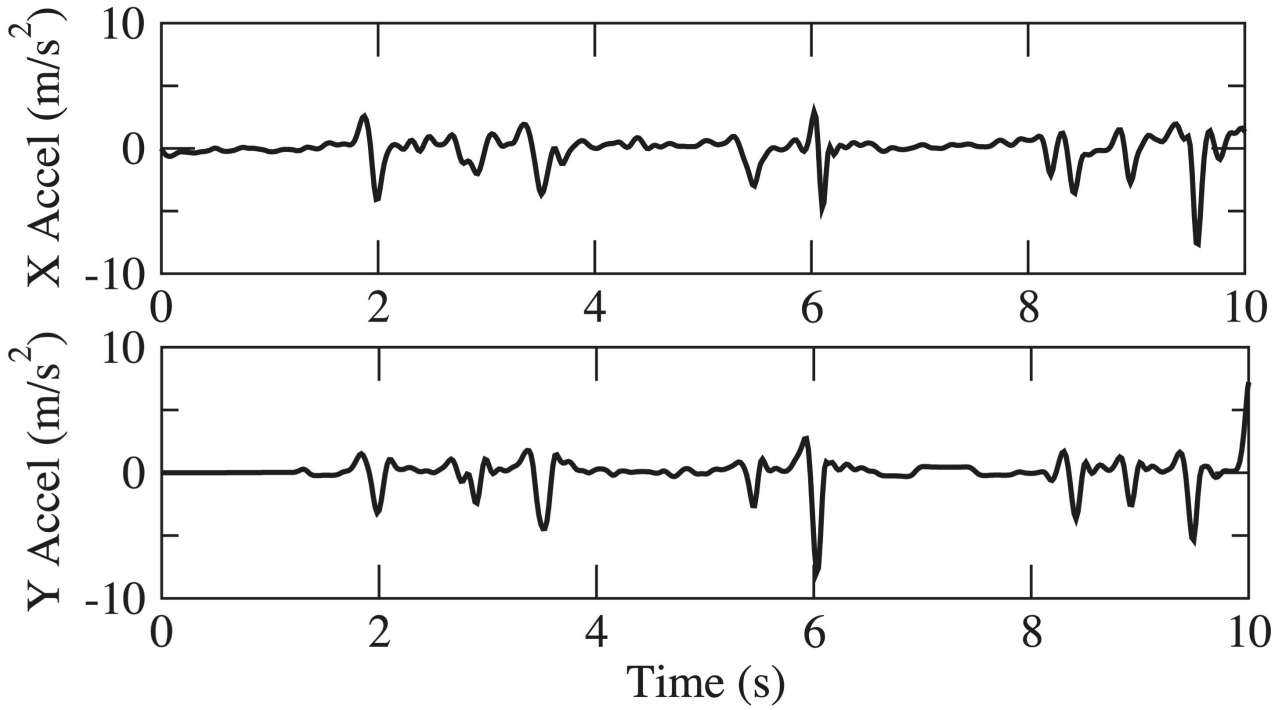


Figure 10. Acceleration in walking, Unified Parkinson's Disease Rating Scale (UPDRS) gait score = 3.



PD Symptoms Detection and Severity Estimation

The two classification models for detecting gait difficulty and hand resting tremor were trained and validated against the experts' evaluation result by using 5-fold cross-validation (CV) [47]. We randomly split data from the 40 patients into five equal size subsets. A single subset was retained as the validation data for testing the model, and the remaining four subsets were used as training data. The cross-validation process was then repeated five times with each of the five subsets used exactly once as the validation data. The validation results demonstrate good sensitivity and specificity. For hand resting tremor detection, sensitivity was .77 and specificity was .82. In gait difficulty detection, sensitivity was .89 and specificity was .81. The regression models also showed that captured motion features have strong correlation with PD disease stage, hand resting tremor severity, and gait difficulty severity. The correlation coefficients for PD stage are r=.81, r=.74 for hand resting tremor, and r=.79 for gait difficulty.

Discussion

Principal Results

Today's mobile devices empower consumers more than ever to measure, collect, access, and manage health data [48]. As acquisition and processing of large scale data become feasible in the cloud, they have the potential to vastly improve decision making and provide important insights about personal health and public health. In this study, we designed a mobile cloud solution, PD Dr, for Parkinson's disease home-based monitoring. This paper describes the system architecture, basic functional components, and data flow of the mobile cloud app in remote health monitoring and chronic disease management for patients with PD. This system could be extended to assessment of other movement disorders.

Although home-based monitoring increases health care access and saves patients' time and money, it also places stringent constraints on system: cost, size, unobtrusiveness, and ease of use are all factors impacting usefulness of the system. System testing by recruited patients showed PD Dr is simple and easy to use. Users can finish all tests within 5 minutes. Another advantage of PD Dr is that it can provide a more objective and quantitative measurement for PD assessment than subjective evaluation by physicians in PD assessment. Results of system evaluation tests demonstrated that PD Dr can effectively capture important motion features from accelerating signals to differentiating tremor and severity of gait impairment. The acceleration amplitude and power spectrum density of hand tremor give more quantitative and objective measurement than subjective rating. Motion features extracted from walking and turning demonstrated intuitive description of the subject's walking ability, and comparison of walking and turning motion features show significant difference between gait impairment. The predictive models constructed in this study to estimate disease severity demonstrated acceptable accuracy and promising future. The ability to monitor secular changes in tremor amplitude and various components of the gait cycle can provide a powerful tool for the patient and clinician to monitor progression of disease and need to optimize treatment and use services like physical therapy to address incipient problems in gait and postural stability. Further, the modular design of the cloud-based data processing and decision support units allow the ability to process accelerometer-based data acquired using a multitude of wearable devices, which are being introduced in the consumer market at a rapid pace.

Despite many studies and research on ambulatory assessment systems for Parkinson's disease, most of the previous approaches were based on using a separate sensor network and control module. In Patel's recent study based on wearable sensors, the user needs to wear eight accelerometers on the body, and requires a mobile phone to receive and send data [8]. In Keijsers's study on ambulatory motor assessment in PD, they used six sensors at different positions of body to collect data [13]. In the above systems, the sensed data needs to be transmitted to a control device and wearing multiple sensors on the body is not easy or convenient for PD patients. The detached sensor and control device also increase the system complexity and reduce the system reliability. Users need to set up and configure the system properly, which also decreases the usability [44,49]. In PD Dr, no complicated set-up or configuration is needed. Users simply use one smartphone and one strap to finish all tests, with no environment and space limitations. No peripheral equipment, such as sensors, cables, or power supply is needed, which greatly improves the usability of PD Dr. Another advantage of PD Dr is it provides an integrated service from data capturing to symptom detection and severity assessment. More importantly, PD Dr serves as an ambulatory PD evaluation platform; it is easy to add new tests to extend function and measure more PD characteristics by taking advantage of the smartphone sensor and various data input channels. For example, the touch screen can be used for measuring finger tapping speed, and video recording ability can capture the facial expression to evaluate loss of facial expression.

Limitations

Since this paper mainly focuses on system design, components, and architecture, we did not present details about data processing, motion feature extraction, and decision-making models for severity estimation or symptoms identification. We plan to discuss details about the data pipeline, motion feature extraction, and results of estimating disease severity using machining learning to support decision-making in a subsequent paper.

As a pilot study, this prototype system first focused on tremor and gait assessment in PD. Other than these two key PD characteristics, bradykinesia, motor fluctuation, and dyskinesia are also substantial symptoms that have important clinical meaning and also impair patients' quality of life. Those three PD characteristics are also measurable by using accelerometers. In the next step, we will extend PD Dr to include more tests to cover broader dimensions of Parkinson's disease.

Unlike the wearable sensor network, PD Dr is not an ideal platform to provide continuous monitoring over a long period of time, but more focuses on intermittent assessment of key motor issues of PD. This intermittent assessment approach, to some extent, has lower temporal resolution compared to wearable sensor networks, which users can wear for a longer time. Therefore, for some specific PD symptoms, like on-off phenomenon, PD Dr has poor ability to catch the change of motor ability during a certain period of time.

In this initial evaluation, due to funding and time limitations, we recruited only 40 PD patients as test subjects. The small number of test subjects, to some extent, limits training a more accurate decision model, as well as validating the performance of the entire system. In the next step, with more available testing data from recruited subjects, we plan to refine the algorithm of cloud server side data analytics to improve the accuracy of key PD symptoms detection and severity estimation.

Another limitation of our evaluation is the absence of feedback from PD physicians. This limitation will be taken into account in future usability tests. The system is still under development. Some additional functionality, including firing alerts when symptoms become worse, providing distributed access to

clinicians for reviewing and accessing data repository, will be implemented in the future work.

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Conflicts of Interest

None declared.

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Abbreviations

ACC: average acceleration
CT: gait cycle time
FoG: freezing of gait
NUM_TURN: the number of step used to finish turning 360o
PD: Parkinson’s disease
PSD: power spectrum density
SL: stride length
SP: walking speed
TURN_SP: the speed of turning 360o, calculated by 360o / time
UPDRS: Unified Parkinson’s Disease Rating Scale

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Corrigenda and Addenda

Correction: Texting Teens in Transition: The Use of Text Messages in Clinical Intervention Research

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The authors of “Texting Teens in Transition: The Use of Text Messages in Clinical Intervention Research" (JMIR *mHealth uHealth* 2014; 2(4):e45) neglected on submission to acknowledge the support and assistance of Dr Miriam Kaufman from the Good 2 Go Transition Program, The Hospital for Sick Children, in the use of the MyHealth Passport. The authors also did not update reference 72 (which they previously cited as Web reference discussing MyHealth Passport, http://www.webcitation.org/6GIIRwHSd) to the following article: Wolfstadt J, Kaufman A, Levitin J, Kaufman M. The use and usefulness of my health passport: an online tool for the creation of a portable health summary. *Int J of Child and Adolesc Health*. 2011;3(4):499-506. These errors have been corrected in the online version of the paper on the JMIR MHealth and UHealth website on February 2nd, 2015, together with publishing this correction notice. A correction notice has been sent to PubMed and the correct full-text has been resubmitted to Pubmed Central and other full-text repositories.

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