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Contents

Original Papers

Developing an Internet- and Mobile-Based System to Measure Cigarette Use Among Pacific Islanders: An Ecological Momentary Assessment Study (e2)
James Pike, Bin Xie, Nasya Tan, Melanie Sabado-Liwag, Annette Orne, Tupou Toilolo, Steven Cen, Vanessa May, Cevadne Lee, Victor Pang, Michelle Rainer, Dorothy Vaivao, Jonathan Lepule, Sora Tanjasiri, Paula Palmer. 4

Ecological Momentary Assessment of Illicit Drug Use Compared to Biological and Self-Reported Methods (e27)
Beth Linas, Andrew Genz, Ryan Westergaard, Larry Chang, Robert Bollinger, Carl Latkin, Gregory Kirk. 20

“Smart” RCTs: Development of a Smartphone App for Fully Automated Nutrition-Labeling Intervention Trials (e23)
Ekaterina Volkova, Nicole Li, Elizabeth Dunford, Helen Eyles, Michelle Crino, Jo Michie, Cliona Ni Mhurchu. 32

Tracking Health Data Is Not Enough: A Qualitative Exploration of the Role of Healthcare Partnerships and mHealth Technology to Promote Physical Activity and to Sustain Behavior Change (e5)
Sheridan Miyamoto, Stuart Henderson, Heather Young, Amit Pande, Jay Han. 44

Developing mHealth Remote Monitoring Technology for Attention Deficit Hyperactivity Disorder: A Qualitative Study Eliciting User Priorities and Needs (e31)
Lucy Simons, Althea Valentine, Caroline Falconer, Madeleine Groom, David Daley, Michael Craven, Zoe Young, Charlotte Hall, Chris Hollis. . 5 6

Possibilities and Expectations for mHealth in the Pacific Islands: Insights From Key Informants (e9)
Elaine Umali, Judith McCool, Robyn Whittaker. 70

The PAediatric Risk Assessment (PARA) Mobile App to Reduce Postdischarge Child Mortality: Design, Usability, and Feasibility for Health Care Workers in Uganda (e16)
Lauren English, Dustin Dunsmuir, Elias Kumbakumba, John Ansermino, Charles Larson, Richard Lester, Celestine Barigye, Andrew Ndamira, Jerome Kabakyenga, Matthew Wiens. 79

Design of a Tablet Computer App for Facilitation of a Molecular Blood Culture Test in Clinical Microbiology and Preliminary Usability Evaluation (e20)
Lasse Samson, Louise Pape-Haugaard, Michelle Meltzer, Martin Fuchs, Henrik Schønheyder, Ole Hejlesen. 89

MoodHacker Mobile Web App With Email for Adults to Self-Manage Mild-to-Moderate Depression: Randomized Controlled Trial (e8)
Amelia Birney, Rebecca Gunn, Jeremy Russell, Dennis Ary. 101

Uptake of a Consumer-Focused mHealth Application for the Assessment and Prevention of Heart Disease: The <30 Days Study (e32)
Shivani Goyal, Plinio Morita, Peter Picton, Emily Seto, Ahmad Zbib, Joseph Cafazzo. . . . 120

Outcomes of a Mobile Health Coaching Platform: 12-Week Results of a Single-Arm Longitudinal Study (e3)
Steven Willey, James Walsh. . . . 132

A Group-Based Mobile Application to Increase Adherence in Exercise and Nutrition Programs: A Factorial Design Feasibility Study (e4)
Honglu Du, Anusha Venkatakrishnan, Gregory Youngblood, Ashwin Ram, Peter Pirolli. . . . 141

A Mobile Phone App to Stimulate Daily Physical Activity in Patients with Chronic Obstructive Pulmonary Disease: Development, Feasibility, and Pilot Studies (e11)
Sigrid Vorrink, Helianthe Kort, Thierry Troosters, Jan-Willem Lammers. . . . 157

Acceptance of Commercially Available Wearable Activity Trackers Among Adults Aged Over 50 and With Chronic Illness: A Mixed-Methods Evaluation (e7)
Kathryn Mercer, Lora Giangregorio, Eric Schneider, Parmit Chilana, Melissa Li, Kelly Grindrod. . . . 169

A Mobile App for Hypertension Management Based on Clinical Practice Guidelines: Development and Deployment (e12)
Hannah Kang, Hyeoun-Ae Park. . . . 186

Design Considerations for Smoking Cessation Apps: Feedback From Nicotine Dependence Treatment Providers and Smokers (e17)
Jennifer McClure, Andrea Hartzler, Sheryl Catz. . . . 200

Automated Behavioral Text Messaging and Face-to-Face Intervention for Parents of Overweight or Obese Preschool Children: Results From a Pilot Study (e21)
Lisa Militello, Bernadette Melnyk, Eric Hekler, Leigh Small, Diana Jacobson. . . . 210

Smartloss: A Personalized Mobile Health Intervention for Weight Management and Health Promotion (e18)
Corby Martin, L. Gilmore, John Apolzan, Candice Myers, Diana Thomas, Leanne Redman. . . . 224

Development of a Weight Loss Mobile App Linked With an Accelerometer for Use in the Clinic: Usability, Acceptability, and Early Testing of its Impact on the Patient-Doctor Relationship (e24)
Seryung Choo, Ju Kim, Se Jung, Sarah Kim, Jeong Kim, Jong Han, Sohye Kim, Jeong Kim, Jeehye Kim, Yongseok Kim, Dongouk Kim, Steve Steinhubl. . . . 236

Preferred Tone of Nutrition Text Messages for Young Adults: Focus Group Testing (e1)
Christina Pollard, Peter Howat, Iain Pratt, Carol Boushey, Edward Delp, Deborah Kerr. . . . 253

Unpacking the Black Box: A Formative Research Approach to the Development of Theory-Driven, Evidence-Based, and Culturally Safe Text Messages in Mobile Health Interventions (e10)
Marion Maar, Karen Yeates, Zsolt Toth, Marcia Barron, Lisa Boesch, Diane Hua-Stewart, Peter Liu, Nancy Perkins, Jessica Sleeth, Mary Wabano, Pamela Williamson, Sheldon Tobe. . . . 267

Hypertension Health Promotion via Text Messaging at a Community Health Center in South Africa: A Mixed Methods Study (e22)
Damian Hacking, Hanne Haricharan, Kirsty Brittain, Yan Lau, Tali Cassidy, Marion Heap. . . . 280

Guidelines and Recommendations for Developing Interactive eHealth Apps for Complex Messaging in Health Promotion (e14)
Kayla Heffernan, Shanton Chang, Skye Maclean, Emma Callegari, Suzanne Garland, Nicola Reavley, George Varigos, John Wark. 289

Mobile Phone Apps for the Prevention of Unintended Pregnancy: A Systematic Review and Content Analysis (e6)
Emily Mangone, Victoria Lebrun, Kathryn Muessig. 300

Mobile Phone Apps for Inflammatory Bowel Disease Self-Management: A Systematic Assessment of Content and Tools (e13)
Danny Con, Peter De Cruz. 313

Interrater Reliability of mHealth App Rating Measures: Analysis of Top Depression and Smoking Cessation Apps (e15)
Adam Powell, John Torous, Steven Chan, Geoffrey Raynor, Erik Shwarts, Meghan Shanahan, Adam Landman. 330

Short Paper

Health Behavior Theory in Popular Calorie Counting Apps: A Content Analysis (e19)
Siena Davis, Marisa Ellsworth, Hannah Payne, Shelby Hall, Joshua West, Amber Nordhagen. 339

Original Paper

Developing an Internet- and Mobile-Based System to Measure Cigarette Use Among Pacific Islanders: An Ecological Momentary Assessment Study

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Abstract

Background: Recent prevalence data indicates that Pacific Islanders living in the United States have disproportionately high smoking rates when compared to the general populace. However, little is known about the factors contributing to tobacco use in this at-risk population. Moreover, few studies have attempted to determine these factors utilizing technology-based assessment techniques.

Objective: The objective was to develop a customized Internet-based Ecological Momentary Assessment (EMA) system capable of measuring cigarette use among Pacific Islanders in Southern California. This system integrated the ubiquity of text messaging, the ease of use associated with mobile phone apps, the enhanced functionality offered by Internet-based Cell phone-optimized Assessment Techniques (ICAT), and the high survey completion rates exhibited by EMA studies that used electronic diaries. These features were tested in a feasibility study designed to assess whether Pacific Islanders would respond to this method of measurement and whether the data gathered would lead to novel insights regarding the intrapersonal, social, and ecological factors associated with cigarette use.

Methods: 20 young adult smokers in Southern California who self-identified as Pacific Islanders were recruited by 5 community-based organizations to take part in a 7-day EMA study. Participants selected six consecutive two-hour time blocks per day during which they would be willing to receive a text message linking them to an online survey formatted for Web-enabled mobile phones. Both automated reminders and community coaches were used to facilitate survey completion.

Results: 720 surveys were completed from 840 survey time blocks, representing a completion rate of 86%. After adjusting for gender, age, and nicotine dependence, feeling happy (P=<.001) or wanting a cigarette while drinking alcohol (P=<.001) were

positively associated with cigarette use. Being at home (P=.02) or being around people who are not smoking (P=.01) were negatively associated with cigarette use.

Conclusions: The results of the feasibility study indicate that customized systems can be used to conduct technology-based assessments of tobacco use among Pacific Islanders. Such systems can foster high levels of survey completion and may lead to novel insights for future research and interventions.

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KEYWORDS

Pacific Islander; tobacco use; cigarette use; mobile phone; text message; ecological momentary assessment

Introduction

Assessing Health Disparities among Pacific Islanders

Pacific Islander refers to Chamorros, Marshallese, Native Hawaiians, Samoans, Tongans, and other related groups who share a common origin, culture, and customs. These communities face a wide range of social, economic, and health-related challenges. Educational attainment among Pacific Islanders residing in the United States is low, with only 14.4% obtaining bachelor's degrees as compared to the national average of 27.9% [1]. Per capita income among Pacific Islanders is US $19,051 whereas the national average is US $27,334 [1]. Smoking-related conditions, such as cardiovascular and respiratory diseases, are disproportionately high among Pacific Islanders [2]. This fact is often overlooked within epidemiological studies that aggregate Pacific Islander data with those of Asian Americans [3]. Disaggregated Asian-Pacific Islander data from the National Adult Tobacco Survey between 2009 and 2010 revealed past month smoking rates of 20.0% compared with 4.7% for Chinese, 5.5% for Asian Indians, 7.2% for Vietnamese, 13.6% for Filipinos, 15.3% for Koreans, and 18.8% for Japanese [4]. Disaggregated data also indicate that Pacific Islanders have smoking rates of 21.5% for males and 18.4% for females compared with respective averages for the general population of 15.7% and 12.8% [5].

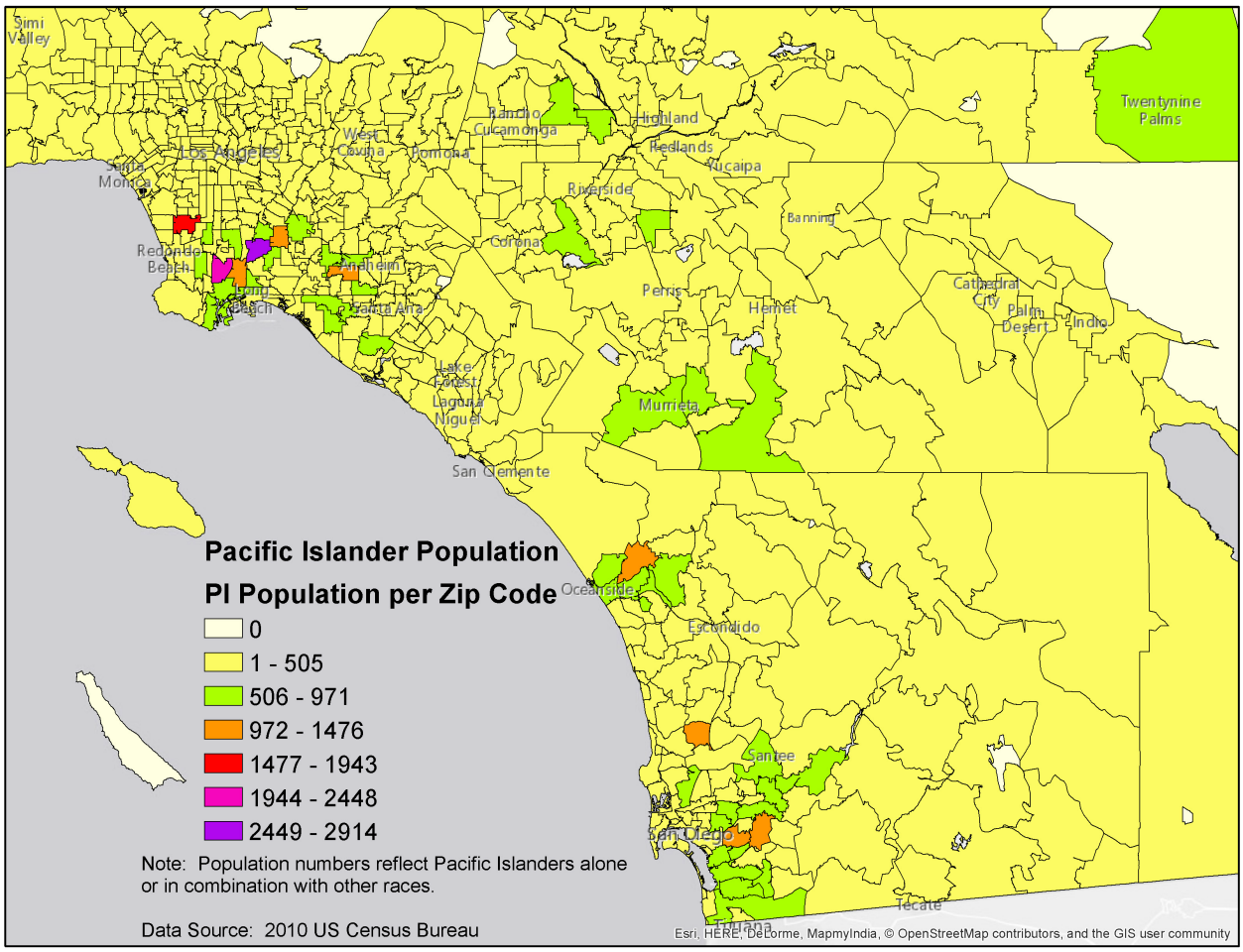
One promising assessment technique that may lead to an improved understanding of the factors that contribute to tobacco use among this population is Ecological Momentary Assessment (EMA). Prior tobacco use research has demonstrated that EMA can generate novel insights for future research and interventions [6-26]. Unfortunately, conducting technology-based research among Pacific Islanders involves numerous challenges. Factors that have hindered past research efforts include Pacific Islanders' broad geographic dispersion and their distrust of academic researchers who often fail to employ culturally-tailored methodologies [27,28]. The objective of the current feasibility study was to overcome these barriers by developing a customized EMA system that facilitated high survey completion rates and fostered new insights into the factors that contribute to cigarette use in this at-risk population.

Developing an EMA System for Pacific Islanders

EMA is a technique that involves the repeated sampling of participants' behaviors and experiences in real time within their natural environment [6]. EMA has been used for more than twenty years to measure such behaviors as smoking [6-26,29,30], exercise [31-37], diet [38-42], substance use [43-50], and health information seeking [51]. Historically, these studies have been conducted using electronic diaries [7,9,13-21,24,30,34,39,40,52] that often facilitate survey completion rates greater than 85% [7,13,14,17] but also require extensive in-person training [40,52]. More recently, researchers have reduced respondent burden by utilizing mobile phone apps [53]. However, these programs are often restricted to specific operating systems [11,25,26,31,35,36,50] and are not always programmed to facilitate real-time, remote monitoring of participant responses [31,35,36,50]. Such barriers can be overcome through text messaging [8,44,51,54-56] which is not linked to a specific operating system and typically has higher completion rates. The drawback is that text messaging uses an open-ended format that permits nonstandard responses that can require extensive, time-consuming data cleaning [54]. Another alternative is to employ Internet-based Cell phone-optimized Assessment Techniques (ICAT) to administer online surveys through the Internet browser of Web-enabled mobile phones. This technique is becoming increasingly popular, yet many studies that utilize this approach fail to achieve survey completion rates above 55% [10,29,57]. Moreover, recent ICAT studies of tobacco use [10,12,29] have not capitalized on the unique features offered by this approach, including the ability to use participant responses from earlier in the day to generate tailored survey questions.

In 2011, the Weaving an Islander Network for Cancer Awareness, Research, and Training (WINCART) Center set out to create a customized EMA system that integrated the ubiquity of text messaging, the ease of use associated with mobile phone apps, the enhanced functionality offered by ICAT systems, and the high survey completion rates exhibited by EMA studies that utilized electronic diaries. The WINCART Center is a community-based participatory research [58] consortium that endeavors to reduce cancer health disparities among Pacific Islanders [59] throughout Southern California (see Figure 1). Over a period of several months, members of the consortium collaboratively developed a culturally-tailored system. A feasibility study was then conducted to determine whether young, adult Pacific Islander smokers would be able to effectively utilize the system and whether the resulting data would offer new insights into the intrapersonal, social, and ecological factors associated with cigarette use.

Figure 1. Geographic distribution of Pacific Islanders in Southern California.



Methods

Participants

Using strategies employed in prior studies [60], 5 community-based organizations recruited 208 young adults who self-identified as Chamorro, Marshallese, Native Hawaiian, Samoan, Tongan, or other Pacific Islander. A 12-item screening survey administered in person or over the phone was used to select 61 current smokers who (a) were between 18 and 29 years old, (b) resided in Southern California, and (c) had smoked at least 100 cigarettes in their lifetime. Trained research staff met with each participant at a mutually agreed-upon location. During this meeting, written consent was obtained using a protocol approved by the Institutional Review Boards at Claremont Graduate University and California State University, Fullerton. The participant completed a computer-based questionnaire that assessed their demographic characteristics, tobacco use behavior, and nicotine dependence [61-63]. Research staff also conducted a brief, one-to-one semi-structured interview about the intrapersonal, social, and ecological factors that influenced the participant's cigarette use. Data from both assessments were used to develop a series of EMA measures for the feasibility study.

Due to the potential burden placed on community coaches tasked with ensuring EMA survey completion during the 7-day feasibility study, the members of the WINCART Center voted to restrict enrollment to 20 participants (see Table 1). These participants were selected to parallel the larger sample in terms of gender, age, tobacco use, and geographic distribution. Of these participants, 60% (12/20) were male. Over half (55%, 11/20) of the participants reported smoking more than 10 cigarettes per day. A mid-point recoding strategy (i.e. 0 for the response "did not smoke," 0.5 cigarettes for the response "less than 1 cigarette," 3.5 cigarettes for the response "2-5 cigarettes," etc) was applied to estimate that an average of 11.8 cigarettes (SD 5.75) were smoked per day per participant.

Table 1. Descriptive statistics for demographics and tobacco use from 20 participants.

General characteristics		Male N (%)	Female N (%)
Ethnic identification			
	Chamorro	2 (16.7)	0 (0)
	Native Hawaiian	1 (8.3)	0 (0)
	Marshallese	0 (0)	0 (0)
	Samoan	5 (41.7)	2 (25)
	Tongan	4 (33.3)	5 (62.5)
	Other Pacific Islander	0 (0)	1 (12.5)
Age			
	18-20	1 (11.2)	0 (0)
	21-23	2 (22.2)	1 (16.7)
	24-26	2 (22.2)	2 (33.3)
	27-30	4 (44.4)	3 (50)
Education			
	Less than high school	0 (0)	0 (0)
	High school or GED	8 (72.7)	4 (50)
	Some college/trade school	1 (9.1)	3 (37.5)
	2-year college	1 (9.1)	1 (12.5)
	4-year college or above	1 (9.1)	0 (0)
Employment status			
	Employed	7 (58.3)	4 (57.1)
	Unemployed	5 (41.7)	3 (42.9)
Days smoked in past 30 days			
	0 days	0 (0)	0 (0)
	1 or 2 days	0 (0)	0 (0)
	3 to 5 days	1 (9.1)	1 (12.5)
	6 to 9 days	0 (0)	0 (0)
	10 to 19 days	0 (0)	0 (0)
	20 to 29 days	3 (27.3)	1 (12.5)
	All 30 days	7 (63.6)	6 (75)
Cigarettes smoked per day			
	Less than 1 cig	0 (0)	0 (0)
	1 cig	0 (0)	0 (0)
	2-5 cig	3 (25)	2 (25)
	6-10 cig	2 (16.7)	2 (25)
	11-20 cig	5 (41.7)	4 (50)
	More than 20 cig	2 (16.7)	0 (0)
FTND nicotine dependence score			
	Low (<=5)	12 (60)	8 (40)
	High (>=6)	0 (0)	0 (0)
Lifetime use of alternative tobacco products			
	Hookah	8 (72.7)	6 (75)

General characteristics		Male N (%)	Female N (%)
	Cigars	8 (72.7)	4 (50)
	Pipe	4 (36.4)	1 (12.5)
	Smokeless (chew, betel nut, etc.)	4 (36.4)	1 (12.5)
	Cloves	3 (27.3)	0 (0)
	Bidis	1 (9.1)	1 (12.5)
	Kreteks	0 (0)	0 (0)
	Other	0 (0)	1 (12.5)
	None of the above	2 (18.2)	1 (12.5)

Procedures

Each of the twenty participants enrolled in the EMA study attended a one-on-one, follow-up appointment at which the customized system was presented. Surveys were initiated by sending a text message to the participant. This text message contained a link to a secure SQL Server hosting a real-time, Web-based survey system formatted to work on any Web-enabled mobile phone (see Figure 2) as well as any Web-enabled tablet or computer. Participants accessed the system with a self-created username and password. After logging in, the system recognized the participant, recalled the responses entered earlier in the day, and presented a tailored survey.

The Web-based survey was programmed so that if a participant did not complete the first question within 15 minutes of the first text message being sent another text message was delivered. This process was repeated every 15 minutes for up to one hour (see Figure 3). The system then waited an hour before initiating the next survey. If the participant failed to begin a survey after ten text messages, an automated email was sent to a community coach who contacted the participant by phone and reminded the individual to complete the survey. This reminder process was explained to the participant through 8 one-minute, animated videos (see Multimedia Appendices 1-8). These videos used Pacific Islander characters to demonstrate key concepts and were posted online [64] so that the participant could review the materials remotely throughout the study.

After watching the animated videos, the participant selected six consecutive two-hour time blocks during which they would be willing to receive automated text messages each day. These text messages were delivered on even-numbered hours (2:00 PM, 4:00 PM, 6:00 PM, etc.) and asked the participant to report their cigarette use since the last time a survey was completed. Text messages were delivered to a Web-enabled mobile phone either owned by the participant or provided to the participant for the duration of the study. The videos informed the participant that 6 surveys would be administered each day for a period of 9 days. The first 2 days were designed to help the participant acclimate to the process of completing the surveys and to resolve any technical problems encountered. The 7 days after that were the critical test days. At the end of this 9-day period, research staff provided each participant with a US $75 gift card to compensate them for their time and travel.

Figure 2. Web-based survey formatted for Web-enabled mobile phones, tablets, and computers.

Measures

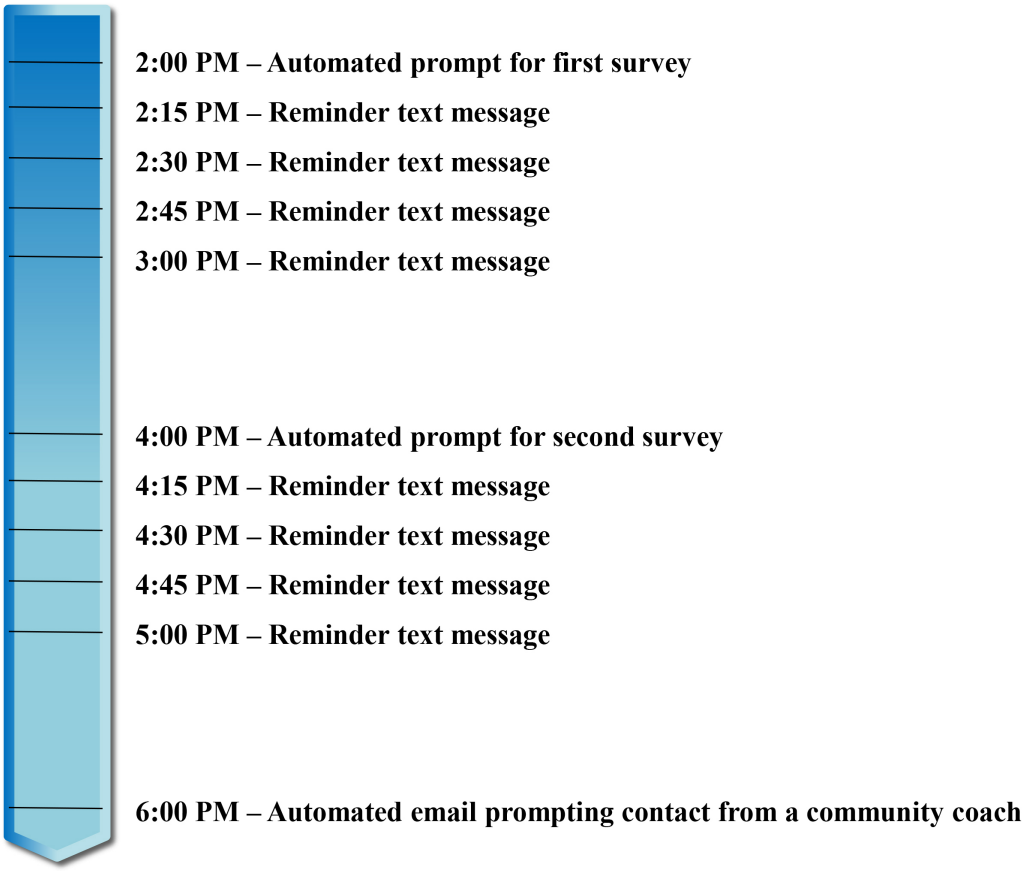
Items for the EMA survey were developed based on data gathered from the computer-based questionnaire and the semi-structured interview. The EMA survey included measures of cigarette use, craving, location, social environment, mood, and rationale for deciding whether or not to smoke. The resulting items were then refined in consultation with the 5 community-based organizations. This process resulted in items that, while unconventional when compared to traditional EMA studies, were more appropriate for the Pacific Islander community.

Participants initially responded to a single question inquiring if they had smoked since the last time they entered a response that day. If they had smoked, the survey asked the number of cigarettes they had ("How many cigarettes have you had since {time of last entered response}?"). This question was designed so that all responses in a single day could be tabulated and compared to self-report measures of daily cigarette use. The question also facilitated the analytic approach which focused on the average number of cigarettes smoked across time blocks within each day. A follow-up question determined when the participant smoked ("When did you smoke?") utilizing four response categories ("<30 mins ago," "30-60 mins ago," "60-90 mins ago," and "90-120 mins ago"). This question did not ascertain the number of cigarettes smoked in each 30-minute sub-block but was instead used to gauge how much time had passed since the last instance in which the participant smoked. The remaining questions asked the participant to reflect on this instance ("Now, please think about the last time you smoked...").

After recalling the last instance in which they smoked, the participant answered one question about the extent to which they craved a cigarette beforehand ("How much were you craving a cigarette?"). Responses were rated on a 4-point Likert scale ranging from "1=Not at all" to "4=A lot" (see Figure 2). The participant then reported their location ("Where were you?") by selecting among the response options "Home," "Work," "School," "At a restaurant/bar," "In a car," "Around church," and "Other (Please type in)." The next question asked the participant to classify their social environment ("Who were you with when you last smoked?") using the response options "Alone," "People who are smoking," "People who are NOT smoking," and "Other (Please type in)." The survey then used a "Check all that apply" format to assess the participant's mood ("How were you feeling?") using the categories "Happy," "Sad," "Angry," "Stressed out," "Anxious," "Bored," "Relaxed," "Fine," and "Other (Please type in)." The final question asked the participant to reflect on why they had chosen to smoke

("Why did you smoke?") and respond using a "Check all that apply" format comprised of the categories "Someone offered me a cig," "Someone was smoking around me," "Wanted a cigarette while drinking alcohol," "Wanted a cigarette while drinking coffee," "Wanted a cigarette after eating," "To eat less," "To relax or calm down," "Have a good time/celebrate," "To concentrate/focus," and "Other (Please type in)."

Figure 3. Example timeline of survey reminders.



Analysis

Cigarette use was reported in 534 time blocks. The analysis focused on the total and average number of cigarettes smoked during each time block. Repeated assessments of factors associated with the most recent cigarette consumed were aggregated by taking the average of these assessments across time blocks within each day. This produced a two-level hierarchical analysis dataset with data on each day (i.e. level-1 data) nested within individual participants (i.e. level-2 data). Multilevel models with both fixed and random effects were then used to quantify between and within subject variability across repeated measurement points [16,65,66].

Variables were created for the associational analysis. These variables included the total number of cigarettes smoked during time blocks per day, the proportion of time blocks per day in which 4 or more cigarettes were smoked, and the proportion of time blocks per day in which the participant reported an intrapersonal, social, or ecological factor related to cigarette use. Multilevel regression models were conducted using SAS Proc Mixed procedure with the participants' age, gender, and nicotine dependence being adjusted in the analysis as covariates [67]. Analysis results with raw data are presented and consistent parameter estimates were obtained with multiple imputation analysis from SAS PROC MI and MIANALYZE [68].

Results

Survey Completion and Reported Cigarette Use

Surveys in which the participant failed to respond to all questions within two hours of the first text message prompt were classified as missed. In total, 20 participants completed 720 surveys from 840 prompted survey time blocks, representing a prompt-based survey completion rate of 86%. Nineteen (95%) participants completed all surveys on the first five days. Sixteen (80%) participants completed all surveys on the sixth day and fifteen (75%) participants completed all surveys on the seventh day. Participants reported smoking in 535 (74%) of the 720 two-hour time blocks with completed surveys. The average total number of cigarettes smoked per day was 13.96 (SD 9.19) which is 18.3% higher than the recoded estimates reported in the computer-based questionnaire.

Factors Associated With Cigarette Use

For each time block in which smoking was reported, participants had an average of 3.07 cigarettes (SD 1.44). Home was the most common smoking location and attempting to relax was the most commonly cited reason for choosing to smoke (see Table 2).

Table 2. Proportions of responses per day during time blocks in which smoking was reported.

Question	Response option	Mean of proportion (SD)
Where were you?		
	At home	0.61 (0.37)
	In a car	0.20 (0.28)
	At work	0.13 (0.28)
	Around church	0.07 (0.23)
	At restaurant/bar	0.05 (0.12)
	At school	0.01 (0.07)
Who were you with when you last smoked?		
	Alone	0.54 (0.35)
	With people who are not smoking	0.41 (0.36)
	With people who are smoking	0.23 (0.29)
How were you feeling?		
	Fine	0.51 (0.39)
	Relaxed	0.37 (0.37)
	Happy	0.18 (0.30)
	Stressed out	0.16 (0.31)
	Bored	0.10 (0.17)
	Anxious	0.09 (0.20)
	Angry	0.03 (0.13)
	Sad	0.02 (0.11)
Why did you smoke?		
	To relax or calm down	0.55 (0.35)
	Wanted a cigarette after eating	0.26 (0.29)
	Someone was smoking around me	0.15 (0.26)
	Someone offered me a cig	0.11 (0.25)
	To concentrate/focus	0.11 (0.24)
	Have a good time/celebrate	0.09 (0.20)
	Wanted a cigarette while drinking alcohol	0.05 (0.14)
	Wanted a cigarette while drinking coffee	0.03 (0.09)
	To eat less	0.03 (0.10)

After adjusting for gender, age, and nicotine dependence, analyses indicated that a one score increase of craving resulted in 3.8 more cigarettes smoked per day on average (P<.001). In addition, feeling happy (P<.001) or wanting a cigarette while drinking alcohol (P<.001) (see Table 3) were positively associated with the total number of cigarettes smoked during time blocks. Being at home (P=.02) or being around people who are not smoking (P= .01) were negatively associated with the total number of cigarettes smoked during time blocks. These associations persisted when participants reported smoking 4 or more cigarettes (see Table 4). Several other associations were also identified when the proportion of time blocks per day in which 4 or more cigarettes were smoked was used as the outcome variable in the analysis. Positive associations included feeling angry (P=.05) and wanting a cigarette while drinking coffee (P=.01). Negative associations included feeling bored (P=.02) and wanting to eat less (P=.02).

Table 3. Associations with total number of cigarettes smoked per day.

Question	Response option	β	SE	*P*
Where were you?				
	At home	-0.72	0.31	.02
	In a car	-0.02	0.42	.96
	At work	0.49	0.44	.27
	Around church	0.79	0.85	.36
	At restaurant/bar	0.17	0.71	.82
	At school	1.51	1.16	.20
Who were you with when you last smoked?				
	Alone	0.54	0.29	.06
	With people who are not smoking	-0.76	0.28	.01
	With people who are smoking	0.65	0.35	.07
How were you feeling?				
	Fine	0.31	0.29	.30
	Relaxed	0.19	0.37	.60
	Happy	1.41	0.37	< .001
	Stressed out	0.13	0.43	.76
	Bored	-0.85	0.54	.12
	Anxious	0.9	0.55	.11
	Angry	0.88	0.71	.22
	Sad	0.03	0.84	.97
Why did you smoke?				
	To relax or calm down	0.41	0.32	.22
	Wanted a cigarette after eating	0.26	0.39	.50
	Someone was smoking around me	0.15	0.43	.72
	Someone offered me a cig	0.72	0.47	.13
	To concentrate/focus	-0.52	0.53	.33
	Have a good time/celebrate	0.46	0.55	.41
	Wanted a cigarette while drinking alcohol	2.31	0.63	<.001
	Wanted a cigarette while drinking coffee	1.85	1.08	.09
	To eat less	-1.32	1.25	.29

Table 4. Associations with proportion of time blocks per day with four or more cigarettes.

Question	Response option	β	SE	*P*
Where were you?				
	At home	-0.19	0.08	.02
	In a car	0.06	0.11	.59
	At work	0.09	0.11	.40
	Around church	0.07	0.20	.74
	At restaurant/bar	0.00	0.19	.99
	At school	0.91	0.29	.003
Who were you with when you last smoked?				
	Alone	0.09	0.07	.23
	With people who are not smoking	-0.17	0.07	.03
	With people who are smoking	0.17	0.09	.06
How were you feeling?				
	Fine	0.01	0.08	.92
	Relaxed	0.08	0.09	.42
	Happy	0.29	0.10	.003
	Stressed out	0.14	0.11	.19
	Bored	-0.32	0.14	.02
	Anxious	0.24	0.14	.10
	Angry	0.37	0.18	.05
	Sad	-0.01	0.22	.95
Why did you smoke?				
	To relax or calm down	0.09	0.08	.28
	Wanted a cigarette after eating	0.12	0.10	.23
	Someone was smoking around me	-0.04	0.11	.75
	Someone offered me a cig	0.09	0.12	.44
	To concentrate/focus	-0.21	0.14	.12
	Have a good time/celebrate	0.19	0.14	.19
	Wanted a cigarette while drinking alcohol	0.38	0.17	.03
	Wanted a cigarette while drinking coffee	0.77	0.27	.01
	To eat less	-0.73	0.31	.02

Discussion

Implications for Future Research and Interventions

This is the first study, of which we are aware, in which a customized EMA system assessed factors associated with tobacco use among young, adult Pacific Islanders. Prior EMA studies of tobacco use that utilized electronic diaries reported prompt-based survey completion rates of 65% [15], 68% [30], 75% [9], 88% [17], 89% [14], 90% [7], and 91% [13]. ICAT studies that relied upon the use of Web-based surveys administered through mobile phones reported prompt-based survey completion rates of 50% [29], 52% [57], 55% [10], 69% [42], and 83% [12]. The survey completion rate of the current study was 86% (720/840), suggesting that young, adult Pacific Islanders were able to effectively use the customized EMA system and that this form of assessment holds promise for future research. The survey completion rate also indicates that remotely accessible standardized training videos (see Multimedia Appendices 1-8) may serve as a reasonable alternative to extensive in-person training and technical support—especially for populations spread out over a large geographic region.

Prior research has suggested that while EMA measures sometimes mirror the results of recall measures they often gather data with less noise and greater sensitivity [6]. The assessment of daily cigarette use provides additional evidence to support this conclusion. Self-report measures administered at the outset of the study indicated that each participant smoked an average of 11.8 (SD 5.75) cigarettes per day. In contrast, the EMA

system cataloged an average of 13.96 (SD 9.19) cigarettes smoked per day. The health implications of this are notable in that they translate to an estimated 769 additional cigarettes, or approximately 38.5 packs, per year per participant.

An analysis of the EMA data also offers new insight into the intrapersonal, social, and ecological factors associated with cigarette use among young, adult Pacific Islanders. Previous studies have identified the home as a place where smoking frequently occurs [13]. Yet, the fact that Pacific Islanders in the current study smoke fewer cigarettes than average at home suggests that this location could serve as a constructive environment for practicing smoking cessation techniques. Past EMA research has also highlighted how smokers are more likely to have a cigarette when in the presence of other smokers [11-15]. However, the protective influence of nonsmokers on Pacific Islander tobacco use suggests that such individuals may function as a deterrent that can be relied upon in social situations where smoking is prevalent. Future smoking cessation interventions tailored for Pacific Islanders may choose to test these concepts by providing educational materials that promote the use of nonsmoking social networks when attempting to quit using tobacco products.

A technological innovation within the current study, the creation of tailored survey questions based on participant responses entered earlier in the day, hints at new opportunities for additional research. Future studies may choose to capitalize on this feature by administering brief, tailored surveys to multiple, linked individuals within the Pacific Islander community each time one individual reports smoking behavior in a prior assessment. Such investigations may lead to an improved understanding of friend and familial perceptions of Pacific Islander tobacco use, which previous research has suggested is highly relevant in explaining both past and current smoking among Native Hawaiian youth [69].

The correlation between increased tobacco craving and increased cigarette use parallels previous findings that cravings precipitate smoking [9] and that higher levels of craving at one time point within a day tend to produce more smoking at the next time point [8]. Similarly, other studies have identified significant positive associations between alcohol consumption and tobacco use [52] and coffee consumption and tobacco use [13]. These similarities suggest that components of existing evidence-based interventions that address these factors may be highly effective for young, adult Pacific Islanders. The results for mood are more ambiguous. Some studies suggest negative affect is predictive of smoking [8,15] while others find no prospective relationship with either positive or negative affect [13,14]. Unfortunately, the measure utilized in the current study does not delineate whether the mood indicated preceded cigarette use or was a direct outcome of it. The correlation between tobacco use and happiness may therefore be the participant experiencing higher positive affect before or after smoking [16]. The inconclusive nature of this finding exposes the need for additional research within this population.

Limitations

There are several limitations to the current study. Perhaps the most relevant is the small sample size and homogeneity of the participants. Specifically, the generalizability of the sample to other Pacific Islander communities may be limited by the fact that all participants were identified via nonprobability sampling. Moreover, key subgroups, including female Chamorros, Native Hawaiians, and Marshallese, were not represented nor were Pacific Islanders over the age of thirty. The small sample size also prohibited analytic techniques that have generated valuable insights in prior EMA research. Examples include explorations of how situational and mood factors differ between light and heavy smokers [12] and analyses that reveal situational covariates that influence smoking patterns [17].

Another limitation within the current study is the focus on regular cigarettes. With the advent of electronic cigarettes, as well as the common usage of alternative forms of tobacco within the Pacific Islander community [4], the range of behavior measured by future tobacco use studies may need to be broadened. Within the current sample, lifetime hookah use was reported at 73% for males (8/11) and 75% (6/8) for females (see Table 1). This is significantly greater than the averages for the general population of 42% for current male smokers and 23% for current female smokers [5] and suggests that future research should explore the different factors that may be associated with the use of alternative tobacco products.

An additional limitation is that all surveys were initiated on even-numbered hours and only assessed factors associated with the most recent cigarette smoked. Future studies should consider initiating surveys at random intervals within time blocks to avoid potential time-based covariates. Such methods will help clarify the causal relationship between cigarette use and the factors associated with it. Nevertheless, future interventions may still consider applying the current findings even if their causal relationship remains unclear [70,71].

Conclusions

This feasibility study provides new insights on factors that contribute to cigarette use among young, adult Pacific Islanders. It suggests new directions for conducting advanced, technology-based research aimed at understanding tobacco use within the Pacific Islander community and offers new possibilities for crafting culturally-tailored interventions, which past research has demonstrated is often more effective within this population [72]. Given the disproportionately high smoking rates among Pacific Islanders [5], these types of research and intervention efforts are sorely needed to address the health disparities evident within this population.

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Authors' Contributions

JRP and BX conceived and drafted the manuscript. BX performed the analyses with support from NT and MAR. NT, MDS, AO, TT, SC, VM, CL, VKP, MAR, DESV, JTL, SPT, and PHP edited the manuscript for content. All authors reviewed and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Introduction to the ecological momentary assessment study.

[MOV File, 22MB - mhealth_v4i1e2_app1.mov]

Multimedia Appendix 2

Using an iPhone.

[MOV File, 55MB - mhealth_v4i1e2_app2.mov]

Multimedia Appendix 3

Accessing a Web-based survey with an iPhone.

[MOV File, 30MB - mhealth_v4i1e2_app3.mov]

Multimedia Appendix 4

Completing a Web-based survey with an iPhone.

[MOV File, 46MB - mhealth_v4i1e2_app4.mov]

Multimedia Appendix 5

Accessing a Web-based survey after receiving a text message.

[MOV File, 29MB - mhealth_v4i1e2_app5.mov]

Multimedia Appendix 6

Selecting times to receive text message survey reminders.

[MOV File, 19MB - mhealth_v4i1e2_app6.mov]

Multimedia Appendix 7

Receiving text message survey reminders.

[MOV File, 38MB - mhealth_v4i1e2_app7.mov]

Multimedia Appendix 8

Contacting technical support.

[MOV File, 16MB - mhealth_v4i1e2_app8.mov]

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Abbreviations

EMA: Ecological Momentary Assessment
ICAT: Internet-Based Cell Phone-Optimized Assessment Technique
NCI CRCHD: National Cancer Institute Center to Reduce Cancer Health Disparities
SQL: Structured Query Language
WINCART: Weaving an Islander Network for Cancer Awareness, Research, and Training

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Original Paper

Ecological Momentary Assessment of Illicit Drug Use Compared to Biological and Self-Reported Methods

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Abstract

Background: The use of mHealth methods for capturing illicit drug use and associated behaviors have become more widely used in research settings, yet there is little research as to how valid these methods are compared to known measures of capturing and quantifying drug use.

Objective: We examined the concordance of ecological momentary assessment (EMA) of drug use to previously validated biological and audio-computer assisted self-interview (ACASI) methods.

Methods: The Exposure Assessment in Current Time (EXACT) study utilized EMA methods to assess drug use in real-time in participants' natural environments. Utilizing mobile devices, participants self-reported each time they used heroin or cocaine over a 4-week period. Each week, PharmChek sweat patch samples were collected for measurement of heroin and cocaine and participants answered an ACASI-based questionnaire to report behaviors and drug using events during the prior week. Reports of cocaine and heroin use captured through EMA were compared to weekly biological or self-report measures through percent agreement and concordance correlation coefficients to account for repeated measures. Correlates of discordance were obtained from logistic regression models.

Results: A total of 109 participants were a median of 48.5 years old, 90% African American, and 52% male. During 436 person-weeks of observation, we recorded 212 (49%) cocaine and 103 (24%) heroin sweat patches, 192 (44%) cocaine and 161 (37%) heroin ACASI surveys, and 163 (37%) cocaine and 145 (33%) heroin EMA reports. The percent agreement between EMA and sweat patch methods was 70% for cocaine use and 72% for heroin use, while the percent agreement between EMA and ACASI methods was 77% for cocaine use and 79% for heroin use. Misreporting of drug use by EMA compared to sweat patch and ACASI methods were different by illicit drug type.

Conclusions: Our work demonstrates moderate to good agreement of EMA to biological and standard self-report methods in capturing illicit drug use. Limitations occur with each method and accuracy may differ by type of illicit drugs used.

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KEYWORDS

mHealth; ecological momentary assessment; illicit drug use; sweat patch; ACASI

Introduction

The detection of biochemical markers of illicit drugs in biological samples of hair, urine, sweat, or blood is considered the gold standard for assessing illicit drug use and is widely used in drug treatment and employment drug testing settings [1]. The utility of these methods lies in their ability to detect metabolites of illicit drugs used within a specific window of time that varies depending on the biological specimen. Despite being the gold standard for the assessment of drug use, biological samples are often difficult to collect in the field, may be cost prohibitive, and can require greater participant engagement (eg, frequent urine screens at a treatment facility). Additionally, biologic samples typically only assess whether an individual has used drugs rather than quantifying how much and how often the drug was consumed [2,3].

In epidemiological studies, the most feasible method of assessing illicit drug use is self-report, which is recounted over extended periods of recall (eg, 6 to 12 months or longer) [4-7]. The benefit of self-report includes the ease of use, convenience, and low cost. However, whether assessed via study interviewer or audio-computer assisted self-interview (ACASI), these methods may involve recall, response, or social desirability biases [8,9]. Additionally, these methods require participants to return to the clinic or study site at regular intervals, which not only requires participants to have reliable transportation options but also disrupts their daily routines. Despite these potential issues, assessment of illicit drug use through self-report has been repeatedly shown to be a valid and reliable measure of drug use [3,10-12].

Yet, self-report and biological testing methods of capturing drug use lack the ability to assess real-time drug use, miss varying periods of intense or intermittent drug use, and cannot ascertain the proximate context of an individual's drug using experience [13]. Ecological momentary assessment (EMA) is a mobile health (mHealth) method that is capable of collecting participant-level data in real time over notably shorter time intervals.

Mobile devices that employ mHealth strategies (eg, smartphones or other handheld devices) can utilize EMA methods for remote data collection and monitoring as well as health education and intervention [14]. EMA methods have been utilized in smoking cession studies [15-21] and among methadone-maintained outpatient drug users [22-26] but have yet to be validated as a reliable method for assessing drug use. By capturing drug-using events in real-time, outside of the study clinic and in a participant's natural settings, a more robust, vibrant, and comprehensible understanding of drug use can be generated beyond periodic biological detection or infrequent self-reports of drug use.

Prior studies have examined concordance between the assessment of drug use by biological measures and self-report [27-29]. The aim of the current study was to investigate the concordance of assessing drug use via EMA methods compared to biological (eg, sweat patch) and ACASI methods. Additionally, we identified correlates of discordance and examined the feasibility, strengths, and weaknesses of these methods in assessing drug use among a community sample of drug users in Baltimore, Maryland.

Methods

EXACT Study Participants

Exposure Assessment in Current Time (EXACT) study participants were recruited from the AIDS Linked to the IntraVenous Experience (ALIVE) study, an on-going, community-recruited, observational cohort of people with a history of injecting drugs in Baltimore, Maryland [7]. The ALIVE cohort is community-based, rather than clinic-based, and thereby avoids selection bias toward people seeking or accessing health care. Details of the EXACT study have been previously described [30,31] and included 4 successive trials conducted from November 2008 through May 2013. Each trial was planned to follow 30 participants for 30 days.

Eligibility criteria for the EXACT study included current enrollment in ALIVE and the ability to understand and follow directions on a personal digital assistant (PDA) or mobile phone. Convenience sampling was utilized to identify individuals for participation in EXACT. The specific inclusion criteria regarding drug use and HIV status were varied slightly to ensure a diverse overall sample; both injection and noninjection drug users were included. Individuals were excluded if they had any medical conditions that would prevent them from operating the handheld device (eg, vision impairment) or failed to attend the screening appointment where they were trained on device use.

For Trials 1-3, participants were provided with a Palm Z22 PDA running applications developed using Satellite Forms software. All PDA programs were disabled except for study-required applications. In Trial 4, participants were provided with a Motorola Droid X2 Android mobile phone running an application developed using the electronic MObile Comprehensive Health Application platform, which was created at Johns Hopkins School of Medicine [32].

The Johns Hopkins Bloomberg School of Public Health Institutional Review Board approved the study protocol. All participants provided written informed consent. Participants were informed that involvement (or noninvolvement) in EXACT would not affect their participation in ALIVE.

EMA Data Collection

For 30 days of observation, participants were asked to self-initiate a survey on their handheld device and self-report each time they either used heroin or cocaine (or both) in any manner (ie, smoked, snorted, or injected). For each event, participants answered questions concerning their drug use, mood, and social, physical, and activity environment, using survey instruments adapted from previous EMA studies [22-26]. To ensure responses were recorded in real-time, participants were required to indicate that drug use had occurred within 30 minutes of completing this survey. The device also delivered an end-of-day (around 9 pm) survey that asked if there was any drug use that was not reported earlier in the day. The surveys were designed to be completed in less than 3 minutes.

Sweat Patches

PharmChek Drugs of Abuse Patches were collected weekly for the assessment of heroin or cocaine use. These patches detect traces of cocaine or heroin secreted in sweat during the period it is worn. Drugs captured via PharmChek sweat patches represent "parent" drugs (ie, same chemical compound that was taken by the drug user) and drug metabolites (ie, breakdown products of the parent drug) excreted through sweat. The patch can be worn for up to 10 days and is able to capture any drug use that occurred during the period of wear as well as 24 hours prior to patch application [33]. To ensure the patch stayed in place, an additional overlay made of the same adhesive material was worn atop the sweat patch. Once removed, patches were sent to a commercial laboratory for drug evaluation. Specimens were initially screened using an enzyme immunoassay technique with positive patches undergoing confirmation using liquid chromatography/mass spectrometry/mass spectrometry [33].

Cocaine predominates in sweat after cocaine use, however, the most common metabolite of cocaine is benzoylecgonine (BZ). A positive sweat patch result for cocaine use is confirmed by the presence of both BZ and cocaine at or above the limit of detection of 10 ng/mg. Topical analgesics, such as lidocaine or novocain, contain BZ and are used in various surgical procedures, however cocaine is structurally unique and does not resemble any of these products [33].

Opiate metabolites detectable by sweat patch include heroin, 6-monoacetylmorphine (6-MAM), codeine, and morphine. The presence of 6-MAM can only come from the use of heroin. A positive sweat patch for heroin includes the presence of the parent drug (heroin) and morphine above the limit of detection of 10 ng/ml, 6-MAM and morphine above the limit of detection of 10 ng/ml, or 6-MAM alone above the limit of detection of 10 ng/ml. The presence of morphine alone may be due to the use of other opiate-containing legal medications (eg, oxycodone, hydrocodone) or the consumption of certain foods (eg, poppy seeds). Therefore, the presence of morphine alone does not indicate a positive sweat patch for heroin [33].

Self-Report by ACASI

Participant baseline characteristics were obtained from ACASI completed at enrollment into EXACT and/or from the prior ALIVE study visit. Additionally, at the conclusion of each study week, participants returned to the study site to answer an ACASI that included questions concerning activities, behavior, and drug use frequency during the prior week. In addition to sociodemographic variables (eg, age, sex, race, education, marital status, employment, income, homelessness, and health insurance status), baseline data collection included self-reported alcohol, tobacco, and illicit drug use; an index of drug abuse (Drug Abuse Screening Test (DAST)) [34]; and depressive symptoms (Center for Epidemiologic Studies-Depression Scale (CES-D)) in the prior 6 months [35]. Clinical characteristics (eg, HIV/antiretroviral therapy status, CD4 T-cell count, HIV RNA levels, and hepatitis B and C status) were obtained from the existing ALIVE database.

Data Analysis

Data from all 4 trials were aggregated and analyzed together. To ensure accurate comparisons between each method of capturing drug use, all analyses were assessed by week (this was necessary as the ACASI and sweat patch data were only collected weekly). The day during which the sweat patch was placed on the participant's arm and when the handheld device was provided represented the start of the study week 1. Seven days later, when the ACASI was completed, marked the end of the week. At this time, the sweat patch was removed and replaced with a new patch. This process was repeated for all 4 weeks of the study. Drug use reported by ACASI and sweat patch indicated use or no use within the prior week.

Real-time heroin or cocaine use, reported via the EMA entries or the end-of-day survey were summed by day and week for each participant. For analysis, an individual was considered to have used drugs if at least 1 report of drug use (eg, heroin or cocaine use by any manner) was reported in real-time within a given study week. Heroin-only and cocaine-only reports incorporated any reports of heroin or cocaine use (including those jointly used with another drug).

Because the sweat patch was able to capture drug use that included the 24 hours prior to adhesion, the EMA week was offset by 1 day to ensure concurrent periods of time were evaluated when comparing the methods. There was no adjustment for time for comparisons between EMA- and ACASI-assessed drug use.

To examine the concordance of drug use reported by EMA to sweat patch or to ACASI methods, percent agreement and concordance correlation coefficients were calculated. The concordance correlation coefficient is a measure of the level of agreement that takes into account the agreement occurring by chance for repeated measures (much like the kappa statistic is for categorical variables measured at 1 point) [36]. Using the same scale for kappa values for comparing categorical variables, concordance correlation coefficients of less than 0.2 are considered poor; 0.21-0.40 fair; 0.41-0.60 moderate; 0.61-0.80 good; and 0.81-1.00 very good [37].

If the number of EMA events in any week was greater than the number of ACASI or sweat patch responses it was considered EMA overreporting, while EMA underreporting was determined if the number of EMA reports were fewer than those reported by sweat patch or ACASI. To determine correlates of discordance between methods of assessing drug use, logistic regression models with generalized estimating equations (GEE) were examined. GEE methods adjusted for the correlation of repeated measures within each subject ID over the 4 weeks of follow-up. Variables selected for the final multivariable models were chosen through step-wise logistic regression with inclusion of significant variables ($P<.1$) from the univariate analyses. The different technologies used (eg, PDA vs mobile phone) were not accounted for analytically because the mobile platforms were very similar and we had no a priori reason to suspect that mobile platform type would in any way influence measurement. All analyses were performed using Stata release 12 (StataCorp LP, College Station, Texas).

Results

Among 109 EXACT participants contributing 436 weeks of observation (Table 1), the median age was 48.5 years (interquartile range (IQR) 43-53 years), 98 (90%) were African American, 58 (52%) were male, and 64 (59%) were HIV infected. In the 6 months prior to baseline assessment, 23% of participants reported recent methadone treatment and 83% reported smoking cigarettes.

Table 1. Baseline characteristics of EXACT participants by trial[a].

Type of Variable	Characteristics	All Trials (N=109)
		n (%)
Sociodemographic	Median age, y (IQR)	48.5 (43.3-52.9)
	African American	98 (90)
	Male	58 (52)
	Completed high school	44 (41)
	Never married	66 (61)
	Annual income < $5000	83 (78)
	Medical insurance	93 (85)
	Homeless	9(8)
Substance Use	Cigarettes	91 (83)
	Alcohol	71 (65)
	Marijuana	27 (25)
	Cocaine, any route	50 (46)
	Heroin, any route	49 (46)
	Speedball[b]	25 (24)
	Drug Abuse Screening Test, DAST>16	6 (18)
Clinical	Have primary care doctor	97 (89)
	Emergency room visit	28 (26)
	Depressive symptoms, CES-D>23	26 (23)
	Methadone treatment	26 (23)
	Hepatitis C virus seropositive	94 (86)
	HIV positive[c]	64 (59)
	Median CD4 (IQR)[c]	360.5 (239-529)
	HIV viral load > 500 copies/mL[c]	35 (55)
	Any retroviral therapy	42(65)

[a]All baseline characteristics represent behavior within the 6 months prior to the start of EXACT.

[b]A speedball is defined as the simultaneous injection of a mixture of cocaine and heroin.

[c]HIV-positive status was an inclusion criterion for Trials 3 and 4; CD4 and viral load were tested on HIV-positive participants only.

Comparison of Methods to Capture Illicit Drug Use

Out of a possible 436 weeks of follow-up (109 individuals followed for 4 weeks), 12 weeks did not have evaluable EMA assessments of drug use, resulting in 424 weeks (97%) of observable data. Over 436 weeks, 396 (91%) sweat patches were returned and 410 (94%) ACASI surveys were completed. Missing data was the result of 22 individuals who were unable to return 29 (7%) sweat patches that were damaged or removed prematurely and 12 individuals failing to complete 14 (3%) ACASI surveys. Reports of drug use by EMA represent any report in a week and not the number of individuals or the total amount of uses in a week.

Total weeks of drug use obtained from sweat patch, ACASI, and EMA methods are described in Figure 1. Over 436 weeks of study follow-up, 212 (49%, green bars) sweat patches, 192 (44%, blue bars) ACASI surveys, and 163 (37%, orange bars) weeks of EMA reports were positive for any cocaine use. For heroin use, 103 (24%) sweat patches, 161 (37%) ACASI surveys, and 145 (33%) weeks of EMA reports were captured over follow-up. Seventy-seven (18%) sweat patches, 117 (27%)

ACASI surveys, and 96 (22%) weeks of EMA reports captured both cocaine and heroin use. The proportion of sweat patches with heroin and cocaine detected remained stable by study week.

For cocaine use, the overall percent agreement between EMA and sweat patch methods was 70% (Figure 2a, blue bars) (Table 2) and for EMA and ACASI methods was 77% (Figure 2a, green bars). For heroin use, the percent agreement between EMA and sweat patch methods (Figure 2b, orange bars) was 72% and for EMA and ACASI methods (Figure 2b, yellow bars) was 79%. With heroin or cocaine use, the percent agreement was slightly higher between the EMA and ACASI methods compared to EMA and sweat patch assessments.

Percent agreement does not take into consideration the agreement between 2 methods solely due to chance. The concordance correlation coefficient is a measure of inter-rater reliability that takes into account the agreement occurring by chance for repeated measures. The concordance correlation coefficients were slightly lower for comparisons of drug use between EMA and sweat patch methods than observed for EMA and ACASI methods. The concordance correlation coefficients for the comparison of EMA and sweat patch methods were in the moderate agreement range for both cocaine 0.51 (0.48-0.59) and heroin 0.48 (0.40-0.55) use. The agreement in reports between EMA and ACASI methods for cocaine use was 0.59 (0.53-0.65) and for heroin use was 0.61 (0.55-0.67), with the former representing moderate agreement and the latter representing good agreement. The agreements in reports between ACASI and sweat patch methods were not as consistent between heroin and cocaine use. The concordance correlation coefficient for the comparison of ACASI and sweat patch methods for cocaine use was 0.72 (0.67-0.77), representing good agreement, while the concordance correlation coefficient for heroin use was 0.58 (0.51-0.64), representing moderate agreement.

Misreporting of responses by EMA relative to sweat patch and ACASI methods were assessed for cocaine and heroin separately (Table 2). Relative to sweat patch results, underreporting of drug use by EMA methods was more likely for heroin than cocaine use (19% vs 9%), but overreporting by EMA methods was greater for cocaine than heroin use (21% vs 8%). Misreporting was identified less commonly between EMA and ACASI methods. Compared to ACASI reports, underreporting by EMA was infrequent and similar for both cocaine and heroin use (8% vs 9%). Overreporting by EMA relative to ACASI was slightly greater for cocaine than heroin use (15% vs 13%).

Figure 1. Reported drug use as assessed by sweat patch (green bars), EMA (orange bars) or ACASI (blue bars) methods.

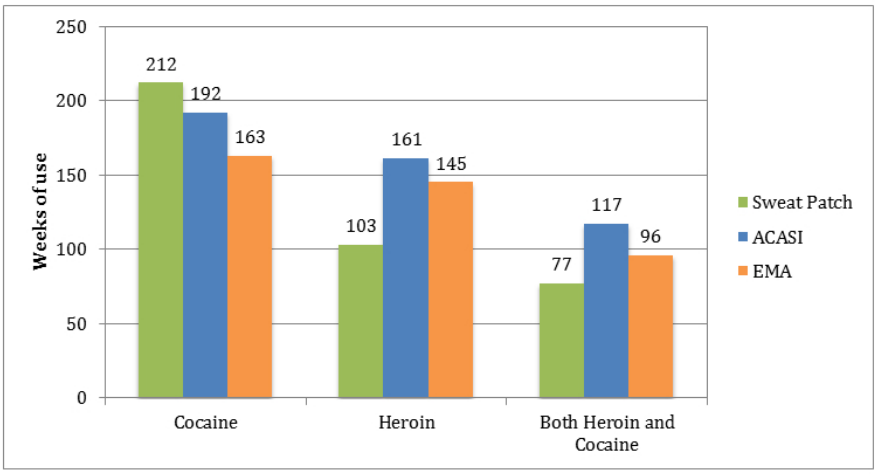
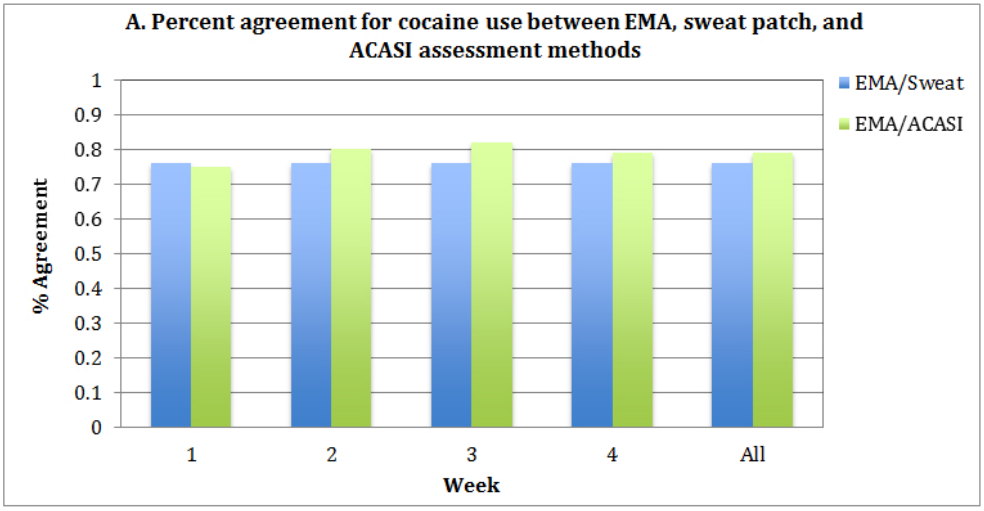


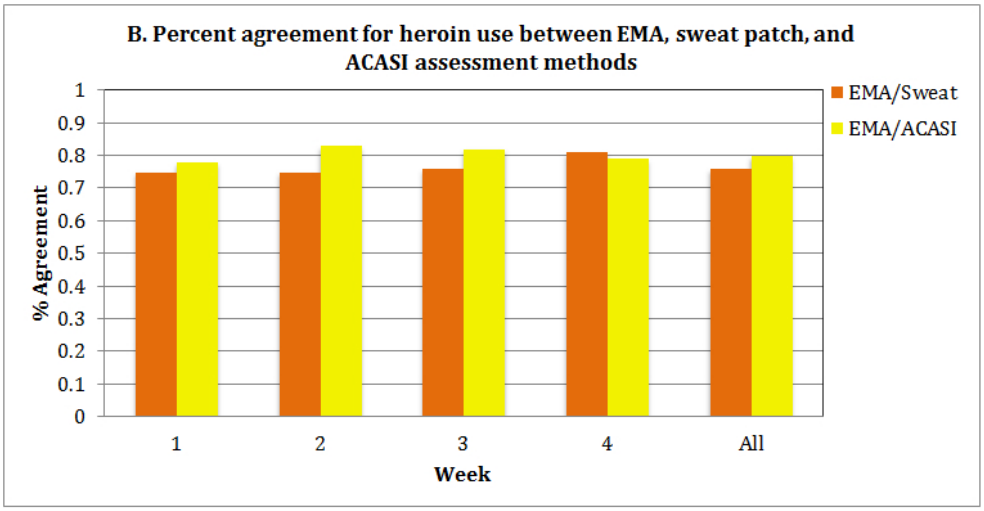
Table 2. Percent agreement and over- and underreporting of EMA responses compared to sweat patch and ACASI responses by drug use type[a].

		Cocaine	Heroin
		n (%)	n (%)
Sweat Patch	Reported yes on EMA/sweat patch negative (overreport)	30 (9%)	70 (19%)
	EMA & sweat patch concordant	298 (70%)	307 (72%)
	Reported no on EMA/sweat patch positive (underreport)	79 (21%)	28 (8%)
ACASI	Reported yes on EMA/ACASI negative (overreport)	29 (8%)	33 (9%)
	EMA & ACASI concordant	327 (77%)	335 (79%)
	Reported no on EMA/ACASI positive (underreport)	58 (15%)	49 (13%)

[a]Sweat patches and ACASI captured both cocaine and heroin use (ie, there is double counting); therefore, numbers do not add up to 100%.

Figure 2. Percent agreement by drug type and week comparing EMA, sweat patch, and ACASI methods. Panel A: Percent agreement between EMA/Sweat Patch methods (blue bars) and EMA/ACASI methods (green bars) by week for cocaine use. Panel B: Percent agreement between EMA/Sweat Patch methods (orange bars) and EMA/ACASI methods (yellow bars) by week for heroin use.





Correlates of EMA Misreporting

We sought to identify sociodemographic, behavioral or clinical factors associated with over- or underreporting of drug use by EMA. Relative to sweat patch results, there were no significant correlates of EMA overreporting of cocaine use (Table 3). Underreports of cocaine use by EMA were almost 2-fold less likely among females (odds ratio (OR) 0.47, 95% confidence interval (CI): 0.23-0.98) and 80% less likely among individuals who reported injecting once per day or more at baseline (OR 0.21, 95% CI: 0.05-0.87). Although only marginally significant, individuals under 50 years of age were found to be less likely to underreport cocaine use as well (OR 0.51, 95% CI: 0.25-1.07).

EMA overreports of heroin use relative to sweat patches were twice as likely if heroin was used at baseline (OR 2.10, 95% CI: 1.0-4.56), but baseline heroin use was also the only factor significantly associated with EMA underreporting of heroin use (OR 5.56, 95% CI: 1.37-22.46). Female gender also achieved marginal significance in being less likely to underreport heroin use via EMA methods (OR 0.31, 95% CI: 0.08-1.10).

Compared to ACASI methods (Table 3), EMA overreports of cocaine and heroin use were twice as likely if a participant reported sharing injection needles at baseline (OR cocaine 2.79, 95% CI: 1.03-7.5; OR heroin 2.96, 95% CI: 1.17-7.51). Underreporting of cocaine use by EMA was marginally associated with being married and was 6-fold more likely if individuals reported having medical insurance at baseline (OR 6.62, 95% CI: 1.16-37.76). EMA overreports of heroin use were positively associated with baseline heroin use (OR 3.04, 95% CI: 1.33-6.95) as well as over 4-fold more likely if the participant was HIV infected (OR 4.56, 95% CI: 1.80-11.58).

Table 3. Correlates of misreporting cocaine and heroin use by EMA compared to sweat patch or ACASI methods[a].

		Cocaine EMA overreport	Cocaine EMA underreport	Heroin EMA overreport	Heroin EMA underreport
		OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Sweat patch	Female		0.47 (0.23-0.98)[b]		0.31 (0.08-1.10)[c]
	Age≥50			0.52 (0.24-1.14)	
	Never Married		0.51 (0.25-1.07)[c]		0.68 (0.21-2.19)
	Alcohol Use		1.55 (0.72-3.36)		
	Insurance		3.15 (0.76-13.05)		
	Any heroin			2.10 (1.0-4.56)[b]	5.56 (1.37-22.46)[b]
	Any cocaine		1.55 (0.72-3.36)	1.68 (0.79-3.62)	
	Same doctor for at least 2 years			0.60 (0.30-1.23)	
	Inject≥1/day		0.21 (0.05-0.87)[b]		
ACASI	Age≥50			0.42 (0.17-1.07)[c]	
	Never Married		0.47 (0.21-1.02)[c]		0.53 (0.24-1.18)
	Cigarette use		2.73 (0.64-11.72)	2.88 (0.61-13.57)	2.76 (0.46-16.55)
	Alcohol use		1.73 (0.69-4.29)		
	Insurance		6.62 (1.16-37.76)[b]		
	Any heroin			0.77 (0.29-1.99)	3.04 (1.33-6.95)[b]
	Any cocaine		1.78 (0.76-4.20)	1.86 (0.77-4.51)	1.19 (0.53-2.68)
	HIV infected	0.52 (0.18-1.5)			4.56 (1.80-11.58)[b]
	Shared needles	2.79 (1.03-7.5)[b]		2.96 (1.17-7.51)[b]	
	Primary care physician	0.57 (0.15-2.14)			
	Yearly income<$5000			1.69 (0.45-6.34)	

[a]Correlates included in multivariable models had $P<.1$ in univariate analyses and represent behaviors occurring within the 6 months prior to the start of EXACT.

[b]Statistical significance, $P<.05$.

[c]Marginal statistical significance, $P<.1$.

Discussion

This analysis demonstrated moderate to good concordance and inter-rater reliability of reported drug use by EMA when compared to either biological measures of sweat patches or more conventional ACASI self-report methods. However, our data raised concerns regarding the use of sweat patches as a gold standard for drug use assessment due to the notably lower prevalence of heroin use defined by biological detection compared to the prevalence of heroin use we determined in this study based on self-reported methods and to the expected prevalence based on prior data in our ALIVE cohort [7,38]. Even relative to imperfect gold standards, we provide evidence that researchers should be confident that EMA methods can accurately capture and characterize illicit drug use comparable to currently used methods. Given the relative benefits of daily real-time assessments of drug use in terms of reductions in recall bias, social desirability bias (reductions in participant need to please the interviewer), participant burden, and follow-up time, EMA methods for assessing drug use may have broad applications in settings ranging from epidemiological studies to behavioral interventions.

EMA Compared to Sweat Patch Assessment

Biological samples serve as the gold standard for assessing drug use because they are able to capture the biochemical components of drug use as the body excretes them. Sweat patches are often used to detect longer-term drug use and can continuously capture drug metabolites in sweat until the patch is removed. It is designed to be flexible, waterproof, and safe from environmental contaminates [39]. However, once the patch comes off the skin, it cannot be put back on to resume drug use capture. Current applications of sweat patch testing include use in drug treatment for monitoring drug relapse and for determining the effectiveness of medical and psychological therapy [40,41].

Our results suggest moderate concordance between EMA and sweat patch methods for assessing drug use. Prior studies have shown substantial discordance between self-report of drug use and biochemical tests results across out-of-treatment populations [42]. A 10-week outpatient clinical trial in which participants wore sweat patches and provided urine samples and self-reports of cocaine use thrice weekly demonstrated the concurrent validity of urine and sweat patches to be reasonable (correlation: 0.76, $P<.001$), but the correlation between self-report and the patches was lower (correlation: 0.40, $P<.05$) [43]. A separate outpatient study examining the utility of sweat testing for monitoring drug use also found the level of agreement between positive sweat test results and positive urine results to be 33% for heroin and 92% for cocaine [40].

The results of our sweat patch analyses demonstrated a notably greater number of cocaine-positive sweat patches compared to heroin-positive sweat patches. This finding was unexpected as our prior analyses with this EXACT population demonstrated heroin to be the predominant drug of use over 30 days of follow-up [30]. Additionally, recent estimates indicate that Baltimore suffers from a far greater public health burden of heroin abuse compared to cocaine abuse [44] and this is mirrored in the participants of the ALIVE study [7,38]. Upon consultation with PharmChek, manufacturers of the sweat patches, it was suggested this difference may have been the result of our heroin-using participants using such small amounts of heroin that, even after a week of wearing the patch, they did not secrete enough heroin metabolites to be detected at the limit of detection of 10 ng/ml (Matthew Hartley, personal communication).

Although concerns have been raised that sweat patches may serve as a deterrent to drug use [33], there was no incentive in this study to modify behavior and our self-reported drug use data did indicate greater heroin use. To explain our findings, there would have to be a differential effect resulting in heroin misreporting relative to cocaine in response to sweat patch placement, which seems implausible. Yet, despite these problems of relatively lower heroin detection via sweat patches, the inter-rater reliability of EMA methods compared to sweat patch analysis remained moderate for both heroin and cocaine use as evidenced by concordance correlation coefficients.

EMA Compared to ACASI Assessment

ACASI methods have now become the standard approach for collecting sensitive data in epidemiologic research studies. The use of ACASI has resulted in greater disclosure of sensitive behaviors such as drug and sexual risky behaviors in some population [45-47], thereby reducing social desirability bias and improving accuracy of self-report.

Although the best time interval for assessing drug use exposure remains unknown, several studies have found that reporting sensitive sexual behaviors can be accurately recalled for intervals of 1-3 months [48,49]. Longer time frames may be more representative of a person's behavior patterns, but can be more difficult to recall. It is likely that participants asked to recall behaviors over longer time periods may rely on a strategy such as "guestimation" of the average number of days per week they have been with a specific partner or used drugs [50]. Despite the potential problems with accuracy of information collected over longer periods of time, ACASI assessments are rarely done in shorter intervals due to practical issues.

In this analysis, the inter-rater reliability and concordance of EMA methods compared to ACASI methods for assessing drug use appear stronger for heroin use (concordance correlation coefficient for heroin use had good agreement, 0.61 (0.53-0.69)) than for cocaine use. Both methods involve self-report in settings with increased privacy over traditional face-to-face interviews providing greater anonymity when disclosing sensitive information. In the current analysis, the ACASI reports captured more drug use than EMA methods. It is hard to differentiate between "fuzzy" recall that may have been reported via ACASI (leading to overreports) from participants that may have been impaired from drug use when answering the EMA survey (leading to underreports).

While we document good concordance between EMA methods with both ACASI and sweat patch approaches, this analysis neglects to consider a primary analytical strength of EMA methodology, namely the examination of real-time drug use. EMA methods allow for the examination of the variation and amount of drug use by day. ACASI methods are unable to examine daily drug-using patterns due to feasibility issues (eg, study visits, etc). Despite these differences in methodologies, our EMA results remained reliable when compared to ACASI-based methods and could prove extremely useful in understanding drug use among chronic drug users.

Misreporting by EMA

Relative to sweat patch reports, there were no demographic or behavioral correlates of overreporting of cocaine use by EMA whereas having a stable partner, male gender, and daily injection at baseline were associated with underreporting of cocaine use by EMA. Baseline heroin use was the only significant correlate of misreporting of heroin by EMA relative to the sweat patch. In total, these data suggest that more regular heroin users were more likely to both overreport and underreport heroin, raising concerns regarding misclassification due to the limitations of sweat patch detection of heroin as highlighted above. In-depth or timeline follow-back interviews could be used to better understand discordant events, as we do not know if the dynamics of overreporting and underreporting are the same.

Relative to ACASI, sharing injection needles was positively associated with EMA overreporting of both cocaine and heroin use, while underreports of cocaine use was positively associated with having medical insurance. In contrast, EMA underreporting of heroin use were positively associated with baseline heroin use and HIV status. Stable factors, such has having insurance, may lead to underreporting of cocaine use as a result of a social desirability bias. The associations of misreporting with sharing needles, baseline heroin use, and HIV status most likely reflects the recruitment criteria of EXACT, which included a large proportion of HIV-infected individuals with more recent and intense drug use.

Conclusions

Substance abuse is commonly associated with a chaotic or disordered life, mental illness, financial and legal difficulties, and inadequate housing or transportation [51-53]. As members

of the ALIVE cohort, all EXACT participants had a history of abusing illicit drugs and most were HIV infected. Long-term chronic drug abuse has physical ramifications but also cognitive effects. Working memory deficits are also prominent among HIV-infected individuals. During periods of intoxication, heroin users suffer a slow drop-off in attention and often fall asleep [54]. Baseline cocaine and heroin use heavily impacted EMA misreporting of heroin use but not cocaine use. It is possible that inattention or sleep may have contributed to heroin users (more so than cocaine users) having difficulties in recalling drug use on a weekly basis (both as overreports and underreports) as was required of drug use assessed by ACASI. With respect to EMA underreporting, we found no evidence of exhaustion from using the handheld devices in reporting drug use across study week or by drug type. Notwithstanding these differences in reporting by drug type, EMA methods captured much of the drug use reported by ACASI methods.

There are several strengths of EMA methods that make them desirable to capture illicit drug use among community-dwelling populations. Because they are assessed in essentially real-time, EMA does not require individuals to recall or remember behaviors for prolonged periods. Social desirability bias is a reporting bias that arises when individuals underreport specific behaviors or actions because they believe these actions are sensitive and not socially acceptable to report [55]. ACASI methods have been shown to decrease social desirability bias by allowing greater respondent privacy since questions are administered audibly and in text on a computer screen in a private room without the direct participation of a study interviewer [46]. However, EMA methods may allow for even greater respondent privacy since participants are able to answer questions in their natural environment, which allows participants to calmly respond to questions where they feel most comfortable, away from a study site. ACASI interviews and sweat patches require participants to visit study sites at regular intervals.

EMA methods can provide more intensive follow-up opportunities compared to sweat patch or ACASI assessment. Daily outcome assessments over extended periods of time are feasible when using EMA methods because participants can carry the devices 24 hours a day, 7 days a week. Prior studies have involved participants using the devices for up to 6 months [24]. Real-time data capture allows for the daily context and "situatedness" of drug use to be assessed, including information on the number of days used, frequency and amount used in a day, as well as participant behaviors that occur due to specific cultural, organizational, and structural environments [13]. Historically, ACASI has resulted in greater disclosure of sensitive information [45-47] and previous EMA analyses by ourselves and others have demonstrated that EMA is capable of capturing this type of information as well [23,25,26,30,56].

Assessing drug use in epidemiologic studies ideally involves an approach that is unobtrusive, does not rely on recall, has limited requirements for participant participation, and is accessible and affordable. mHealth may provide an excellent solution for assessing drug use in the field. The level of concordance between EMA and traditional biological and self-report methods suggests that utilizing EMA mHealth strategies are feasible for assessing drug use among community dwelling, nontreatment-seeking drug users. Future studies integrating EMA methods with the use of sensors for assessing drug use will likely provide both the biological and environmental cues of illicit drug use as well as provide a more complete picture of drug-using behaviors.

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Conflicts of Interest

None declared.

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Abbreviations

ACASI: audio-computer assisted self-interview
ALIVE: AIDS linked to the intravenous experience
BZ: benzoylecgonine
CES-D: Center for Epidemiologic Studies-Depression Scale
CI: confidence interval
DAST: drug abuse screening test
EMA: ecological momentary assessment
EXACT: Exposure Assessment in Current Time
GEE: generalized estimating equations
IQR: interquartile range
mHealth: mobile health
OR: odds ratio
PDA: personal digital assistant
6-MAM: 6-monoacetylmorphine

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Original Paper

"Smart" RCTs: Development of a Smartphone App for Fully Automated Nutrition-Labeling Intervention Trials

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Abstract

Background: There is substantial interest in the effects of nutrition labels on consumer food-purchasing behavior. However, conducting randomized controlled trials on the impact of nutrition labels in the real world presents a significant challenge.

Objective: The Food Label Trial (FLT) smartphone app was developed to enable conducting fully automated trials, delivering intervention remotely, and collecting individual-level data on food purchases for two nutrition-labeling randomized controlled trials (RCTs) in New Zealand and Australia.

Methods: Two versions of the smartphone app were developed: one for a 5-arm trial (Australian) and the other for a 3-arm trial (New Zealand). The RCT protocols guided requirements for app functionality, that is, obtaining informed consent, two-stage eligibility check, questionnaire administration, randomization, intervention delivery, and outcome assessment. Intervention delivery (nutrition labels) and outcome data collection (individual shopping data) used the smartphone camera technology, where a barcode scanner was used to identify a packaged food and link it with its corresponding match in a food composition database. Scanned products were either recorded in an electronic list (data collection mode) or allocated a nutrition label on screen if matched successfully with an existing product in the database (intervention delivery mode). All recorded data were transmitted to the RCT database hosted on a server.

Results: In total approximately 4000 users have downloaded the FLT app to date; 606 (Australia) and 1470 (New Zealand) users met the eligibility criteria and were randomized. Individual shopping data collected by participants currently comprise more than 96,000 (Australia) and 229,000 (New Zealand) packaged food and beverage products.

Conclusions: The FLT app is one of the first smartphone apps to enable conducting fully automated RCTs. Preliminary app usage statistics demonstrate large potential of such technology, both for intervention delivery and data collection.

Trial Registration: Australian New Zealand Clinical Trials Registry ACTRN12614000964617. New Zealand trial: Australian New Zealand Clinical Trials Registry ACTRN12614000644662.

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KEYWORDS

randomized controlled trial; smartphone; public health; nutrition labeling

Introduction

Smartphone technology offers promising new ways to deliver health interventions and undertake research [1], and smartphone-assisted randomized controlled trials (RCTs) are an emerging methodology. The role of smartphone technology in RCTs varies from provision of simple information or text message reminders to participants to more complex tools enabling, for example, self-monitoring or data collection [2-4]. Messages have been the most common tool used in smartphone-assisted studies to date, although specialized smartphone apps are increasing in popularity [5]. Although systematic reviews suggest mixed evidence of the effectiveness of smartphone-delivered health interventions compared to traditional methods [6,7], advantages of such programs include ability to deliver an intervention remotely and a potentially wider population reach. Greater participant retention and adherence to the intervention and improved convenience for participants compared to traditional methods have also been reported for smartphone-assisted interventions [2,8,9].

Most smartphone RCTs to date have been only partially technology-assisted, that is, smartphone technology is used as an add-on to an existing behavior change program or an automated intervention is compared with a standard technology-free control group [3,10]. Automated RCTs conducted entirely via a smartphone app are a novel approach in health research, and thus, limited published data are currently available in this field. To date, we are aware of only 1 other RCT (a smoking cessation app) that used this approach [11].

Here we describe a new smartphone app developed for use in automated RCTs on the effects of different nutrition label formats on the healthiness of consumer food purchases in 2 countries (Australia and New Zealand) [12,13]. The app (Food Label Trial, FLT) was designed to overcome 2 common challenges of nutrition-labeling interventions: (1) delivery of various nutrition label formats for foods in real-world supermarkets (the intervention) and (2) collection of reliable, objective, household-level food shopping data.

Although the potential public health benefits of interpretive, easy-to-understand nutrition labels are generally accepted [14], it is difficult to test the effectiveness of such labels as an intervention in real-world retail settings. Therefore, assessment of their effectiveness is often only possible in controlled settings [15] or in nonrandomized natural experiments [16]. Technology used in the FoodSwitch smartphone app [17], available in Australia and New Zealand, enables delivery of nutritional information via digital nutrition labels. FoodSwitch users place their smartphone camera over the barcode of a packaged food, the unique barcode is then matched with a product in the underlying food database, and an interpretive nutrition label for the scanned product is displayed on screen. The intervention delivery mode of the FLT app uses the same technology to deliver a nutrition-labeling intervention to trial participants.

A second challenge is collection of individual-level data on food purchases. Traditional methods involve collection of itemized food shopping receipts. However, this requires manual coding and data entry, which is time-consuming and resource intensive [18-20]. Other ways of recording individual purchases, for example, via barcode scanners [21], have also been explored but have presented limitations such as the need for additional equipment or being limited to specific participating stores. To overcome this challenge, our RCT app was designed to have inbuilt data collection functionality using barcode scanning technology.

The aim of this paper is to describe the development and functionality of the smartphone app used for the trials, provide an overview of the end product, and report preliminary usage statistics and common technical issues.

Methods

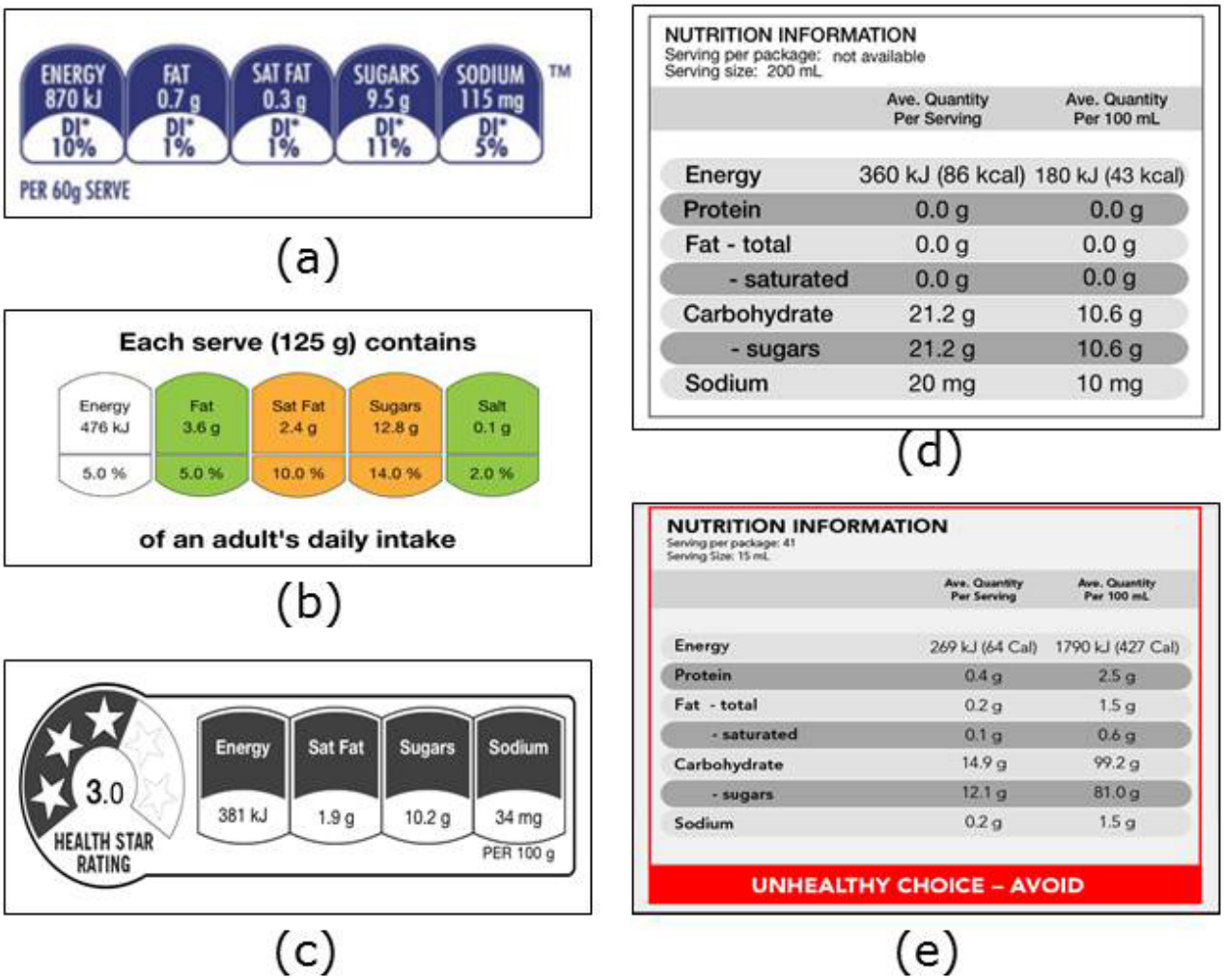
Approvals

Both trials received appropriate ethics approvals (University of Sydney Human Research Ethics Committee, reference number 460; University of Auckland Human Participant Ethics Committee, reference number 011390).

Trial Overview

Full trial protocols, including aims, design, outcome measurements, and power calculations, have been previously published [12,13]. In summary, the randomized controlled trials aimed to assess the effects of different nutrition label formats on the healthiness of consumer food purchases. Individual food and beverage shopping data were collected during 5 weeks (1-week baseline and run-in and a 4-week intervention period). Eligible participants were randomized to 1 of 5 nutrition-labeling formats in Australia and 1 of 3 labeling formats in New Zealand (Figure 1): Daily Intake Guide [22] (Australian trial only), Traffic Light labels [23], Health Star Rating [24], Nutrition Information Panel (control) [25], or a Warning Label [13] (Australian trial only). Both intervention and control nutrition labels were delivered via the smartphone app to minimize technology bias.

Figure 1. Nutrition-labeling formats allocated to intervention and control groups in the trials. (a) Daily Intake Guide*. (b) Traffic Lights. (c) Health Star Rating. (d) Nutrition Information Panel (control arm). (e) Warning Label*. *Australian trial only.



Development of the App

Key Requirements

The app had 3 key functionality requirements: (1) fully automating the conduct of RCTs [12,13], that is, consent, screening, randomization, and questionnaire administration; (2) delivering trial intervention, that is, nutrition labels; and (3) facilitating data collection.

The framework for the first function is presented in Figure 2 as a sequence of the key trial events. Progression through those events was determined by in-app and server-side checks, including an email address check to prevent duplicate registrations, a check that consent has been provided and terms and conditions have been accepted, eligibility at screening, and a check that at least 15 barcoded food or beverage items were recorded during week 1 (run-in phase requirement). A timeline check (from the moment of registration) was also required to ensure delivery of key events such as randomization (end of week 1) and the follow-up questionnaire (end of week 5).

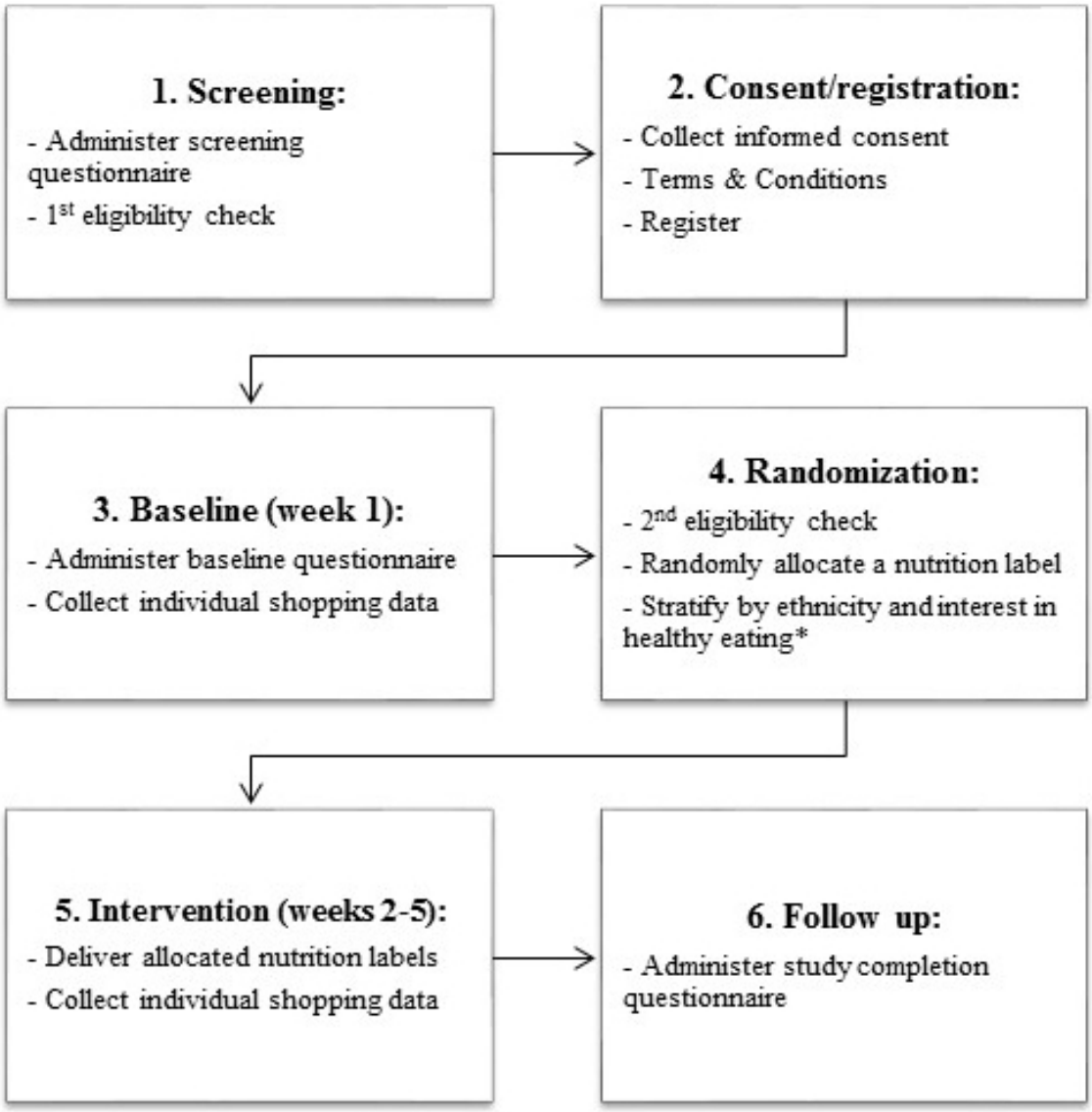
Intervention delivery functionality provided users with a nutrition label for a scanned food product. The format of the label provided was determined by the participant's randomization allocation (Figure 1). Designs of digital nutrition labels in the app were based on the relevant style guides [22-25]. Similar to the FoodSwitch app, nutrient content information for the scanned product was obtained by matching the barcode number with one from the food composition database at the back end.

Data collection functionality used barcode scanning to create electronic itemized records of food purchases made by participants, and the smartphone camera was used to photograph the till receipts. Participants were requested to record all food purchases during the 5-week trial period. Additional information on demographics and usual shopping patterns was collected via in-app baseline and follow-up questionnaires. Two in-app tutorials were developed for user training purposes. In-app and push notifications and reminders were developed to prompt user engagement and adherence to the trial protocol and timelines. The following ethical and security requirements were adhered to: (1) A participant information statement was available to participants via the app throughout the trial, and (2) all data collected via the app were stored securely with identifiable information stored separately from trial outcome data.

Two similar versions of the FLT app were created for the Australian and New Zealand RCTs, with the following

differences between the apps for the two countries: (1) five intervention arms in the Australian app versus 3 for New Zealand; (2) different randomization algorithms with (New Zealand) or without (Australia) stratification by ethnicity and self-reported interest in healthy eating [12]; (3) Australian and New Zealand trial-specific participant information and consent statements, terms and conditions, logos, and content-management systems; and (4) country-specific back-end food composition databases.

Figure 2. Sequence of the key trial events automatically delivered via the FLT mobile app. *New Zealand trial only.



Backend Food Composition Databases

Country-specific food composition databases provided the nutrient information to create nutrition labels and assess outcome measures. The Australian version of the app used The George Institute for Global Health's FoodSwitch database [17], which currently contains nutrition information for more than 65,000 Australian packaged food items. The New Zealand version of the app used the NZ FoodSwitch database, which currently contains nutrition information for more than 21,000 products. The most up-to-date versions of the food composition datasets available at the time of app development were used.

Usability Evaluation

The initial decision on whether an FLT smartphone intervention was feasible to conduct in Australia and New Zealand was based on the popularity of the FoodSwitch app, which currently has more than 600,000 downloads in Australia (population 23.7 million in 2015) and 65,000 downloads in New Zealand (population 4.5 million in 2015). Because the FoodSwitch and FLT apps' core functionality were very similar, separate usability evaluation was not deemed necessary for the FLT app.

Development and Testing

The app was designed by research teams at used The George Institute for Global Health, University of Sydney, Australia, and the National Institute for Health Innovation, University of Auckland, New Zealand. Software and interface development was led by Buzinga Apps, Australia. The app was developed for Android and iOS platforms, the most common smartphone platforms in Australia and New Zealand [17]. During the

development period, weekly online conference meetings were held between the used The George Institute for Global Health, National Institute for Health Innovation, and Buzinga teams. The time frame for development was approximately 9 months, with the framework, interface, technical requirements, and algorithms being developed over the first 5 months (Jan-May 2014) and the iterative development and testing process implemented over the following 4 months (June-Sep 2014). All components of the FLT app and the final versions were pretested by the software developer and research teams. Final products, for both Android and iOS, were tested by independent volunteers from the same research institutions who were not involved in the project. Final versions of the FLT app were submitted to Apple and Android app stores in October 2014. The initial version of the app was compatible with smartphones running either iOS 7 and above or Android 4.3-4.4. The app was updated as new versions of the operating systems became available.

Data Management

All data collected via the FLT app were automatically transmitted to a trial database located on a remote server. Country-specific content management systems were developed for data processing, management, and extraction. Automatic in-app and server-side logic checks on the incoming data were used to ensure adherence to trial requirements and progress through the stages.

Technical Issue Management

On-going quality control of the collected data was carried out by research teams to identify any potential issues. Any identified issues were prioritized by the research team and addressed by Buzinga Apps based on the impact on trial data and the level of inconvenience to participants. Weekly meetings were held between researchers and the app development teams to ensure timely resolution of major technical problems. Two updates of the app for the Android platform and 1 for iOS platform were released after the initial app launch to provide fixes for identified issues.

Analysis of the App Usage

Data collected from the trial app between October 2014 and June 2015 were used for analyses and represent the first nine months of the trial. Simple descriptive statistics were used to report the number of downloads, registrations, randomizations, and the amount of individual shopping data collected via the app. The final trial completion rates will be reported in the results papers (the trials were ongoing at the time of drafting).

Results

Functionality Overview

A flowchart with sample screenshots is presented in Figure 3, and the 16 main functionality components of the FLT app are summarized in Table 1. The first event in the FLT app was the informed consent and registration process. All subsequent events were automatically triggered either by a task completion (eg, a questionnaire) or by reaching a key trial time point (eg, end of baseline phase after 1 week). The trial tutorials are available in the Multimedia Appendices 1 and 2. The logic and schedule of key reminder messages and notifications are summarized in Table 2. The messages were triggered either by the trial timelines or user's progress on task completion.

Table 1. Main functions of the Food Label Trial app.

Component	Time point	Description
Consent and T&C[a] statement	User opens the app for the first time	On-screen consent statement with links to full PIS and T&C documents. Multichoice tick box answer options. Acceptance of the consent statement and T&C were mandatory.
Registration form	After screening questionnaire	Questions with free text answer options. A requirement to enter a unique email address.
Questionnaires	Screening: after consent Baseline: prior to week 1 Follow-up: end of week 5	Questions with multi-choice (tick-box or sliding scale) or free text answer options.
Eligibility checks	First: at screening Second: at the end of week 1	Eligibility was determined from the screening questionnaire answers (first check) and the number of products recorded during baseline (second check).
Randomization	End of week 1	Server-side central blocked randomization with variable block sizes.
Barcode scanning	Weeks 1-5	Barcode numbers of the scanned products were matched with an in-app backend food database.
Electronic lists of purchases	Weeks 1-5	Automatically generated electronic list of scanned product items
Till receipt capture	Weeks 1-5	Smartphone camera is engaged to photograph the till receipt images.
Intervention (nutrition label) delivery	Weeks 2-5	For recognized products, a nutrition label was displayed. The label format was determined by the user's randomization allocation. A random selection of other products from the same category was displayed under the label.
Crowdsourcing: missing product information	Weeks 2-5	An optional functionality allowed users to submit photos of missing products (as with the crowdsourcing function of the FoodSwitch app [17].
Tutorials	First: before week 1 Second: before week 2	Short in-app video clips introducing the app functionality and the required tasks.
Reminders and notifications	Throughout the trial	Automatically triggered in-app and push notification messages. The logic and schedule are described in Table 2.
Progress tracker	Weeks 1-5	Showed the number of weeks completed on the trial.
History	Weeks 1-5	A history of all previously sent electronic lists
Trial information	Weeks 1-5	Information about the trial, research team and technical support contacts, PIS.
Link to FoodSwitch	Ineligible users, end of trial	A link to the FoodSwitch app offered as an alternative resource for healthy food choices.

[a]PIS: participant information statement, T&C: terms and conditions.

Table 2. Key notification and reminder messages delivered by the Food Label Trial app

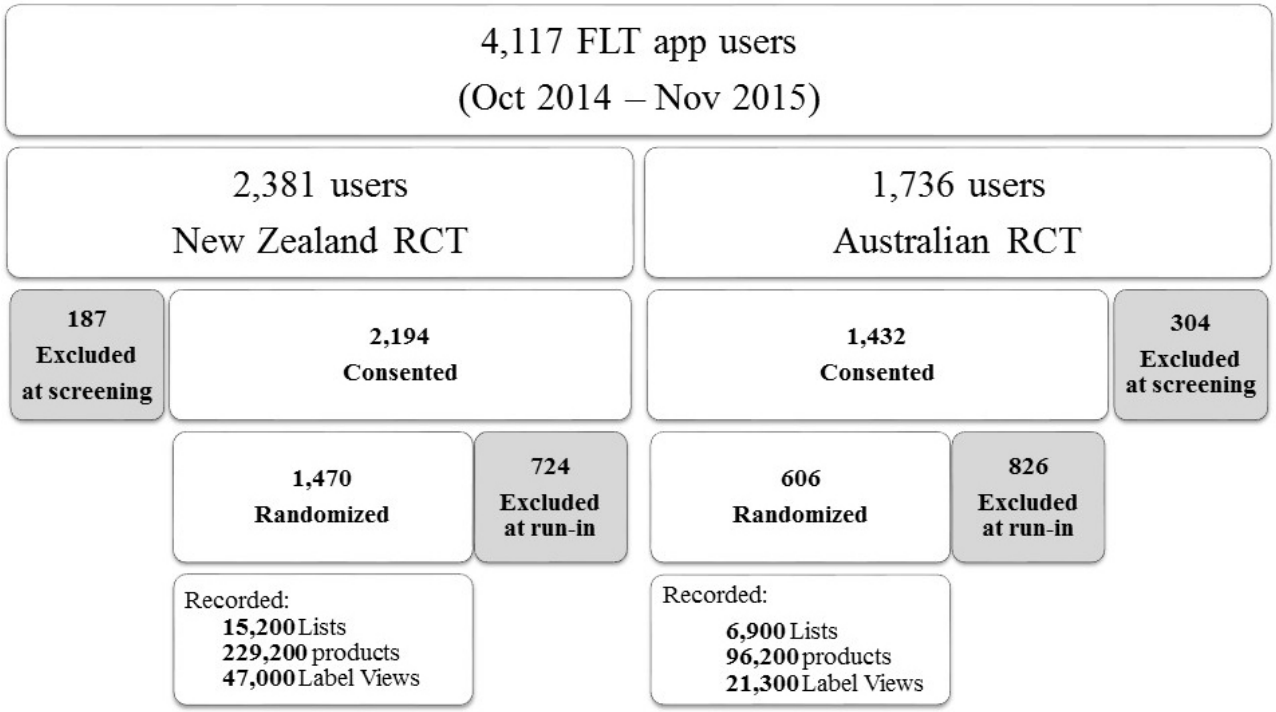
Message description	Trigger	Time point and frequency	Type
Notification informing of ineligibility for the trial; offered a link to the FoodSwitch app.	First eligibility check failed	Once after the screening questionnaire	In-app message
Reminder to complete the registration or baseline questionnaire	Registration form not completed	Two days after consent, then once a week up to 4 times, then once a month until 5 weeks before the overall trial recruitment completion	Push notification
Reminder to record at least 15 items during week 1	User submitted a list of purchased products during week 1, and the total number of items recorded by the user to date is less than 15	After every submitted list that meets the criteria	In-app message
Notification that the product list has been successfully sent	User submitted a list of purchased products, and it was successfully transmitted to the trial database. The number of products recorded during week 1 is 15 items or more	After every submitted list that meets the criteria	In-app message
Reminder to record food purchases (baseline phase)	User has not sent any product lists since the beginning of week 1	At days 3 and 5 of week 1	Push notification
Reminder to keep recording food purchases (intervention phase)	User has not been sending through any new product lists	At days 4, 6, 9, 12, 18, and 24 since the last product list was sent OR since the beginning of the intervention phase	Push notification
Reminder that the trial is ending soon	Day 26 of the intervention phase	Day 26 of the intervention phase	Push notification
Request to complete the follow-up questionnaire	Day 28 of the intervention phase	Day 28 of the intervention phase	In-app message
Reminder to complete the follow-up questionnaire	User has not completed the follow-up questionnaire	Days 6, 12, 18, 24, and 30 from completion of the intervention phase	Push notification
Notification of the trial completion	User completed the follow-up questionnaire	Once after the follow-up questionnaire	In-app message

Figure 3. Food Label Trial app key functionality flowchart with sample screenshots (from the New Zealand version of the app). (a) Welcome screen. (b) Consent and terms and conditions screen. (c) Baseline questionnaire screen. (d) Tutorial. (e) Data collection mode: barcode scanning. (f) Data collection mode: adding a matching till receipt image. (g) Intervention delivery: traffic light label arm. (h) Postrandomization in-app notification. (i) End of trial screen, offering a link to the FoodSwitch app.

Preliminary App Usage Statistics

The FLT app usage statistics for the initial 13 months since the app launch are summarized in Figure 4 (October 2014-Nov 2015). In total, 3000 users downloaded the FLT app to undergo an eligibility check, and of these, close to 1500 unique users were randomized to receive the trial intervention. During this time, participants submitted close to 13,000 electronic shopping lists, with more than 150,000 individual food or beverage items and over 20,000 matching receipt images. The labeling intervention usage rates are reported in Figure 4 as a total number of "label views."

Figure 4. Food Label Trial app usage statistics for the period of October 2014-November 2015.



Key Technical Issues

The most common issues encountered were intermittent problems in connecting to the server while recording purchased products and reminder messages being sent very frequently. Other less-frequent issues, potentially caused by attempts to use the app on incompatible devices, included incorrect recording of consent status, problems viewing nutrition labels, registration issues, issues with focusing smartphone camera on barcodes during scanning, and multiple identical copies of baseline and follow-up surveys recorded for some users. A small number of users experienced issues accessing the trial intervention after the iOS 9.1 release in October 2015.

Discussion

The FLT app is a novel smartphone app designed to conduct an automated RCT on the effects of different nutrition labels on food purchases. To our knowledge, this is the first fully automated smartphone-based trial in public health nutrition. The use of the FLT app overcomes a major challenge commonly encountered in current nutrition-labeling interventions, that is, delivery of randomly allocated nutrition labels to study participants in their regular real-world food shopping locations. Previously, real-world effect of nutrition labels was assessed at a large scale in a natural experiment observation study [16]. Another large study used shelf-labeling in a selected chain of supermarkets [15]. However, a randomized controlled approach has not been possible, and as a result, the current trials are the first RCTs to measure the real-world effect of nutrition labels on food purchasing [26].

The FLT app enabled simplified collection of participant household food purchase data, automatically linked to demographic characteristics (via the participant ID number) and to the food database (via product barcodes). Compared to previous research in this area using shopping receipts as a primary data collection mode for food purchases [18-20], the FLT app substantially reduces the requirements for manual coding and data entry of packaged foods. To minimize potential bias due to technology influence, a control group nutrition label was also delivered via the smartphone, which replicates current mandatory nutrition labels found on the back of the pack of most food and beverage items in Australia and New Zealand.

Preliminary statistics of the FLT app usage have been promising; a large amount of data on intervention usage (label viewing) and individual food purchases has been collected to date. Completeness of electronic shopping data collected will be verified against the shopping receipts at the end of the trial. It will be useful to determine feasibility of this data collection approach in contest of the result of the studies using traditional grocery shopping receipt data collection methods [18].

Previous smartphone-assisted public health intervention trials have mainly focused on comparing the efficacy of technology-based intervention with traditional methods (eg, face-to-face behavior change consultations [3]). The described

"smart" trials use a different approach: The FLT app is not just an intervention within a trial, but a platform enabling a fully automated RCT to be conducted. The app allows screening, consent, registration, and management of study participants remotely, without any manual input from the research team. Ethical and security requirements have also been considered during the app development, which is important, as previous systematic reviews have identified patient privacy as a potential area of concern when using smartphone technology [5].

This novel, "smart" RCT approach offers potential learning benefits for future trials, eliminating the need for in-person or telephone appointments and substantially reducing the time commitment for both researchers and trial participants. To date, limited data have been published on other trials using this approach. A study protocol by BinDhim et al [11] uses a similar "smart" RCT design. This smoking cessation trial also uses an app for screening, consenting, and randomizing trial participants, intervention delivery, and data collection. However, there are 2 key differences compared with the FLT app functionality. First, the FLT app provides a personalized intervention based on participants' interactions with their environment, rather than delivering a generic intervention to all participants. Second, similar to the app used in the study by BinDhim et al [11], the FLT app passively records app usage and collects self-reported data via questionnaires. However, the FLT app also enables participants to actively record their food purchase data. This is of particular importance for a nutrition-labeling intervention, where there is a known shortage of outcomes based on objectively measured shopping data [27].

The FLT app design has certain limitations. Because of the relatively long duration of the projects (18 months recruitment period), it was necessary to update the app following the release of new versions of Android and Apple operating systems. Each app update required time for additional testing and resubmission to the app stores, and thus some users could experience issues with the app functionality until the update was finalized. In addition, because of the large range of smartphone devices available on the market, it was not possible to test compatibility with every one, and thus identify in advance device-specific issues. The issues affecting trial intervention delivery, such as barcode scanning or issues with producing nutrition labels, were considered of high importance for the trial, and thus were prioritized for fixing. The impact of data collection issues was partially offset by using backup data collection methods (hard copies of till receipts) [12,13]. The issues that affected the trial management process, such as very frequent reminders, created inconvenience for participants but had fewer implications for the trial outcomes.

Another limitation is that static backend food databases were used for the app. Therefore, new products appearing on the market after the app release were not recognized by the app. This may have affected both data collection and intervention delivery modes of the app, because both functions work by barcode identification within existing food databases. The impact on data collection can be managed by linking a complete trial dataset with an updated food database at a later time, and thus matching all previously unrecognized barcode numbers with new product information. However, the impact on the intervention delivery is greater, as participants cannot view nutrition labels for missing products.

Finally, the technology-based nature of the trial has a potential to contribute to sample selection bias. Although smartphone ownership is high in both Australia (up to 80% [28]) and New Zealand (up to 70% [29]), a range of factors, such as lack of an active Internet connection, may limit accessibility of some population groups to this research medium. Thus, generalizability of the smart RCT's findings need to be further examined.

In conclusion, the FLT demonstrates the feasibility of using smartphone apps to undertake real-world nutrition-labeling interventions and enable easy collection of individualized electronic food purchasing data. The app technology allows immediate access to intervention nutrition labels in any real-world retail outlet and enables randomized comparison of the label effectiveness. The FLT app is among the first smartphone apps to enable conducting fully automated RCTs.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Food Label Trial app tutorial 1.

[MP4 File (MP4 Video), 3MB - mhealth_v4i1e23_app1.mp4]

Multimedia Appendix 2

Food Label Trial app tutorial 2.

[MP4 File (MP4 Video), 4MB - mhealth_v4i1e23_app2.mp4]

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Abbreviations

RCT: Randomized controlled trial
FLT: Food Label Trial

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Original Paper

Tracking Health Data Is Not Enough: A Qualitative Exploration of the Role of Healthcare Partnerships and mHealth Technology to Promote Physical Activity and to Sustain Behavior Change

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Abstract

Background: Despite the recent explosion of the mobile health (mHealth) industry and consumer acquisition of mHealth tools such as wearable sensors and applications (apps), limited information is known about how this technology can sustain health behavior change and be integrated into health care.

Objective: The objective of the study was to understand potential users' views of mHealth technology, the role this technology may have in promoting individual activity goals aimed at improving health, and the value of integrating mHealth technology with traditional health care.

Methods: Four focus groups were conducted with adults interested in sharing their views on how mHealth technology could support wellness programs and improve health. Participants (n=30) were enrolled from an employee population at an academic health institution. Qualitative thematic analysis was used to code transcripts and identify overarching themes.

Results: Our findings suggest that tracking health data alone may result in heightened awareness of daily activity, yet may not be sufficient to sustain use of mHealth technology and apps, which often have low reuse rates. Participants suggested that context, meaning, and health care partnerships need to be incorporated to engage and retain users. In addition to these findings, drivers for mHealth technology previously identified in the literature, including integration and control of health data were confirmed in this study.

Conclusions: This study explores ways that mHealth technologies may be used to not only track data, but to encourage sustained engagement to achieve individual health goals. Implications of these findings include recommendations for mHealth technology design and health care partnership models to sustain motivation and engagement, allowing individuals to achieve meaningful behavior change.

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KEYWORDS

mHealth; health behavior; motivation; goals; physical activity

Introduction

The Field of mHealth Technology

Mobile health (mHealth) technology has captured the attention of health care providers, health system researchers, and the technology industry because of its potential to improve health outcomes, health care services, and health research. The result is an industry that has attracted over US $1.2 billion in venture capital investment in 2014 [1]. Mobile health technologies range from simple text message reminders for health care appointments, to fitness/health apps downloaded for use on mobile phones, to more complex technology that records real-time patient generated data from wearable sensors. Recent research has explored the potential use of mHealth to improve broad health outcomes as well as its utility in specific conditions such as diabetes, heart disease, and cystic fibrosis [2-5]. Despite vast attention paid to this new field, more evidence is needed to understand how this technology can be used, and what health care partners might be involved, to encourage and sustain health behavior change.

mHealth Technology and Apps

Given that 91% of adults in the United States own a mobile phone [6], 64% of adults own a smartphone, and 15% of smartphone owners report having limited ways to access the Internet outside of their mobile phone [7], mHealth technology has a number of promising apps and possibilities, especially in the areas of health monitoring and health care access. Regarding health monitoring, proponents believe that bidirectional, timely communication of data combined with tailored feedback could play an important role in influencing health behaviors, which may prevent or mitigate factors that lead to disease. For instance, if the technology is connected with pervasive sensors that are either embedded in the environment or on the person, it “can produce continuous streams of data on an individual's biology, psychology (attitudes, cognitions, and emotions), behavior, and daily environment” [8]. With 96% of the US population currently living in areas where mobile networks exist, mHealth supporters also consider the technology to have the potential to improve health care access and reduce health care disparities for hard-to-reach and underserved populations [8]. In a best-case scenario, mobile technology offers the possibility to deliver specialty care where it may not exist, reduce transportation burden, and move care away from traditional clinic and hospital-based care settings, allowing patients to be active participants in the management of their conditions wherever they may be, at times convenient to them [9].

Motivating Behavior Change

A critical issue for those developing mHealth technologies is the creation of an interface or product that engages the intended user and provides enough value to encourage continued use. A number of studies examining the views of intended consumers of mobile technologies designed to improve health have shown that mobile diaries increased patient’s focus on their disease or their health behavior [3,10,11], mobile displays were effective in encouraging participants to maintain activity levels [12,13], and reminder notifications aimed at goal achievement were desirable features [14]. Evidence also is emerging that indicates text messaging delivered through mobile devices may be beneficial for behavior change, such as smoking cessation, which has implications for other desired health behavior changes that are difficult to undertake and lie within the control of the individual [15]. These studies suggest that customized messaging, feedback, and goal setting are important components of mHealth interventions [2,3,14,16-19].

Research on users of mHealth technology has also identified key design elements such as apps that fit within users’ busy lives [11,20,21], provide personal awareness of activity [11,12,14,18,22], support social networks for sharing, support, or competition [11,12,18,22,23], and provide professional health support [13,18]. Finally, participants in an automated mobile physical activity intervention suggested that individualized coaching that goes beyond messaging prompts was also important [3].

Sustaining Behavior Change

Prior studies have gathered essential information about the needs and desires of intended users of mHealth technology. Despite these promising findings, however, studies using mobile technology to target health behavior change for physical activity, weight loss, and management of chronic disease have rarely demonstrated long-term effectiveness [24].

To be effective in health behavior change, continuous use of mHealth apps is vital, yet 26% of apps downloaded by consumers are never used a second time [25]. Additionally, 33% of activity tracker owners abandon use of wearable sensors after 6 months [26]. These statistics point to the need for mHealth designers and researchers to focus on how mHealth technology might be used for sustained health behavior change and improved health. The research in this area suggests that behavior changes are more likely to be sustained if patients are involved in identifying and establishing their own goals and include partnerships with health care providers [27].

The broad objective of this study was to further understand potential user’s views of the usefulness of commercially available mHealth technologies to improve individual health and wellness. A more specific aim was to explore sustained use and the role of health care partnerships as users engage with mHealth technology. Sustained behavior change takes time, therefore we sought to determine what elements would encourage ongoing engagement and would assist individuals to make incremental steps in health behavior change and a corresponding improvement in health. Additionally, as a great deal of innovation and consumer health development is occurring without partnership within traditional health care systems, a key point of inquiry was to examine potential mHealth users’ views about including health care partners in their efforts at behavior change.

Methods

Setting and Participant Recruitment

This research was initiated to ultimately inform the development of an intervention study (the Wireless Health and Wellness Intervention) focused on improving self-efficacy and exercise health among a health system employee group using mHealth

technology. For this reason, we targeted a sample of working adults from an academic institution who were interested in sharing their perspective on what could be offered within an employee wellness program to support sustained health behavior change. The academic health care institution employs over 11,000 faculty and staff.

A convenience sample of focus group participants was recruited through an announcement on the university's website. Prior to attending the focus group sessions, participants completed a survey that asked for demographic information, past experience with mHealth technology, and self-rated health. Participants were compensated US $50 for their time attending the group. The Institutional Review Board reviewed the study protocol and, as no personal identifiers were collected during the focus group sessions, the research was determined to be exempt from human subjects research.

Focus Group Data Collection

The research team conducted three focus groups and a final group to confirm study findings (groups included 8-12 participants and the confirmatory group contained three participants). Experienced social science and qualitative researchers, using standard techniques for focus group research, led the focus group sessions [28,29]. Two of the study authors cofacilitated every session. Each session lasted for 1½ hours and was digitally recorded and transcribed. In the beginning of the group session, mHealth was explained and several examples were provided (from pedometers to FitBit, Nike Fuel Band, and other health apps for mobile phones). Participants were asked about their reactions to the mHealth technology, preferences for the type of health data to be collected, potential features or incentives that would sustain their motivation and use of mHealth technology, and their views on sharing data with others, including health coaches or additional health care partners. Although a semistructured interview guide was used, the groups were conducted as "guided conversations", allowing for frequent probes and unexplored topics to arise [30].

Data Analysis

The study investigators used a combination of deductive and emergent strategies to identify codes from the focus groups [31,32]. Initially, a review was conducted to identify key issues in the research literature. These ideas, such as privacy, social networking, etc, were used as *a priori* codes. Emergent codes were developed through an iterative process. After the first three focus groups, four members of the research team met and discussed the major issues and topics that arose. These initial topics were used along with the *a priori* codes to conduct an initial independent review and coding of the focus groups. In the review of the transcripts, the researchers found additional ideas that had not previously been coded and the team met again to establish new codes. Continuing this iterative process of coding and review, the research team identified the linkages between the codes and grouped them into broader themes [32].

By the end of the third focus group, the main ideas being introduced in the groups were coalescing around similar themes, such that data saturation was determined to have been met. At that point, one additional small group (n=3) was conducted to validate identified themes and confirm that no additional themes were missed. The validation group was smaller to allow for a more in-depth discussion of the themes than a larger group would have allowed. The coding and analysis process was completed using the qualitative data analysis software program Dedoose [33]. Since conversational analysis was not a goal of the project, in the reporting of quotes, participants' verbal hesitations and false starts (eg, "umms") were deleted to improve readability.

Results

Participants

The sample of participants was comprised of 24 women and six men (see Table 1). Each group conducted had relative diversity of representation from the various categories (age, income, self-rated health, and use of technology), allowing for balanced perspectives among participant differences. Similar themes were discovered in the three main groups. Participants ranged in age from 25 to 64 years old; with 14/30 (47%) being between the ages 45-54 years old (see Table 1). All participants had some college education with the greatest percentage 13/30 (43%) having attained a bachelor's degree. Income ranged from US $25,000-$149,999 per year, with the largest number of participants (n=12) reporting earning between $25,000-$49,999. Participants varied in self-reported health ratings. Health rating responses were divided evenly among the "fair", "good", and "very good" categories with no respondents rating their health as "poor", and only 2/30 (7%) rating their health as "excellent" (see Table 2). Over half of the participants 19/30 (63%) stated they were living with at least one chronic condition and 7/30 (23%) reported living with more than one condition. Asthma was the most frequently identified chronic illness 9/30 (30%), followed by obesity 7/30 (23%), arthritis 4/30 (13%), diabetes 3/30 (10%), heart disease, cancer, and prediabetes 1/30 (3% each).

Table 1. Demographics of focus group participants (N=30).

Characteristics	Responses n (%)
Age	
25-34	3 (10)
35-44	6 (20)
45-54	14 (47)
55-64	3 (10)
Missing	4 (13)
Gender	
Male	6 (20)
Female	24 (80)
Race/ethnicity	
White	19 (63)
Black or African-American	6 (20)
Asian	3 (10)
American Indian or Alaska Native	2 (7)
Latino/Hispanic/Spanish	4 (13)
Missing	1 (3)
Education	
Some college, but no degree	8 (27)
Associate degree	3 (10)
Bachelor degree	13 (43)
Graduate or professional degree	6 (20)
Income (US $)	
25,000-49,999	12 (40)
50,000-74,999	3 (10)
75,000-99,999	10 (33)
100,000-124,999	4 (13)

Participants' Mobile Technology Use

Regarding their experience with technology, the majority of participants used mobile phone technology 22/30 (73%) and self-identified as being comfortable with technology. Half of the study participants had used a health-related app prior to the focus group 15/30 (50%). All of the participants who attended the group had heard of, or used, a pedometer in the past. Most, however, had not used specialized mobile health activity trackers such as FitBit, Nike Fuel Band, or other devices that measure activity, although they were aware of the technology.

Drivers for mHealth Technology Use

Participants were introduced to a variety of mHealth technology and were asked to reflect on what factors would encourage or discourage them to use these tools for health improvement. Their initial reactions often focused on the practical dimensions of the technology. Specifically, they considered their daily activities and thought about how the technology might support or augment their current health tracking and monitoring approaches. For example, some participants suggested it was important for the mHealth data to be reliable, such as capturing distance accurately during an exercise session or measuring all of their activities; others emphasized that the device needed to be functional and intuitive. As one participant explained,

> *I think ease of use completely determines whether I'm going to use it or not because I've had lots of apps, and if they're not easy to use, and not easy to [navigate] and they can't search…you know, forget it. I'll stop using it.* [Female, age 45-55]

Although participants described a wide range of drivers they thought would impact their use of mHealth technology, we focus here on two interdependent, overarching themes—integration and control—that shaped their reflections.

Table 2. Technology experience and self-rated health of focus group participants (N=30).

Characteristics	Responses n (%)
Mobile phone owners	
No	8 (27)
Yes	22 (73)
Self-reported overall health	
Poor	0 (0)
Fair	8 (27)
Good	9 (30)
Very good	11 (37)
Excellent	2 (7)
Chronic disease	
Yes	19 (63)
No	11 (37)
Types of mobile apps used to reach health/wellness goals	
Exercise apps	12 (40)
Improved nutrition apps	9 (30)
Meditation/stress reduction apps	2 (7)
Sleep apps	3 (10)
Haven't used a health-related mobile app	10 (33)
Other (mood tracker, exercise plan/reminder)	4 (13)
None	5 (17)

Integration

The first theme, integration, represents the idea that mHealth technology needs to connect with or complement existing habits and tools. For instance, many participants said the mHealth device should not be redundant with other devices or be something extra that they would have to do. If they already had health tracking tools, they wanted the technology to be integrated with those devices. The most commonly described health tracking tool used by participants was the smartphone. Although not everyone had smartphones in the focus group, the idea of a single integrated device that could capture a range of data in a single platform was appealing.

In addition to wanting data tracking capabilities to be integrated, participants also suggested that data storage and visual display of progress should also be integrated. There was general recognition that the data collected during the course of daily life held value not only as a personal gadget to self-gauge activity, but as an important window into health and overall functioning. Many of the participants had health and medical information collected through a personal health record and thought the integration of health behavior tracking with their health record could provide a more complete picture for themselves and their health care provider. As a participant in one group explained,

> *[It would be good] to integrate everything together, so, you know, as we get older and have various issues and problems that our physicians have access to information about our exercise, diet, etc, etc and [be able to] bring all that together.* [Male, age 50-60]

Another participant agreed saying,

> *And it would just be great to have, in a perfect world, everything all integrated so that my health is a full picture.* [(Female, age 35-45]

Control

A second overarching theme in the focus groups was the desire to control the data that would be collected and shared. Some participants wanted to collect an abundance of information such as blood pressure, heart rate, sleep, or mood, whereas others said they wanted minimal information such as calorie intake or energy expended because they would be overwhelmed by too much data.

> *Look if you give me too much data, you're just gonna make me crazy. Period. I won't be able to track it; it wouldn't do me any good. I'll get frustrated and I'll probably [stop using it].* [Female, age 40-50]

Equally important was the desire to control the type and level of data that would be shared with others, including social network groups or members of their health care team. The majority of participants in the focus group did not want to share their health information through social media networks unless it was shared with a group working toward a common goal that

could offer support and motivation. However, without exception, participants thought that the option of sharing their information with health providers was useful. There was some concern, though, as to whether shared data could be potentially available to insurance providers, who might exercise punitive premiums related to negative data. A participant explained,

> *Right, who has access to the information? Is it protected? I'd like it to be spelled out for me. "No, this cannot be included on any chart that's going to go to an insurance company or go to whatever." But, if it's not clear, then you know, I would probably shy away from [using the technology] until I could be assured that it couldn't hurt me.* [Female, age 40-45]

Sustained Motivation and Engagement: Data Are Not Enough

Beyond the practical features identified by participants as key to encouraging initial interest and use, they discussed how mHealth tools could motivate them to work on health behavior change. In these conversations, it became clear that for most participants, tracking and collecting data were not enough to promote sustained engagement. Participants described needing additional support or structure to help them understand the broader meaning and implications of the data. In discussions of how they might make sense of mHealth data, the importance of context emerged.

Adding Context

As a participant said, "Unless there's context to [the data], unless you pull it together and give me some context, I don't want to sit and figure it out." Context, as it was talked about in the focus groups, was a sense making activity that included some combination of education and health expertise and could be provided by the mHealth tool or a health care provider.

Context often meant providing information or education that participants were not already aware of, such as whether or how their exercise or sleep habits affect their mood or health. A participant explains how more information would help her place her sleeplessness in context,

> *Ah, sleep, for me right now, I've gotten blind-sided with hot flashes, and you know, I would be really interested to see how often a night I'm woken up by this, how long the hot flash lasts, you know, how it disrupts my sleep because I'm usually a really good sleeper. Then maybe, you know, seeing things that might decrease it. Like if I exercise more.* [Female, age 40-50]

Some individuals suggested the context could be built into the mHealth device. For example, one participant described wanting an app that could shift her understanding and provide new context to her nutrition habits,

> *I think it would be cool, if there was a device where we can put on a daily basis like what our calorie intake [is] and then the device could calculate calorie intake with your age, your weight, your physical activity. And let's say I had 2 bowls of chili for today, and so it will say, "Hey, [name], maybe you should run for 5-1/2 miles to burn whatever calories, you know, that you should burn."* [Female, age 35-45]

Although some participants, like the one above, emphasized present context, others wanted the device to provide historical context (ie, to compare their current activity to their past activity). As a male participant explained,

> *I think for me, I'd much rather have something that could go and ping me when I need it…. Where [the device scans] the data, and it sees that 10,000 steps a day is what my average is and suddenly I've got a week of, you know, 7500, 8000. "Hey how are you feeling? What's going on?" Where I can respond back, "Well, I've been sick," or "Got a big project at work and I'm sitting down..."* [Male, age 40-45]

Adding Health Care Partnerships

In addition to discussions about the data not being enough, for some participants, the mHealth devices were not enough to encourage or reinforce behavior change. An active subset of the participants did not want to "figure out" the meaning of their mHealth data on their own. Many were not confident that they would either be able to synthesize the different data elements to understand how it relates to their overall health or that they would have the expertise to know what small changes they might implement to see progress toward their health goals. Noting the limitations of mHealth apps, even those that might be set up to send personalized messages, one participant said,

> *[A] device could [send]...a simple text like, "Hey, great job on climbing 25 stairs yesterday," or whatever it may be, you know. So encouragement like that through your device could be useful, but I think to be successful you're going to have to have some type of interaction with somebody else...because everybody knows kind of what their motivations are, but you also know how easy it is to fall into those pitfalls.* [Male, age 30-40]

To sidestep potential pitfalls, participants highlighted the importance of interaction, not with the device, but with a health professional to provide context or meaning to the data. As another participant described,

> *[A health provider] could give me context about oh, this is, you know, the stuff I can't see maybe, and then kind of tease that out a little bit and say, "Well, you know, you seem to be doing good in this area. How did you feel about how you were doing? But, you know, I notice that your blood pressure has been up or are you taking your meds, or have you been stressed out at work or what's up?" You know, those kinds of things I think, but absent one or the other, I think there is like a piece missing.* [Female, age 50-55]

In this understanding of the health care partner's role, they are not only helping to motivate, but they also provide expertise and help make sense of data. Even more broadly, some saw the inclusion of data as a first step of initiating a "wellness" conversation with a health provider.

> *I'm tracking all of this stuff, but having somebody say, "Yes, this age group suffers from this. Yes, but this is where you are with it. These are the things that you can do and yes, you're on track with that." That confirmation means everything I think in treating one's wellness....I think everyone looks for that confirmation or the extra knowledge that they are, I use the word on track, that they are doing the right thing to improve their own health.* [Female, age 45-55]

Some participants raised concerns about whether their providers had the time or interest to review a patient's personal health goals and the corresponding data, especially given the time constraints of many primary care providers. In discussions of whether the health professional needed to be their primary care physician or whether someone else on the health team could interact with them around the data, participants were open to nurse health coaches, nutritionists, or others who were seen as having expertise in assisting with health self-management. The participants had significant interest in health coaching, which we presented as a partnership where a nurse coach works with someone to set short-term, reasonable, and attainable goals that are patient-centered and monitored over time.

Finally, it is worthwhile to note that not all intended users wanted or needed their data connected to context and meaning. A few participants, for example self-described athletes, were confident they were meeting and often exceeding their own health goals. They reported being highly aware of their activity and health behaviors and suggested that they did not need external context. These participants often were already tracking multiple physical activity performance measures through commercially available sensors or apps on their phone.

Discussion

Principal Findings

In our study of potential users of mHealth technology, our findings confirm previous research, which suggests that for potential users of mHealth technology, integrated technology and control are key elements for acceptance and use [3,5,10,11]. Most notable in the discussion for control over data sharing was that there was essentially universal interest in sharing all collected activity data with health care providers. Moving beyond prior research, we also found that study participants envision mobile support that goes well beyond data collection. Our findings suggest that to engage, encourage, and activate individuals to make positive changes in their health behavior, mHealth technology that only tracks and reports data may be insufficient. To maximize the usefulness of the data, focus group participants suggested that the data needed to be placed into context, given meaning, and ideally integrated with their health care data so they can receive individual support and guidance from a health care partner (see Textboxes 3 and 4).

Textbox 3. Patient identified drivers for use of mHealth technology to promote health behavior change.

1. Integration with:
   - Existing technology
   - Personal health records

2. Control of:
   - Data collected
   - Data shared- type, detail, and with whom

Textbox 4. Patient identified needs to sustain use of mHealth technology to promote health behavior change.

1. Adding context/meaning through:
   - Information/Education
   - Awareness
   - Trends to understand relationship between behavior and outcomes/symptoms

2. Adding health expertise/partnership for
   - Data synthesis
   - Goal setting for incremental success
   - Informed, tailored, regular feedback
   - Confirmation of value and importance of patient-centered behavior change work

Context and Meaning

Context and meaning can develop through multiple avenues. Individuals may find meaning through heightened awareness of their current behavior, through new understanding of how specific behaviors impact their experience of health and wellness, or through partnerships with members of the health care team who can help interpret patient generated data.

Participants in this study identified context as a key ingredient for adding value to the data, supporting the theory of "sensemaking", which highlights that making sense of information requires a process of "acquisition, reflection, and action" [4,34,35]. Sensemaking theory suggests that people use information gathered through their experiences, and if they derive meaning of those experiences in relation to their environment and actions, it allows them to better predict how to make changes and respond to similar situations in the future. Simply collecting patient generated data is only the first stage of the sensemaking process. As our study participants noted, and sensemaking theory suggests, there needs to be opportunities for both reflection and action on information obtained. Often there is a gap in an individual's ability to synthesize the data and abstract the meaning that may lead to new understanding and ultimately to change. For instance, it may require multiple points of data collection, reflection over time, and consolidated feedback of data to determine if a specific individual sleeps better on days when he or she engages in a vigorous exercise session.

How reflection and action occur will vary depending on the ability of the individual to synthesize and understand how the data relates to their health and behavior. A recent study found that as individuals conduct exploratory causes of changes in health outcomes, they seek affirmation from social networks or their health care provider that they are, in fact, on the right track as they implement changes [36]. If, as many suggested in our focus groups, help is required to synthesize data and create meaning, this could theoretically either be built into device responses or occur in partnership with the individual through collaboration with a member of the health care team. A "patient work" design framework, as outlined by Valdez et al [37], is in alignment with our findings. Specifically, this framework calls for design to include context-sensitive alerts, tailored education, feedback, and personalized settings to support the creation of technologies that are patient-centered [36]. Additionally, we found evidence that some mHealth users may benefit from a "patient-provider" design framework, a design strategy that places the patient-provider relationship (not only the patient) at the center of sensemaking. Potential users not only believed that data gathered from their daily activities were important as they work to make healthy choices, but they also saw the data as a window into their health overall and, therefore, felt it was important for it to be shared with their health care provider. Building on the patient work design, a patient-provider design could have context-sensitive alerts, education, and personalized settings, yet the summary of these interactions and outcomes would be viewable by both patients and health providers so they may share patient-generated health information, leading to collaborative reflection and action.

The patient-provider design is a shared partnership design with foundational elements originally described in the Chronic Care Model [38]. A recent adaptation of the original model, the eHealth Enhanced Chronic Care Model [39], highlights the importance and integration of eHealth components (Internet, social networking, electronic health records, mHealth, and patient portals) into the Chronic Care Model [38]. The elements identified by our participants directly map onto the elements of this model in that they identify a need for education, support, and guidance to be readily accessible to them within their community and outside of traditional office visits. Additionally, participants cited their desire to have the data they generate during their daily activity integrate into their electronic health record specifically so their health care provider could view their activity and provide regular, timely, informed, and personalized feedback to help them reach their goals.

Limitations

This research was exploratory and had several limitations. One of the limitations was that we asked participants to speculate on what they wanted from mHealth technology. We did not have a mobile health platform for them to test, so they may have had different reactions to the technology if they were interacting with it. We also were not able to test whether their understanding of motivation would in fact motivate them to use the mHealth technology. In future studies, we will interview individuals who have used a specific technology during and after the intervention to get a more complete understanding of how mHealth might be able to help with behavior change.

A second limitation relates to the sample of respondents participating in this study. Participants were selected from a convenience sample of health system employees who responded to a study advertisement. The participants in the focus groups likely had a higher education, were more familiar with the health care environment, were more comfortable with technology, and had higher income than would be expected in a general population. Similar to other studies related to physical activity, more women participated than did men [39-42]. In our focus groups, both women and men suggested the desire for context and health care partnerships. If more men were recruited for the focus groups, we may have seen some variation in the types or levels of partnerships they desired as compared to women. Additional research is needed to explore the generalizability of our findings to other populations, especially if mHealth technology will be used in older populations, lower income groups, or populations less experienced with mobile technology.

Design Considerations

The findings from this study related to integration suggest the need for consolidated information in one easy-to-access location, with meaningful data points that correlate to other measures of health. The most often identified solution by participants was to link mHealth data with patient portals or personal health records connected to their health system. Issues of control were considered satisfied if sharing rules could be set by the user related to which data elements were shared with each person in their network. When considering the exchange of data with a member of the health care team, there was less concern about sharing all relevant data gathered as long as there was assurance there would not be punitive insurance premiums for "bad data". Use and sharing of data would need to be defined and made clear to users joining programs where data are incorporated or shared with their health system to alleviate those concerns.

If the findings from this study are to be incorporated into a mHealth intervention design aimed at behavior change, there are a number of challenges. Bringing patient-generated data

into closed electronic health record systems presents significant security and system challenges, which must be addressed to provide the desired level of integration identified in our findings. Determining how best to distill big data streams to the right-sized, meaningful summary data that are actionable and can be readily available to both patients and clinicians is also essential.

In addition to technical challenges, there are other clinical considerations that must be explored. It is imperative to determine whether providers believe patient generated data will augment patient care, and if so, what data are important, how much they would like to see (summary vs granular), how the data should be displayed, and how this additional information would fit within current patient care workflow. Importantly, as the above challenges are considered and solutions are found, we must determine how to evaluate the impact of the tools and system integration on the patient experience and outcomes.

Finally, it is important to acknowledge that patients are only one part of the equation in the use of mHealth. Development of mHealth technologies requires an iterative process of obtaining information and guidance from key stakeholders (patients, information technology specialists, and providers), identifying and potentially repurposing existing technology, designing user-friendly systems and taxonomies for data collection and analysis, integrating with health system interfaces, and testing through interventions or randomized trials. Additional structural factors also would need attention, including deciding which health care activities are tied to reimbursement, how health care providers are educated to interact with patients and with other members of the health care team, the culture of medicine and health care (for example, the attention to wellness vs disease), the mode and/or location of health care delivery, and liability issues associated with receiving patient-generated data that might require timely provider action.

Conclusions

mHealth technology to manage chronic conditions and improve wellness is becoming ubiquitous. Yet this development is occurring in large part independent of the health care system. This study contributes to our understanding of the desired technology and health care elements identified by potential users, which can bridge the gap between personal technology development and integration with the health care system.

Improved health outcomes are essential to encourage health care providers, health systems, insurers, and funders to invest in and adopt novel mHealth technologies on a broader scale. Measurable outcomes will likely require sustained behavior change from both patients and health providers. Because of this, a better understanding of the underlying motivation of intended users of mHealth technology and health providers is essential for intervention success. We must recognize, and address, through programmatic and technological design, the drivers and barriers to technology engagement so that we ultimately offer users the elements to support and motivate them for the difficult task of behavior change. At a basic level, the mHealth tools offered to users should be intuitive, integrate with existing technology, and should allow the user to control what data are collected and shared. At a deeper level, the importance of linking data with context and meaning, suggests that mHealth technology should ideally provide the user with some new understanding of how their behavior affects their health. Finally, to accomplish the goal of providing a fuller picture of health, integrating daily health activities into the clinical record can offer an opportunity for clinical reinforcement of health behavior change.

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Authors' Contributions

SM and SH conducted the focus groups, analyzed the data, and synthesized the results. JH, HY, and AP contributed to the discussion and conclusion of the results and to the editing of the final manuscript.

Conflicts of Interest

None declared.

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Abbreviations

mHealth: mobile health

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Original Paper

Developing mHealth Remote Monitoring Technology for Attention Deficit Hyperactivity Disorder: A Qualitative Study Eliciting User Priorities and Needs

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Abstract

Background: Guidelines in the United Kingdom recommend that medication titration for attention deficit hyperactivity disorder (ADHD) should be completed within 4-6 weeks and include regular reviews. However, most clinicians think that weekly clinic contact is infeasible, and audits have shown that this timeline is rarely achieved. Thus, a more effective monitoring and review system is needed; remote monitoring technology (RMT) may be one way to improve current practice. However, little is known about whether patients with ADHD, their families, and clinicians would be interested in using RMT.

Objective: To explore patients', parents', and health care professionals' views and attitudes toward using digital technology for remote monitoring during titration for ADHD.

Methods: This was a qualitative study, and data were collected through 11 focus groups with adults and young people with ADHD, parents of children with ADHD, and health care professionals (N=59).

Results: All participant groups were positive about using RMT in the treatment of ADHD, but they were also aware of barriers to its use, especially around access to technology and integrating RMT into clinical care. They identified that RMT had the most potential for use in the ongoing management and support of ADHD, rather than during the distinct titration period. Participants identified features of RMT that could improve the quality of consultations and support greater self-management.

Conclusions: RMT has the potential to augment support and care for ADHD, but it needs to go beyond the titration period and offer more to patients and families than monitoring through outcome measures. Developing and evaluating an mHealth app that incorporates the key features identified by end users is required.

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KEYWORDS

attention deficit hyperactivity disorder; mHealth; eMental Health; remote monitoring technology; mental health services; qualitative methods; feasibility testing; user requirements

Introduction

Attention deficit hyperactivity disorder (ADHD) is a neurodevelopmental syndrome characterized by 3 core behaviors—inattention, hyperactivity, and impulsivity—and affects approximately 5% of school-aged children [1]. Left unmanaged, ADHD can result in impairments in multiple domains, including academic performance, productivity, and social adjustment, and can lead to an increased risk of conduct and personality disorders or substance misuse [2]. Medication is the most common treatment, with psychosocial interventions, such as behavior training and parent training, being the main alternatives [3]. Using digital technologies for eMental Health (ie, the use of information and communication technologies (ICT) to support and improve mental health, including the use of online resources, social media, and mobile phone apps [4]) and mHealth (ie, mobile health [5]), has the potential to transform the delivery of mental health care by connecting patients, services, and health data in new ways [6]. Certain features of digital technologies target specific deficiencies for people with ADHD, such as automated reminders and task scheduling to support organizational skills and immediate access to avoid delay and waiting. They also offer the potential to increase access to resource-intensive, and therefore scarce, psychosocial interventions.

Developments of eMental Health for ADHD include digital and Web-based psychometric tools [7]; behavioral interventions [8]; cognitive and biofeedback training packages (some with game-like features) [3,9]; and computerized cognitive assessments [10]. While there is some evidence emerging about these approaches, they remain largely experimental, and have limited alignment to clinical practice [3,9]. For example, the delivery of synchronous and asynchronous behavioral interventions for ADHD with patients and parents has been found to be acceptable, feasible, and effective [8]. Similarly, in child and adolescent mental health services (CAMHS), recent research has shown that eMeasures (ie, outcome measures delivered electronically) are perceived positively by patients and clinicians, and tend to have significantly higher completion rates than do the standard approaches [7,11].

Internet availability and mobile devices are now within the reach of most of the population, enabling new systems of health monitoring to be considered without the previous problem of excluding large sections of the population. In the United Kingdom, 85% of all adults have household access to the Internet, and this rises to 94% among 16-24 year olds; furthermore, mobile Internet appears to have the fastest growing audience (an increase of 11% from 27.2 million unique users in March 2103 to 30.2 million by March 2014) [12]. By March 2015, 66% of all adults owned a mobile phone; among younger age groups, there was nigh-universal ownership (87% for 25-34 years; 90% for 16-24 years) [13]. The mobile phone apps for ADHD currently available through commercial app stores are primarily tools for self-testing and information and management strategies, task and scheduling aids, and brain training games (according to a review of the Google Play and iTunes stores performed in August 2015). While most apps target patients and provide information and non-clinical advice, a small number target clinicians to provide support for treatment decisions. However, most apps have been developed outside of clinical environments and few are supported by an evidence base [14]. Neither is it clear whether potential end-users have been involved in the design and development of these tools. Given these limitations in this and other health areas, serious concerns have been raised about the safety, usability, and effectiveness of unregulated health apps [15].

In the United Kingdom, an identified unmet need in ADHD treatment is the delay in reaching the optimum dose for patients commencing medication (personal communication, unpublished audit, Hall, 2015). During initial medication titration, the National Institute for Health and Care Excellence (NICE) ADHD Guideline [1] recommends that progress be reviewed regularly, such as by weekly telephone contact and at each dose change, and that the entire process should occur over 4-6 weeks [1]. However, weekly contact during titration is not viewed as feasible by most clinicians in the UK National Health Service (NHS) because of time and resource constraints (personal communication (unpublished audit), Hall, 2015). Evidence from the landmark Multimodal Treatment Study of Children with ADHD in the United States [16] highlighted the importance of high quality medication management in ADHD, including carefully monitoring individual dose titration with regular follow-up, in facilitating better outcomes for patients. Therefore, a more effective system is needed to ensure that patients are monitored closely but without increasing the strain on clinic resources.

Remote monitoring technology (RMT) is a means of collecting physiological or health-related data from individuals passively or by their active input on an electronic device, such as a mobile phone, and relaying these data over an internet or phone connection to a remote server. Given the ubiquity of mobile device use and Internet availability in the population, the conditions for using RMT as an adjunct to traditional models of service delivery appear better than ever. Using RMT offers a potential solution to delays in titration currently experienced in the NHS. However, little is known about whether patients and health care professionals in the NHS context would support the introduction of RMT to aid treatment monitoring for ADHD. Moreover, there is a need to ensure the quality of any RMT products and that patient and families' needs remain at the center of any technology development and implementation [17]. Therefore, the aim of this study was to explore patients', parents', and health care professionals' views regarding the use of RMT during medication titration for ADHD.

Methods

Design and Context

We conducted an exploratory cross-sectional focus group study with patients, parents, and health professionals. Focus groups were chosen as the preferred method of data collection for this study because they enable an exploration of experiences and views and facilitate discussion between participants on a topic of shared interest [18]. The setting was 4 NHS mental health provider areas in the East Midlands region of England, the United Kingdom. An industrial partner [19] developed an initial

prototype RMT system, which was used as a vehicle for exploring participants' views of this technology.

The prototype RMT enabled automated text messages to be sent to patients who were invited to complete Web-based versions of routine outcome measures (ROMs) to monitor symptoms and side effects. The system comprised a clinician dashboard where patient details were entered and the specific ROMs required for each individual patient were selected. The dashboard indicated when patients had completed their measures and showed red flags for any issues of concern. To use the RMT patients required a mobile phone to receive text messages and activate the links to the Web-based versions of the ROM. Once completed, the data were relayed back to the system server and the clinician dashboard updated. The primary aim of the prototype was to enable the clinic to receive information about responses to and side effects of medication during the titration period in addition to that obtained from face-to-face appointments. Screenshots of the prototype are displayed in Figures 1-3.

Figure 1. Screenshot of the prototype RMT: Text message received by patient.

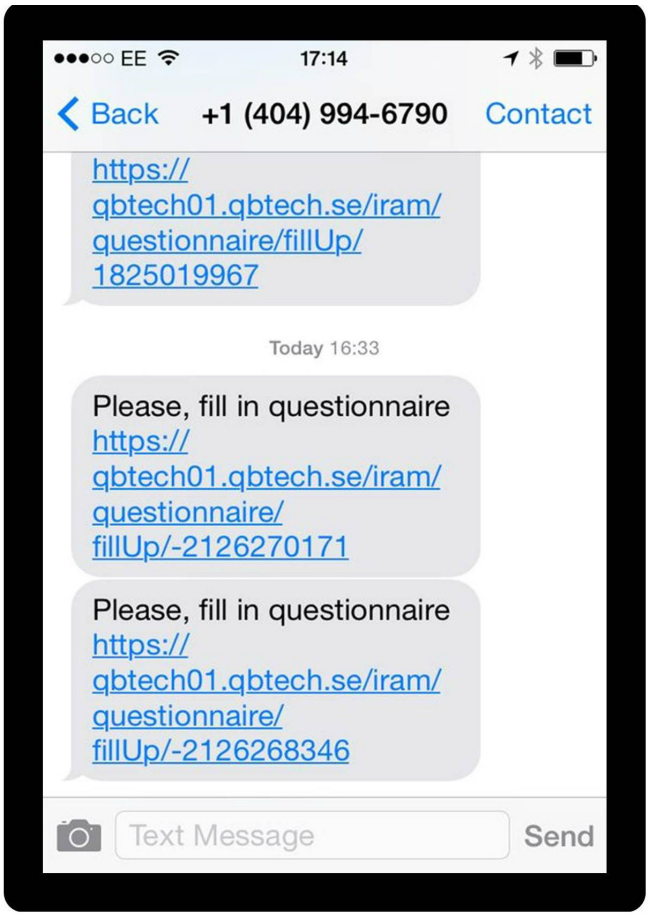


Figure 2. Screenshot of prototype RMT: Example ROM.

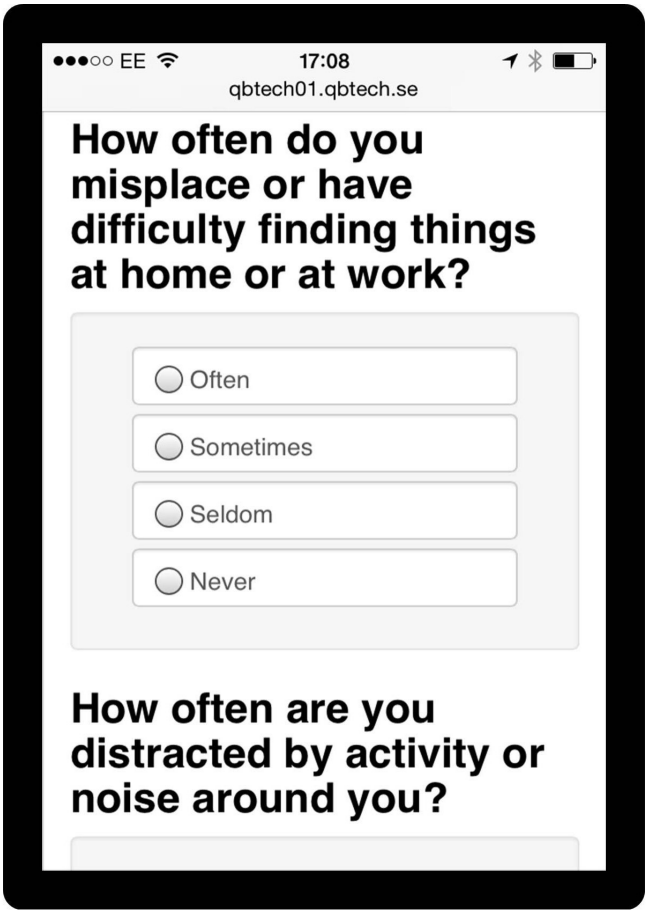
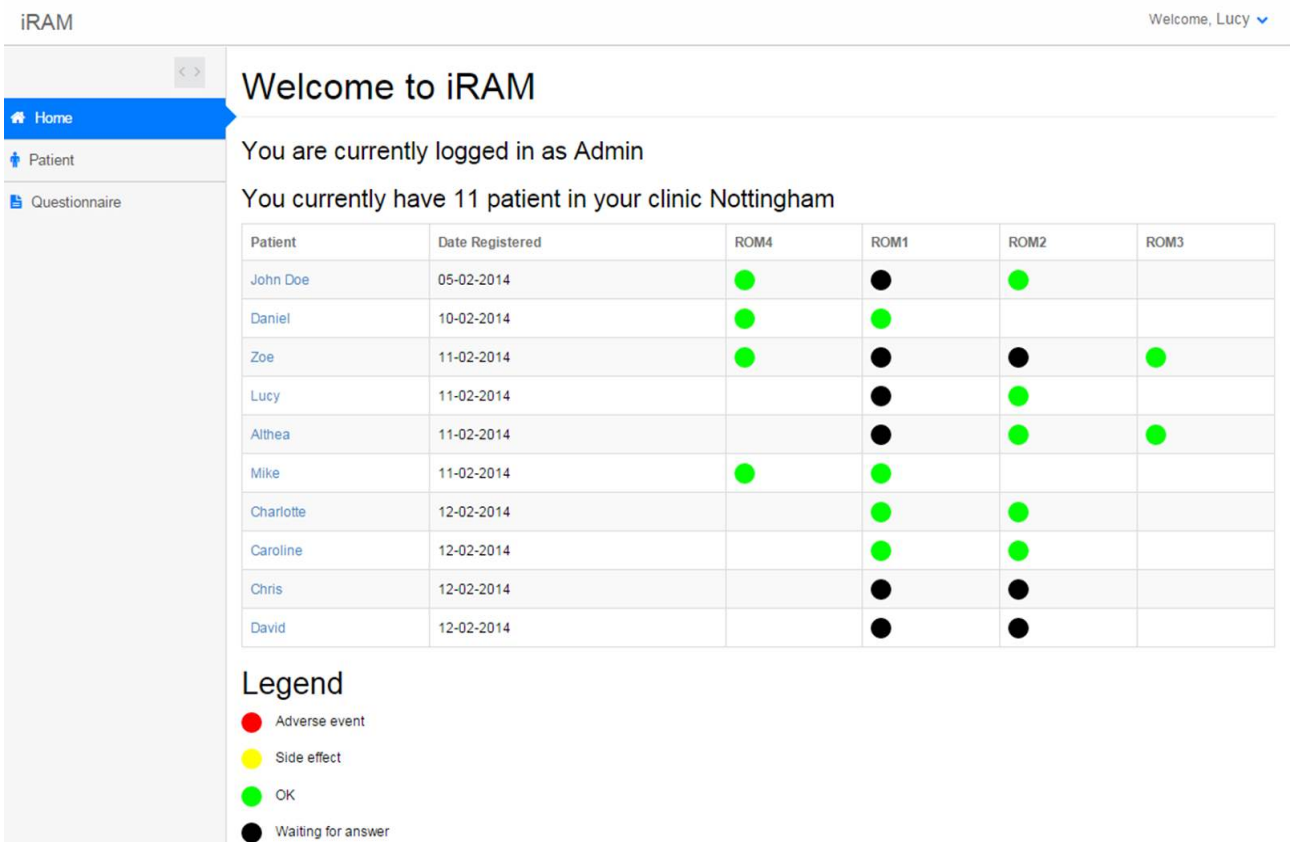


Figure 3. Screenshot of prototype RMT : Clinician dashboard.



User Involvement in Study Design

Before undertaking the focus groups, a workshop was held to elicit feedback on the prototype RMT system from potential end-users. It was attended by a young person with ADHD and his parent, 2 adults with ADHD, 1 psychiatrist, 1 psychologist, and 1 medical technology researcher. This workshop identified key factors to explore in more detail in the focus groups. The experience of the workshop suggested that demonstrating the prototype system during the focus groups would risk diverting attention away from the primary research purpose. This was primarily because the "on-boarding" process for the prototype RMT was lengthy—individual patient details needed to be entered into the clinician dashboard and patients needed to both receive and reply to SMS text messages. In the short time we had available in the scheduled focus groups, we determined that this process would dominate the session and limit the time needed for exploring participants' views and acceptability of the general concept of RMT. Therefore, we decided not to use the prototype RMT in the focus groups, but instead created printed materials from the system to aid in discussion (see Figures 1-3).

Participants

The study sample comprised 8 young people with ADHD (YP), 11 adults with ADHD (adults), 9 parents of children with ADHD (parents), and 31 health care professionals (HCP) working with people with ADHD (see Table 1). YP, adults, and parents were recruited through 2 routes: NHS ADHD clinics (CAMHS and community pediatrics) or community ADHD support groups.

Inclusion criteria were a self-reported diagnosis of ADHD or having a child with a self-reported diagnosis of ADHD. This was checked by asking participants to confirm where they had received the diagnosis (90% had received it in NHS clinics and 10% in private health care facilities). HCPs were recruited by the local investigators at each NHS provider organization. The criterion for inclusion was employment in a service treating people with ADHD. A purposive sample of HCPs was sought to reflect the range of staff involved in medication management in clinical settings and implementation of any new systems.

Procedure

Eleven separate focus groups took place in areas with variable relative deprivation including inner cities, post-industrial towns, and semi-rural districts. They were held in locations convenient to the participants (either NHS clinic or support group premises) and took place between June and September 2014. Each group was limited to a single participant type (see Table 1) [18] and we aimed to hold at least 2 focus groups for each participant type. We also made sure that each different mental health care provider was represented by at least 1 HCP focus group to enable an exploration of any differences in practice or attitudes between the different provider organizations [18]. The YP groups lasted for 45 and 50 minutes, while the groups with adults, parents, and HCPs lasted 75-90 minutes.

The study received ethical approval from the UK National Research Ethics Service Committee South Central - Berkshire B (ref 13/SC/0641). Information about the study was sent to all potential participants before the scheduled focus group date. At the beginning of each session, the study was explained to participants and any questions were answered. All adult participants gave their written informed consent to take part. Parents of the YP aged under 16 gave their written informed consent for their children to take part, while the YP gave their verbal assent. YP, adults, and parents were all given a £20 shopping voucher as a reward for their participation. HCPs all took part during their usual working times, so no remuneration was given to them.

Each focus group was facilitated by 2 members of the research team. One member brought domain (insider) knowledge about ADHD (ZY), while the other brought methodological (outsider) knowledge about focus groups (LS or MC). The facilitators sought to remain "background figures" [20] in the groups, guiding the process, rather than leading it. Moreover, the insider (domain) and outsider (methodological) perspectives were combined to ensure the discussions remained focused on the core topic while ensuring that researchers could still seek clarification on assumed knowledge and implied meanings between those with common experiences.

The discussions were guided by a topic schedule covering 4 key areas: using technology for health; medication titration experience/practice; remote monitoring for effects and side effects; and aspirations for using technology to manage ADHD (see Appendix 1). Drawing on best practice advice for focus groups [20], and especially for young people [21], we included different activity-oriented questions in each group (see Table 2). These were designed to enrich the data collected, make it easier to talk about sensitive topics (for example, medication taking), and, importantly for our participants, reduce lapses in attention [22]. Some of these activities were designed to ensure that participants could express their views individually, and thereby avoid inadvertent acquiescence bias to the researchers or censoring by the other participants. Although 2 of the focus groups had only 2 participants, the discussions were similar to those in the larger groups in that they were highly interactive and yielded equally rich data. Participants also completed a short questionnaire on their demographic characteristics and current technology use.

Table 1. Number of participants in each focus group by study area

Site	Health care professionals	Adults	Young people	Parents	Total
Site 1	9[a]	4	-	-	13
Site 2	7	7	6	7	27
Site 3	7	-	2	2	11
Site 4	8	-	-	-	8
Total	31	11	8	9	59

[a] Two focus groups were held with health care professionals at Site 1: 1 with 3 participants and 1 with 6 participants.

Table 2. Overview of the activity-oriented questions included in the focus groups

Activity	YP	Adults	Parents	HCPs
Warm-up "rapid-fire" quiz		✓	✓	
Data visualizations	✓	✓	✓	✓
Ideas on sticky notes	✓	✓	✓	
Rating personal experience		✓	✓	
Personas and scenarios	✓			
Prototype screenshots	✓	✓	✓	✓

Data Analysis

All focus groups were audio recorded and transcribed. Adopting an applied approach [23], thematic analysis [24] and charting [25] were used to search for data patterns within and across the different participant groups. An initial coding frame was developed by 2 researchers (LS and AV), one of whom had not been involved with data collection. This included independent open coding of 4 transcripts each and joint discussion to agree on a comprehensive coding frame. Through constant comparison [26], all data were coded into the coding frame, which was iterated when required and reapplied to the earlier transcripts. The initial coding of the 4 transcripts (representing approximately 35% of the dataset) was cross-checked for reliability; this yielded 93% agreement (κ=0.922, P<.001). Once all of the data were organized into the refined coding frame, members of the wider research team (LS, AV, CF, and MC) engaged in detailed discussions, which led to the identification of overarching, interpretative themes. These themes aimed to capture the essence and strength of the participants' experiences and views; by assigning individual codes to these themes, we were able to maintain a close fit between the data and the more abstract, interpretative themes. Theme-level matrixes [25] were created to compare the nature and distribution of the data across the participant groups.

Questionnaire data were entered into a database and analyzed in SPSS 21 (IBM) by 1 team member (CF).

Results

Overview

Table 3 summarizes the demographic characteristics of the 59 participants. Both the patient and parent samples were predominantly white British, and were mainly male, and female, respectively. In all groups, there was a wide spread of ages, apart from YP, who were all aged 12 or 13 years. The HCP sample included 9 medical staff and 15 non-medical clinical staff, of which 11 were prescribers, 5 were in non-clinical health care roles, and 2 were IT managers.

Using digital technology was a frequent activity in all participants' lives. The vast majority of HCPs (27/31, 87%), adults (10/11, 91%), and parents (7/8, 88%) used mobile phones on a daily basis, whereas YP were more likely to use game consoles (5/8, 63%) and tablet computers (5/8, 63%) on a daily basis. Participants mostly used these devices to access the Internet (54/59, 92%), while a majority also used them for apps (39/59, 66%) and some adults, YP, and parents regularly used them for playing games (15/28, 54%).

The qualitative analysis resulted in 5 key themes (see Table 4), 2 of which related to treatment and support for ADHD (ie, complexity of medication decision making and access to diagnosis, treatment, and support), while the other 3 related to the role of RMT (potential of RMT to support people living with ADHD, barriers and limitations to technology, and imagining the ideal app). These themes are described and expanded on below, and are supported by key quotations from the participants. Although all 4 participant groups provided data to support all 5 themes, we highlight any discrepancies in emphasis across participant groups in the theme description.

Table 3. Participant demographic information

Participant Group	Total	Gender (female)	Age range (years)	Ethnicity (white British)	Employment status (employed)
Health care professional	31	22	18-64	25	31
Adult	11	7	18-54	10	7
Young person	8	1	12-13	7	0
Parent	9	7	25-54	8	5

Table 4. Overview of the analytic interpretative themes and contributing data codes

Analytic interpretative themes	Subthemes	Contributing data codes
Complexity of medication decision making		Personal expectations of medications
		Medication—decision making
		Medication effects
		Confidence in prescribing
		Communication with education professionals
		Questionnaires
		Communication with patients
Access to diagnosis, treatment, and support		Medication—experience of titration
		Experience of diagnosis (of ADHD)
		Communication with health care professionals
Potential of RMT to support living with ADHD	Symptom tracking to improve the quality of clinic appointments	Range of current use of websites
	Supporting greater self-management	Range of current use of other technology
		Anticipated impact—self management
		Anticipated impact—health care consultation
		Acceptability and receptiveness (positive)
		Tracking
		Medication—experience
Barriers and limitations to using RMT	Access to technology	Barriers and limitations (negative)
	Perceived challenges of incorporating RMT into clinical care	
Imagining an ideal app	Organization aid	Content in ideal app
	Coach/supporter/ motivator	
	Reliable, trustworthy and tailored information	
	Monitoring and tracking side effects and symptoms	

Complexity of Medication Decision Making

Across the sample, experiences of the titration period were mixed. Some participants were content with the speed of the titration and their level of contact with the clinic, while others believed it to be a lengthy period to attain an acceptable level of medication effect (up to 18 months). Very few participants reported that titration had been achieved within the 6-week period recommended by the NICE ADHD Guideline, and most participants reported monthly or less face-to-face contact with the clinic during titration. While few adults were satisfied with this amount of contact, most of the parents were. In the adult and parent groups, a visual scale was used for participants to indicate their satisfaction with the titration process (see Figure

4). This composite visualization (re-created to include all participants' responses and pseudonyms) shows a broad variation in satisfaction.

HCPs generally reported that while titration may not always meet NICE guideline timescales, their practice was as good as could be delivered within current facilities and resources—more frequent contact was prevented by limited clinic capacity or high caseloads. Weekly monitoring and dose changes were difficult to achieve as prescribers gathered information from a number of sources (such as school reports) to guide their decisions.

> *You need information from the young person, the parent/carer, and ideally from the teacher, because sometimes the young person doesn't realize that the medication is beneficial but the parent does.* [HCP, Site 1]

Despite being optimistic about the effects of the medication when first prescribed, many participants described difficulties in deciding whether to start or continue with it. Adults and parents wanted to achieve an acceptable balance of positive effects and side effects.

> *It's a balancing act of getting enough done…You need to say when it is "good enough". Not getting everything done but weighing up the health issues and side effects.* [Adult, Site 1]

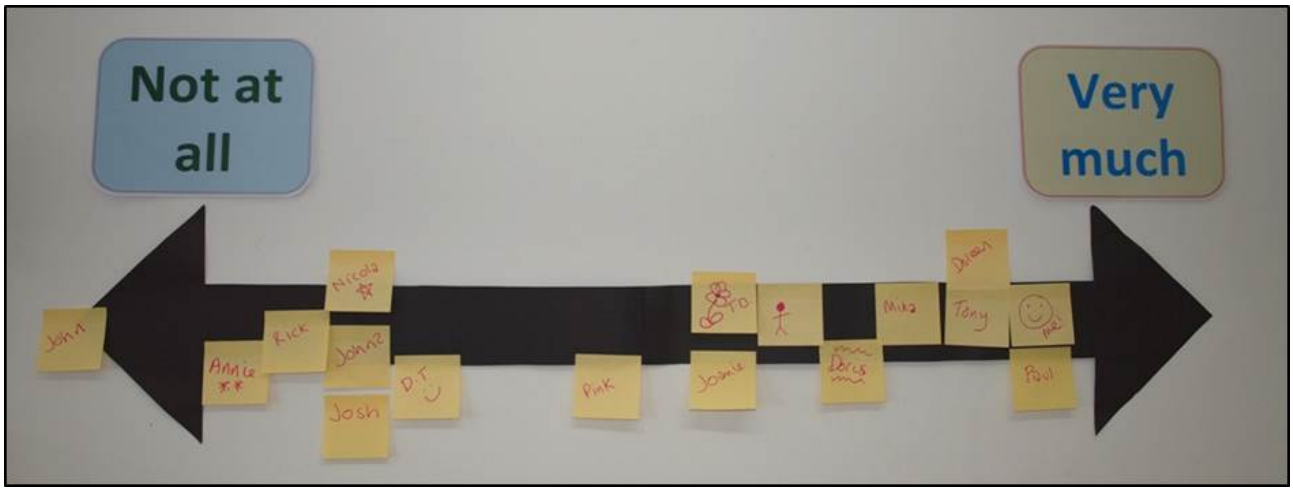
Because of these experiences, many participants chose when to take (or give their child) medication. HCPs were aware of this and had differing degrees of acceptance of this. Whereas some supported the patient or parent taking control, others were concerned about inconsistent medication taking.

The use of clinical rating scales (or ROMs) to support titration was not consistent across the study sites; where they were used, it was always as an adjunct to the detailed, qualitative information gathered in conversation and written school reports.

> *You can get a better understanding through a telephone call and you can unpick things more in a conversation, for example, a child is sleeping more than they used to but not as much as the parent would like.* [HCP, Site 2]

HCPs across all groups raised concerns about the validity and reliability of ROMs, such as whether they are sensitive enough to detect subtle effects. ROMs were also believed to become less informative with repetitive use, open to manipulation, and difficult to interpret when responses differed between respondents (eg, parents, teachers).

Figure 4. Visualization of adult and parent satisfaction with the titration period. (Note: this is a representation of data and all names are pseudonyms).



Access to Diagnosis, Treatment, and Support

Despite the primary focus of this study being the use of RMT during the titration period, the focus group discussions were dominated by issues relating to access to diagnosis, treatment, and support, especially for adults and parents. Participants recalled the "*frustrating*" and "*lengthy process*" of getting a diagnosis and that it often took something "*drastic*," such as a "*breakdown*", "*meltdown*," or a number of job losses, before they were taken seriously. Adults specifically mentioned that "*getting someone to listen*" or "*having a doctor that believed in [ADHD]*" was key to their diagnosis, as opposed to being "*fobbed off*," "*labeled lazy and idle*," or "*[labeled as] naughty*." The difficulties in access to diagnosis, treatment, and support appeared to eclipse the experience of medication titration. By the point of diagnosis and commencing medication, adults and parents were so relieved to have access to treatment and support that the time needed to reach the optimum dose of medication was of less importance to them. This experience was supported by comments from some HCPs, as well.

> *My cases are usually diagnosed in adolescence so they have been waiting for their ADHD to be treated for years, so a few more weeks [for titration] is not a big deal. The important thing is that the process has started.* [HCP, Site 1]

Although there were some examples of positive experiences, most parents and adults highlighted substantial organizational and logistical issues regarding access to treatment; in particular, they cited long waiting times, brief appointments, lengthy intervals between appointments, inconsistent doctors, unpredictable communication, and frequent cancellations.

Both parent and adult groups expressed a need for further support. One adult specifically reported "*I'm getting down, I'm*

not coping. I feel like I've been left on my own a bit really" [Adult, Site 2]. In addition to support for side effects and symptoms, participants expressed the need for *"reassurance" [Parent, Site 2], "someone there if you have a problem" [Parent, Site 3],* and *"information from someone who "gets it" more than professionals do" [Adult, Site 1]*.

Potential of RMT to Support Living With ADHD

As described above, there was widespread use of Internet-enabled mobile devices, computers, and game consoles across the sample, but their use in relation to ADHD was fairly limited. With the exception of YP, all other groups reported using websites for ADHD information. Parents, adults, and HCPs were cautious about Web information; they wanted to access (or recommend) only trusted or reputable websites. A small number of participants used existing generic mobile phone functions to support daily activities (calendar, reminders, lists, and timers). HCPs described how they sometimes recommended general relaxation and meditation apps, rather than apps specifically designed for people with ADHD.

However, across the whole sample, there were highly positive attitudes toward the potential for RMT to play a greater role in the management of ADHD. Many participants reported that it could improve communication with the clinic; furthermore, participants across all groups saw its potential to (a) improve the quality of the clinic appointments/consultations and (b) support greater patient self-management.

Symptom Tracking to Improve the Quality of Clinic Appointments

Parents, adults, and HCPs thought that using RMT would save time in clinic appointments by enabling a quicker review of the patient's recent history and thereby swifter identification of what matters most to the patient/parent.

> *This way you can look back over the previous 4 weeks or 3 months and focus on questions such as—"you scored sleep a 2 here, what was happening at the time that made it so unsettled?" It should help parents to be more productive in giving the information we need.* [HCP, Site 3]

Participants also thought that data collected contemporaneously, rather than retrospectively, would not be biased by patient recall and selective memory.

Supporting Greater Self-Management

Participants saw the potential for RMT to provide the ability to easily monitor symptoms, chart them over time, and identify any patterns or unusual behaviors. This would increase people's knowledge, self-awareness, and understanding of and confidence in dealing with their condition. All of the groups also saw the potential for RMT to offer personalized feedback in response to patient-entered data. This could be used for reassurance, to avoid unnecessary contact with the clinic, and for motivating feedback to reinforce positive behaviors.

> *It could be a bar with red at the bottom and green at the top and a little person and after each check-up, it moves up or down to show how well you are doing so it gives you the opportunity to realize and change it.* [YP, Site 3]

> *Sometimes I think I'm doing well for a few weeks, then I look back and realize I wasn't. Something to help me accurately monitor that. That in itself would be an aid to the medication… so you can look back and see what you've done well and what things you need to concentrate on doing better.* [Adult, Site 2]

While participants broadly welcomed the concept of RMT, specific feedback on the prototype pointed to some important limitations in this approach. For YP, adults, and parents, the prototype did not allow them to retain and use their own (or the child's) data, and therefore was unable to realize their vision of its supporting greater self-management described above. For HCPs, the primary issue was that the prototype was perceived as onerous to use and difficult to incorporate into current workflows (for a further description of this, see the "Barriers and limitations to using RMT" section below). They emphasized the need for an RMT that saves clinician time rather than adds to it by requiring additional management outside of the current electronic patient record.

Barriers and Limitations to Using RMT

The barriers and limitations to using RMT were highlighted in all focus groups, although HCPs foresaw more barriers than did parents, YP, or adults.

Access to Technology

Although most participants used Internet-enabled mobile devices, they thought that other people might have had difficulties in physically accessing the technology or having the necessary skills to use it. This included access to mobile devices, especially ones that would support any new app/software (all groups); access to phones when at school (YP); access to wireless Internet in different locations (YP and HCPs); and capability for interoperability with NHS hardware (HCPs).

Perceived Challenges of Incorporating RMT Into Clinical Care

RMT was seen as a positive addition to the clinical process only if it *"adds to what's there already...not if it's used as an excuse to see people less" [Adult, Site 2]*. HCPs were keen on receiving digital information that coincided with patients' appointments, but noted that *"if you start getting notifications about patients from another area clinic it will take up too much time" [HCP, Site 3]*, and stressed that all of their time spent dealing with digital data be accounted for and appropriately factored into the provider contract. Confidentiality of personal data and privacy was discussed by several groups, as was the need to consider information governance problems and to protect young people from any harms arising from digital tools.

Some HCPs and adults were concerned with providing information digitally to clinics, as it may not be responded to promptly, whereas a phone call would be more likely to elicit a response. Others felt this could be useful information, as long as it was understood that the information might not be seen immediately and that patients should be directed to alternative sources of support when needed.

Imagining an Ideal App

Participants across all groups were keen to imagine and discuss the functions of their ideal mobile phone app for ADHD. There were similarities across groups regarding the proposed primary functions as well as the preference for personalization, regarding both users' ability to control settings and to receive tailored responses. YP also wanted any tool intended for daily use to be *"challenging… and funny" [YP, Site 3]*. Taken together, the feedback on the prototype RMT and their views on an ideal app points toward a preference for RMT to be controlled by patients, rather than clinics. Four primary functions were identified: organizational aid; a digital coach or mentor; reliable, trustworthy, and tailored information; and symptom or side effect monitoring.

Organization Aid

Organization aids were frequently mentioned in all groups, apart from YP. For example, 1 HCP thought that a reminder system would be useful:

> *The difficulties I come across, [are that] young people are on medication and they tend to run out at the end of the month and their behavior will go sky high, and it will take them a week to get all the medication back into their system. I think it would be really useful if somewhere in the app, say when they're...near the end [they receive a message saying] "You need to put in a request for repeat prescription."* [HCP, Site 3]

Parents supported this idea, especially as YP begin taking more responsibility for managing their ADHD. Adults wanted support with day-to-day tasks: *"something that helps you keep on task and achieve goals...incorporating pre-set plans and lists of tasks" [Adult, Site 2]*. Another discussed the utility of a timing app*:*

> *To figure out how long it takes you to do certain daily tasks eg, showering. The app could then tell you what time you would need to get up to get everything done [Adult, Site 1].*

A Coach/Supporter/Motivator

Adults, YP, and HCPs identified potential features that could act as a virtual *"coach" [Adult, Site 1]*, such as providing supportive statements and motivation:

> *[It] could have some information based on how long the process should take with messages such as "you may not be seeing any improvements yet, but stick with it"... or you could have messages to parents, such as "Derek might be struggling this week"* [HCP, Site 3]

Reliable, Trustworthy, and Tailored Information

All participant groups suggested that the app should provide reliable and precise information, based on both personal experiences and professional knowledge. Information about medications was in particular sought by adults, while parents and HCPs wanted links to reputable sites and resources, including existing apps and support groups; YP wanted information about ADHD books. HCPs suggested that an app could give proactive advice about behavior, sleep, and diet. They also felt advice should be targeted with frequently asked questions and specific, tailored responses, such as *"I'm feeling dizzy—[the] advice would be to go to see your GP" [HCP, Site 4]*.

Monitoring and Tracking Side Effects and Symptoms

There was strong support across all groups to track information visually, such as using a graph to illustrate changes in symptoms, side effects, and behavior over time. YP suggested that monitoring mood swings and side effects might be useful. HCPs wanted the ability to monitor medication compliance and side effects, as well as tracking behaviors such as eating, sleeping, and drug and alcohol use during titration. The usefulness of being able to link this information with life events was also identified:

> *Graphs would be useful for example for... patients who stop taking meds but parents and teachers say they have improved. It might help to have the parent and teacher graphs to see.* [HPC, Site 4]

Adults wanted the mode of recording information to be tailored to individual preferences, for example, using smiley faces to record mood, using the voice recorder, and linking with other apps such as work calendars. HCPs felt it would be useful if school staff could provide feedback through the app. Parents were happy for YP to enter their own data when they were mature enough, but also wanted to provide feedback and report how they themselves are doing.

Discussion

Principal Results

The participants in this study reflect current trends in technology use [12,13], particularly with regard to their high use of mobile technologies (eg, Internet-enabled mobile phones and tablets). While few currently used these devices in relation to ADHD (ie, patients or HCPs), we found widespread support for augmenting ADHD treatment and support with RMT, eHealth, and mHealth apps. However, 2 important findings from this study indicate that the purpose and functions of the initial prototype did not align with participants' priorities.

First, while our initial interest in conducting this study was to explore how RMT could improve titration management, and even though our findings support audit work suggesting that the NICE guidelines are not currently met in NHS services (personal communication (unpublished audit) by Hall, 2015), few participants identified this as an area of high unmet need. The exploratory nature of the study enabled new ideas to emerge that moved us beyond titration. Through participants' detailed accounts, we identified 3 clear phases of living with ADHD: initial assessment and diagnosis; starting treatment (including medication titration); and ongoing support and management. The group discussions with adults, YP, and parents were dominated by their experience of the first phase—namely, trying to access services and getting a formal diagnosis, as described in our second theme (access to diagnosis, treatment, and support). This adds to previous evidence of this being an area

of high unmet need [2]. Once diagnosed, the experience of relief and optimism was similar to that reported in other studies [27], as was their recognition of the long-term implications of ADHD [28], the need for ongoing support in living with ADHD, and the limitations of medication [27].

Second, participants identified that RMT's greatest potential was in improving ongoing support and management of ADHD. The use of RMT to improve ADHD by continuing the health care interventions between appointments has previously been recognized [14]. In this study, 2 key advantages were highlighted—tracking to improve the quality of clinic appointments and support for greater self-management.

While there have been calls for increased use of ROMs and clinical measures to enhance clinical practice [29], there are several barriers to widespread adoption [30]. Some of these barriers were identified in this study—specifically, increased burden on clinics, questions about the clinical utility of the data, and the need for information from a range of sources, particularly regarding medication-decision making. It has been argued that technology may make ROMs more useful by providing data in a form that is timely and accessible by patients, families, and clinicians [31]. Our findings support those of Hall et al. [11], who found that regular monitoring using electronic ROMs allowed for tracking progress and facilitating communication and engagement. As identified by participants in this study, using mobile phone/tablet apps for completing ROMs has the potential to save time for both clinicians and patients [32] and may provide more accurate data than paper-based questionnaires [33]; however, some academics caution against simple translation of paper-based questionnaires to digital formats without further validation [34].

Participants in this study demonstrated a preference for an RMT system that supports greater self-management—namely, one that is patient-owned and controlled, such that patients/parents can choose when and how to use it and specifically when to share the information with their clinician. The widespread adoption of mobile phones and tablet computers in the population makes them advantageous over other digital devices as they are very portable and frequently in the owner's possession throughout the day [15]. These devices afford the opportunity for the use of low-cost apps that can support clinical management at any time of day or in any location [35] through provision of trusted information, real-time monitoring and symptom tracking, prompts and medication reminders, personalized behavioral support, and communication with health care services. However, the value of apps to the health care system will only be fully realized once the data generated from them is shared between patients, carers, and clinicians to improve their efficiency and quality of care.

Although there are some ADHD-specific mobile phone apps available, we are not aware of any evaluations or evidence of their clinical benefit. Research has shown that using generic mobile phone features such as calendars, task lists, and notes, with the support of a human online coach, can be effective in managing ADHD symptoms [36]. Extending this approach with a bespoke ADHD tool that incorporates the 4 key features identified in this study (organizational aid, virtual coach, reliable and tailored information, and monitoring and feedback) is proposed as the next step for research. This tool also needs to include positive reinforcement such as rewards for completion and game-like features (a process called "gamification") to enhance user engagement [14], which could meet YP requirements for any tools to be fun and challenging. In addition to rating symptoms and treatment progress monitoring, an RMT system could complement therapy, psychoeducation, support, and advice [37].

Our study has demonstrated the vital importance of developing systems in collaboration with the end users. The next stage of research and development for RMT for ADHD will be to adopt well-established user-centered approaches with rapid, iterative cycles of requirements elicitation, design, testing, and redesign [38]. The findings of this study provide a strong foundation to commence this stage, and will also help with testing the efficacy of the RMT during its development; this is a crucial part of beginning to build evidence for the clinical effectiveness of any new RMT.

Greater patient activation, including self-management and self-monitoring, is a goal for many long-term conditions, not only ADHD. The primary findings from this study—that RMT has a place throughout the patient's journey (not only targeted at a single stage) and the overwhelming preference for patient-controlled, rather than clinic-controlled systems—may also apply across other neurodevelopmental and mental health disorders. Our use of the HCP sample in this study adds support to this point, as they came from CAMHS and pediatric services where they would treat a range of different conditions. However, it will be important to test these assumptions with other populations; in particular, the detailed user requirements for an ADHD-focused RMT may not transfer directly to other conditions and populations.

Strengths and Limitations

By engaging with a range of participants, we have explored the commonalities and differences across the key stakeholder groups. We found universal support for technology innovation across these groups and identified their preferences for how this could be implemented. Diversity with respect to gender, age, and ethnicity across our sample was limited, meaning that we may have missed some important perspectives. However, it should be noted that the ethnic profile of our sample reflects previous findings of studies of access to care, where white children were twice as likely as access services than were children from other ethnic groups [39].

By using a defined prototype as a discussion vehicle for RMT within a defined clinical condition, we may have narrowed the scope of the discussion and the ideas of what would be useful or possible. For example, while access to diagnosis was identified as the most significant unmet need, participants' aspirations for technological support focused on treatment and support. However, many of the ideas proposed diverged from the specific approach taken with the prototype, suggesting that participants had clear ideas for when and how technology would be helpful to them.

Conclusions

The findings from this study strongly suggest that YP, parents, and adults with ADHD are looking for a more personalized, responsive approach to ADHD treatment and support in the long term. Patients and their families want more targeted information at a time they need it most, to have control over interventions including medication, to have facilities to record and monitor personal and sensitive information about themselves, and to have support in developing personal strategies that fit with their lives. This study of patients', parents', and HCPs' views of using RMT for ADHD leads us to the conclusion that a technology-based personalized approach for living with ADHD, driven by user requirements, is required. However, implementing RMT requires a key change in the philosophy of health care from routinized clinic-centered care to personalized patient-centered care.

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Conflicts of Interest

DD receives education, travel, and research funding from Eli Lilly and Co., Shire Pharmaceuticals, and HP Pharma. CH receives research funding from Shire Pharmaceuticals

Multimedia Appendix 1

Example focus group schedule: Parents.

[PDF File (Adobe PDF File), 211KB - mhealth_v4i1e31_app1.pdf]

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Abbreviations

ADHD: Attention deficit hyperactivity disorder
CAMHS: Child and adolescent mental health services
HCP: Health care professionals
NHS: National Health Service
NICE: National Institute for Health and Care Excellence
NIHR: National Institute for Health Research
ROM: Routine outcome measure
RMT: Remote monitoring technology
UK: United Kingdom
YP: Young people

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Original Paper

Possibilities and Expectations for mHealth in the Pacific Islands: Insights From Key Informants

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Abstract

Background: The increase in mobile phone use across the globe is creating mounting interest for its application in addressing health system constraints. Although still limited, there is growing evidence of success in using mobile phones for health (mHealth) in low- and middle- income countries. The promise of mHealth to address key health system issues presents a huge potential for the Pacific Island countries where mobile use has radically increased. Current projections indicate an improved information and communications technology (ICT) environment to support greater access to mobile and digital devices in the Pacific region.

Objective: The objective of the study was to explore key stakeholder perspectives on the potential for mHealth in the Pacific region.

Methods: A series of in-depth interviews were conducted either face-to-face, via Skype or by email, with a series of key informants from the Pacific Rim region. Interviews were audio-recorded and later transcribed for detailed thematic analysis.

Results: We found widespread support for the potential to use mobile phones as a mechanism to facilitate improved health service delivery in the region. Essential elements for the successful development and implementation of mHealth were identified by these stakeholders. These included: developing an understanding of the local context and the problems that may be usefully addressed by the addition of mHealth to existing strategies and services; consideration of local infrastructure, capability, policy, mobile literacy and engagement; learning from others, particularly other low- and middle-income countries (LMICs); the importance of building supportive environments and of evaluation to provide evidence of impact and total cost.

Conclusions: The rapid growth of mobile phone use in the region presents a unique juxtaposition of opportunity and promise. Though the region lags behind other LMICs in the adoption of mHealth technologies, this offers the convenience of learning from past mHealth interventions and applying these learnings to achieve scale, sustainability and success. This study deepens the understanding of the potential of mHealth for the region, and offers a baseline from which discussions can be made to examine the limitations, barriers and complexities inherent in mHealth applications.

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KEYWORDS

mHealth; Pacific Islands; prevention; health systems; health policy

Introduction

The rapid spread of mobile technology (mobile phones) has become the impetus for the recognition of its potential to create economic opportunities and enhance developmental interventions through mobile tools [1-2]. The traction of "mobile health" or "mHealth" within the health sector relies on its

potential to extend the reach of health information and services, particularly among vulnerable populations [3].

Conservatively, it is estimated that almost 60 per cent the Pacific region population have access to a mobile phone [4]. According to the Groupe Speciale Mobile Association (GSMA) the Asia Pacific region will increase mobile subscribers from 1.7 billion in 2013 to 2.4 billion by 2020 [5]. Of course, the Asia Pacific region includes some of the world's wealthiest and poorest countries, as well as the largest population. However, despite massive demographic and economic differences across the region, one factor remains; mobile phone use is expanding, rapidly [5]. As of 2015, a series of major infrastructure operations are underway to enhance the coordination and delivery of information technology services across the region [6]. The establishment of the Pacific Regional Infrastructure Facility (PRIF) has indicated a concerted effort to ensure donor partners in the region work together to maximize efforts to improve information and communications technology (ICT) infrastructure.

mHealth remains a novel practice in the Pacific region, a situation that brings with it some considerable opportunities. Despite increased access to mobile phones and network coverage in the Pacific Islands, mHealth has remained small-scale, restricted to pilot projects, and not integrated into the mainstream public health systems [7]. The challenges of initiation reflect a lack of local technological knowledge and, therefore, empirical evidence of efficacy of mHealth specific to the region. Moreover, the extent to which mobile literacy has kept pace with the expansion of Pacific markers is not clear [3,8]. To understand more about expectations, opportunities and challenges for building mHealth in the Pacific region, we sought the perspectives of a range of key stakeholders.

In this paper we present formative research findings on stakeholders' views on the potential of mobile phones to improve health service delivery in the Pacific region. The experiences of health workers in the Pacific region and mHealth innovators in other low and middle-income countries, offer valuable insight into how policy makers and program developers can capitalize on previous experiences on mHealth interventions to ensure benefits are experienced in the Pacific region. The aim of the study was to explore key stakeholder perspectives on the potential for mHealth in the Pacific region, and how it could fit into existing broader health system structure.

Methods

Sampling

As this study was concerned with exploring the potential of mHealth in the Pacific region, a purposive sampling strategy was used to identify key informants that could provide a rich and diverse interview data. An initial environmental scan was conducted to identify possible key informants. Participants were selected for their expert knowledge and experience of Pacific life and health status. The key informants included participants from organizations that could potentially become stakeholders for mHealth initiatives in the region as well as professionals with regional or in-country experience implementing public health initiatives.

However, as the study progressed and new categories emerged from preliminary data analysis, it became obvious that more sampling was needed to develop these categories further. Chenitz and Swanson [9] described this aspect of theoretical sampling as the need to collect more data to "examine categories and their relationships and to assure that representativeness in the category exists". As there was no precise number of predetermined key informants, additional sampling was added until preliminary data analysis showed that concepts have achieved theoretical saturation. The additional key informants were recommendations from participants and mobile solutions expert with a proficient understanding of mHealth initiatives in low- and middle-income countries.

Data Collection

All interviews were conducted by one of the investigators (EU). In order to facilitate access to informants, including those who were based in different regions of the world, interviews were done in person, or online. Prior to the interviews, an introductory email and information sheet were provided to all potential participants. The participants who indicated interest to participate in the study were sent copies of the consent form.

The online interviews were either synchronous or asynchronous [10]. The synchronous interviews used online video call applications (ie, Skype or Google Hangouts). Whenever possible, face-to-face interviews and online video calls were preferred, however due to poor Internet connection especially in some Pacific countries, some interviews were conducted via Email. This form of interview has been one of the most popular Internet mediated methodologies to date [10].

The interview schedule was developed after an initial review of literature. The interview process was semi-structured and open-ended to allow the participants to focus and expound on issues they deemed important. The interviews followed a series of questions developed after an initial review of literature. Although the questions had specific themes, some topics were allowed to emerge during the course of the interviews. The synchronous online interviews and face-to-face interviews started with a short introduction, an explanation of the research, and a brief description of how mHealth is defined for the purpose of this research. The asynchronous interviews consisted of an introductory Email and a brief discussion on how to answer the interview questions that came as a separate attachment. The participants were given two to three weeks to return completed questionnaires. Additional follow-up or clarificatory questions were sent to key informants when necessary. All face-to-face interviews and online video calls ranged between 30 to 50 minutes.

The ethics approval for this study was granted by the Ethics Committee of the University of Auckland.

Data Analysis

Interviews were digitally recorded and transcribed by the lead researcher. A preliminary data analysis was conducted during data collection to ascertain if there is a need to collect more data

to examine emerging categories, their relationships, and to assure their validity in relation to other emerging themes [9]. This involved the analysis of interview transcripts after each interview to identify gaps and issues that needed to be clarified in subsequent interviews.

The coding and succeeding data analysis involved an open-coding process, where verbatim transcripts were coded, then re-coded according to an agreed coding framework that reflected the dominant themes within the text. Joint coding and analysis were conducted with other investigators to increase validity and reliability of the coding process.

Results

A total of 19 key informants participated in the interviews. In the final sample, 8 were health professionals representing 8 Pacific island countries, 6 held regional public health roles in the Pacific region, 3 of which have some experience with mHealth, and 5 were from organizations in Africa, the United States, and Asia, widely involved in mHealth in developed and developing countries in areas such as research, planning, implementation, evaluation, policy-making and advocacy.

The analysis of the respondents' interviews led to the identification of several themes which can be classified into nine key considerations for the development and scale-up of mHealth in the Pacific region. Verbatim quotes are present to illustrate and support the analyses. Quotes are presented by reference to their contributor (Pacific Health Provider, Regional Health Representative, and mHealth Practitioner). A brief background on the current mHealth activities in the region as discussed by key informants is also provided.

mHealth Activities in the Pacific

All participants from each of the Pacific island countries (n=8) and regional public health representatives (n=6) knew of some form of mHealth activity in the region although they were not well aware of how these initiatives were implemented. Most participants had heard of the initiatives as second hand information—from colleagues or conference presentations—but most of these had been small-scale activities or pilot projects that were not part of any large-scale health program. As one interviewee expressed,

> *I am aware of mHealth activities but I don't think it's been clearly thought-through program or approach to improving health.* [Regional Health Representative 4]

The earliest mHealth activity mentioned was an outbreak detection system in Fiji using mobile phones to report cases such as diarrhea, measles, dengue, prolonged fever and rash observed in outpatient clinics. This was initiated in 2008 and used basic or feature phones programmed to have an additional menu that could send data directly to an online database.

Start With the Problem—Then Ask If mHealth Can Contribute

Participants were adamant that the need for mHealth in the region was based on what the current health programs provided and whether there were gaps in health delivery. This was widely considered the first step to be taken before even considering using mobile technology. Identifying these problems can be done through a thorough review of current strategies and consultations with local and national health authorities.

> *We basically start with a problem first. What is the problem? Lost to follow-up? Referrals aren't happening? Information gaps? Lack of communication between health workers? When we hear about those kinds of problems then we start thinking, okay, there might be a way to apply mobile technology or just eHealth technology to this.* [mHealth Practitioner 2]

Identifying problems in the health system also means identifying particular groups who are affected by these problems. Health problems affecting large groups of people were considered by participants to be more easily identifiable because of the significant burden they impose on the region's health resources. In essence, the participants agree to focus on the existing health system challenges before considering whether mHealth, if at all, could provide solutions.

> *...we have to identify the gaps that mHealth could fill on our needs. We have to look at the gaps and the capacity of mHealth whether mHealth alone can fill those gaps. We have to study how mHealth will interact with other things.* [Pacific Health Provider 2]

Despite a lack of direct experience with mHealth, participants from the region concurred that using mobile technology may offer some advantages as well as limitations. Similarly, detailed knowledge about the health problems in-country forms the basis for decision-making about the value of introducing mHealth. This view was echoed by the mHealth practitioners who were swift to acknowledge the need to know each health system and current priorities before embarking on the journey into mHealth.

> *So part of the real question that you should ask is what are the major challenges to achieving better health outcomes in the Asia-Pacific region, and according to those challenges what are the reasonable mHealth strategies that have worked in other places that can help us...overcome these challenges that are particular to this region.* [mHealth Practitioner 4]

Being "problem-centered" moves the discussion away from mHealth to a more comprehensive approach to solving the challenges that are preventing the region from achieving better health outcomes. For some participants, the concept of looking at mHealth as the best solution potentially overshadows alternative system strengthening or policy-related intervention.

> *...look at how mobile fit into existing health system. Do we need mobile? Is there a different solution? So it's very easy to think straight from... especially like me, I'm someone who always thinks from the mobile perspective. That's what you first need to see—what is the challenge?* [Regional Health Representative 6]

Tailor Interventions to the Local Environment and Local Needs

Since mHealth is largely technology dependent, participants emphasized the need to look at the capacity of current mobile technology in each country; this includes the mobile network coverage of the country, as well as the quality of mobile connectivity. Although the mobile infrastructure in the Pacific Islands region is gaining momentum in recent years, participants were quick to note that there are still areas that do not have mobile connectivity. One participant noted that

> *when you talk about Kiribati, if I remember correctly, it has about 60 islands, but mobile phone coverage is only in Tarawa and probably Christmas Island...* [Pacific Health Provider 1]

The recent deregulation of the telecommunications industry in some countries of the Pacific was thought to have helped improve mobile networks in many remote areas and significantly reduce the cost of mobile subscriptions. Participants believed that similar policy attempts in other Pacific countries to introduce competition and improvements in service could help improve access to mobile networks in remote areas of the region. One commented that

> *I think the policy attempts to introduce competition in the telecoms market would probably open up possibilities.* [Regional Health Representative 3]

Knowing the capacity of mobile connections in the area to identify which types of mHealth applications would best suit certain areas was considered a core priority when considering mHealth in the region. Participants also mentioned the need to look at existing policies that could affect mobile technology use and identify the gaps in these policies so that standards can be put in place to support mHealth initiatives. One interviewee observed the need to enable,

> *...environment for the use of technology—whether it's looking at policies, the frameworks, the standards that need to be put in place as well as the human resource needs over the short and long term...* [mHealth Practitioner 4]

The existing health infrastructure is quite an essential part of the enabling environment. If the current public health system is largely dysfunctional at supporting existing infrastructure, the introduction of a new innovation such as mHealth would most likely be ineffective.

> *...look at the capacity of the system you are building on top of. What kind of capacity is in place to support existing health structures to deliver information, respond to new influx of patients who maybe responding to information they received? Is the system in place to support those people? Start not necessarily looking on the solution, but on the support structure that exist to support the solution.* [mHealth Practitioner 2]

In addition to understanding the technology environments, participants mentioned the importance of generating a detailed understanding of the users of mobile technology. One participant (mHealth practitioner 6) emphasized the need to invest in ethnographic research prior to starting anything else. Some essential questions to answer include: who is using mobile phones—is it the women or the men, younger generation or older—and who controls the device? In the Pacific Island region, cultural and societal barriers could also affect phone ownership and use. Women in some societies need to ask for permission from a man before using or owning a mobile phone.

> *...fathers or husbands don't necessarily want their wives to own a mobile phone. They say it will be a means for them to go rogue, to have boyfriends, have an affair. And then women don't necessarily want a mobile phone if they think their families can use it to control them.* [mHealth Practitioner 3]

Mobile phones are often shared among members of the family, creating potential barriers (eg, for sexual health) and opportunities (eg, for healthy eating) for different mHealth initiatives. Participants also noted that there might be generational gaps in phone usage or preferences in certain mobile phone functions (ie, SMS or voice calls) among the population.

> *I think finding out who has coverage, who has mobile phone, who in the family—is it just the father who has a mobile phone, or the whole family.* [Pacific Health Provider 5]

> *I think it's really important again to go back to like the ethnography piece and really understand who they are or how they interact with the world, how they interact with technology, how they communicate, how they access services already, and then delve that into the design of technology solutions.* [mHealth Practitioner 5]

A few respondents raised the issue of the perceived integrity of research in the Pacific. However, the majority of participants valued the contribution of dedicated research to understand the nuances of potential users, particularly when the intervention aims to promote behavior change.

> *Our instinct is to rush to build solutions on top of mobile devices without really seeing if the population is ready to use those solutions.* [mHealth Practitioner 2]

> *...when you're looking into behavioral, behavior-related programs that really understanding the users and the potential beneficiaries whatever technology solution or content you are planning to implement is really, really important.* [mHealth Practitioner 5]

Can Lessons Be Learnt From Other Settings?

Most of the respondents suggested studying the lessons learned in other low- and middle- income countries that have already implemented mHealth. Identifying what worked in previous initiatives, and what didn't work, can help in the decision-making and design of future activities.

> *I think the other is also to look into what other people are doing and see what range of activities should be explored in mHealth. And then think about it from*

> *that perspective as well—what's applicable, which ones are aligned with what we are trying to achieve.* [Regional Health Provider 5]

A few respondents warned about "innovating in isolation". They suggested of looking at what is being implemented in the region to see how it could complement or work with planned mHealth programs. Interviewees mentioned trying not to "reinvent the wheel" as it could cause duplication of efforts and fragmentation which can reduce the effectiveness of mHealth solutions. As one said,

> *Look at the evidence and look at what is working, what scaling, what lessons learned were garnered through other implementation so you don't have to like, one, start from scratch, reinvent the wheel.* [mHealth Practitioner 5]

Genuine Engagement From the Start

Key informants emphasized the importance of engaging potential stakeholders early on in the implementation of the mHealth strategy. Strong partnerships were considered imperative from the very beginning of any initiative planning stage. A participant mentioned that engaging people in the government to get their perspective in defining what the key challenges are is important when looking at establishing a broad mHealth strategy for the Pacific region.

> *I think it is important to engage governments from the outset, so particularly if you are looking at public health interventions. Ultimately it's the government who has to sustain it. And so one of the biggest lessons learned is that a lot of programs fail because there is no government intervention. And it's not even "get government engagement eventually", it's "get government engagement from the beginning"* [mHealth Practitioner 5]

Strategic partnerships with the private sector, especially the mobile providers, are also crucial. Mobile network operators are well placed to provide technical expertise, resources and network to help operationalize and scale up the project. According to participants, the private sector involvement is crucial for any mHealth strategy but the public sector needs to set the priorities and direction, as the ultimate driver of the mHealth strategy.

> *...private sector partnerships are really important, a lot of these things are things that the private sector is well-placed. But it really needs to be defined by the public sector and the priorities need to be set by the public sector and the guidance need to be set by the public sector. But a lot of the types of like applications and tools that need to be implemented could easily be done by the private sector.* [mHealth Practitioner 5]

Participants also highlighted end-user engagement. Having health-providers and community involved, as they are the ultimate end-user of mHealth, is important in every phase of the mHealth strategy. One participant mentioned that a current trend in many developing countries right now is to actively involve the civil society in providing feedback on what's happening in their local communities. Encouraging social accountability and valuing end-user engagement is making an impact on how decisions are being made.

> *...we are starting to see people become more engaged and even the most vulnerable people are providing citizen feedback of what's happening in their local communities. And I think that's one major area where we're already seeing some really good progress and inputs. And it's making an impact on how the allocations are being made and that sort of thing which is really exciting.* [mHealth Practitioner 5]

Participants commented that mHealth initiatives will work best as a multisectoral approach. One of the main policy issues may include addressing how different stakeholders from the private and public sector, including NGOs and civil society, work together to mainstream mHealth as a viable solution to health problems.

> *cause you are dealing with unusual actors-you are dealing with telecommunications companies; you are dealing with phone companies-and these are people who are not used to working in the space of health. So it's a new space for them and I think they need that guideline.* [mHealth Practitioner 4]

Building a Supportive Health System

An issue that some participants raised was that implementing a mHealth program could be seen as an alternative to improving the health system infrastructure. These interviewees stressed that mHealth is a supplementary activity to existing health programs not a replacement. If core health infrastructures are defective or lacking, investment in mHealth cannot be used to replace investment to improve health services.

> *I see it [mHealth] more as a way to provide additional support for people without adequate services but it doesn't make up for inadequate services...And certainly it should not be seen as an investment into the infrastructure of proper health services. It's a supplementary activity, because the health services are inadequate at the moment and there's insufficient capacity. So it should not be seen as supporting or encouraging investment not to be put into those services which are crucially needed.* [Regional Health Representative 5]

Adequate personnel or human resources to deliver quality health service must also be in place before the implementation of the mHealth initiative. As some mHealth applications create more demand for health services, the system must be ready to accommodate the influx of new patients or new users.

> *I would first look at how the health system works in general. Like for example, we can encourage people to go for a service, that's what we do for mobile. But if there is no doctor available, if there are no medicines, it works counter effective.* [mHealth Practitioner 1]

Building Local Capacity for mHealth

The majority of participants acknowledged the lack of technical capacity in mHealth as a challenge. mHealth will have a greater impact if stakeholders are trained and upskilled in the use of mobile technologies and users are educated to a higher level of mobile literacy. For instance, if the ultimate users of the mHealth tool are health workers, increased mobile literacy and understanding of ICT applications will save time and increase their efficiency, expressed succinctly by this interviewee

> *If you are collecting data using mobile phones, it will require training and specific skills set.* [Pacific Health Provider 3]

Participants suggested establishing a coordinating body composed of different stakeholders to establish standards and systematize efforts. This would allow for more coordinated and integrated efforts as well as sharing relevant data to aid decision-making.

> *...if there are 10 NGOs and they are all working with pregnant women, are they collecting at least the same few data elements that allow them to share information with the national health system or with each other? So it often helps to have some kind of national eHealth or mHealth committee or user-group or ministry agency which serves as the focal point for these activities within that country.* [mHealth practitioner 4]

Several participants advocated establishing a regional network that would endorse a regional approach to mHealth would be beneficial for the region for initial start-up or scaling-up. Having a regional network would encourage information sharing of best practices and innovative solutions that worked in other parts of the region.

Designing Interventions With the End-User in Mind: Use the Best Technology Options

In order to maximize the potential of mHealth, the majority of participants recommended keeping the end-users' wants and needs in mind when designing mHealth solutions. This underscores the earlier recommendation of doing an ethnographic study to understand the end-users. Data from earlier baseline studies as well as from the consultations with the end-users could feed into the design of the mobile application.

> *...go back to the end user time and time again. And by end user, I don't mean the NGOs, I mean the person the NGOs are serving right down the end of the line.* [Regional Health Representative 5]

> *I don't think there's huge amount of research done around types of in terms of what people want, what beneficiaries want. And I don't know if there's research been done to what the health system feels will be useful.* [Regional Health Representative 6]

There is a range of available types of mHealth solutions. However, participants suggest that decision makers consider the level of mobile literacy of end-users and their response to the technology when choosing which mHealth solution to use. Simple mHealth applications with minimum technical requirements, for instance, would require less technical skills among end-users.

> *As the majority of the PNG [Papua New Guinea] population live (sic) in rural areas and as there is very low literacy levels, I believe simple mHealth applications that have the minimum technological requirements and require minimal effort and comprehension on the user's behalf are best suited to PNG.* [Pacific Health Provider 6]

Integrate mHealth Into Wider Program Strategies and Design for Scale

Participants commented that mobile solutions are not 'stand-alone' efforts, they serve as support mechanism to deliver better quality healthcare, and must align with national health system goals.

> *mHealth initiatives can't be effective as 'stand-alone' efforts—there needs to be support and coordination with existing work that's already taking place in the local communities.* [Pacific Health Provider 9]

> *...the mHealth strategy does not succeed in a vacuum, okay? That's very, very critical to keep in mind. Any successful mHealth strategy has to be part of a multifaceted approach to solving a problem.* [mHealth Practitioner 4]

Mobile solutions can complement and support a wider program strategy. For example, in a behavior change communication initiative, mHealth is just one of the channels by which the health message could be delivered.

In designing the mHealth strategy, participants identified the need to plan for scalability. There have been quite a number of pilot projects but few examples of successful mHealth projects that have gone on to a national-level scale. The lack of foresight to plan for scale-up among pilot projects, limits the ability to be sustainable and the potential to deliver positive health outcomes. Administrators of mHealth initiatives must have the knowledge on how to scale-up pilot projects and integrate this knowledge from the outset.

One participant said,

> *we're on a phase right now where we don't need any more pilot projects.* [mHealth Practitioner 5]

The number of pilot projects in many low- and middle- income countries would provide extensive lessons on how important scalability is to the mHealth strategy.

Evaluate the Whole Impact and Calculate the Real Cost

Cost is one of the biggest barriers to sustainability. Understanding the cost attached to mHealth can give a better perspective on how these costs could be managed. Participants identified two costs involved in the operation of mHealth: the cost to the individual of accessing the service, and the cost to the country of delivering the service.

Cost was widely perceived as an intractable challenge that users, especially from poorer countries, will face to access mHealth. How cost can affect the users' willingness and ability to pay for using mHealth services should be carefully assessed, as this will affect the implementation and sustainability of the mHealth strategy. One participant wondered,

> *...if you want people to respond, does that mean people need to have money to top up their phones to respond or is it just messaging that's going to be just for your information where they don't need pay to respond to you?* [Pacific Health Provider 5]

Secondly, developing and implementing an mHealth strategy will incur costs. There will be fixed costs associated with the capital investments to set-up the technology required for the intervention, and operational and maintenance costs to sustain the system. One participant from the Pacific region expressed his skepticism about the financial viability of investing in mHealth. This is an opinion that might be shared by other Pacific countries with limited financial resources. One interviewee expressed it thus,

> *...we are very mindful of the operational cost. Investment cost can last for 12 months but the operational cost including the placement of the equipment is something that I don't think the country can afford.* [Pacific Health Provider 2]

Most participants from the Pacific region are optimistic that telecommunication service providers could assume some of the cost for the mHealth strategy. They are banking on these companies' commitment to social responsibility to provide their technical expertise and network connection. As one said,

> *I think it's about selling the idea to governments, to the telecom and have their social responsibility be on board in that angle to reduce costs for sending texts* [Pacific Health Provider 4]

But for providers to come on board, participants highlighted the need to adopt business models that will provide mutual benefits for public-private partnerships. One participant argued that most people assume the companies stand to gain much financially from mHealth, although in reality this may be very limited. Therefore to leverage support from telecom companies, decision-makers need business models that will clearly define the opportunities and value that mHealth could deliver.

Discussion

Principal Findings

The acceleration of mobile connectivity across the Pacific, presents potential of mHealth to improve access to health information and quality of services across the region [11,12]. At face value, the concept of mHealth was widely considered an appealing option for supplementing and bolstering overworked or inefficient systems (surveillance, for example [13]). Similarly, the prospects for mHealth-based innovations in new domains such as noncommunicable disease (NCD) prevention, disaster response and maternal health, are well recognized [14]. However, overwhelmingly both our mHealth and local public health providers erred toward realism over optimism; the extent to which a mobile technology based initiative can remedy systemic issues was the challenge. The Pacific Islands region is facing some of the most significant health challenges ever to confront the region. Burgeoning NCD rates are overwhelming under-resourced health systems and infrastructure. A chronic lack of trained health and allied personnel places additional demands on donor-dependent countries. Yet, a cautious optimism was expressed among Pacific and international stakeholders.

At the recent Pacific Health Ministers Meeting in Fiji (April, 2015), a declaration by Dr Tuktuitonga of the Secretariat of the Pacific Community (SPC) speaks of the radical developments in the region and the need to draw upon the strengths and assets of all contributors—public and private for health gains:

> *The Pacific today is a different place than it was 20 years ago, and our region faces a multitude of challenges. We have an opportunity to build on the progress already achieved in Pacific health through increased cooperation between governments, non-governmental organizations, civil society and the private sector, to work together to improve the lives of all Pacific people [14]* [14]

The evidence is clear; the Pacific regional health challenges can only be overcome with coordinated, innovative and multisectoral actions led by the countries. Can mHealth play a part in these solutions? Time will tell. However, the foundations are firming; with young, increasingly media savvy populations, enthusiastic telecommunications sector and not yet saturated mHealth environment, timing is right to explore the possibilities.

Limitations

A limitation of this study is that we interviewed people who were considered and recommended as potential users or stakeholders of current or future mHealth initiatives. It is likely therefore that we missed the opportunity to interview those who held contrary or unique perspectives that were not raised by our sample. Qualitative research methodologies, in general values subjectivity and accordingly there is potential for variation in interpretation of participants perspectives [15]. We have been fastidious in our coding and analysis process and used quotations to support our findings. Interviews conducted via Skype may well be qualitatively different than those conducted face to face. However, with consideration of limited resources and increasing technological capacity for Internet based interviews, this proved effective for our study. There were also numerous attempts to obtain a representative from the telecom industries present in the Pacific region, but none agreed to participate in the interviewed. Knowing what the telecom industries think about mHealth especially since they are essential stakeholders in mHealth implementation could have provided critical inputs to this study. At present, although deregulation and reforms in the telecommunications sector in the Pacific have driven the increase in mobile phone access in the region [4] it is largely unknown how receptive the telecom industries are to establish a presence through mHealth.

Conclusions

This study deepens the understanding of the potential of mHealth for the region, and offers a baseline from which discussions can be made to examine the limitations, barriers and complexities inherent in mHealth applications. The experiences of developed and developing countries in implementing mHealth over the past years combined with local conditions of the region has revealed potential barriers and risks such as access to mobile phones, literacy, lack of complementary infrastructure and supportive environment, over-expectation and the underlying technical limitations of local institutions to implement mHealth. Although this research was done under the context of how mHealth could be adapted in the Pacific region, the findings of this research are also applicable and useful to other settings. What this study has established is to emphasize the primary importance of user-engagement, stakeholder collaboration and the careful consideration of local contexts to support long-term implementation of mHealth. These considerations cut across various mHealth applications and disease preventions initiatives in many countries. The biggest challenge for the Pacific region and in many countries is how to bring initial pilots to scale and become mainstreamed to national health system structures.

Finally, although the Pacific region lags behind other low- and middle- income countries in the adoption of mHealth technologies [8], this position offers the convenience of learning from past mHealth interventions and applying these learnings to adapt tools, achieve scale, sustainable positive impacts [3,16-18]. Cautious optimism is, however, the safest position as there is plenty of work still to be done to fully appreciate how to adapt this technology to achieve equitable beneficial outcomes within the Pacific Islands.

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Authors' Contributions

EU contributed to the research development, implementation, interviews, analysis, manuscript preparation and drafting. JMC contributed to the research development, analysis, and manuscript preparation. RW contributed to analysis, and verification of findings.

Conflicts of Interest

None declared.

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Abbreviations

GSMA: Groupe Speciale Mobile Association
ICT: information and communications technology
NCD: noncommunicable disease
PNG: Papua New Guinea
PRIF: Pacific Regional Infrastructure Facility
SPC: Secretariat of the Pacific Community
WHO: World Health Organization

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Original Paper

The PAediatric Risk Assessment (PARA) Mobile App to Reduce Postdischarge Child Mortality: Design, Usability, and Feasibility for Health Care Workers in Uganda

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Abstract

Background: Postdischarge death in children is increasingly being recognized as a major contributor to overall child mortality. The PAediatric Risk Assessment (PARA) app is an mHealth tool developed to aid health care workers in resource-limited settings such as Sub-Saharan Africa to identify pediatric patients at high risk of both in-hospital and postdischarge mortality. The intended users of the PARA app are health care workers (ie, nurses, doctors, and clinical officers) with varying levels of education and technological exposure, making testing of this clinical tool critical to successful implementation.

Objective: Our aim was to summarize the usability evaluation of the PARA app among target users, which consists of assessing the ease of use, functionality, and navigation of the interfaces and then iteratively improving the design of this clinical tool.

Methods: Health care workers (N=30) were recruited to participate at Mbarara Regional Referral Hospital and Holy Innocents Children's Hospital in Mbarara, Southwestern Uganda. This usability study was conducted in two phases to allow for iterative improvement and testing of the interfaces. The PARA app was evaluated using quantitative and qualitative measures, which were compared between Phases 1 and 2 of the study. Participants were given two patient scenarios that listed hypothetical information (ie, demographic, social, and clinical data) to be entered into the app and to determine the patient's risk of in-hospital and postdischarge mortality. Time-to-completion and user errors were recorded for each participant while using the app. A modified computer system usability questionnaire was utilized at the end of each session to elicit user satisfaction with the PARA app and obtain suggestions for future improvements.

Results: The average time to complete the PARA app decreased by 30% from Phase 1 to Phase 2, following user feedback and modifications. Participants spent the longest amount of time on the oxygen saturation interface, but modifications following Phase 1 cut this time by half. The average time-to-completion (during Phase 2) for doctors/medical students was 3 minutes 56 seconds. All participants agreed they would use the PARA app if available at their health facility. Given a high PARA risk score, participants

suggested several interventions that would be appropriate for the sociocultural context in southwestern Uganda, which involved strengthening discharge and referral procedures within the current health care system.

Conclusions: Through feedback and modifications made during this usability study, the PARA app was developed into a user-friendly app, encompassing user expectations and culturally intuitive interfaces for users with a range of technological exposure. Doctors and medical students had shorter task completion times, though all participants reported the usefulness of this tool to improve postdischarge outcomes.

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KEYWORDS

infectious disease; postdischarge mortality; mHealth; prediction model; risk assessment; usability; Africa; resource-limited settings

Introduction

Background

Infectious disease in Sub-Saharan Africa is the leading cause of child mortality, accounting for 6.3 million deaths among children under 5 years old [1]. A systematic review of pediatric postdischarge mortality found that in-hospital mortality was often exceeded by mortality rates after hospitalization. Postdischarge deaths generally occurred within several weeks of discharge and in many cases did not occur in hospitals [2]. Postdischarge death in children is increasingly being recognized as a major contributor to overall child mortality, and strategies are needed to address this issue.

One promising approach is a clinical tool to allow for early identification of at-risk patients. The PAediatric Risk Assessment (PARA) mobile app is a simple, easy-to-use mHealth tool developed to aid health care workers in resource-limited settings to identify pediatric patients at high risk of mortality. The PARA app uses prediction models to accurately predict and categorize newly admitted patients as having high or low risk of death, both in-hospital and after discharge [3,4]. This has the potential to improve in-hospital and postdischarge care provided to these children. The purpose of this manuscript is to summarize the usability evaluation conducted for the PARA app, in order to develop a user-centric design that will be accepted, useful, and usable by health care workers to ultimately reduce child mortality.

mHealth Tools

Improved access to technology in Sub-Saharan Africa, particularly mobile technology, creates an enabling environment for mobile apps such as the PARA app. The mobile network coverage in Sub-Saharan Africa is high, with availability of third generation (3G) connections rapidly growing [5,6]. As of 2014, approximately 53% of Ugandans had a telephone connection, which has grown by 48% over the past 10 years [7]. This technological leap has opened many opportunities for mHealth initiatives in low-resource settings [5,8].

Mobile phones are currently utilized for a wide array of mHealth interventions [5]. These range from health communications to monitoring and prevention to medical decision making. There are numerous advantages to enlisting mobile technologies for public health initiatives, including their low cost, easy distribution, and wide accessibility [5,6].

The PAediatric Risk Assessment Prediction Models

The primary PARA models [3,4] were developed to predict the likelihood of in-hospital or postdischarge mortality for children under age 5 years admitted with acute infectious diseases. The models predict risk of future mortality using demographics (time since last hospitalization), anthropometric measurements (either mid-upper arm circumference or weight for age z-score), and clinical indicators (human immunodeficiency virus status, Blantyre coma score, and oxygen saturation) collected on admission. For the prediction of postdischarge mortality, the derived models have positive and negative predictive values of 11% and 99%, respectively [4]. For the prediction of in-hospital mortality, the derived models have positive and negative predictive values of 15% and 99%, respectively [3,4]. The PARA models have particular potential for targeting high-risk children for appropriate postdischarge care. In the populations where the PARA models were derived, only 30% of children are flagged as high risk. Adoption of any postdischarge intervention in a resource-limited environment, therefore, becomes much more feasible.

The Phone Oximeter

The Phone Oximeter is a mobile app module integrated into the PARA app that takes input from a connected noninvasive pulse oximeter. This enables users to instantaneously and accurately perform 30-second spot-check measurements of oxygen saturation (SpO_2) when connected to a pulse oximeter [9,10]. The SpO_2 is then recorded in the PARA app and incorporated as a variable in the PARA prediction models.

Design Constraints and Considerations

The intended setting for the PARA app is in-patient health facilities in resource-limited countries, particularly in rural or semiurban areas. These environments pose unique design constraints, as they often do not have Internet access or consistent electricity [11]. Therefore, the app was created for offline data entry on a mobile (battery-powered) touch screen device to produce an automatic risk prediction.

The intended users of the PARA app are health care workers (ie, nurses, doctors, and clinical officers) with varying levels of education and technological exposure who work in resource-constrained settings. With these considerations, the PARA app was intentionally given a simple, compact design that utilizes routine patient data collected during pediatric admissions. It is packaged to be accessible to those with limited

experience with technology, producing timely results within a busy clinical context.

Usability Testing Objectives

This usability evaluation of the PARA app was conducted to accomplish the following objectives: (1) evaluate user performance and understand common errors made by health care workers using the PARA app, (2) iteratively improve the design, functionalities, and work flow of the PARA app, (3) elicit user satisfaction regarding the utility and design of the PARA app, and (4) understand user perceptions of the PARA app and suggested interventions using this tool.

Methods

System Design

At each stage of the system design process, there were multiple revisions. An initial design document was created describing the app screens necessary to collect all variables in the predictive models. From this document, the Balsamiq Mockups software (Balsamiq Studios) was then used for the generation of mockups to illustrate the intended interfaces and functionalities. The prototype PARA app was then built as script within the LNhealth platform, which was developed using Lambda Native, a cross-platform open-source development environment [12,13]. The PARA app provides many features that are not possible or much more time consuming using paper systems. These include encryption of stored data with a login page to access the app, calculation of age from date of birth, calculation of weight for age z-score, measurement of SpO_2 with a 30-second spot-check recording, and classification of each variable contributing to the predictive model risk score as high, medium, or low contribution to mortality risk.

Hardware Specifications

For this usability study, the PARA app was installed on the Dell Venue 7 (model 3740) device. The device was hardwired via a micro–universal serial bus (USB) connection to a mobile audio-based pulse oximeter (LionsGate Technologies). The pulse oximeter provides the photoplethysmograph waveform, the processed trend values for the SpO_2 and heart rate, and a signal quality index (SQI).

User Interfaces

The PARA app enables users to input, summarize, and edit select clinical information for pediatric patients admitted with an acute infectious disease. The app also allows for storage of this patient data for future review. All entries are assigned a patient ID to ensure unique identification. All interfaces contain open data entry fields or dropdown menus, with the exception of the oxygen saturation interface. The oxygen saturation interface records 30-second SpO_2 measurements from a pulse oximeter using a color-coded SQI, time progress bar, and directional messages [7]. The postdischarge and in-hospital risk scores, displayed on the final interface, are calculated based on the specified prediction models [4]. Error messages are in place to alert the user to missing or insufficient patient data.

Usability Evaluation Design

Early prototypes were first evaluated by study investigators and research staff in Canada and Uganda for ease of interface navigation, functionality, and basic workflow. From these initial evaluations, a testable prototype was created. This usability study was conducted in two phases to allow for iterative improvement and design of the PARA app. Ethics approval was obtained from the Mbarara University of Science and Technology (08/09-14) and the University of British Columbia (H14-01045). Participants were recruited at Mbarara Regional Referral Hospital (MRRH) and Holy Innocents Children's Hospital (HICH), both in Mbarara, Southwestern Uganda. Health workers involved in pediatric care from MRRH and HICH were purposively sampled based on level of medical training. This may have led to participants who had a higher degree of interest in mHealth apps. An equal number of doctors/medical students and nurses/clinical officers enrolled for each phase to ensure the primary user groups were represented. No participants had used the PARA app previously. Both phases of the study had a target sample size of 15 participants (30 in total). The recommended number of participants for usability testing is at least 10 people [14]. Written informed consent was obtained from all participants. Each participant was paid an honorarium of approximately US $10.

Participants completed a short demographic questionnaire (ie, gender, occupation, age, technology use) before a facilitator guided them through the evaluation process and study instructions. The evaluation was conducted in a quiet environment with no distractions. During the evaluation, the facilitator, seated next to the participant, recorded user interaction with each interface, comments, and errors. No other individuals were present during testing. Time-on-task measurements began when the participant started the first task and ended when they completed the final task.

Following a brief introduction to the purpose of the study (see Multimedia Appendix 1), participants were given two patient scenarios with identical length and format, which listed hypothetical information (demographic, social, and clinical data) to be entered into the app (see Multimedia Appendix 2). This information reflected routine data collected upon pediatric hospital admission at MRRH and HICH. Participants were instructed to enter this information into the PARA app as though this patient was newly admitted and to determine the child's risk of in-hospital and postdischarge mortality. The context of use during the evaluation differed from the context of expected use since the evaluation was done in a controlled environment with relevant information provided directly to the user, rather than being directly obtained from patients or their records.

During the patient scenarios, each participant was asked to think aloud, in order to assess their thought process as they used the app [15]. They were specifically instructed to comment on the layout of the app screen, the dialogue on each interface, the order of tasks, and any additional observations or opinions. Participant dialogue was recorded during each patient scenario using a digital audio recorder. At the end of each patient scenario, participants were asked to qualitatively interpret the

risk score and distinguish the risk factors (listed on the summary interface) that most contributed to a high risk score.

A modified computer system usability questionnaire (CSUQ) was utilized at the end of each session to elicit participant satisfaction with the PARA app (see Multimedia Appendix 3) [16]. On the CSUQ, usability statements were evaluated on a scale from 1-7, indicating "strongly agree" to "strongly disagree." In addition, five qualitative questions were asked to understand the practical benefits and drawbacks of incorporating the PARA app into a clinical context: (1) "What do you like most about the app?," (2) "What do you like least about the app?," (3) "How could the app be changed to make it easier to use?," (4) "Please describe how you might use this app to enhance the discharge process and care after discharge," and (5) "When would you enter patient information into the app?"

Usability Tasks

The usability tasks (provided as a paper evaluation form) were adapted from the Pre-eclampsia Integrated Estimate of RiSk on the Move usability study and developed to encapsulate the specific functionalities of the PARA app (see Table 1) [17]. These tasked were deemed the primary essential tasks required for full use of the PARA app.

Table 1. Usability tasks performed.

Number	Task
1.	Log in to system
2.	Start a new patient
3.	Enter patient demographics
4.	Enter anthropometric data
5.	Measure oxygen saturation
6.	Enter clinical data
7.	Interpret summary
8.	Calculate risk score

Metrics

The PARA app was evaluated using quantitative and qualitative measures, which were compared between Phases 1 and 2 of the study. Quantitative measures were limited to descriptive statistics. Time-to-completion was recorded for each participant and compared between patient scenarios and occupational groups.

User errors were recorded for each patient scenario and evaluated based on severity. An error was defined as any unproductive action (eg, pushing back instead of next, choosing to continue past an error message, not obtaining SpO_2). Severity was based on the impact of errors on the achievability and specificity of the PARA risk score. Errors were categorized into navigation errors (low severity), control usage errors (medium severity), and outcome errors (high severity) (see Table 2). High severity errors prevented the risk score from being calculated or reviewed, thereby truncating the utility of the PARA app.

Table 2. Type of user errors.

Type of error	Definition	Common user errors
Navigation error	Misguided or unnecessary interactions often due to unfamiliarity with the app, which do not change the intended outcome (ie, accurate risk score)	Selecting the wrong button on the interface; Re-entering data unnecessarily; Starting the SpO_2 recording with poor signal quality
Control usage error	Input of inaccurate patient or login information	Recording incorrect patient data; Entering a hypothetical SpO_2; Entering incorrect login information
Outcome error	Risk score is not attained or incomplete data entry occurred	Bypassing error messages; Leaving data fields incomplete; Not reaching final interface to attain risk score

Results

Study Population

In total, 30 health care workers (ie, 11 doctors, 3 senior medical students, 14 nurses, and 2 clinical officers) participated in the PARA app usability study, with 15 male and 15 female. Participant populations between Phases 1 and 2 of testing had an equivalent number of doctors/medical students and nurses/clinical officers for each phase. More participants came from HICH (17/30, 57%) than MRRH (13/30, 43%). The majority of participants (26/30, 87%) were between 20-30 years old. All participants owned a cell phone, with the majority of doctors/medical students owning a smartphone (12/30, 40%). Few had used a tablet (6/30, 20%) or health app (7/30, 23%) previously.

Usability Evaluation: Phase 1

For the first patient scenario, the average time-to-completion was 9 minutes 58 seconds. By the second patient scenario, the average time-to-completion dropped to 6 minutes 23 seconds. In particular, the average amount of time spent obtaining the

SpO_2 dropped from 2 minutes 23 seconds for the first patient scenario to 1 minute 28 seconds for the second patient scenario. Doctors took the least amount of time to complete the app, averaging 4 minutes 38 seconds during the second patient scenario.

In addition to time, the average number of errors dropped between the first and second patient scenario from 4.3 to 3.2 errors (see Table 3). The majority of errors were navigation errors (low severity), which decreased between the first and second patient scenarios. However, medium and high severity errors increased or stayed the same between these patient scenarios. Approximately half of the 15 participants had outcome errors, due to the SpO_2 not being recorded. Two participants did not reach the final interface and failed to calculate the patient's risk score.

Table 3. Summary of user errors by type for Phase 1.

Scenario	Navigation errors (low severity)	Control usage errors (medium severity)	Outcome errors (high severity)	Total errors (average)
1	34	20	2/7[a]	63 (4.3)
2	16	23	2/8[a]	49 (3.2)

[a]These numbers represent outcome errors leading to no risk score being generated versus outcome errors leading to incomplete data entry.

Adaptations Between Phases 1 and 2

Based on Phase 1 results and participant feedback, modifications were made to the PARA app to decrease user errors and time-to-completion of tasks. Error-producing interfaces were simplified by adjusting the instructional dialogue, interface design, or error messages.

Errors caused by the oxygen saturation and summary interfaces were the most common issues. The oxygen saturation interface produced the most difficulties, as participants had trouble accessing the SpO_2 screen and interpreting how to use the tablet-based system. Since the previous SpO_2 recording was retained, some participants thought the SpO_2 was already recorded when it was not. One participant said "So what will happen? Will [the SpO_2 recording] stop? Will it stop or am I the one to stop it? [Sees SpO_2 from previous recording] But I think the oxygen saturation is 93, it is just at 93. So I am moving to the next."

Participants also had difficulty interpreting the summary of risk factors screen. When asked to identify the most important risk factors listed on the summary interface, one participant said:

> *I am imagining that red means danger so if it is more red, then it is contributing a lot. But you can't tell to what degree, to what percentage. Here they are almost all the same for example, so you almost think that perhaps they all almost have perhaps the same contribution. I'm thinking like that but it's not so clear here to tell which one or to what degree.*

Based on this user feedback, the PARA app was modified and subsequently tested during Phase 2 for improved usability (see Figure 1). Instead of showing a menu with options for measuring SpO_2, the tablet-based SpO_2 was changed to be the default display, with an option to enter SpO_2 from another device at the bottom of the screen. Additional instructional messages were incorporated, indicating when to push start and when the SpO_2 recording was complete. These were moved to the top of the screen and the current SpO_2 and heart rate values were not displayed until the recording was started, to avoid users' thinking they were already done. To avoid confusion, each new assessment started with a blank SpO_2 screen instead of the previous values. For the summary interface, the risk factor scales were removed; instead risk factors were categorized into red, yellow, and green boxes and labeled as having high, medium, or low contribution to risk. A large "Calculate Risk Mortality" button was added at the bottom of the screen. This was in addition to the top right navigation button but was felt to be necessary to prevent users from stopping the app early with unattained risk scores.

Figure 1. PARA app modifications to the Oxygen Saturation and Summary pages from Phase 1 to Phase 2.

Usability Evaluation: Phase 2

For the first patient scenario, the average time-to-completion was 7 minutes 10 seconds. By the second patient scenario, the average time-to-completion dropped to 4 minutes 44 seconds. In particular, the average amount of time spent obtaining the SpO_2 dropped from 1 minute 32 seconds for the first patient scenario to 1 minute 4 seconds for the second patient scenario. Doctors again took the least amount of time to complete the app, averaging 3 minutes 56 seconds during the second patient scenario.

The average number of errors dropped between the first and second patient scenario from 3.4 to 2.5 errors (Table 4). The majority of errors were navigation errors (low severity). These errors decreased between the first and second patient scenarios, as did control usage errors (medium severity). There were no unattained risk scores during Phase 2 of the evaluation. Though incomplete data entry occurred, it was uncommon for both patient scenarios (n=2 and n=3, respectively).

Table 4. Summary of user errors by type for Phase 2.

Scenario	Navigation errors (low severity)	Control usage errors (medium severity)	Outcome errors (high severity)	Total errors (average)
1	32	17	0/2[a]	51 (3.4)
2	22	12	0/3[a]	37 (2.5)

[a]These numbers represent outcome errors leading to no risk score being generated and outcome errors leading to incomplete data entry, respectively.

Comparison of Phases 1 and 2

The average time to complete the PARA app was lower for Phase 2, following user feedback and modifications, than for Phase 1 of testing, decreasing by 30% (Table 5). Participants spent the longest amount of time on the oxygen saturation interface, but modifications following Phase 1 cut this time by half. This time savings was likely underestimated, since outcome errors (such as incomplete data entry) during Phase 1 may have artificially lowered average time-to-completion.

The average time-to-completion (during patient Scenario 2) for doctors/medical students was 4 minutes 38 seconds for Phase 1 and 3 minutes 56 seconds for Phase 2, as compared to nurses/clinical officers whose average was 7 minutes 54 seconds for Phase 1 and 5 minutes 26 seconds for Phase 2. The differences in completion times between doctors/medical students and nurses/clinical officers was statistically significant ($P<.05$) when combining Phases 1 and 2. The adjustments made to the PARA app between Phases 1 and 2 decreased the number

of errors and overall time-to-completion, particularly for those with less medical education.

Table 5. Summary of user results for Phases 1 and 2.

	Phase 1		Phase 2	
	Scenario 1	Scenario 2	Scenario 1	Scenario 2
Average overall time	9.96 min	6.38 min	7.17 min	4.47 min
Average SpO_2 time	2.38 min	1.47 min	1.54 min	1.07 min
Average errors	4.27 errors	3.2 errors	3.4 errors	2.5 errors

Overall, doctors/medical students had fewer user errors on patient scenarios than nurses/clinical officers ($P<.05$). During Scenario 1, doctors/medical students averaged 2.3 errors while nurses/clinical officers averaged 5.2 errors. User errors bilaterally decreased with Scenario 2, with doctors/medical students averaging 1.6 errors and nurses/clinical officers averaging 3.9 errors. Nurses/clinical officers were more likely to make outcome errors (high severity) than doctors/medical students. They accounted for all of the errors leading to no risk score (n=4), and the majority of the errors leading to incomplete data entry (n=13).

Participant Feedback

Computer System Usability Questionnaire Results

CSUQ results were very low (indicating positive opinions) with no substantial differences according to phase. On a scale from 1-7 (from "strongly agreed" to "strongly disagreed"), most responses were 1, with an average score of 2.07 on all questions. Overall, people found the app easy to use and understand. All participants (n=30) strongly agreed to the statements "I liked using this app," "The organization of information on the app screen is clear," and "I would use this interface if it were available at my health facility."

Qualitative Feedback

When asked about the positive aspects of the PARA app, participants generally commented on simplicity and utility. One participant summarized, "The app is advanced, but the interface is easy to understand." Most reported that the app was easy to learn how to use, though some, particularly those with less medical education, requested more training. Participants felt the error messages helped guide them through the app, and many felt the PARA app was quick, as it automatically calculated the risk score preventing added burden on the health care worker. One provider said, "But the most important thing is it's really very fast and saves time—so you are not wasting the patient's time or your own time. That's the most important thing, it's really very fast."

Potential Applications of the PAediatric Risk Assessment App

Participants suggested several means by which the PARA app could improve patient care both in-hospital and after discharge. For children at high risk of in-hospital mortality, health care workers thought these patients would need more attention on the ward, through more frequent assessment or prioritized medication during shortages. One participant explains, "So if they are on the ward, still I can know this is a high-risk child and take extra caution in caring for this child."

For children at high risk following discharge, participating health care workers suggested clinical and educational interventions to curb mortality (Table 6). Many recommended improved follow-up care by referring the child to a nearby health center, scheduling more frequent follow-up visits at the hospital, or calling caregivers with appointment reminders. Others suggested extending hospital stay to ensure the patient has fully recovered before discharge. Patient caregivers, particularly mothers, could be given health education at discharge, especially focused on danger signs for child mortality. This education could empower the caregiver to identify their child's health status and respond in a timely manner.

Table 6. Postdischarge interventions suggested for high-risk children identified through the PARA app.

Suggested interventions	Illustrative quotes
Refer to nearby health center	"Or maybe if there is a nearby health center or what, they could also be informed about the risk of the child. They could really be followed up closely."
Shorter review date	"I would want to see them shortly after they had been discharged and then more frequently, at least for about 3-6 months."
Health education	"You can give advice to the patient [or caregiver]: eat well, take the medicine at the right time, make sure feed baby well, give medicine at the right time. In case of minor illness, bring child back to the hospital."
Longer hospital stay	"I would give them a longer duration of stay in hospital but also take precaution, monitor them more closely because they are risk of dying."
Teach parents about danger signs	"First you need to talk to the parents to make sure they understand the child is very sick and even when they improve, they still have a high risk of mortality at home, so they need to keep a close watch on the child. And in case of any symptoms, you explain to them the risk symptoms and if they feel they have identified any of them, they should call a doctor and ask if they should come [to the hospital] or if they can manage it at home."

Though rated highly on the CSUQ, the purpose and practical application of the PARA app was sometimes unclear. The purpose of this clinical tool is to provide early indication of heightened risk of pediatric mortality. Some participants mistook the PARA app as electronic medical records, while others assumed the PARA app could be used to continually assess a patient's progress through treatment or to make discharge decisions. These misinterpretations were summarized by one participant's comment:

> *The app helps a lot because it tries to make for you a decision. It decides for you whether to discharge or not to discharge...If the patient is at high risk while at the hospital, it gives you the opportunity to discharge the patient early before the risk comes in. So I feel it can help you make a rightful decision.*

Discussion

Principal Findings

Development of a mobile app to be utilized in a low-resource, cross-cultural setting requires iterative testing and adaptation to produce an intuitive design. Through feedback and modifications made during this usability study, the PARA app was developed into a user-friendly design, encompassing user expectations and culturally intuitive interfaces for users with a range of technological exposure. Time-to-completion and number of user errors decreased between Phases 1 and 2 of testing, following modifications made to PARA app interfaces. Overall, participants consistently reported the ability to learn and utilize the PARA app quickly and easily. The majority of errors, particularly the navigation errors, were due to unfamiliarity with apps and touch screen devices for those with limited experience.

Based on time-to-completion measurements, doctors and medical students were identified as the ideal end-users, or at least the most likely early adopters. With fairly little guidance, doctors and medical students had an intuitive grasp of the app's purpose and functionalities. On average, nurses and clinical officers had less previous exposure to touch screen technology and therefore experienced more difficulty with the PARA app. However, all participants found the PARA app to be a useful clinical tool, agreeing they would use it if available at their health facility. The impact on workflow in a clinical environment could not be assessed in our standardized testing environment. Future research will be conducted in clinical environments utilizing actual end-users.

However, education gaps were identified during the study, which would impact future implementation and training. Some participants overestimated the scope and purpose of the PARA app, leading them to mistake the app for an electronic records system or continual assessment tool. As the PARA app is scaled in clinical settings, consideration should be given to the best way to train and educate clinicians on appropriate functionalities. The addition of a training video upon installation of the PARA app may curb misunderstanding during scale-up. Other studies have found that stakeholder collaboration, governmental support, and local adaptation are important factors to successful implementation of mHealth programs [18].

Given a high PARA risk score, participants suggested several interventions that would be appropriate for the sociocultural context in southwestern Uganda. Most suggestions centered on strengthening discharge and referral procedures within the current health care system. Participants felt that educational interventions on discharge or convenient and consistent follow-up after discharge could improve mortality outcomes for children with high PARA scores (indicating >10% risk of postdischarge mortality). Though these interventions have been studied in other contexts, little evidence exists on their effectiveness at diminishing postdischarge mortality, and more research regarding effective strategies to decrease postdischarge mortality are urgently required [2,19].

Limitations

As this was an initial evaluation of a novel app, this usability study was not conducted in a clinical context, but instead with purposively sampled potential end-users in an artificial environment. Therefore, findings may not be generalizable to a clinical context. However, efforts were made to encompass a variety of target users, in order to understand the utility of the app from a variety of professional perspectives and technological skill levels. Further, our clinical scenarios were carefully developed to ensure a balanced and representative evaluation from both a clinical and usability/design perspective.

In addition, given varied exposure to technology, there was some degree of novelty and expectancy effects. To address these concerns, clear instructions were given to each participant on how to use a touch screen, as well as reinforcement that the only expected outcome from the study was improvement of the app. The patient scenario instructions were adjusted between Phases 1 and 2 to account for modifications made to the app. However, patient scenarios and sequence of tasks remained standardized between phases, so comparable testing conditions were preserved.

Future Plans

Postdischarge mortality is a neglected but significant cause of child mortality in resource-constrained settings. The PARA app can begin to address this burden through its ability to quickly identify children at highest risk of death during the postdischarge period. Our research team in Uganda is currently conducting a feasibility study of a comprehensive postdischarge intervention (discharge kits) to distribute to vulnerable children at discharge. Over the next 24-36 months, our research team in Uganda will begin to integrate the PARA app with discharge kits to evaluate their effect on health seeking, hospital re-admissions, and mortality during the postdischarge period.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Introduction to PAediatric Risk Assessment (PARA) app.

[PDF File (Adobe PDF File), 300KB - mhealth_v4i1e16_app1.pdf]

Multimedia Appendix 2

Patient information.

[PDF File (Adobe PDF File), 249KB - mhealth_v4i1e16_app2.pdf]

Multimedia Appendix 3

Poststudy questionnaire.

[PDF File (Adobe PDF File), 249KB - mhealth_v4i1e16_app3.pdf]

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Abbreviations

CSUQ: computer system usability questionnaire
HICH: Holy Innocents Children's Hospital
MRRH: Mbarara Regional Referral Hospital
PARA: PAediatric Risk Assessment
SpO2: oxygen saturation
SQI: signal quality index

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Original Paper

Design of a Tablet Computer App for Facilitation of a Molecular Blood Culture Test in Clinical Microbiology and Preliminary Usability Evaluation

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Abstract

Background: User mobility is an important aspect of the development of clinical information systems for health care professionals. Mobile phones and tablet computers have obtained widespread use by health care professionals, offering an opportunity for supporting the access to patient information through specialized applications (apps) while supporting the mobility of the users. The use of apps for mobile phones and tablet computers may support workflow of complex tasks, for example, molecular-based diagnostic tests in clinical microbiology. Multiplex Blood Culture Test (MuxBCT) is a molecular-based diagnostic test used for rapid identification of pathogens in positive blood cultures. To facilitate the workflow of the MuxBCT, a specialized tablet computer app was developed as an accessory to the diagnostic test. The app aims to reduce the complexity of the test by step-by-step guidance of microscopy and to assist users in reaching an exact bacterial or fungal diagnosis based on blood specimen observations and controls. Additionally, the app allows for entry of test results, and communication thereof to the laboratory information system (LIS).

Objective: The objective of the study was to describe the design considerations of the MuxBCT app and the results of a preliminary usability evaluation.

Methods: The MuxBCT tablet app was developed and set up for use in a clinical microbiology laboratory. A near-live simulation study was conducted in the clinical microbiology laboratory to evaluate the usability of the MuxBCT app. The study was designed to achieve a high degree of realism as participants carried out a scenario representing the context of use for the MuxBCT app. As the MuxBCT was under development, the scenario involved the use of molecular blood culture tests similar to the MuxBCT for identification of microorganisms from positive blood culture samples. The study participants were observed, and their interactions with the app were recorded. After the study, the participants were debriefed to clarify observations.

Results: Four medical laboratory technicians, for example, representative of end users of the app, participated in the clinical simulation study. Using the MuxBCT app, the study participants successfully identified and reported all microorganisms from the positive blood cultures examined. Three of the four participants reported that they found the app useful, while one study participant reported that she would prefer to make notes on paper and later enter them into the LIS.

Conclusions: The preliminary usability evaluation results indicate that use of the MuxBCT tablet app can facilitate the workflow of the MuxBCT diagnostic test.

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KEYWORDS

usability; mobile applications; tablet computers; clinical simulation; health information systems; diagnostic test; clinical microbiology

Introduction

Health Care Workers and Mobile Technology

Support of user mobility is an important aspect to consider when developing clinical information systems (CIS) [1-3]. Physicians and nurses continuously move between offices, wards, patients, and workstations while conducting their work. Other employees such as laboratory workers are also mobile in their work, as they move between labs, specialized equipment, and offices to acquire and report laboratory results [4]. With the ongoing trend of increased digitization of information in health care and thus a move away from paper documentation, this sets a requirement for clinical staff being able to access CIS while away from workstations.

In recent years, mobile devices in the form of mobile phones and tablet computers have become almost ubiquitous in daily life and their use has spread to clinical settings [5-7]. The mobile devices are generally lightweight, intuitive to use, and contain powerful data processing abilities. Thus, they offer a potential solution for providing the necessary access to CIS, while supporting the mobility requirements of health care professionals. While mobile phones and tablet computers are seeing more widespread use by health care professionals in clinical settings, there is still a need for more research to discover and document the benefits and potential difficulties these mobile devices may bring to particular applications (app) [7,8].

Mobile phones and tablet computers offer an interesting option for providing workflow assistance and guidance of complex tasks. For example, in clinical laboratories the development of specialized apps may facilitate the workflow of preparing, interpreting, and reporting results of diagnostic tests. In clinical microbiology, many new diagnostic tests have been developed in recent years that allow for rapid identification of microorganisms that cause bloodstream infections [9]. Many of these tests are based on molecular biology techniques and have the potential for providing more specific results in a shorter time than current tests. However, the molecular tests are often more complex to use compared to the conventional techniques and therefore may require more skill from the operators [10].

Multiplex Blood Culture Test

Multiplex Blood Culture Test (MuxBCT) (AdvanDx, Woburn, MA, USA) is a new blood culture diagnostic test under development based on the molecular technique fluorescence in situ hybridization (FISH). The MuxBCT uses fluorescence-labeled, peptide nucleic acid (PNA) probes that bind to specific DNA targets in microorganisms, which can then be detected by fluorescence microscopy. Like other molecular diagnostic tests, the MuxBCT involves more complexity than conventional methods used for blood culture diagnostics in clinical microbiology. To reduce the time required for data capture, test interpretation, and results reporting, a MuxBCT tablet computer app was developed as a research project. The aim of the app is to reduce the complexity of the diagnostic test by guiding the user, for example, a medical laboratory technician (MLT), stepwise through the diagnostic test and the interpretation process of the MuxBCT diagnostic test. Additionally, the app will allow users to report results directly to the Laboratory Information System (LIS).

In this study, we describe the system design and development considerations for the MuxBCT tablet app, and we report the results of a preliminary usability evaluation of the MuxBCT app.

The Multiplex Blood Culture Test App

App Description

The MuxBCT app has been developed as a research project and functions as an accessory tool to facilitate the use of the MuxBCT diagnostic test. The app was developed based on requirements set through observations of the workflow during blood culture analysis in a clinical microbiological laboratory [4]. End users have been involved in the development life cycle of the MuxBCT app, for example, by identifying flaws in a prototype of the app through a participatory heuristic evaluation [11]. The app is integrated with the LIS in use at the Department of Clinical Microbiology (DCM) at Aalborg University Hospital, Denmark. The LIS integration of the app is important for clinical use, as a lack of an integration would require reentry of test results and likely lead to an inefficient and more error-prone workflow [12]. The MuxBCT app is developed as a native app for the Android operating system and has been designed to support 10.1-inch tablet computers.

When using the app, users must initially complete a sample setup (Figure 1 shows this), where the sample identification number is entered into the app. The sample identification number can optionally be entered via a barcode reader. The entered sample identification number is used to retrieve relevant clinical information about the patient and that sample from the LIS, which is then displayed to the user. The user selects one or more positive blood cultures for analysis. The Kit ID (lot information) for each MuxBCT diagnostic test used must be entered for each selected blood culture. The lot information is stored for quality control purposes.

The MuxBCT diagnostic test is divided into 10 different analysis areas (wells). In most cases, a classification well followed by three identification wells will need to be examined. The user will start fluorescence microscopy with a classification well and will be prompted to enter the findings into the app through the use of multiple choice questions. The app has an algorithm that guides users to analyze only relevant wells based on observations entered for the classification well. During analysis of the selected identification wells (Figure 2 shows this), the user will again enter observations via multiple choice questions. In the user interface, users can choose to display reference

images of the same type of fluorescent microorganism to assist them in analyzing their observations.

When the user has completed the test analysis, a result summary of any microorganism findings, for example, a bacterium finding and a yeast finding, will be displayed to the user. Once the user has submitted the analysis result, it becomes available for all relevant staff through the LIS. The user also has an option to enter notes along with the result, which will either be visible for all clinical staff or only staff in the clinical microbiology laboratory. Until the result is submitted to the LIS, users can go back in the app and revise any entered data.

The app offers a training mode where fictitious data are generated and displayed to the user. In the training mode, no data are communicated between the LIS and the tablet app. The training mode allows users to become familiar with the app before they use it to facilitate the analysis of positive blood culture samples.

Figure 1. Sample screenshot of the Multiplex Blood Culture Test (MuxBCT) app showing the initial sample setup where a sample ID is entered into the system, data are retrieved from the Laboratory Information System (LIS), and displayed in the app. The patient information displayed in the image is fictitious.

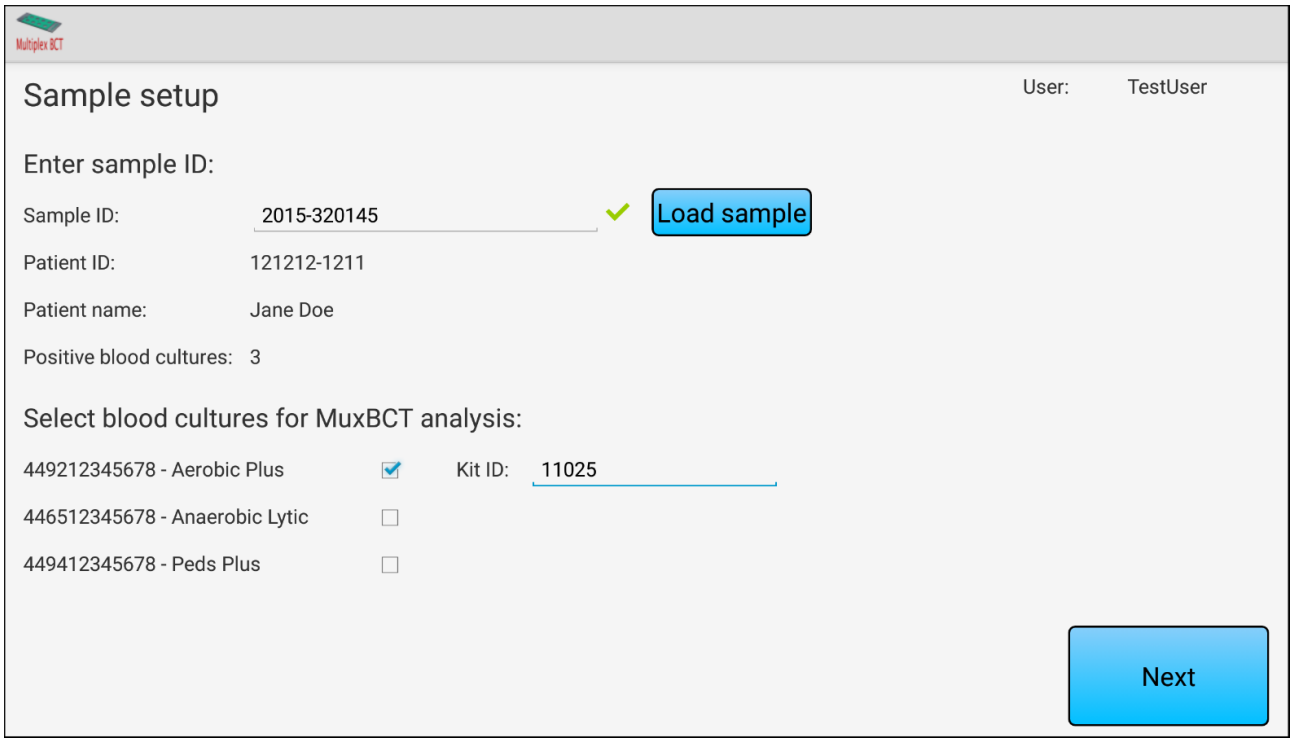
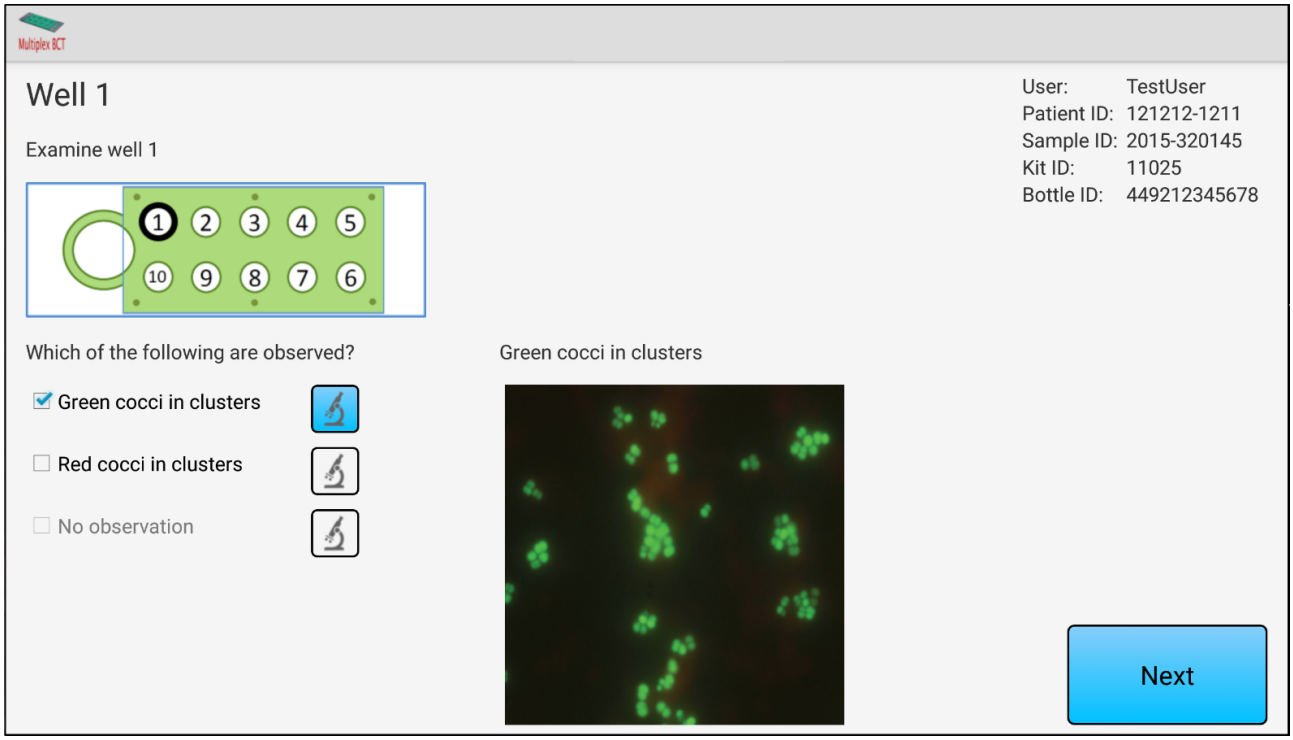


Figure 2. Sample screenshot of the Multiplex Blood Culture Test (MuxBCT) app showing data entry of test results acquired through fluorescence microscopy of the MuxBCT diagnostic test. The patient information displayed in the image is fictitious.



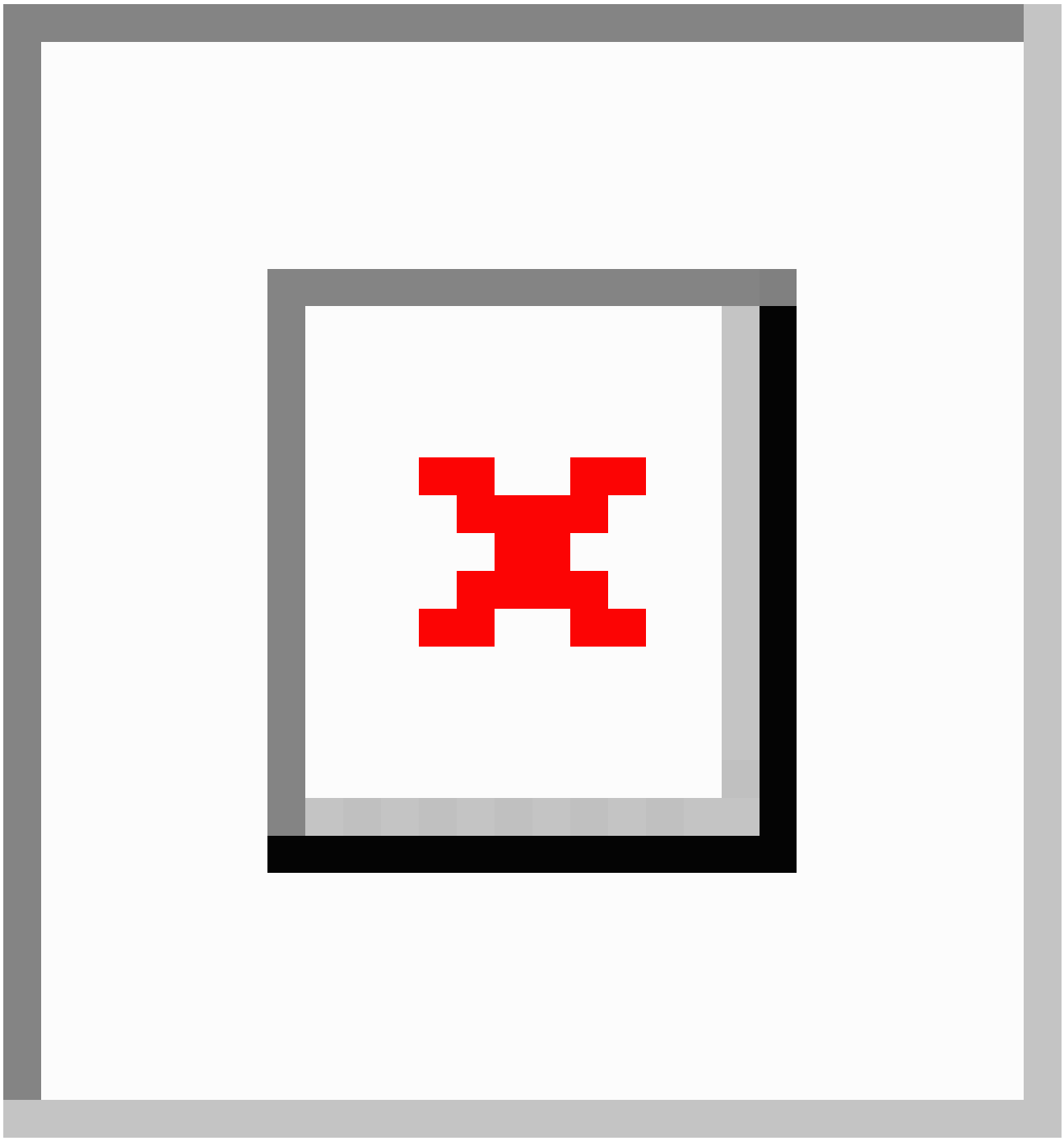
System Architecture

The MuxBCT system consists not only of a tablet computer with the MuxBCT app, but also of a server with a MuxBCT server app (Figure 3 shows this). The MuxBCT server communicates with the LIS of the clinical microbiology laboratory. Additionally, the tablet app supports the use of a Bluetooth barcode scanner as an accessory for the MuxBCT app to reduce the potential for data entry errors [13]. Once the scanner is connected, it allows for data entry by scanning sample identification barcodes. The MLTs interact directly with the MuxBCT tablet app during analysis of a MuxBCT diagnostic test.

The app exchanges data with a MuxBCT server, which is integrated with the LIS. The server processes any results received by the tablet app, so that the data can be exchanged with the LIS. The server app communicates with the LIS to receive patient information relevant to the sample being analyzed and to store results of the MuxBCT diagnostic test in the LIS. Once data have been transmitted to the LIS, they become available for clinical microbiologists, who can access it through the LIS. The clinical microbiologists can then communicate the results to a patient's treating physician to optimize the patient's treatment. When the DCM has approved the results in the LIS, the results become available from the electronic health records system through LIS integration.

A database is associated with the MuxBCT server, which is used to store test results. This allows data to be reviewed for quality assurance purposes. Additionally, user interactions with the system are logged in the MuxBCT database.

Figure 3. Overview of the Multiplex Blood Culture Test (MuxBCT) system design. The medical laboratory technician (MLT) will use the MuxBCT app for facilitation of the MuxBCT diagnostic test. The MLT can use a wireless barcode scanner to enter barcodes into the tablet app. Clinical microbiologists can access the MuxBCT results through the LIS. The HTTPS protocol is used to ensure encrypted communication of data. The arrowheads indicate direction of data flow. Dashed lines in the figure indicate wireless connections.



System Security

Because of an inherent risk of tablet computers more easily being misplaced or stolen than regular workstation computers, several security design considerations have been built into the MuxBCT app, which aims to keep patient data secure and private (Figure 4 shows this). The security design considerations are divided into three categories: user security, device security, and data security.

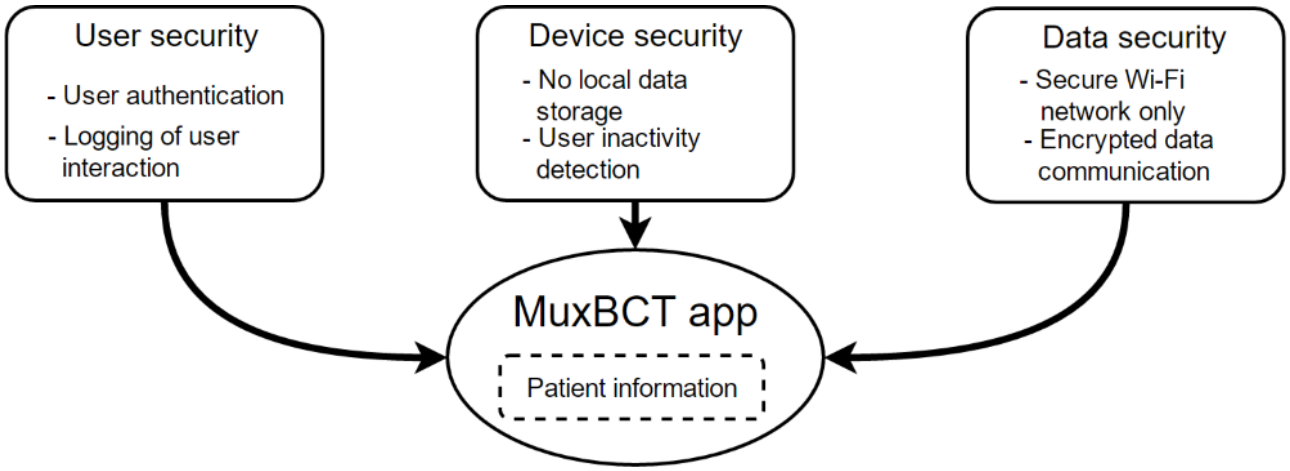
The user security design considerations consist of user authentication and of logging user interactions. To gain access to the functionality of the MuxBCT app, a user must provide a username and password, which must then be successfully authenticated. Additionally, any user interaction that provides access to patient information will be saved as a log entry in the MuxBCT server's database. This enables an audit functionality, where any potential misuse of the system can be tracked, and users can be held accountable for their actions.

The device security is based upon not storing any data locally on the tablet computer and automatically logging out inactive users. To prevent potential patient data leaks, the app is designed to store data only temporarily in the memory of the tablet

computer while the MuxBCT app is being used. Once a user completes a task with the app, any information related to that task is cleared from the tablet computer. If any users are inactive for more than a predefined period, for example, 20 minutes, the system will automatically log the user out of the system. The user will then have to authenticate again if she wishes to resume using the MuxBCT app. The system administrator can adjust the inactivity period that must pass before a user is logged out of the system.

Letting the tablet app exchange data with the MuxBCT server only through the hospital's secure Wi-Fi network ensures data security. Additionally, all data communication is protected with encryption that relies on the HTTPS protocol (Figure 3). By encrypting the Bluetooth connection, data entered using an accessory Bluetooth barcode scanner are protected.

Figure 4. Overview of the security design considerations that in unison protect the patient information of the Multiplex Blood Culture Test (MuxBCT) application (app). It is a requisite that the security considerations are implemented before the deployment of the MuxBCT app. Wi-Fi is the local wireless network.



Methods

Study Design

To gain insights about the use of the MuxBCT app, a preliminary usability evaluation was conducted at the DCM at Aalborg University Hospital. This allowed the app to be tested in its normal context of use. The evaluation was structured as a clinical simulation study and aimed for a high degree of realism. The study took place within normal working hours at the DCM, which meant that normal minor background disturbances occurred, which further aided in making the study a near-live simulation for the participants. A scenario of use with a focus on realistic tasks was developed in cooperation with staff at the DCM, where the MuxBCT app was used to support result interpretation and data entry of FISH-based blood culture diagnostic tests. A pilot study was conducted with one MLT to validate the study design before the main study took place.

The study aimed to recruit 4-5 participants, which is commonly used as a cost-efficient approach for finding usability problems through usability evaluation methods [14]. An informational flyer about the study was presented to the MLTs of the DCM. For inclusion in the study, participants were required to have prior experience with blood culture analysis. Potential participants were excluded if they had any prior experience with MuxBCT or the MuxBCT app prototype. A senior staff member of the DCM handled selection of participants for the study, with a goal of achieving a mixed level of seniority among the participants. The participants were compensated for their time.

At the onset of each study session, the participants were introduced to the concept of the MuxBCT diagnostic test and the accessory tablet app. The first author acted as test leader during the study and provided the users with instruction and training. The study participants then participated individually in a MuxBCT app training session lasting roughly 10 minutes. The training session followed a structured approach so each participant had the same introduction to the app. If the study participant was not familiar with tablet computers and the Android operating system, they were given a brief introduction to this. Once the participant was comfortable with the tablet, a scenario of use of the MuxBCT app was described for the participant. Each participant carried out 5 predefined tasks using the MuxBCT app. The 5 tasks were divided into 24 steps, for which they received instructions to complete one at a time. If the participant was stuck on a step, they were allowed to ask questions and to receive help from the test leader.

During the study, the participants were not offered any assistance in the interpretation of diagnostic test results or in the use of the app. The participants were asked to think-aloud during the study. After the study, the participants were debriefed in a short interview that followed a semistructured approach, which was based on the observations made by the test leader during the study.

The test leader acted as an observer during the study and took notes of the participants' interactions with the tablet app and the diagnostic tests. Furthermore, all interactions with the tablet app were recorded as a video file with the Android app Recordable, where user interactions with the app, for example, touch gestures, were saved as an overlay on the video. Audio was recorded using a dictation machine and by the built-in

microphone of the tablet computer. The video and audio files were transferred to a computer and synchronized, allowing for analysis of the study results.

The debriefing interviews and the audio data from the users' interaction with the app were analyzed by coding the data through the process of meaning condensation and categorization followed by an interpretation of the processed data [15]. An inductive approach was used in the analysis of video data, which was supported by the audio data of users thinking aloud during their interaction with the app. Different types of events were coded in categories based on their characteristics. Once structured into themes and categories, the data were summarized, which allowed for an analysis of the total time spent for MuxBCT analysis. In addition, the structured data were interpreted, which allowed for identifying the users' perspectives about potential difficulties when interacting with the app.

Materials

The MuxBCT diagnostic test was undergoing development at the time of the study. While the general concepts of the test were fully designed, it was not ready for use in a clinical microbiology laboratory. Therefore, the MuxBCT was unavailable at the time of the study. Instead, MuxBCT was simulated by using the QuickFISH Enterococcus and QuickFISH Candida (AdvanDx, Woburn, MA, USA) tests. The QuickFISH tests are predecessors to the MuxBCT and require the same fluorescence microscopy analysis to interpret test results, but each QuickFISH test identifies fewer microorganisms. By using the QuickFISH tests, two out of ten analysis wells of the MuxBCT were simulated. The use of the two QuickFISH tests necessitated that the study participants changed the microscopy slide once during the analysis phase. As part of the training session, it was explained to the participants that the QuickFISH tests were used to simulate the MuxBCT.

A senior MLT who had been involved in the MuxBCT app development process assisted in the study by helping with the preparation of the QuickFISH tests. Additionally, the senior MLT inoculated samples drawn aseptically from blood culture bottles negative at termination of incubation (BacT/Alert, bioMérieux, Marcy l'Etoil, France) with the bacteria, *Enterococcus faecalis* or *Enterococcus faecium*, and the yeasts, *Candida albicans* or *Candida glabrata*, so that each sample grew two of these microorganisms. Each study participant was assigned a random blood culture sample to analyze using the QuickFISH test kits. The study participants were kept blinded to the microorganisms in their assigned blood culture sample.

For the study, the MuxBCT app was installed on a Samsung Tab Pro 10.1-inch tablet computer (Samsung Electronics, Seoul, Korea) running Android 4.4.2. All text in the app was in Danish, the first language of the study participants. The tablet was connected to a CHS 7DiRx 1D Bluetooth barcode scanner (Socket Mobile, Newark, CA, USA) and the hospital's secure Wi-Fi network. Access to the secure Wi-Fi network was approved by the hospital's Information Technology Department before the study took place.

In preparation for the study, the MuxBCT app was connected to the MuxBCT server. However, because the study was a simulation, the MuxBCT server was not connected to the LIS during the study, but instead returned realistic, fictitious patient data to the tablet app. All MuxBCT analysis results were sent to the server and saved in the associated database for later validation.

Results

Study Participants

There were four MLTs that participated in the clinical simulation study, which was conducted in one day at the DCM. All study participants were female. The mean age of the study participants was 37 years, and the mean experience in blood culture diagnostics was 7 years (range 3-14 years). There were three participants that described their skill level with fluorescence microscopy as practiced, while one described her skill level as novice. All participants described themselves as experienced in the use of mobile phones and tablet computers based on personal use outside the clinical microbiology department. The study spanned across several rooms in the clinical microbiology department. Preparation of the QuickFISH molecular tests took place in one room with specialized equipment primarily for molecular diagnostics. The interpretation of the tests required fluorescence microscopy and took place in a dark room that was located near the first room. Training and debriefing took place in a larger room in the department, where there was little activity and few potential disturbances.

Participant Results

All participants correctly identified all microorganisms in the simulated blood culture samples. The participants correctly entered their findings into the MuxBCT app and submitted them to the MuxBCT server. The analysis results were retrieved from the database of the MuxBCT server to verify that they had been transmitted successfully. It was confirmed that all results were stored correctly in the database. On average, the analysis of the blood culture sample and data entry of the results into the MuxBCT app took 10.2 min (range 6.5-16.0 min).

All results were entered correctly on the first attempt. However, when two participants attempted to mark their findings, they initially changed the reference image being displayed instead; this was the result of clicking on the microscope icon associated with each possible finding instead of marking the checkboxes corresponding to their findings (Figure 4). Both participants noticed that they had not entered the results and marked their findings successfully before continuing.

During the debriefing interview, three participants expressed that they found the system useful. A participant noted that she would prefer to continue making notes of analysis results on paper and entering them later into the LIS at a workstation. The main reasoning behind this was that the text on the tablet computer was too small to read during data entry (Figure 4). Another participant also expressed an interest in larger text on the app. Both of these participants wore glasses, which they would remove during use of the fluorescence microscope.

It was observed for all participants that they made only minor use of the reference images displayed during data entry. When prompted about this during the debriefing, two participants

explained that the reference images were not needed during the study, as the samples being analyzed by fluorescence microscopy provided a clear picture. They remarked that the reference images would be useful in cases where the fluorescence signal was less clear. A participant noted that the reference images would likely be most valuable for users with limited experience in fluorescence microscopy.

All participants used the barcode scanner successfully to enter sample identification data into the app. A participant initially had troubles entering the sample identification with the barcode scanner because the relevant input field had not been selected before the barcode was scanned (Figure 4). Throughout the study, the Bluetooth barcode scanner functioned without loss of connection to the tablet computer. There were three participants that expressed that the mobility of the tablet in combination with the barcode scanner was satisfactory; however, one participant suggested that a slightly smaller tablet computer could be used.

The majority of the app's security features were enabled and used successfully during the study. The user authentication was not enabled, as study participants logged in with fictitious user data. Additionally, the user inactivity detection was not enabled in the app, as the study participants were not involved in normal job functions during the study, and thus there was no risk of inactivity for long periods. During the study, there were no issues with loss of connection to the Wi-Fi network at the DCM.

Discussion

Principal Results

The MuxBCT tablet app was developed as a research project for the facilitation of the MuxBCT diagnostic test that is designed for rapid identification of bacterial and fungal pathogens in positive blood cultures. This study describes the MuxBCT app and a preliminary usability evaluation of the MuxBCT tablet app based on a clinical simulation study conducted at a clinical microbiology laboratory. The MuxBCT diagnostic test is intended to provide fast and accurate identification of microorganisms causing bloodstream infections, allowing the physician to treat with more appropriate antimicrobials sooner. However, the use of molecular diagnostic tests such as MuxBCT involves a more complex workflow than conventionally used methods of analysis [10]. Specialized apps such as the MuxBCT app may facilitate the workflow of diagnostic tests in the clinical laboratory, which can lead to a more accurate and faster result. In the case of treating patients with severe sepsis, this is critical, as each hour of delay in the administration of an effective antimicrobial treatment is associated with a decrease in survival rate [16]. While some specialized apps may be more suitable for use on existing workstation PCs, which are commonly distributed throughout clinical laboratories, this is not a practical solution for the MuxBCT app, as MuxBCT requires use in a dark room due to the use of fluorescence microscopy for reading the test results. As the app is designed to guide users through the interpretation process in a stepwise manner, the app needs to be accessible directly from the location where the test is being analyzed. The results of this study indicate that although there were some usability issues for the users to interact with the tablet in the dark room, the app was viewed as a useful adjunct to this kind of test and that the light from the tablet did not disturb the analysis process.

All participants in the study managed to correctly identify and report the microorganisms from the blood culture samples they examined. The foundation for the use of the app was a short training session. The participants were able to use the MuxBCT app for guidance during the examination of the QuickFISH molecular diagnostic tests. The QuickFISH tests with the same detection method were used to simulate the MuxBCT, which was still undergoing development at the time of the study. The initial classification well could not be simulated by use of QuickFISH tests in a realistic manner, so, as a compromise, the participant received instructions of what findings to input for this well. The classifier is a molecular equivalent to the classical Gram stain with minor differences in distinction between bacterial groups. Common use of the MuxBCT would require analysis of the classifier well followed by analysis of three identification wells. The analysis of additional identification wells is only necessary when the results from the classification well indicate a polymicrobial bloodstream infection.

The participants were able to access the necessary clinical information they required during the test without having to access the LIS using a workstation. Additionally, all participants successfully made use of the barcode scanner during the study. During the debriefing interviews, three out of four participants expressed that they found the system useful. A participant expressed a preference for writing the results on paper, for example, like the normal workflow during blood culture analysis, and later entering the results into the LIS. Some usability issues were noted during the study, but overall the usability evaluation found that the MuxBCT app was a reliable tool for facilitating the workflow of the MuxBCT diagnostic test, as all participants managed to correctly interpret, enter, and communicate the test results.

The results of the study have led to some updates of the MuxBCT app. The main structure of the app has not been changed; however, several changes have been made to improve the user interface of the app. For example, the font size has been increased throughout the app, making text more easily readable, and the check boxes where users mark their findings of microorganisms have been increased in size.

Based on the results of the development process and this study, we believe that the involvement of clinical microbiology staff in the development and evaluation processes of the MuxBCT app has led to an improved quality of the app. In general, there is a growing focus on the need for involvement of medical professionals throughout the entire app development process to ensure the quality of the app and to prevent possible patient harm [17].

The structure of the study was a near-live clinical simulation that aimed for a high degree of realism. The study was conducted in a clinical microbiology laboratory using simulated blood culture samples, molecular diagnostic tests, and fluorescence microscopy. The combination of these factors allowed the MLTs in the study to carry out their analysis with

minimal assistance from the test leader. This provided findings about the usability of the system, which may not have been discovered if other usability evaluation methods had been applied. The use of a think-aloud protocol may have detracted from the realism of the study. However, this did not seem to cause any issues during the study. Furthermore, the think aloud-protocol was necessary to gain knowledge of the fluorescence microscopy observations and to confirm that the participants entered their observations correctly. The realism of the study may have been further diminished by a senior MLT assisting with the preparation of the QuickFISH tests and by the test leader observing the participants during the study, but this did not affect the context of use for the MuxBCT tablet app. Therefore, it is unlikely that it had any large impact on the results of usability evaluation.

A challenge in selecting a device for the MuxBCT app was to ensure mobility of the system, while providing enough screen space for displaying the necessary information clearly and allowing for easy input of data. The mobility of the system was tested as the study spanned several rooms in the clinical microbiology laboratory. Although the app has been designed for use on a 10.1-inch tablet computer, two of the study participants noted that they would prefer text size in the app to be increased. In regards to the mobility of the system, three study participants noted that they found the mobility of the system adequate, while one study participant would prefer a smaller tablet computer. It may be possible to redesign the app to support a slightly smaller tablet computer, while increasing the text size. However, this requires a careful redesign of the graphical user interface.

While the MuxBCT app was not connected to the LIS during this study, it was connected to the MuxBCT server. This meant that it was possible to test communication of test results and to validate that they were transferred correctly. To simulate LIS connectivity, fictitious patient data were returned by the MuxBCT server. The data were visible by the participant within the app during the study, which helped to ensure a high degree of realism. If the system had been connected to the LIS, it may have induced some additional delays during use of the app while data was being transferred. However, any such delays would only affect test setup and result reporting and would not have changed the evaluation of how the MuxBCT app aided in the analysis and interpretation of test results, as these steps of the MuxBCT app do not require communication with the LIS.

Data security of patient information is an important factor to consider in the development of apps for mobile phones and tablets [18,19]. To secure the privacy of patient information, several security related features were built into the MuxBCT app. The design of security features for the MuxBCT app has a high similarity to those described by Landman et al used in the implementation of the CliniCam mobile phone app [19]. While the MuxBCT app required access to the hospital's protected Wi-Fi network for use, the participants did not experience any loss of connectivity during the study. As clinical laboratories are of fixed dimensions, it should be a manageable task to setup adequate Wi-Fi coverage throughout an entire laboratory. Other mobile device apps for facilitation of clinical workflow may experience challenges with sufficient Wi-Fi network coverage, as larger areas need to be covered [18,19].

Future development on the MuxBCT app could include the functionality to directly communicate test results electronically to selective stakeholders, for example, the patient's treating physician or to clinical microbiologists within the DCM. This could potentially reduce errors related to communication of test results and reduce the total test turnaround time [20,21]. Future evaluation studies will be required to see how the MuxBCT app affects the use of the MuxBCT diagnostic test once both are put into daily use in a clinical microbiology laboratory. It should be stressed that the current iteration of the MuxBCT app was developed as a research project. If future development of the MuxBCT app aims to prepare it for commercialization and regular use in a clinical microbiology laboratory, the app must conform to national regulatory requirements governing medical devices.

Limitations

A significant limitation of this study is the low number of study participants. Each participant, who was an expert in the field of use for the MuxBCT app, conducted an analysis of a positive blood culture sample with two microorganisms. This allowed for a total of 8 microorganisms being successfully identified. While this number is too low to accurately determine the quality of MuxBCT diagnostic test results being facilitated by the MuxBCT app, these results in combination with the results from observations and debriefing interviews provided an insight into the usability of the MuxBCT app.

The realism of the study was also diminished to some degree by the MuxBCT diagnostic test being unavailable for the study. The test was substituted with the QuickFISH tests, and as there is a high coherence between the QuickFISH tests and the MuxBCT, it is unlikely that this had a significant impact on the study results.

The results of the clinical simulation cannot be generalized, as they are specific to the MuxBCT app being evaluated. However, our study results indicate that a clinical simulation is a valuable tool for evaluating the usability of a mobile device app that aim to support clinical workflow. Other developers and implementers may find this as an effective tool to use preimplementation. The system design of the MuxBCT app and the considerations of security features may inspire the design choices of other mobile apps being developed for clinical use. However, their effect should be evaluated through a full system implementation in daily clinical workflow.

Related Work

To our knowledge, there has not been any previous publication describing the use of a mobile phone or tablet computer app for facilitating the use of a diagnostic test in a clinical laboratory. However, the use of mobile phone or tablet computer apps designed for use by health care professionals in clinical settings is becoming increasingly common [7,8,18,19,22].

There is a growing interest in clinical simulation studies as a tool for evaluating usability of hospital information technology (HIT) [23,24]. It is a common goal of simulation studies to

create a near-live simulation, which requires a setting representative to where the system will be used [1,23,25,26]. While most clinical simulation studies focus on the evaluation of stationary HIT, some simulation studies have been used to examine the usability of HIT designed for use on mobile devices [27,28]. This study differentiates itself from previous clinical simulation studies, as it took place in a clinical laboratory. This meant that the context of use for the system being evaluated did not involve patient contact, but involved a focus on the diagnostic test laboratory analysis process, which included a focus on the use of laboratory equipment as part of the user workflow. A realistic simulation of the use of specialized laboratory equipment may be difficult to achieve outside an actual clinical laboratory.

Conclusions

The MuxBCT tablet computer app facilitates the workflow of a novel molecular diagnostic test using PNA FISH technology for blood culture analysis and was developed with system flexibility and security of patient data as high priorities. The app was developed based on previous analysis of user requirements. However, additional functionalities such as user authentication and user inactivity detection were added to create a secure app. The security features are vital to protect patient data. A preliminary usability evaluation was conducted as a clinical simulation study in a clinical microbiology laboratory. The study aimed to provide a high degree of realism by having end users conduct fluorescence microscopy of molecular diagnostic tests employing available PNA FISH technology, while using the MuxBCT app to facilitate the workflow. The study results indicate that users can successfully use the app to facilitate the MuxBCT diagnostic test workflow. All diagnostic test results were interpreted, entered, and communicated successfully to the MuxBCT server with use of the MuxBCT tablet app, which validates the system design considerations. The study provided useful feedback on the app usability, for example, in regards to font size and tablet size. The clinical simulation method can be a valuable tool for evaluating the usability of mobile apps intended for clinical use, as the method provides insights into complex use case scenarios where context of use is important.

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Authors' Contributions

MM and MF contributed to the study by participating in the design of the tablet app, by providing feedback on the study design of the preliminary usability evaluation, by contributing to the discussion of results, and by revising the manuscript.

Conflicts of Interest

AdvanDx employs MM and MF. To avoid any potential conflicts of interest, MM and MF were not directly involved in data collection and data analysis.

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Abbreviations

app: application
CIS: clinical information system
DCM: Department of Clinical Microbiology
FISH: fluorescence in situ hybridization
HIT: health information technology
LIS: laboratory information system
MLT: medical laboratory technician
MuxBCT: multiplex blood culture test
PNA: peptide nucleic acid

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Original Paper

MoodHacker Mobile Web App With Email for Adults to Self-Manage Mild-to-Moderate Depression: Randomized Controlled Trial

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Abstract

Background: Worldwide, depression is rated as the fourth leading cause of disease burden and is projected to be the second leading cause of disability by 2020. Annual depression-related costs in the United States are estimated at US $210.5 billion, with employers bearing over 50% of these costs in productivity loss, absenteeism, and disability. Because most adults with depression never receive treatment, there is a need to develop effective interventions that can be more widely disseminated through new channels, such as employee assistance programs (EAPs), and directly to individuals who will not seek face-to-face care.

Objective: This study evaluated a self-guided intervention, using the MoodHacker mobile Web app to activate the use of cognitive behavioral therapy (CBT) skills in working adults with mild-to-moderate depression. It was hypothesized that MoodHacker users would experience reduced depression symptoms and negative cognitions, and increased behavioral activation, knowledge of depression, and functioning in the workplace.

Methods: A parallel two-group randomized controlled trial was conducted with 300 employed adults exhibiting mild-to-moderate depression. Participants were recruited from August 2012 through April 2013 in partnership with an EAP and with outreach through a variety of additional non-EAP organizations. Participants were blocked on race/ethnicity and then randomly assigned within each block to receive, without clinical support, either the MoodHacker intervention (n=150) or alternative care consisting of links to vetted websites on depression (n=150). Participants in both groups completed online self-assessment surveys at baseline, 6 weeks after baseline, and 10 weeks after baseline. Surveys assessed (1) depression symptoms, (2) behavioral activation, (3) negative thoughts, (4) worksite outcomes, (5) depression knowledge, and (6) user satisfaction and usability. After randomization, all interactions with subjects were automated with the exception of safety-related follow-up calls to subjects reporting current suicidal ideation and/or severe depression symptoms.

Results: At 6-week follow-up, significant effects were found on depression, behavioral activation, negative thoughts, knowledge, work productivity, work absence, and workplace distress. MoodHacker yielded significant effects on depression symptoms, work productivity, work absence, and workplace distress for those who reported access to an EAP, but no significant effects on these outcome measures for those without EAP access. Participants in the treatment arm used the MoodHacker app an average of 16.0 times (SD 13.3), totaling an average of 1.3 hours (SD 1.3) of use between pretest and 6-week follow-up. Significant effects on work absence in those with EAP access persisted at 10-week follow-up.

Conclusions: This randomized effectiveness trial found that the MoodHacker app produced significant effects on depression symptoms (partial eta^2 = .021) among employed adults at 6-week follow-up when compared to subjects with access to relevant depression Internet sites. The app had stronger effects for individuals with access to an EAP (partial eta^2 = .093). For all users, the MoodHacker program also yielded greater improvement on work absence, as well as the mediating factors of behavioral activation, negative thoughts, and knowledge of depression self-care. Significant effects were maintained at 10-week follow-up for work absence. General attenuation of effects at 10-week follow-up underscores the importance of extending program contacts to maintain user engagement. This study suggests that light-touch, CBT-based mobile interventions like MoodHacker may be

appropriate for implementation within EAPs and similar environments. In addition, it seems likely that supporting MoodHacker users with guidance from counselors may improve effectiveness for those who seek in-person support.

Trial Registration: ClinicalTrials.gov NCT02335554; https://clinicaltrials.gov/ct2/show/NCT02335554 (Archived by WebCite at http://www.webcitation.org/6dGXKWjWE)

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KEYWORDS

depression; cognitive behavioral therapy; behavioral activation; positive psychology; mobile apps; Internet; computers

Introduction

Background

Major depressive disorder is one of the most prevalent mental conditions to afflict adults in the United States, with estimates in the United States for major depression of 16.6% for lifetime occurrence and 6.7% for a 1-year period [1,2]. Worldwide, depression is rated as the fourth leading cause of disease burden, and the World Health Organization projects that by 2020 depression will rank as the second leading cause of disability [3,4]. The prevalence of mild-to-moderate or subclinical depression is equal to, or greater than, major depressive disorder, with lifetime rates up to 26% and annual prevalence of 5-10% [5,6]. Subclinical depression is associated with substantial functional impairment, including poor work performance [3,7-9]. Further, subclinical depression is associated with a two- to five-fold increased risk of full-syndrome depressive disorders [10-13].

Based on data from 2010, depression-related costs in the United States exceeded US $210.5 billion, with employers incurring US $102 billion in losses due to presenteeism (US $78.7 billion), absenteeism (US $23.3 billion), and disability, and another US $98.9 billion incurred as direct medical costs [14]. Each year, US employers lose approximately 32 workdays per depressed employee to presenteeism [14]. Approximately 40% of direct medical costs are due to major depressive disorder, 10-11% are due to other depressive conditions, and roughly half of costs (48-51%) are due to comorbid physical or psychiatric conditions, such as pain and sleep disorders [14]. In addition, the economic costs of subclinical depression are considerable, approximately two-thirds the per capita costs of major depression [15-18].

Because most adults who suffer from depression never receive treatment [19], there is a need to develop interventions that can be more widely disseminated, such as through channels like employee assistance programs (EAPs) and directly to individuals who will not seek face-to-face care. Interventions that reduce the performance-impairing symptoms of subclinical depression and prevent the onset of major depression can improve employee well-being, while reducing health care costs and improving productivity [20]. EAPs offer services specifically designed to improve and/or maintain workplace productivity, including individual mental and behavioral health services offered to employees and family members experiencing personal difficulties, like depression. With wide reach into medium-to-large US employers and rapidly growing reach worldwide, EAPs offer a meaningful channel for delivering effective interventions as part of a larger population health management strategy.

Cognitive Behavioral Therapy for Depression

The Coping with Depression (CWD) cognitive behavioral therapy (CBT) skills-training program [21,22] is based on behavioral [23,24] as well as cognitive formulations of depression [25-27]. The CWD skills-training program combines cognitive and behavioral strategies aimed at ameliorating problems common to depressed individuals (eg, pessimism; internal, global, and stable attributions for failure; low self-esteem; low engagement in pleasant activities; poor social skills; anxiety and tension; low social support; and increased conflict) with a focus on awareness of specific and current actions and cognitions as targets for change. CWD-based interventions are based on the premise that activating a variety of coping skills and strategies allows depressed individuals to effectively address the diverse personal and environmental triggers that underlie their depressive symptoms.

The CWD approach has been validated for use with a variety of age, gender, and race/ethnic groups and using a variety of delivery methods, including as a guided self-help intervention [28]. Based on a meta-analysis of 18 CWD-based intervention studies, the approach has been associated with clinically significant effects ranging from d=0.28 to 0.62, depending on the outcome measure used [28]. In trials that targeted adults with subthreshold depression, CWD participants were 38% less likely to escalate to full-syndrome depression [28].

Positive Psychology Interventions for Depression

Cognitive and behavioral approaches to mood have evolved from a focus on treating disorders to including an emphasis on promoting positive emotion and experiences. Positive psychology interventions (PPIs), such as mindful self-awareness, gratitude expression, and identifying and utilizing strengths, have been shown to impact both well-being and depressive symptoms [29-31]. Mindfulness and acceptance are increasingly integrated in CBT approaches to depression self-management, drawing attention to both increasing positive cognitions and experiences, and accepting or releasing negative cognitions. Mindfulness-based interventions are particularly effective for managing stressors and enhancing positive emotions, resulting in psychological and social benefits and reducing depression symptoms [31-35]. PPIs that focus on building conscious awareness and expression of gratitude increase positive emotion and yield a wide variety of physical and affective benefits [31,36-38]. Identifying and using one's strengths has been shown to have robust emotional effects, and setting strength-based goals and plans has been shown to increase

optimism and reduce depression, with long-lasting effects [31,39-41].

Web and Mobile Delivery of Depression Interventions: Efficacy

Internet-delivered CBT-based programs for depression symptom management have been shown to be effective both for adults with major depressive disorder and those with elevated, but subthreshold, depression symptoms, although one recent review identified concerns with dropout and lack of long-term effects [42-45]. Traditional computer- and Internet-based CBT programs typically involve four to 12 lessons or modules delivered in sequence, either weekly or self-paced [43,46]. Effect sizes have been estimated at d=0.44-1.90 for clinician-supported, and d=0.21-0.70 for self-guided, interventions [42-45,47,48]. One review reports somewhat larger effects in studies targeting populations with clinically significant depression symptoms (d=0.42-0.65) than for populations with mild-to-moderate symptoms (d=0.30-0.53) [43].

To date, very few randomized clinical trials of mobile apps targeting depression have been published in the peer-reviewed literature [49]. We found only one such study specifically targeting adults with mild-to-moderate depression [50,51]. In this study, participants who used the CBT-based myCompass app, delivered via mobile phone and Internet, reported improvements in depression and anxiety at 7-week post-test compared to an attention control intervention and a waiting list condition. Treatment gains were maintained at 3-month follow-up, and improvements in the attention control condition matched those of the myCompass group [50].

The SuperBetter mobile Web app was evaluated in a three-arm randomized controlled trial, with results showing the original, "general" version of SuperBetter—with activities focused on self-esteem and social support—more effective at reducing depressive symptoms over both a combined SuperBetter-plus-CBT and positive psychology strategies condition and the waiting list condition. Ly et al [52] found no between-group effects between mobile-based behavioral activation and mindfulness apps for depression. Kauer et al [53] and Reid et al [54] found no differences in the Depression, Anxiety, and Stress Scale scores between a mobile app with ecological momentary assessment (EMA)-based emotional self-awareness training and feedback and an attention control condition. Watts et al [55] reported statistically significant large within-group effect sizes for depression symptoms in a nonrandomized study of their CBT-based Get Happy mobile app, which was derived from, and evaluated against, its Web-based predecessor, The Sadness Program. Burns et al [56] conducted a single-group pre/post pilot of Mobilyze!, a website with a mobile EMA component, finding large within-group effect sizes on depressive symptomatology.

The CWD-based Overcoming Depression on the Internet program provided early evidence that a Web-based program with reminders was effective in reducing depression symptoms, particularly among individuals with mild-to-moderate depression [57,58]. Spek et al [59] found similar improvements among individuals over 50 years old with subthreshold depressive symptoms from a CWD-based, self-administered Internet treatment program and those receiving CWD-based group therapy, both significantly greater than the improvement seen in waiting list controls. Treatment effects for the Internet-based group were maintained 1 year following treatment [60].

Web and Mobile Delivery of Depression Interventions: Access

Internet delivery of mental health interventions offers individuals with online technology broad access to evidence-based treatment. Mobile apps offer an additional channel to increase access further, both as self-guided tools and as those supported by counseling professionals, such as EAPs. Globally, use of mobile and broadband mobile services is rising, while fixed broadband service is slowing, especially in developing countries [61]. Worldwide penetration of broadband mobile services doubled between 2011 and 2014 to an estimated 32% (84% in developed countries and 21% in developing countries) [61]. In 2014, there were nearly 7 billion active mobile subscriptions worldwide, with 2.3 billion using broadband services [61]. In 2015, 64% of Americans owned a mobile phone and 19% used it for their only or primary access to the Internet [62]. Mobile phone-dependent Americans tend to be younger, nonwhite, and have low income and education [62]. Capitalizing on mobile Internet access as a delivery channel for evidence-based mental health interventions is critical.

Mobile interventions offer the potential for anytime, anywhere convenience and the ability to promote regular use of behavioral and cognitive self-management strategies known to impact mood. Consumers express high interest in, and willingness to use, mobile phones and short message service (SMS) text messaging to monitor and manage symptoms and cite essential considerations such as ease of use, privacy, and security [63-66]. Proven mobile apps can provide a tool for clinical professionals to use with help-seeking clients, while also increasing access and retention over in-person mental health services [67,68]. Unfortunately, although the consumer app stores offer over 200 depression-specific apps, judging the credibility and efficacy of those apps is difficult without clinical validation [69].

MoodHacker Mobile Intervention

The MoodHacker mobile intervention is one of few clinically validated CBT-based depression self-management mobile apps currently available. MoodHacker is designed to directly activate key cognitive and behavioral skills from the validated CWD program [21] and positive psychology strategies [70] (eg, mood and positive activity planning and tracking, cognitive restructuring, mindful self-awareness, gratitude expression, and identifying and utilizing strengths). In contrast to the more common lessons-based structure of many online and mobile CBT programs, MoodHacker is optimized for a brief daily interaction with the high-quality production value and mobile user experience common in consumer mobile apps.

Objectives

To demonstrate the efficacy of this light-touch, mobile, Web CBT-based experience, we compared MoodHacker as a fully self-guided intervention to an alternative-treatment control group that received an email with links to vetted online information about depression. It was hypothesized that MoodHacker users

would experience reduced depression symptoms and negative cognitions, and increased behavioral activation, knowledge of depression, and functioning in the workplace. This study of the MoodHacker intervention extends the evidence base for CBT-based mobile interventions for adults with mild-to-moderate depressive symptoms. Because the MoodHacker mobile Web app was designed primarily to target employees who present with depression through their EAP, the extent to which the program effects generalize to users with and without access to EAP support was an important research question.

Methods

Research Design

The efficacy of the MoodHacker mobile Web app intervention was assessed with a randomized controlled trial (ClinicalTrials.gov NCT02335554) with two factors: condition and EAP access (ie, subjects who had access to an EAP versus those who did not). See Multimedia Appendix 1 for the CONSORT-EHEALTH checklist for the trial [71]. There were three assessments: baseline, follow-up at 6 weeks after baseline, and follow-up at 10 weeks after baseline. After screening into the study, agreeing to the online informed consent, and submitting the baseline assessment, participants were blocked on race/ethnicity and randomized within block into either (1) treatment intervention group (n=150), which used the MoodHacker intervention for 6 weeks, or (2) alternative care group (n=150), which received links to six websites with information about depression. All study protocols, the consent process, and subject communications were reviewed and approved by the ORCAS Institutional Review Board (IRB) for protection of human subjects. There were no changes to the trial design after the trial commenced.

Participants

Inclusion criteria for participation were defined as follows: (1) 18 years or older, (2) mild-to-moderate depressive symptoms as measured by the Patient Health Questionnaire-9 (PHQ-9) (score of 10-19), (3) not currently suicidal or meeting criteria for bipolar or schizoaffective disorder, (4) employed at least part time, (5) English speaking, and (6) have access to a high-speed Internet connection. Eligibility was assessed using a two-stage screening protocol. In total, 3064 individuals completed an online screening survey, which included questions on demographics, technology access, and depression symptoms (using the Patient Health Questionnaire-2 [PHQ-2]), as well as brief screening for bipolar and schizoaffective disorders. Of those, 856 (27.94%) qualified for secondary telephonic screening to more fully assess their depression symptoms with the PHQ-9 and to confirm their assessments for bipolar and schizoaffective disorders. Of those 856 who qualified, 294 (34.3%) individuals failed to complete the secondary screening, 205 (23.9%) did not meet the PHQ-9 criteria, 44 (5.1%) endorsed suicidal ideation or showed symptoms of bipolar or schizoaffective disorder, and 13 (1.5%) were dropped due to suspicion of fraud (see below). A total of 300 individuals out of 856 (35.0%) from 37 US states completed the online baseline assessment and were randomly assigned to one of two conditions: treatment or alternative care. See Figure 1 for a CONSORT diagram describing study enrollment and allocation.

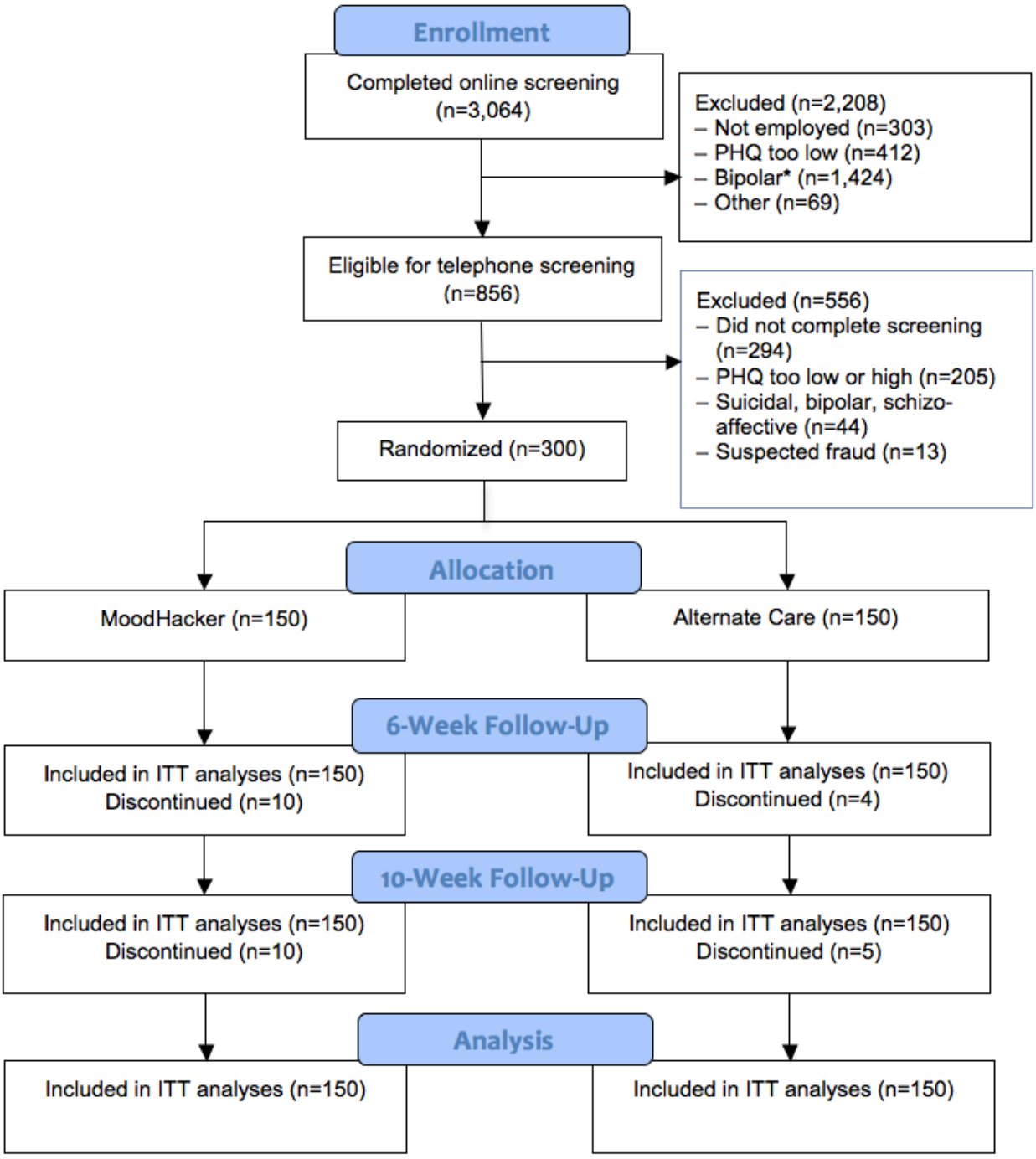
Study Setting and Data Collection

Participants were recruited from August 2012 through April 2013 in partnership with several organizations, including Chestnut Global Partners EAP as our primary recruitment partner. Non-EAP recruitment partners included Hope to Cope, Esperanza, Mental Health America, National Alliance on Mental Illness, LIVESTRONG, eHow, other eHealth websites, Chamber of Commerce offices, employee support organizations, and Craigslist. Outreach was conducted via the Chestnut EAP call center, print ads, online postings and ads, email listservs, and flyers. All interested potential participants were directed to an informational website that described the broad characteristics of the study's purpose, activities, and compensation, concluding with an online screening survey.

All subjects participated fully online from the location(s) of their choice, using their own Internet-capable computers and mobile devices. All self-report, online screening and assessment data were collected via encrypted websites. Upon prequalification based on the initial screening survey, research staff conducted telephone interviews with potential participants to determine eligibility per the inclusion criteria referenced above. Potential participants who reported current suicidal ideation and/or bipolar or schizoaffective disorder during screening were offered appropriate resources according to an IRB-approved crisis protocol and were excluded from the study. The number of participants who self-identified with bipolar disorder symptoms in the initial screening survey was elevated due to suspected fraudulent individuals attempting to qualify with severe symptoms.

Throughout the study, individuals who reported current suicidal ideation and/or severe depression symptoms (PHQ-9 > 19) were contacted by telephone and offered appropriate resources according to an IRB-approved crisis protocol. Calls were made to 114 individuals (50 treatment, 64 control) and all remained in the study. No subjects reported suicide risk severe enough to transfer to a suicide hotline. Nor did any subjects report any adverse events related to the use of the MoodHacker app via email or during follow-up calls. Although research assistants were aware of group assignment, all other interactions with subjects were delivered by emails that were standardized across groups and fully automated to avoid differential interactions by group assignment. All other research team members were blinded and, aside from crisis calls, no research team members had direct interaction with subjects after randomization.

Figure 1. CONSORT diagram for the MoodHacker randomized trial.



Lack of direct contact with study participants in a fully online study lends itself to potential participants self-reporting false information to qualify (eg, same name or IP address shows inconsistent age, gender, race, and/or ethnicity across multiple attempted screenings). To identify these individuals, demographic and contact data were cross-checked for fraudulent information against other individuals in the study database, as well as in our database of over 20,000 records of previous Internet study applicants. Those suspected of submitting fraudulent data were dropped from the study prior to randomization.

To enhance sample representativeness in each experimental condition, qualified participants were blocked on race/ethnicity and then randomly assigned within each race/ethnicity block to condition—treatment or alternative care—using the random number function in our subject database. Emails indicating group assignment and linking participants to the online informed consent form were auto-generated in the database and sent to participants by a research assistant. Upon completion of the consent form, they were immediately linked to the online baseline self-assessment. Participants also completed online follow-up self-assessments at 6 weeks and 10 weeks after baseline. Participants were compensated US $50 per completed assessment.

Study Conditions

Overview

After completing the baseline assessment, participants in the treatment condition were emailed a link to the MoodHacker mobile Web app and instructed to use the app for the next 6 weeks. Participants in the alternative care condition were sent an email with links to credible online resources about depression and instructed to review it on their own schedule for the next 6 weeks. Alternative care participants were offered use of the MoodHacker app upon completion of the 10-week assessment.

Treatment: MoodHacker App Intervention

The MoodHacker responsive mobile Web app was designed to educate users about depression and the benefits of CBT-based strategies to improve mood self-management and to activate (1) daily mood and activity monitoring, (2) increased engagement in positive behavioral activities, (3) decreased negative thinking and increased positive thinking, (4) increased practice of gratitude, mindfulness, and strength-based cognitions and behaviors, and (5) daily practice of these skills to improve depression symptoms and increase resilience to future mood disturbances.

The 6-week MoodHacker intervention is structured around the key learning and behavioral objectives above. Content was adapted from the CWD group therapy course [21], and enhanced with mindfulness-based [33] and other evidence-based positive psychology strategies [29,31,36]. Content is sequenced to follow the enhanced CWD approach and delivered through daily emails, in-app messaging, and in the *Articles & Videos* library. Daily emails (see Figure 2) are sent to engage users in program content, provide sequenced guidance through the learning objectives in the articles and whiteboard-style videos, give tips for getting the most out of MoodHacker, and prompt the user to track their mood and activities daily. Users are encouraged to view the articles and videos as ordered, but viewing is not restricted, and users can view content according to their interests. The emails, articles, and videos promote daily use of the featured cognitive and behavioral skills outside the app experience.

Users are encouraged to monitor their mood and positive cognitive and behavioral activities daily via mobile and/or desktop access to MoodHacker. The tracker shows daily (Figure 3), weekly (Figure 4), and monthly views to highlight progress over time and patterns between positive activities and mood ratings. A customizable list of positive activities is presented by domain and promotes the types of activities known to have the highest impact (ie, social, physical, and success). The tracker includes a journaling feature for users to note mood triggers, experiences with the suggested activities, or personal information about their day. A goal-setting feature allows the user to set a goal for the number of positive activities they want to accomplish each day.

Participants in the treatment arm accessed the password-protected MoodHacker app with unique usernames and passwords provided for the study. Although daily app use was recommended in the app content, participants were not required to achieve any app use milestones to advance through the app experience. Participants received no clinical support as part of the study.

Development of the MoodHacker app was undertaken by a multidisciplinary team of researchers and developers at ORCAS; input was incorporated from experts with extensive experience in CBT-based self-management interventions for adults with depression and the benefits of positive psychology. Additional program modifications were made based on data from individual interviews and iterative user testing with the population of interest during the formative and production phases of the project. The randomized trial was conducted with the first version of the MoodHacker app. No changes were made to the app during the study period.

Figure 2. Sample MoodHacker daily email.

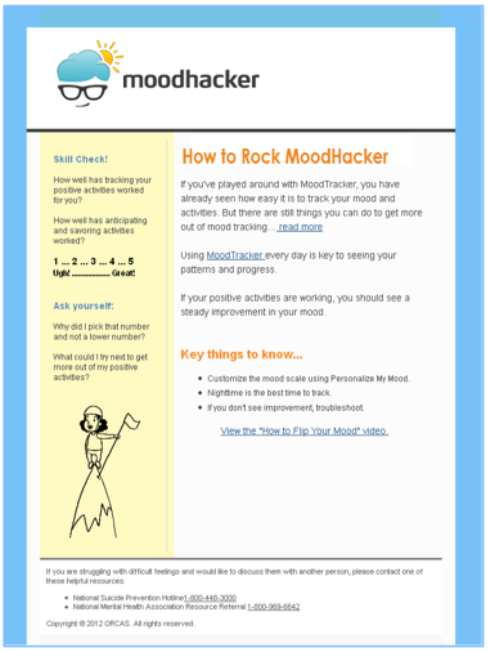
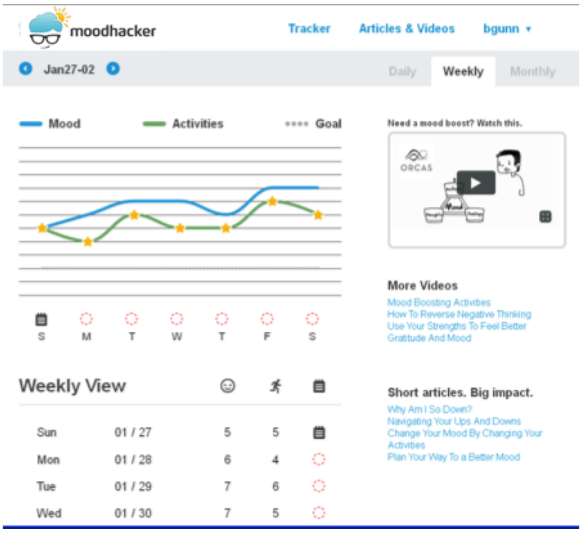


Figure 3. MoodHacker daily mood and activity tracking page.

Figure 4. MoodHacker weekly mood and activity graph page.



Alternative Care: Vetted Websites

Alternative care participants received an email with links to vetted online information about depression from Help Guide [72], the Mayo Clinic, Mental Health America [73], and the National Institute of Mental Health [74]; they were encouraged to browse these sites on their own schedule for 6 weeks. The educational links were emailed after the baseline assessment. Participants in the alternative care group were then given access to the MoodHacker program after the 10-week assessment.

Outcome Measures

Overview

Online surveys were used to assess the following: (1) depression symptoms, (2) behavioral activation, (3) negative cognitions, (4) worksite outcomes, (5) knowledge, and (6) user satisfaction and program usability. The primary outcome measure was depression symptoms, which was the target of the intervention. Secondary or exploratory measures included the following: (1) potential mediators (ie, behavioral activation, negative cognitions, and knowledge) and (2) potential worksite outcomes that may be influenced by improvement in worker depression. Participants completed self-report assessments at each of the assessment points: baseline, 6 weeks, and 10 weeks.

Demographics

Demographic data were collected during the screening process, including the following: (1) gender, (2) age, (3) race/ethnicity, (4) marital status, (5) highest completed education, (6) household income, and (7) employment status.

Depression Symptoms

Depressive symptomatology was assessed at each assessment point using the self-reported PHQ-9 (alpha = .71) [75] to assess the nine symptoms of major depression, based on the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV). The PHQ-9 has been shown to be a reliable and valid brief depression assessment tool [76]. Scores are summed, with higher scores indicating higher dysfunction.

Behavioral Activation

How actively individuals are taking care of themselves, including making positive life choices, was expected to increase as a result of the intervention. Behavioral activation was measured using the Behavioral Activation for Depression Scale

(BADS) Short Form [77,78]. This scale consists of nine items (alpha = .67). Items are summed, with lower scores indicating higher dysfunction.

Negative Thinking

Change in negative thinking was assessed using the Automatic Thoughts Questionnaire-Revised (ATQ-R) scale Short Form [79]. A 12-item adaptation of the ATQ-R instrument asked respondents to rate how many times over the past week they have had thoughts that are consistent with 12 negative self-statements (alpha = .92). Items are summed, with higher scores indicating higher dysfunction.

Knowledge

Participants were assessed for increase in knowledge about depression. The scale consisted of 14 multiple-choice items developed for this study based on the 12 learning objectives addressed in the MoodHacker articles and videos. Higher scores indicate higher knowledge. Test/retest reliability over a 6-week interval for this scale was .65.

Worksite Outcomes

Worker productivity was assessed using the Work Limitations Questionnaire (WLQ) (alpha = .87) [80-82]. The WLQ Short Form consists of eight items divided into four subscales measuring the degree to which a person was limited in their job's (1) time demands, (2) physical demands, (3) mental demands, and (4) output demands. Work productivity loss was calculated using methods outlined by Lerner and colleagues [83], with higher scores indicating greater loss in worker productivity.

Productivity loss due to work absence was assessed using the two-item WLQ Work Absence Module, which asks about the number of full days and part days missed in the last 2 weeks due to health problems or medical care [84]. The percentage of productivity lost due to absences is the ratio of total missed hours to total usual work hours in a 2-week time frame [85]. Higher scores indicate greater work loss due to absence from work.

Worksite outcomes were also assessed using the Workplace Outcome Suite (WOS) (alpha = .74-.88) [86]. This instrument is designed as an open-access instrument to facilitate empirical research on EAP interventions. The suite contains five scales, with five items each, that assess workplace distress, absenteeism, presenteeism, work engagement, and life satisfaction. Each scale is summed separately, with three scales—workplace distress, absenteeism, and presenteeism—indicating dysfunction, and two scales—work engagement and life satisfaction—indicating positive workplace outcomes.

User Satisfaction and Program Usability

At 6 weeks, treatment participants completed the System Usability Scale, which is a quantitative measure of program ease of use [87]. The scale includes 10 items, and users were asked to what degree they agreed or disagreed with program use and satisfaction statements on a 6-point scale from 1 (strongly disagree) to 6 (strongly agree). Items were scored using methods outlined by Bangor and colleagues [88], with a higher score indicating higher usability.

Statistical Analysis

Statistical power calculations for the analysis of covariance (ANCOVA) indicated that a sample size of 300 yielded sufficient power (>.80) to detect a condition effect of Cohen's d=0.34 or larger (moderately small effect size). A recent meta-analysis of Internet-based CBT interventions for depression [59] had found a mean effect size of d=0.32 for change in depressive symptoms and the mean effect size obtained in a randomized pilot study evaluating an abbreviated prototype of this app was d=1.05. Thus, this sample size provided adequate statistical power to detect the anticipated effects for the primary outcomes of interest.

Univariate effects of intervention condition, EAP access, and their interaction on outcome measures were examined using between-subjects ANCOVA, adjusting for pretest outcomes. These analyses were conducted to evaluate effects on outcome measures assessed at both 6-week and 10-week follow-up. If the condition by EAP access interaction was significant for an outcome measure, separate subpopulation ANCOVA analyses were conducted on that outcome measure for subjects with and without EAP access. We explored dose-response relationships and self-monitoring participation within the treatment group by correlating process indicants with change in outcome measures. All subjects were included in intent-to-treat (ITT) analyses at each follow-up. Prior to conducting these analyses, we employed the single imputation procedure available in SPSS, version 21.0 (IBM Corp) to account for missing data. Alpha was set to P<.05, two-tailed, for all tests.

Results

Baseline Equivalency and Attrition

The expectation of baseline equivalency due to random assignment of groups was examined. The treatment and alternative care groups were compared on demographic characteristics and outcome measures collected at pretest. Contingency table analyses and t tests were conducted on categorical and continuous measures, respectively. The groups did not significantly differ on any demographic characteristics or pretest outcome measures. See Table 1 for demographic descriptive data.

Table 1. Demographic characteristics by condition.

Demographic characteristics		Treatment (n=150)	Alternative care (n=150)
Age in years, mean (SD)		40.6 (11.5)	40.7 (11.2)
Number of children, mean (SD)		2.0 (1.2)	2.0 (1.2)
Ethnicity, n (%)			
	Hispanic/Latino	22 (14.6)	21 (14.0)
	Non-Hispanic/Latino	128 (85.3)	127 (84.7)
Race, n (%)			
	Asian	3 (2.0)	6 (4.0)
	Hawaiian	1 (0.7)	0 (0)
	African American	32 (21.3)	25 (16.7)
	Caucasian	102 (68.0)	105 (70.0)
	Mixed	9 (6.0)	9 (6.0)
Gender, n (%)			
	Female	112 (74.6)	118 (78.7)
	Male	37 (24.7)	32 (21.3)
Employment status, n (%)			
	Full time	84 (56.0)	92 (61.3)
	Part time	53 (35.3)	46 (30.7)
	Self-employed	13 (8.7)	12 (8.0)
Marital status, n (%)			
	Married/living with partner	78 (52.0)	72 (48.0)
	Divorced	22 (14.7)	23 (15.3)
	Widowed	3 (2.0)	2 (1.3)
	Separated	5 (3.3)	5 (3.3)
	Single	42 (28.0)	47 (31.3)
Education, n (%)			
	High school diploma or GED[a]	9 (6.0)	20 (13.3)
	Some college, associates, trade school, military	54 (36.0)	47 (31.3)
	College degree (ie, BA[b] or BS[c])	60 (40.0)	54 (36.0)
	Graduate school/professional training	27 (18.0)	28 (18.7)
Annual household income (US $), n (%)			
	$19,999 or less	21 (14.0)	22 (14.6)
	$20,000-$39,999	46 (30.7)	42 (28.0)
	$40,000-$59,999	25 (16.7)	29 (19.3)
	$60,000-$79,999	30 (20.0)	29 (19.3)
	$80,000-$99,999	12 (8.0)	14 (9.3)
	$100,000 or more	16 (10.7)	13 (8.7)
EAP [d] access, n (%)			
	Yes	46 (30.6)	45 (30.0)
	No	99 (66.0)	100 (66.7)

[a]GED: General Educational Development.

[b]BA: Bachelor of Arts.

[c]BS: Bachelor of Science.

[d]EAP: employee assistance program.

The extent to which attrition threatened the internal and external validity of the study was evaluated using contingency table analyses and analysis of variance (ANOVA). Participants who completed each of the follow-up assessments were compared to those who did not complete that follow-up with respect to demographic characteristics and pretest outcome measures. We also conducted analyses to test whether outcome variables were differentially affected across conditions by attrition. These latter analyses examined the effects of condition, attrition status, and their interaction on pretest outcomes. Examination of attrition between pretest and 6-week follow-up revealed only 10 out of 150 (6.7%) treatment participants did not complete the assessment compared to 4 out of 150 (2.7%) alternative care participants. Only 10 out of 150 (6.7%) treatment participants did not complete the 10-week follow-up assessment compared to 5 out of 150 (3.3%) alternative care participants. Attrition rates did not significantly differ by condition. Moreover, we found no statistically significant differences in demographic characteristics or baseline outcomes by attrition status, nor did we find any statistically significant interactions between attrition and condition predicting baseline outcomes, suggesting that attrition was not systematic.

Analyses compared baseline demographic data of subjects with EAP access versus those without EAP access. Subjects with EAP access had significantly more children (P=.003), consisted of fewer Hispanics (P=.01), were more likely to have full-time employment (P=.001), had a higher level of education (P=.047), and had a greater income (P=.001).

Intervention Effects

Table 2 provides ANCOVA results for all outcome measures at 6-week and 10-week follow-up. Multimedia Appendix 2 provides means and standard deviations for each outcome by assessment time and condition, along with pretest to 6-week follow-up and pretest to 10-week follow-up outcome analyses.

Primary Outcome: Depression Symptoms

From pretest to 6-week follow-up, the ANCOVA with the full sample found statistically significant program effects on depression symptoms (PHQ-9) (P=.01, partial eta^2 = .021). However, a statistically significant condition-by-user-EAP-access interaction effect was also obtained (P=.05, partial eta^2 = .013), indicating differential program effects depending upon subjects' access to an EAP. Separate subpopulation analyses indicated significant positive program effects for subjects with EAP access (P=.004, partial eta^2 = .093) and no program effects for subjects without EAP access (P=.66, partial eta^2 = .001). From pretest to 10-week follow-up, the condition-by-EAP-access interaction effect was not statistically significant (P=.21, partial eta^2 = .005), so subpopulation analyses were not indicated. The ANCOVA with the full sample found that there were no program effects (P=.17, partial eta^2 = .006) at 10-week follow-up.

Mediator Outcomes: Behavioral Activation, Negative Thoughts, and Knowledge

From pretest to 6-week follow-up, the ANCOVA with the full sample found statistically significant positive effects for the program on each mediator measure: BADS (P=.004, partial eta^2 = .027), ATQ-R (P=.01, partial eta^2 = .020), and knowledge (P=.02, partial eta^2 = .017). The condition-by-EAP-access interaction effects were not statistically significant on any of the mediator measures, indicating that there was no need for subpopulation analyses. From pretest to 10-week follow-up, the condition-by-EAP-access interaction effects were not statistically significant on any of the mediator measures. The ANCOVA with the full sample found statistically significant program effects on BADS (P=.01, partial eta^2 = .021), but not on ATQ-R (P=.34, partial eta^2 = .003) or knowledge (P=.55, partial eta^2 = .001).

Worksite Outcomes

From pretest to 6-week follow-up, the condition-by-EAP-access interaction effects were statistically significant on the WLQ productivity loss measure (P=.048, partial eta^2 = .016), the WLQ work absence measure (P=.048, partial eta^2 = .016), and the workplace distress measure (P=.03, partial eta^2 = .017). Consequently, subpopulation analyses were carried out for these measures only. The ANCOVA with the full sample at 6-week follow-up found statistically significant program effects on WLQ work absence (P=.003, partial eta^2 = .032). No statistically significant program effects were found on the following: WLQ productivity loss (P=.20, partial eta^2 = .007), WOS absenteeism (P=.16, partial eta^2 = .007), WOS presenteeism (P=.09, partial eta^2 = .010), WOS engagement (P=.75, partial eta^2 = .001), or WOS life satisfaction (P=.12, partial eta^2 = .008). However, separate subpopulation analyses at 6-week follow-up on the WLQ productivity loss measure indicated significant positive effects of the program for subjects with EAP access (P=.047, partial eta^2 = .052) and no program effects for subjects without EAP access (P=.60, partial eta^2 = .002). Similarly, subpopulation analyses at 6-week follow-up on the WLQ work absence measure indicated significant positive effects of the program for subjects with EAP access (P=.02, partial eta^2 = .070) and no program effects for subjects without (P=.51, partial eta^2 = .002). Lastly, the WOS workplace distress measure indicated significant positive effects of the program for subjects with EAP access (P=.007, partial eta^2 = .080) and no program effects for subjects without (P=.64, partial eta^2 = .001).

From pretest to 10-week follow-up, the condition-by-EAP-access interaction effects were statistically significant on the WLQ work absence measure (P=.04, partial eta^2 = .016). Consequently, subpopulation analyses were carried out for this measure only. The ANCOVA with the full sample

at 10-week follow-up found statistically significant program effects only on the WLQ work absence measure (*P*=.02, partial eta^2 = .022). Separate subpopulation analyses at 10-week follow-up on the WLQ work absence measure indicated significant positive effects of the program for subjects with EAP access (*P*=.03, partial eta^2 = .060) and no program effects for subjects without EAP access (*P*=.78, partial eta^2 = 0).

Program Utilization, Satisfaction, and Usability

On average, participants in the treatment arm logged into the MoodHacker app 16.0 times (SD 13.3, range 1-49) for a total duration of 1.3 hours (SD 1.3, range 0-6.5) between pretest and 6-week follow-up. The average rating of program satisfaction was 4.6 (SD 1.0) on a 6-point scale, indicating that the participants were mostly satisfied with the intervention. Participants also completed the System Usability Scale [87] at the 6-week follow-up, which provides a quantitative measure of program ease of use. The average System Usability Scale score was 79.7 (SD 17.1), corresponding to a usability grade of B+ for the intervention program.

Table 2. ANCOVA[a,b] results for all outcome measures at 6-week and 10-week follow-up.

Outcome measure/condition	Pretest to 6-week follow-up condition effect			Pretest to 10-week follow-up condition effect		
	F	*P*	Partial eta[2]	*F*	*P*	Partial eta[2]
Depression symptoms, PHQ-9 [c,d]						
All subjects (n=300)	6.20	*.01* [e]	*.021*	0.93	.34	.003
EAP[f] (n=91)	9.00	*.004*	*.093*	N/A[g]	N/A	N/A
Non-EAP (n=209)	0.20	.66	.001	N/A	N/A	N/A
Mediator outcomes						
BADS[h,i] (n=300)	8.26	*.004*	*.027*	6.39	*.01*	*.021*
ATQ-R[d,j] (n=300)	6.09	*.01*	*.020*	1.90	.17	.006
Knowledge[i] (n=300)	5.15	*.02*	*.017*	0.37	.55	.001
Worksite outcomes						
WLQ [k] productivity loss [d]						
All subjects (n=300)	1.66	.20	.007	1.02	.31	.004
EAP (n=91)	*4.09*	*.047*	*.052*	2.14	.15	.027
Non-EAP (n=209)	0.28	.60	.002	0.10	.76	.001
WLQ work absence [d]						
All subjects (n=300)	*8.69*	*.003*	*.032*	*5.92*	*.02*	*.022*
EAP (n=91)	*6.13*	*.02*	*.070*	*5.19*	*.03*	*.060*
Non-EAP (n=209)	0.44	.51	.002	0.08	.78	0
WOS [l] workplace distress [d]						
All subjects (n=300)	N/A	N/A	N/A	1.32	.25	.004
EAP (n=91)	7.63	*.007*	*.080*	N/A	N/A	N/A
Non-EAP (n=209)	0.22	.64	.001	N/A	N/A	N/A
WOS absenteeism[d] (n=300)	1.97	.16	.007	1.24	.27	.004
WOS presenteeism[d] (n=300)	2.92	.09	.010	1.40	.24	.005
WOS engagement[i] (n=300)	0.10	.75	.001	0.01	.99	.001
WOS life satisfaction[i] (n=300)	2.50	.12	.008	0.65	.42	.002

[a]ANCOVA: analysis of covariance.

[b]Intent-to-treat model: missing data were addressed via a single imputation procedure.

[c]PHQ-9: Patient Health Questionnaire-9.

[d]A higher score represents more dysfunction.

[e]Values in italics represent significant results, $P<.05$.

[f]EAP: employee assistance program.

[g]N/A: not applicable.

[h]BADS: Behavioral Activation for Depression Scale.

[i]A lower score represents more dysfunction.

[j]ATQ-R: Automatic Thoughts Questionnaire-Revised.

[k]WLQ: Work Limitations Questionnaire.

[l]WOS: Workplace Outcome Suite.

Discussion

Principal Findings

This randomized effectiveness trial examined the effect of the MoodHacker mobile Web app on depression symptoms, important cognitive and behavioral mediators, and workplace outcomes among employed adults with and without access to EAP services. The MoodHacker app produced significant effects from pretest to 6-week follow-up for all subjects compared to alternative care subjects on (1) the clinical outcome measure (ie, depression symptoms), with much stronger results among those with EAP access, (2) all three mediating outcome measures (ie, behavioral activation, negative thoughts, and depression knowledge), and (3) one of the worksite outcome measures (ie, work absence). Among subjects with EAP access, larger effects were found on depression symptoms, productivity loss, work absence, and workplace distress. Significant effects were maintained at 10-week follow-up for work absence for all subjects, with much stronger results among those with EAP access. The effect sizes on depression symptoms in this study (partial eta^2 = .021 for the full population and partial eta^2 = .093 for those with EAP access, which convert to approximately Cohen's *d*=0.30 and 0.64, respectively) are comparable to those reported for previous meta-analyses of self-guided, Internet-based CBT programs (Cohen's *d*=0.21-0.31) [42,44].

These findings suggest that the approach used to activate CBT-based skills in MoodHacker was effective and begin to build an evidence base for light-touch, CBT-based mobile apps for depression self-management. Because program effects were small-to-medium size, modifications to increase the potency of the intervention are warranted. Evidence from prior online CBT-based programs suggests that supporting the mobile intervention with counselors, such as those working in EAPs, is likely to increase both adherence to the app and efficacy in reducing depression symptoms [42,43,47,89].

At the 10-week assessment, only effects on work absence remained significant. Effects on depression symptoms were no longer significant, possibly because the daily emails ended after 6 weeks; the emails included prompts to view content, introduction of key concepts and skills, tips to optimize use of the program, and encouragement to track mood and activities. Although our results are consistent with a recent meta-analysis of computerized CBT programs showing that results of computer-based CBT programs typically attenuate over time [45], evidence from other studies suggests that app adherence and, thus, efficacy might be improved by extending program prompts and psychoeducational messaging beyond the original 6-week intervention period and/or providing mobile-friendly prompts (eg, text messages and app notifications) in addition to the emails utilized here [65,90]. More research is needed to determine the optimal level and type of program contact that is needed to retain program efficacy.

Employee Assistance Program Participants Versus Non-Employee Assistance Program Participants

The inclusion of subjects without access to EAP services provided an important opportunity to evaluate program efficacy with this population and to compare program efficacy for subjects with and without EAP access. It was expected that the subjects with access to EAP services who chose to participate in this study were likely to be quite similar to real-world individuals who might elect to use a mobile or online program in conjunction with those services. Thus, these subjects provided a "real-world" effectiveness trial. The effect sizes found on depression symptoms, work absence, and productivity loss among the targeted EAP population are quite encouraging and suggest that EAPs offering use of the MoodHacker app may reasonably expect to find significant depression-related improvements in their employee populations. Conclusions regarding program effects for non-EAP individuals are less clear.

In many cases, the subjects without EAP access were recruited without the endorsement of a trusted partner, most notably when recruitment was through entities such as eHow, Chambers of Commerce, eHealth websites, and especially Craigslist. This raises questions regarding the motivation of these subjects for participation. For example, participants who presented to their EAP with depression symptoms and were willing to use a behavior-change program might reasonably be expected to be motivated to change their depression. In contrast, participants recruited from the other entities listed above might have been more motivated by the financial compensation offered, rather than a desire to improve their depression symptoms. Further evidence of skewed motivations in this recruitment group is indicated in the very high numbers of individuals who were screened out by reporting much higher than expected rates of mania, and to a lesser extent, depressive symptoms during the online screening.

Analyses of baseline data indicated that the non-EAP subjects had lower incomes, were less likely to be fully employed, and had less education. Since these three factors are also related to poorer outcomes in depression, these factors may at least partially explain why the program was not as effective for individuals with no EAP access [91,92]. While the veracity of such attributions regarding motivation for participation is difficult to ascertain, the lack of program effects on depression symptoms in the non-EAP participants is consistent with this notion.

Study Limitations

We acknowledge several limitations in this initial efficacy trial and offer some caution in interpreting the findings. First, although random assignment was used, all the participants volunteered for the study and thus represent a convenience sample of interested individuals and cannot be considered representative of the general population. Second, participants completed self-report surveys, the validity and reliability of which may be somewhat suspect. Third, the reliability of some measures is only moderate and this may have attenuated the effect size of the intervention effects found in the study. Fourth, while the attrition rates in the study were relatively low, subjects were compensated for completing assessments. Thus, it cannot be concluded that the subject completion rate found here would occur at the same rate without compensation for participation. Lastly, attenuation of outcomes at 10-week follow-up suggests

a need for more potent activation of CBT-based skills or a need for extended app contacts to drive continued engagement. Future research will explore the frequency and type of app contacts to optimize extended engagement and improve both short- and long-term efficacy of this light-touch, mobile approach to activating use of CBT skills to self-manage depressive symptomatology.

Summary

Given the high prevalence of depression and the fact that most adults with depression never receive treatment, there is a critical need for effective interventions that can be widely and cost-effectively disseminated through multiple delivery channels. The MoodHacker mobile Web app has demonstrated potential for dissemination (1) as a self-guided intervention for individuals unwilling or unable to seek in-person depression services and (2) through EAP and similar health and wellness organizations supporting employed adults and their families. Ideally, exposure to MoodHacker needs to be extended beyond the 6-week time frame to maintain user engagement and improve longer-term efficacy. Further, the implementation and integration of MoodHacker within EAPs and similar organizations that can provide guidance from counselors seems likely to augment the effectiveness of the MoodHacker app.

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Conflicts of Interest

Amelia Birney was the study Principal Investigator. She is employed as a Behavioral Scientist at ORCAS, a health innovation and technology company that creates self-management programs to improve physical and emotional well-being. Software development was funded with a Small Business Innovation Research grant, which was designed to stimulate research and product development. Thus, improved versions of MoodHacker are being marketed. Ms Gunn and Mr Russell are no longer employed by ORCAS; they will derive no financial benefit from sales of the MoodHacker app or from publication of this research. Ms Birney and Dr Ary remain employees of ORCAS with some potential for financial benefit from sales of the MoodHacker app.

Multimedia Appendix 1

CONSORT-EHEALTH checklist V1.6.1 [71].

[PDF File (Adobe PDF File), 968KB - mhealth_v4i1e8_app1.pdf]

Multimedia Appendix 2

Pretest, 6-week follow-up, and 10-week follow-up descriptive statistics and ANCOVA results for all outcome measures.

[PDF File (Adobe PDF File), 126KB - mhealth_v4i1e8_app2.pdf]

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Abbreviations

ANCOVA: analysis of covariance
ANOVA: analysis of variance
ATQ-R: Automatic Thoughts Questionnaire-Revised
BA: Bachelor of Arts
BADS: Behavioral Activation for Depression Scale
BS: Bachelor of Science
CBT: cognitive behavioral therapy
CWD: Coping with Depression
DSM-IV: Diagnostic and Statistical Manual of Mental Disorders, 4th edition
EAP: employee assistance program
EMA: ecological momentary assessment
GED: General Educational Development
IRB: Institutional Review Board
ITT: intent to treat
N/A: not applicable
PHQ-2: Patient Health Questionnaire-2
PHQ-9: Patient Health Questionnaire-9
SMS: short message service
WLQ: Work Limitations Questionnaire

WOS: Workplace Outcome Suite

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Original Paper

Uptake of a Consumer-Focused mHealth Application for the Assessment and Prevention of Heart Disease: The <30 Days Study

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Abstract

Background: Lifestyle behavior modification can reduce the risk of cardiovascular disease, one of the leading causes of death worldwide, by up to 80%. We hypothesized that a dynamic risk assessment and behavior change tool delivered as a mobile app, hosted by a reputable nonprofit organization, would promote uptake among community members. We also predicted that the uptake would be influenced by incentives offered for downloading the mobile app.

Objective: The primary objective of our study was to evaluate the engagement levels of participants using the novel risk management app. The secondary aim was to assess the effect of incentives on the overall uptake and usage behaviors.

Methods: We publicly launched the app through the iTunes App Store and collected usage data over 5 months. Aggregate information included population-level data on download rates, use, risk factors, and user demographics. We used descriptive statistics to identify usage patterns, *t* tests, and analysis of variance to compare group means. Correlation and regression analyses determined the relationship between usage and demographic variables.

Results: We captured detailed mobile usage data from 69,952 users over a 5-month period, of whom 23,727 (33.92%) were registered during a 1-month AIR MILES promotion. Of those who completed the risk assessment, 73.92% (42,380/57,330) were female, and 59.38% (34,042/57,330) were <30 years old. While the older demographic had significantly lower uptake than the younger demographic, with only 8.97% of users aged ≥51 years old downloading the app, the older demographic completed more challenges than their younger counterparts ($F_{8, 52,422}$ = 55.10, P<.001). In terms of engagement levels, 84.94% (44,537/52,431) of users completed 1–14 challenges over a 30-day period, and 10.03% (5,259/52,431) of users completed >22 challenges. On average, users in the incentives group completed slightly more challenges during the first 30 days of the intervention (mean 7.9, SD 0.13) than those in the nonincentives group (mean 6.1, SD 0.06, t_{28870}=–12.293, P<.001, d=0.12, 95% CI –2.02 to –1.47). The regression analysis suggested that sex, age group, ethnicity, having 5 of the risk factors (all but alcohol), incentives, and the number of family histories were predictors of the number of challenges completed by a user ($F_{14, 56,538}$ = 86.644, P<.001, adjusted R^2 = .021).

Conclusion: While the younger population downloaded the app the most, the older population demonstrated greater sustained engagement. Behavior change apps have the potential to reach a targeted population previously thought to be uninterested in or unable to use mobile apps. The development of such apps should assume that older adults will in fact engage if the behavior

change elements are suitably designed, integrated into daily routines, and tailored. Incentives may be the stepping-stone that is needed to guide the general population toward preventative tools and promote sustained behavior change.

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KEYWORDS

health behavior; lifestyle; cardiovascular disease; prevention; risk reduction; mobile apps; mobile phone; incentives

Introduction

Heart disease and stroke remain the leading causes of death and disability worldwide, and are responsible for almost 30% of all deaths [1]. The majority of the world's adult population has at least one modifiable risk factor for cardiovascular disease (CVD), such as obesity, hypertension, physical inactivity, poor nutrition, and tobacco or alcohol consumption [2]. As with many chronic diseases, modifiable risk factors can be prevented by (1) identifying unhealthy lifestyle behaviors and (2) providing education and support to guide individuals toward behavior change and subsequent lifestyle modification [3,4].

Although health risk assessments have been an effective approach for health promotion and risk projection, the increased awareness of risk does not necessarily translate into behavior change [4,5]. Existing paper and Internet-based assessments are one-dimensional and do not provide patients with the tools and education required to actively work toward reducing their cardiovascular risk on a day-to-day basis [6]. For example, Heart Aware [3], an Internet-based cardiac risk assessment deployed to 373,085 users, provided an overview of risk based on the information that users entered. However, it did not provide continued guidance or actionable knowledge to enable individuals to work toward reducing their risk [3].

While many workplace wellness programs do offer tools with components of self-education and counseling that target and effectively reduce chronic diseases, they are not scalable to larger community-based populations [7]. These programs are typically adopted by large organizations that have the resources and infrastructure needed to successfully implement and maintain such programs. They do not focus on developing capacity among community members, which is necessary to support, implement, and sustain an effective preventive program [8].

Engaging individuals in risk factor identification and modification is crucial for preventing CVD. However, given the high prevalence of CVD, it is clear that current primary preventive actions are suboptimal [9]. Technology, such as mobile phones, can enable people to gain access to health promotion resources and peers within their community [10]. The increasing market penetration of mobile phones presents a unique opportunity not only to deliver evidence-based dynamic health risk assessments, but also to promote lifestyle modification interventions [10].

With this premise, we hypothesized that a dynamic risk assessment delivered as a mobile phone app, hosted by a reputable public nonprofit organization, would promote uptake among community members. The Heart and Stroke Foundation of Canada commissioned the development and public deployment of <30 Days, a mobile CVD risk assessment and management app. We hypothesized that the uptake would be influenced by the incentives offered for downloading the mobile app. We collected usage data at a population level to provide insight on uptake and engagement levels.

The goal of our study was to assess levels of engagement in terms of number of challenges completed and duration of use, and to compare usage and uptake between the incentives group and the nonincentives group. We anticipated that the users from the incentives group would be initially attracted to the app but would subsequently have lower levels of engagement than the nonincentives group.

Methods

The Heart and Stroke Foundation of Canada launched the app on the iTunes App Store (Apple, Inc, Cupertino, CA, USA) and collected population-level usage data over 5 months. We obtained consent to analyze de-identified usage data for research purposes from users in the form of an in-app mobile agreement. Aggregate data included information on download rates, usage, feedback, and demographics of users around the globe.

Mobile App Overview

The aim of the <30 Days app was to empower users to easily and effectively manage their heart health on a daily basis. Principles of user-centered design guided the conceptualization of the app, where feedback from end users informed the concept and key features [11]. In addition to the requirements gathered from users, we used constructs from the theory of planned behavior to guide the overall structure and motivations of the app [12]. The resulting app was available for download in Canada, free of charge, on the iTunes App Store. On downloading the app, users had the option either to complete the risk assessment right away or to temporarily skip the risk assessment and preview the app content. Users who opted to browse the app first were only offered 3 sample challenges before they were required to complete the risk assessment in order to continue using the app.

On completing the risk assessment (see Figure 1 and Multimedia Appendix 1), users were presented with a list of their modifiable risk factors, which they could prioritize (first, second, and third) according to what they wanted to work on over the course of 30 days. The mobile app suggested simple daily activities based on identified risk factors, provided resources and encouragement, and tailored content to individuals' risk profiles. When users were presented with a challenge, they had the option to *skip* the challenge and browse for more options or to *accept* the challenge. If they accepted the challenge, on the following day they would be asked whether they had completed the

challenge, at which point they could proceed to select their next challenge.

To promote the completion of at least one heart health challenge per day, the app included an achievements system in the form of badges and a progress review module that was presented every 7 days. The Heart and Stroke Foundation also launched an incentive promotion for 1 month, where users were rewarded with AIR MILES points (AIR MILES Reward Program, LoyaltyOne, Co, Toronto, ON, Canada) for downloading the app. Previous studies have indicated that positive feedback in the form of a rewards system can motivate users to participate in self-management behaviors and improve health outcomes [13-15].

Figure 1. Components of the <30 Day mobile app for dynamic risk assessment for heart and disease and stroke. Left: users can either commit to the challenge or choose another one. Middle: users can review their risk factors and progress. Right: playful badges highlight various accomplishments throughout the <30 Day challenge.

Data Collection

The primary data source for this evaluation was anonymized usage data collected over 5 consecutive months. The data set consisted of responses to the health risk assessment and subsequent app usage, based on a unique installation of the app. Given that the risk assessment required demographic and anthropometric data, it was possible to evaluate app usage based on demographic and at-risk subgroups. Feedback from users was received through both the iTunes App Store and the technical support emails. Consent was acquired from all users through the mobile license agreement presented in the app on first use. The user group for this evaluation included all those who downloaded and used the app within the study time limits.

Data Analysis

We created output files for data processing using Structured Query Language queries to the <30 Days app database. LabVIEW (National Instruments) was used to further process the data into a format acceptable by SPSS (IBM Corporation). We then ported the resulting data file into SPSS for statistical analysis.

Descriptive statistics helped identify usage patterns and the effectiveness of key features of the app. Independent *t* tests and chi-square statistics determined differences between groups, such as male and female groups, and incentives and nonincentives groups. We conducted between-subjects analysis of variance to analyze differences between age groups and engagements levels. A Pearson correlation analysis was conducted to assess the relationship between factors identified in the risk assessment and engagement levels. A multiple regression analysis on the number of challenges completed by the users was conducted to better understand the effect of the numerous independent variables on the uptake of the app and engagement levels.

Lastly, a thematic analysis was conducted on the comments received from users, where comments were compiled, organized, and assessed for recurrent themes. We derived major themes pertaining to the usability and utility of the app as critical feedback for improving the future versions of the app.

Results

Of the 74,396 users who downloaded the app during the study period, 4,444 users installed the app but never launched it. Of the 69,952 users who downloaded and launched the app, 23,727 (33.92%) users registered during the AIR MILES promotion

period, with 3,957 (5.66%) users who opened the app but did not complete the risk assessment. Altogether, 12,622 users never created a profile and consequently never completed the risk assessment. As Figure 2 shows, the final data set used for this analysis consisted of the data obtained from 57,330 users.

The AIR MILES incentive attracted 41.36% (6,184/14,950) of the total male users and 32.06% (13,586/42,380) of the total female users who downloaded the app and created a profile (n=57,330, χ^2_1= 423.7, *P*<.001, φ_{Cramer} = .086). The incentive engaged primarily users who were 31–70 years of years of age (χ^2_8 = 586.1, *P*<.001, φ_{Cramer} = .101). On average, users in the incentives group completed slightly more challenges during the first 30 days of the intervention (mean 7.9, SD 0.13) than those in the nonincentives group (mean 6.1, SD 0.06, t_{28870} = –12.293, *P*<.001, *d*=0.12, 95% CI –2.02 to –1.47). Additional data showed that during the promotion period, the overall number of downloads per day increased from 326 to 1186.

Demographic Characteristics

As Table 1 shows, most users were female (42,380/57,330, 73.92%), between the ages of 21 and 30 years (19,200/57,330, 33.49%), and white (39,700/57,330, 69.25%). The uptake from the younger demographic was significantly higher than that from the older demographic, with only 8.75% (5018/57,330) of users aged ≥51 years downloading the app compared with 59.38% (34,042/57,330) of users aged 21 to 30 years. The average body mass index (BMI) was 28.0 (SD 5.2) for male and 26.9 (SD 6.5) for female users, classifying the majority of users as overweight (BMI 25–30 kg/m^2).

Figure 2. Number of users who downloaded and launched the <30 Days app and completed the risk assessment.

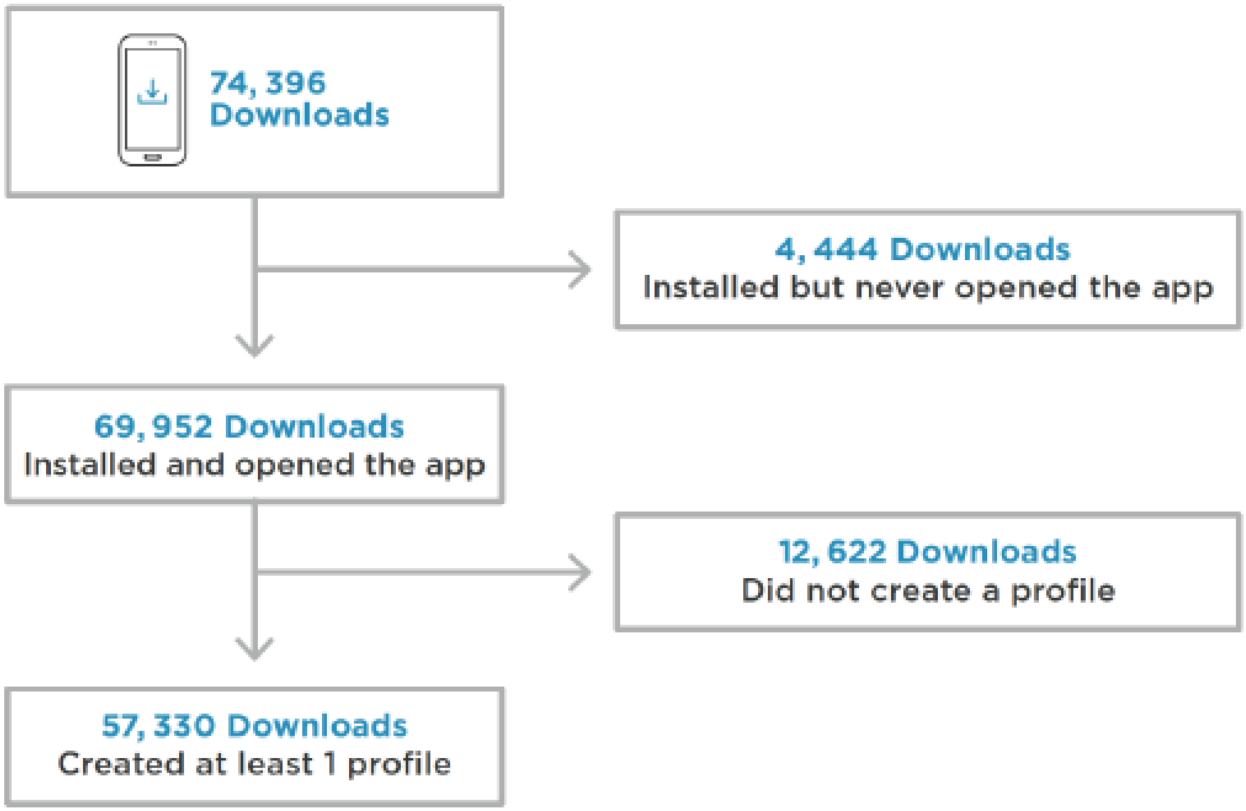


Table 1. Demographics of users who completed the <30 Days health risk assessment app (n=57,330).

Characteristic	n (%)
Sex	
Male	14,950 (26.08)
Female	42,380 (73.92)
Age group (years)	
≤20	14,842 (25.89)
21–30	19,200 (33.49)
31–40	11,464 (20.00)
41–50	6782 (11.83)
51–60	3777 (6.59)
61–70	1125 (1.96)
71–80	116 (0.2)
81–90	13 (0)
≥91+	11 (0)
Ethnicity/race	
White	39,700 (69.25)
Latin American	2374 (4.14)
Chinese	2091 (3.65)
South Asian	2057 (3.59)
African heritage	1928 (3.36)
Other	9180 (16.01)

Modifiable Risk Factors

The most prevalent risk factor was poor nutrition (49,711/57,330, 86.71%), followed by lack of exercise (29,776/57,330, 51.94%), stress (28,592/57,330, 49.87%), excessive salt intake (17,333/57,330, 30.23%), tobacco use (8499/57,330, 14.82%), and excessive alcohol use (5950/57,330, 10.38%). On average, women had slightly more risk factors (mean 2.5, SD 0.01) compared with men (mean 2.3, SD 0.01; $t_{26,446}$= –12.648, d=0.11, P<.001, 95% CI –0.16 to –0.12). Analysis of variance showed a relatively small but statistically significant difference in risk factors between age groups ($F_{8,57}$ 321 = 142.55, P<.001, η^2 = 0.02). More precisely, users in the 21–30 (mean 2.6, SD 0.01) and 31–40 (mean 2.5, SD 0.01) year age groups had a higher mean number of risk factors than those in the 61–70 (mean 1.8, SD 0.3) and 71–80 (mean 1.4, SD 0.9) year age groups.

Health Conditions and Nutritional Habits

The risk assessment asked users to identify health conditions they might have had or health conditions of which they had a family history. Overall, 44.50% (25,511/57,330) of users reported having at least one of the listed conditions (depression, diabetes, heart disease, stroke, high blood pressure, high cholesterol, renal disease, and sleep apnea), and 31.12% (17,839/57,330) of users reported having depression or anxiety, as Table 2 shows. A large proportion of users (39,793/57,330, 69.41%) reported having a family history of diabetes or high blood sugar, heart disease, high blood pressure, high cholesterol, or stroke.

In terms of nutritional habits, the following percentage of users reported eating these foods 3 or more times a week: 45.34% (25,996/57,330) ate high-fat foods, 30.56% (17,520/57,330) ate fast food, 24.24% (13,898/57,330) ate foods rich in omega-3 polyunsaturated fatty acids, 42.37% (24,263/57,330) ate 5 or more servings of fruits and vegetables per day, and 17.95% (10,291/57,330) ate none of these.

Engagement Levels

We selected a subsample of all users (52,431/74,396) who downloaded and opened the app, created a profile, and had at least 30 days to use the app for this part of the evaluation to ensure that all users had an opportunity to complete the challenges. As Table 3 shows, 84.94% (44,537/52,431) of users had very low and low levels of engagement, and 10.03% (5259/52,431) of users had high levels of engagement. The categorization and range of engagement levels were defined a priori by the Heart and Stroke Foundation, where a categorization of very low describes those who completed a profile but did not complete any challenges, and low, moderate, and high describe those who completed 1–14, 15–21, and ≥22 challenges, respectively.

Table 2. Health conditions identified by users who completed the <30 Days health risk assessment app (n=57,330).

Questions posed to users	Positive response, n (%)
Do you have any of the following conditions?	
Depression or anxiety	17,839 (31.12)
Diabetes or high blood sugar	1978 (3.45)
History of heart disease	1736 (3.03)
History of stroke	746 (1.3)
High blood pressure	5564 (9.71)
High cholesterol or triglycerides	4847 (8.45)
Renal disease	209 (0.4)
Sleep apnea	3611 (6.30)
None of the above	31,819 (55.50)
Do you have a family history of any of the following?	
Diabetes or high blood sugar	24,309 (42.40)
Heart disease	15,916 (27.76)
High blood pressure	25,204 (43.96)
High cholesterol or triglycerides	16,678 (29.09)
Stroke	10,806 (18.85)
None of the above	17,537 (30.59)

Table 3. User engagement levels measured by the number of completed challenges in the first 30 days of using the <30 Days health risk assessment app (n=52,431).

Engagement level (challenges completed)	n (%)
Very low (0)	14,546 (27.74)
Low (1–14)	29,991 (57.20)
Moderate (15–21)	2635 (5.03)
High (≥22)	5259 (10.03)

We measured engagement by looking at the number of challenges each user completed in the first 30 days, according to the distribution presented on Table 3. One-sample *t* test indicated that engagement levels among female users (mean 7.10, SD 0.07, n=38,494) was slightly higher than those among male users (mean 6.73, SD 0.15, n=13,937; $t_{52,429} = –2.509$, P=.01, d=0.02, 95% CI –0.648 to –0.08). Analysis of variance showed a small, statistically significant effect of age on engagement levels ($F_{8, 52,422} = 55.10$, P<.001, $\eta^2 = 0.008$), with older participants (>51 years of age) completing more challenges than younger participants (Table 4). The frequency of the virtual rewards (badges) offered to users through the app was also captured. Figure 3 illustrates that a higher percentage of individuals aged 50–70 years achieved rewards for consecutive use of the app over 7 days (Warming Up badge) and completing the 30- day (30 Day badge challenge).

As Table 5 shows, those who reported having health conditions, such as diabetes, heart disease, stroke, high blood pressure, and high cholesterol, completed more challenges. A correlation analysis revealed a positive but weak correlation between the number of challenges completed and the number of personal conditions (r=.025, P<.001) and the number family history conditions (r=.041, P<.001) reported.

We evaluated the effects of several potential predictors on the number of challenges through multiple regression analysis. Due to the large dataset, we tested the model against 14 predictors: sex, age group, ethnicity, height, weight, all 6 risk factors, incentive and nonincentive information, number of conditions, and number of family histories. The assumptions of independence of errors, linearity, unusual points and normality of residuals, and homoscedasticity were met. Of the predictors used in the regression, only sex, age group, ethnicity, 5 of the risk factors (all but alcohol), the presence of incentives, and the number of family histories predicted the number of challenges that the user completed ($F_{14, 56,538} = 86.644$, P<.001, adjusted $R^2 = .021$). Table 6 shows the regression coefficients and standard errors for each of the predictors.

Table 4. Number of challenges in the <30 Days health risk assessment app completed by age group (n=52,431).

Age group (years)	Number of challenges completed in first 30 days		n (%)
	Mean	SD	
≤20	5.44	11.08	13,291 (25.35)
21–30	6.47	12.23	17,571 (33.51)
31–40	7.67	18.11	10,604 (20.22)
41–50	8.59	16.71	6297 (12.01)
51–60	9.78	19.96	3485 (6.65)
61–70	9.74	16.10	1050 (2.00)
71–80	9.89	15.69	110 (0.2)
81–90	10.08	16.09	13 (0)
≥91	19.80	36.59	10 (0)

Table 5. Number of challenges that users completed based on whether they identified as having a personal or family history of various health conditions in the <30 Days health risk assessment app.

Health condition	Had condition			Did not have condition			$t_{52,429}$ value	Cohen *d*	*P* value
	No.	Mean	SD	No.	Mean	SD			
Personal									
Depression	16,112	6.97	15.59	36,319	7.01	14.25	0.25	–0.003	.80
Diabetes	1795	7.87	14.32	50,636	6.97	14.69	–2.56	0.60	.05
History of heart disease	1581	8.60	19.47	50,850	6.95	14.50	–4.42	0.11	<.001
History of stroke	688	9.27	21.33	51,743	6.97	14. 56	–4.10	0.15	<.001
High blood pressure	5079	7.93	14.24	47,362	6.90	14.72	–4.76	0.70	<.001
High cholesterol	4429	8.24	22.19	48,002	6.88	13.77	–5.87	0.09	<.001
Renal disease	191	7.95	14.63	52,240	7.00	14.68	–0.90	0.06	.37
Sleep apnea	3254	7.40	14.78	49,177	6.97	14.67	–1.61	0.03	.11
Family history									
Diabetes	22,177	7.25	16.05	30,254	6.81	13.58	–3.69	0.03	.01
Heart disease	14,533	7.83	17.57	37,898	6.68	13.39	–6.24	0.11	<.001
Stroke	9874	7.83	16.19	42,557	6.81	14.293	–4.096	0.15	<.001
High blood pressure	23,063	7.43	15.52	29,368	6.66	13.97	–5.94	0.05	<.001
High cholesterol	15,233	7.69	17.69	37,198	6.71	13.24	–6.939	0.07	<.001

Table 6. Summary of the multiple regression analysis of predictors of how many challenges would be completed by users of the <30 Days health risk assessment app.

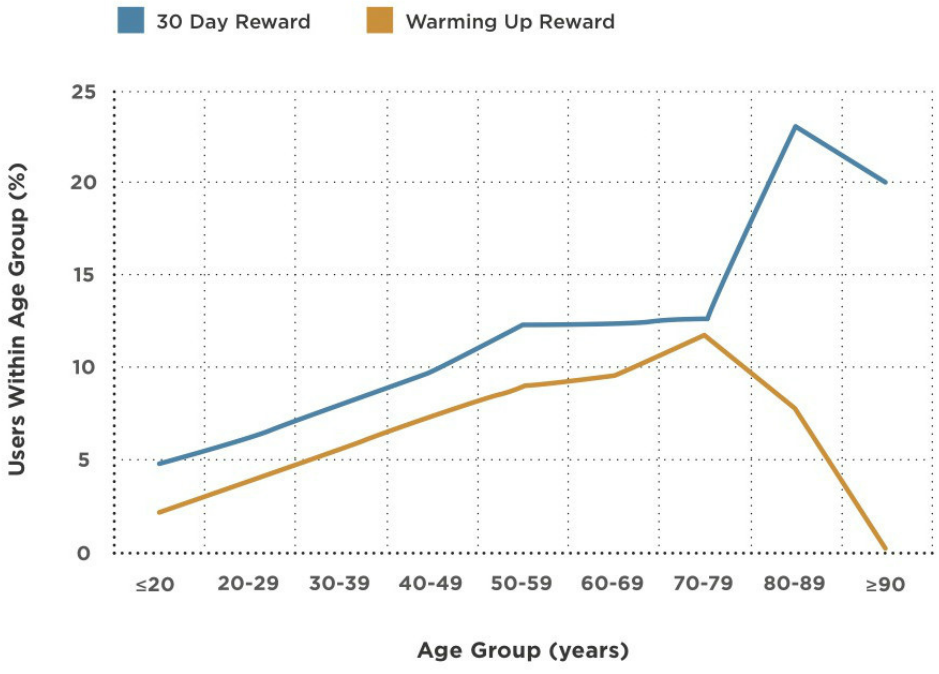
Variable	B[a]	SE_B[b]	Beta	*P* value
Intercept	2.741	0.855		<.001
Sex	1.064	0.154	0.033	<.001
Age group	0.911	0.051	0.083	<.001
Ethnicity	–0.074	0.021	–0.015	<.001
Height	0.006	0.004	0.007	.16
Weight	0.002	0.002	0.005	.37
Risk factor				
Alcohol	0.233	0.199	0.005	.24
Smoking	–0.761	0.171	–0.019	<.001
Stress	0.641	0.126	0.022	<.001
Exercise	–2.015	0.123	–0.071	<.001
Salt intake	–1.174	0.132	–0.038	<.001
Nutrition	–1.071	0.189	–0.025	<.001
Incentive (AIR MILES)	1.573	0.126	0.052	<.001
Number of conditions	–0.007	0.075	0	.93
Number of family histories	0.315	0.043	0.033	<.001

[a]B: unstandardized regression coefficient.

[b]SE_B: standard error of the coefficient.

[c]Beta: standardized coefficient.

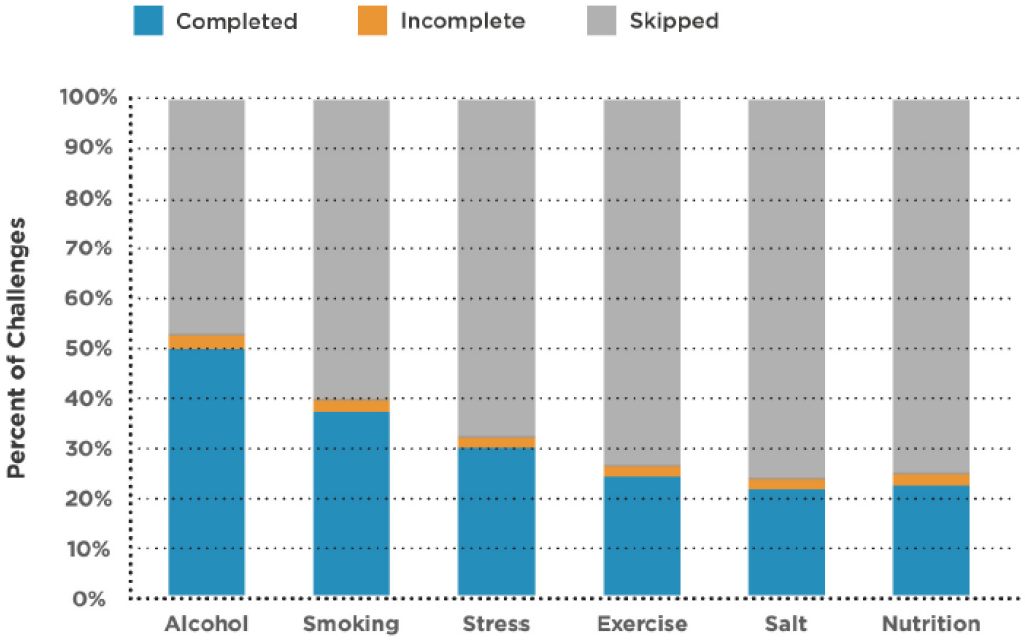
Figure 3. Rewards achieved in the <30 Days health risk assessment app by users per age group. This graph shows the distribution of users (n=52,431) who completed the health risk assessment and were part of the engagement subset.



Analysis of Challenges

When presented with a daily challenge, users have the option either to *skip* or to *accept* the challenge, and then later mark it as *complete* or *incomplete* the following day. Though 92.99% (464,097/499,078) of the *accepted* challenges were completed, a large majority (1,183,013/1,682,091, 70.33%) of the challenges presented to the users for selection were skipped.Figure 4 provides a breakdown of the completion rates per risk factor. Although nutrition was the most prevalent risk factor, the challenges from this category had the highest skip rate (546,850/731,010, 74.81%), with only 8.82% (64,475/731,010) of challenges completed. In contrast, 50.39% (59,460/118,006) of the alcohol challenges were completed, with 46.95% (55,400/118,006) of them skipped.

Figure 4. Challenge completion rates by risk factor by users of the <30 Days health risk assessment app.



User Feedback

Over the study duration, we received 37 user comments, with 24 comments submitted through the iTunes store and 13 comments through the technical support email. Many users (n=17) stated that the daily tips were a good way of incorporating attainable healthy changes into their daily routines and facilitating heart disease prevention. Another subset (n=5) mentioned that the challenges were not applicable to them because the challenges were more focused on urban lifestyles than on the rural setting.

Discussion

Our analysis of the <30 Days usage data provided several insights into the uptake and effectiveness of a consumer-friendly mobile app for the engagement of populations in the management of cardiovascular risk. The majority of users were female and from the younger demographic (21-30 years old) group. However, the older user groups demonstrated higher levels of engagement and completed more challenges. We anticipated that the demographic would skew toward younger adults, who are characteristic of the population who own mobile phones and download mobile apps [16,17].

However, the finding that the level of engagement increased with age was unique. The Pew Research Centre's November 2011 survey showed that younger users not only downloaded more apps but also tended to be 50% more likely than users aged ≥50 years to use the apps [16]. In this case, we can infer that the older user groups were more committed to their health goals and were potentially more willing to participate in daily self-management activities.

The multiple regression analysis suggested that sex, age group, ethnicity, having 5 of the risk factors (all but alcohol), the presence of incentives, and the number of family histories are predictors of the number of challenges completed by a user ($F_{14, 56,538}$= 86.644, P<.001, adjusted R^2 = .021). The analysis also demonstrated that these variables explain only 2% of the variation in the number of challenges completed. The social phenomena around the use of apps for lifestyle modification are complex and multidimensional, consequently making it difficult to explain the large amount of variation. Other factors, such as the influence of the user's environment, familial structure, socioeconomic status, and familiarity with technology, could have affected the number of challenges completed and the resulting low R^2 value [18]. Furthermore, those who identified having a diagnosis or family history of health conditions had higher levels of participation. This implies that individuals who are aware of their familial risk or who have a health condition may have a greater perceived susceptibility or risk and may be more inclined to use a risk management app than would those who have not yet been exposed to health-related problems [19]. A review by Imes et al [20] found that both the awareness of family history and perceived personal risk are necessary predictors of change, and when coupled with interventions that, first, are founded in theoretical frameworks and, second, provide lifestyle modification options, can guide

individuals at risk toward improved health behavior change. Moreover, certain risk factors influenced the number of challenges that an individual completed. Physical inactivity, nutrition, and salt and tobacco intake had a negative association, demonstrating that users who had these risk factors completed fewer challenges than did users without these risk factors. Stress, on the other hand, had a positive association, and consequently users with this risk factor completed more challenges than did users without the stress risk factor. The negative association is counterintuitive, as one would expect that the presence of a risk factor would result in increased engagement with one's health.

Engagement levels were comparable in the incentives group and the nonincentives group, which implies that a one-time monetary incentive could potentially trigger sustained motivation and engage individuals in a short-term preventive intervention. The AIR MILES incentives increased uptake among the male and the older demographics, suggesting that the reward form (cash, points, gift card, etc) and vendors could have an impact on attracting specific user demographics [21]. For example, are the majority of AIR MILES consumers older than the iTunes App Store user base, who may be younger? While evidence that financial incentives are more effective at changing behavior than usual care is increasing, the effect of alternative incentive types on uptake from target populations with varying sociodemographic settings remains unexplored [14,15].

Poor nutrition, physical inactivity, and stress were the most prevalent risk factors identified, coupled with the majority of users having a BMI between 25 and 30 kg/m^2, suggesting that being overweight was a predominant risk factor among the users.

Furthermore, the feedback received in the form of comments from the users expressed the need for challenges that were relevant to their situation and needs. For individuals who work in the service industry, for example, getting up from their desk and going for a walk may not be relevant. Also, the high frequency of challenges skipped suggests that perhaps the challenges were not applicable to the user, forcing them to search for options. The individualization of content and selection of strategies based on personal preference can optimize engagement and have a significant impact on the effectiveness of the intervention [22,23]. Offering customization by presenting users with challenges tailored to their profile (age group, location, ethnicity, etc) could increase the number of appropriate challenges shown to the users, resulting in higher engagement and motivation levels.

Limitations

The data obtained from both the risk assessment and the challenge completion rates were dependent on self-reporting, which could have influenced the overall accuracy of the data. Given that the app was made available to for iOS (eg, iPhone, iPad, iPod Touch; Apple, Inc) users, the usage data do not fully represent all consumers, specifically Android users, who now account for the majority of the mobile phone market [17]. Mobile phone ownership varies by socioeconomic background, and people with higher levels of income and education have been shown to be more likely to own iPhones [17].

Conclusions

While the younger population downloaded the app the most, the older population demonstrated greater and sustained engagement levels. Behavior change apps have the potential to reach a targeted population previously thought to be uninterested in or unable to use mobile apps. However, lifestyle modification and risk reduction tools must be useful, relevant, and integrated into daily routines, where the opportunity to change behavior significantly is the greatest. Mobile devices may be an effective channel for delivering such interventions to populations in various settings. The development of behavior change mobile apps should assume that older adults will engage if the behavior change elements are suitably designed, integrated into daily routines, and tailored to their needs.

While incentives may be the stepping-stone that is needed to guide the general population toward preventive tools and promote maintenance of positive behavior change, the incentive type and its influence on specific user groups needs to be further explored. It is clear, however, that capturing population-level usage information offers tremendous insight into user behaviors and interactions. The possibility of expanding the data collection beyond a single intervention, and capturing data from peripheral devices and the environment, or even linking such findings with long-term outcomes, could better inform the development, delivery, and uptake of preventive tools.

Conflicts of Interest

None declared.

Multimedia Appendix 1

The <30 Days health risk assessment questions.

[PDF File (Adobe PDF File), 3KB - mhealth_v4i1e32_app1.pdf]

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Abbreviations

BMI: body mass index
CVD: cardiovascular disease

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Original Paper

Outcomes of a Mobile Health Coaching Platform: 12-Week Results of a Single-Arm Longitudinal Study

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Abstract

Background: The number of mobile health coaching applications is expanding at a rapid rate. An application that uses a guiding intelligence to deliver an individualized structured program has the potential to provide a significant benefit. However, there are few studies of this approach that examine multiple clinical outcomes in a longitudinal manner.

Objective: The objective of the study was to conduct a 12-week evaluation of participants using the YouPlus Health mobile coaching platform, specifically examining the effects on body weight, waist measurement, blood pressure, lipid profile, glycohemoglobin (A1C), and maximum volume of oxygen consumption (VO2 max).

Methods: A quasi-experimental research design was used. This included a single-arm pre and post intervention assessment of outcomes. Participants underwent a 12-week intervention in which they received the entirety of the mobile health coaching program via an application on their mobile phones and were evaluated in the same physician's office setting every two weeks. Data regarding app usage was continuously collected and maintained in a database.

Results: 10 subjects were enrolled in and completed the pilot study. The mean weight loss was 13.5 lbs. which represented 7.3% of baseline (*P*=.005). Mean waist circumference was reduced by 7.2 cm or 6.6% of baseline (*P*=.005). Both systolic (SBP) and diastolic (DBP) blood pressure measures were significantly lower after 12 weeks of intervention. Mean SBP fell 18.6 mmHg (*P*=.005) and mean DBP declined 6.4 mmHg (*P*=.005). VO2 max increased by an average of 3.13 ml/kg/min from baseline to study end (*P*=.005). From baseline to end-of-study HDL levels increased significantly by 4.0 mg/dL (*P*=.04) Total cholesterol, LDL, triglycerides, and glycohemoglobin (A1C) trended in the desired direction but did not meet statistical significance. All of the participants in the study completed the necessary in-app tutorials and also completed the in-app questions and received feedback. Every individual completed the appropriate amount of program levels necessary to give the specifics of the program, and the mean weekly app open rate ranged from 5.1 to 18.4.

Conclusions: Users of the YouPlus Health mobile coaching platform experienced significant reductions in body weight, waist circumference, and both systolic and diastolic blood pressures, while attaining significant increases in HDL and VO2 Max.

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KEYWORDS

weight loss; weight reduction program; obesity; aerobic exercise; resistance training; waist circumference; oxygen consumption

Introduction

Obesity is among the most crucial health issues facing the United States. Over 35.7 % of U.S. adults are obese, and another 33.1 % are overweight [1]. It is well established that obesity and body composition are associated with many chronic disease states, but it is also associated with diminished quality of life [2]. There is a tremendous economic cost as well, with an impact estimated to be upwards of 215 billion dollars annually [3].These realities have led to a tremendous effort to reduce these burdens

and costs. This effort includes health coaching regarding appropriate diet and exercise behaviors. The traditional approach has used face to face interventions, but advances in technology provide ample opportunity to provide novel solutions via the internet and mobile phones. Currently, the available data shows promising trends in the success of these newer technologies [4]; however recent research regarding the choices available in app stores revealed a shortage of evidence-based apps. Out of 2400 apps initially searched, zero met guidelines for evidence-based aerobic physical activity and only 7 met evidence-based criteria for strength training [5].

Health coaching via digital means has its challenges; it must be doable and sustainable by the average person and ideally should include dietary and exercise guidelines that are supported by medical evidence. While the most widely downloaded apps in the digital-only space are counters, calculators, or trackers [6], an app that uses a guiding intelligence to provide an individualized structured program supported by scientific evidence could potentially more closely approximate face to face coaching and provide a substantial benefit. The YouPlus Health mobile coaching app was developed to provide this unique approach to digital coaching and was tested in this initial study.

As noted, the interventions of digital coaching need to be supported by medical evidence. While there are many dietary approaches, it is of note that higher protein diets have been associated with weight loss and maintenance of weight loss [7]. This effect is seen at quantities of at least 25-30 grams of protein per meal [7]. This effect is thought to be mediated through modulations in energy metabolism, appetite, and calorie intake via protein induced secretion of gastroentropancreatic hormones [8]. This also allows for carbohydrate consumption to be reduced. A meta-analysis of lower carbohydrate and higher protein diets has shown a favorable effect on body mass and composition independent of energy intake, including a 1.74 kg greater loss in body mass and a 1.29% greater decrease in body fat percentage [9]. Even small alterations in the pattern of dietary energy intake can produce significant results. One such example is a diet with an extra 5% more energy from protein and a 5% decreased energy from high glycemic index carbohydrates demonstrated weight reduction and also prevention of weight regain over the 6 month period after initial weight loss [10].

Combining a dietary approach with exercise has been shown to be superior to diet alone in inducing weight loss and metabolic changes [11]. National organizations have recommended that exercise include an aerobic, flexibility, and resistance component for many years [12].

Performing aerobic exercise increases cardiorespiratory fitness and has shown a linear association in decreasing early mortality when measuring exercise capacity in metabolic equivalents (METs) for both men and women [13-14], but there also appears to be a U-shaped association with all-cause mortality when looked at in the context of pace, quantity, and frequency of aerobic exercise [15]. For the best long term health outcomes, this needs to be considered in the design of a program in addition to its effect on weight.

The addition of resistance exercise has been shown to be more effective in inducing weight loss and improvement in body composition. While a hypocaloric balance is necessary for changing body composition, the effect of the imbalance regarding body compositional changes, and biomarkers including insulin levels and adipokines, is greater with the addition of resistance training [11,16]. A key element to effective resistance training is the proper prescription of the program variables. A program which uses progressive overload, variation, and specificity is essential to maximize the benefits associated with resistance training [17].

The purpose of this study was to evaluate a mobile phone app as a coaching tool for these evidence-based recommendations regarding diet and exercise behaviors, and to ascertain if app use was accompanied by positive measurable outcomes.

Methods

Research Design

A quasi-experimental research design was used. This included a single arm pre and post intervention assessment of body weight, waist measurement, blood pressure, lipid profile, glycohemoglobin (A1C), and maximum volume of oxygen consumption (VO_{2max}). Data regarding app usage was continuously collected and maintained in a database. Participants were enrolled at no cost. They were not compensated for participation, but received the intervention and all related lab and VO2 testing at no cost.

Participants

Individuals were recruited from the St. Louis area via print and internet advertisements for a mobile phone app-based health and fitness program. According to Flurry Analytics [18], 62% of health and fitness app users are females, and the 35-54 age group is over-indexed by 47%. Therefore, a study group approximating this demographic was desired. Respondents filled out an online questionnaire to determine eligibility for the study. Inclusion criteria were: 1) females between the ages of 30-50; 2) generally healthy with no significant medical history or use of prescription medications, and; 3) a BMI between 26.6 and 34. They were asked to be willing and able to exercise either at home or at a gym 3 times weekly. Participants attended an orientation meeting where consent forms were signed and the study process was explained. There was an opportunity to ask questions about the study. The app was downloaded during the orientation and the subjects completed the initial on-boarding assessment that ascertained their current diet and exercise habits during the meeting. Twelve subjects attended the orientation, and 10 then entered the study and subsequently completed the full 12 weeks as requested. Participants were Caucasian with an average age of 43.5 years (range 35-49) and an average BMI of 31.6 (range 27.2-36.4). All were non-smokers. All were either employed or served as a caretaker.

Program

The participants used the YouPlus Health mobile coaching platform to follow nutritional and exercise guidelines. There is a sleep tracking and improvement function of the platform, but it was not utilized during this study. Sample screen shots are

demonstrated in Figures 1 and 2. Individuals received the entirety of the program via the app. Participants were asked to complete in-app tutorials, and as they advanced, each level of the program was only available to them by using the app.

The nutritional guidance on the platform uses a ratio-based approach to protein and carbohydrate intake based on the relative size of one component to the other. Unlimited intake of fruits and vegetables is encouraged. No calorie counting or recording was involved. There was in-app education provided on the nutritional concepts, as well as guidance by providing recipes when eating at home and menu recommendations when dining out. Participants received daily in-app questions regarding their nutritional behavior, and then received automated feedback and advice based on their answers to those questions. The number of questions given each individual could vary, depending on the response given. Similarly, there are multiple feedback options for each question and answer pairing which are presented based upon a proprietary algorithm.

The exercise program encompasses aerobic, resistance, and core exercises divided into three sessions that take under an hour. The specific variety, order, frequency, and progression of resistance and core exercises are given in a personal training format with instructions and video. This information was only available within the app. Completing 3 sessions each of core, cardiovascular, and resistance exercise completed an exercise level. The participants were asked to complete a level at least every 7-10 days. At the end of every level, in-app questions were asked about the exercise they had performed and how it was perceived. Based on their answers to those questions, automated feedback and advice was generated. Individuals could not move on in the program until the questions were answered. The number of questions given each individual could vary, depending on the number of exercise levels completed.

To more closely approximate real-world conditions, there were no specific instructions given for frequency of use of the app other than to follow the exercise program.

Figure 1. Sample profile screen and feedback.

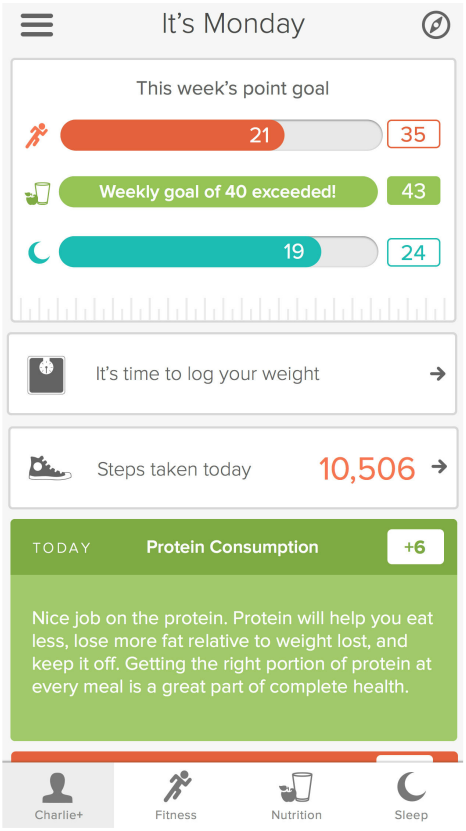
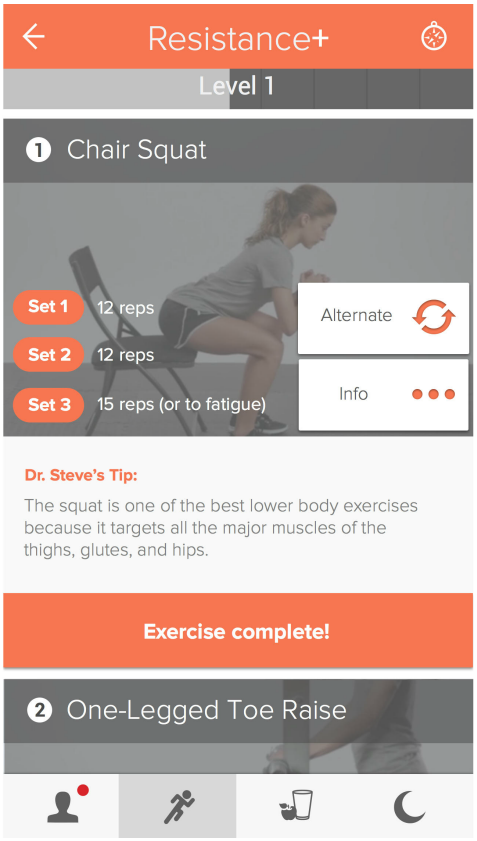


Figure 2. Sample exercise guidance screen.



Measures

Participants had a baseline measurement of weight, blood pressure, and waist circumference assessed in a physician's office setting as well as baseline laboratory measurements of a lipid panel (total cholesterol, high density lipoprotein, low-density lipoprotein, triglycerides,) and a hemoglobin A1C which were performed at LabCorp in St. Louis, MO. At baseline and after 12-weeks VO_{2max} assessments were performed at Lifetime Fitness in Ellisville, MO.

Every two weeks the participants visited the physician's office on the same day of the week and, while being observed by a medical assistant, were weighed on a single calibrated scale and had waist measurements and blood pressure measurements recorded through the end of the study. The protocol of the International Chair on Cardiometabolic Risk was followed for determining waist circumference. All blood pressure and waist assessments were conducted by a single physician using identical procedures throughout the study. After the last office visit, laboratory values and VO_{2max} were re-assessed as above.

App usage information regarding tutorial completion, levels completed, questions asked and answered, and total app opens was recorded throughout the study.

Analysis

Paired-Sample Wilcoxon Signed Rank Tests were used to compare baseline and 12-week post-intervention values. This non-parametric test was used because of the small sample size and non-normal distributions for some variables. All statistical comparisons were repeated with *t* tests with identical findings, but only the non-parametric results are presented below. Because this is the first study of this app, we had no prior data with which to calculate power, nor could we justify using published data from studies of other methods to influence the health outcomes of interest. Effect size estimates for the Wilcoxon tests were calculated and interpreted as proposed by Cohen [19]. Finally, Spearman rho and Pearson *r* correlation coefficients were calculated to examine potential associations of app use and outcome measures which showed significant group changes. Results were essentially the same with the parametric and non-parametric correlational methods, but only the non-parametric are presented below.

Results

App usage

Results are summarized in Table 1.

Table 1. Usage data for key parameters.

Participant	Completed nutrition tutorial	Completed fitness tutorial	Levels completed	Questions asked	Questions answered	Mean weekly opens
1	Yes	Yes	14	185	185	11.5
2	Yes	Yes	18	276	276	15.1
3	Yes	Yes	9	125	125	8.2
4	Yes	Yes	9	127	127	6.8
5	Yes	Yes	16	16	187	16.8
6	Yes	Yes	14	215	215	15.0
7	Yes	Yes	14	218	218	18.4
8	Yes	Yes	9	126	126	5.1
9	Yes	Yes	8	100	100	5.6
10	Yes	Yes	16	238	238	16.1

Table 2 contains mean and median baseline and 12-week post-intervention values for all outcome measures collected during the study, as well as the z-scores and 2-tail *P*-values for Wilcoxon analyses, and effect size estimates.

Changes in Weight and Waist Measurement

Significant reductions in body weight and waist circumference were observed between baseline and 12-week measurements. Mean body weight declined 13.5 lbs. representing 7.3% of baseline (z=-2.805; *P*=.005). Mean waist circumference was reduced by 7.2 cm or 6.6% of baseline (z=-2.825; *P*=.005). Effect size was -.63 for both metrics suggesting a “large” magnitude of change.

Changes in Blood Pressure and VO2max

For blood pressure, an average of the baseline and first 2-week visit was used to determine the beginning blood pressure, and an average of the 10-week and 12-week visits were used to determine the ending blood pressure measurements.

Both systolic (SBP) and diastolic (DBP) blood pressure measures were significantly lower after 12-weeks of intervention. Mean SBP fell 18.6 mmHg (z=-2.810 ; *P*=.005) and mean DBP declined 6.4 mmHg (z=-2.805; *P*=.005).

VO_{2max} increased by an average of 3.13 ml/kg/min from baseline to study end (z=2.803; *P*=.005).

Effect size was -.63 for both BP metrics and .63 for VO_{2max}, all suggesting a “large” magnitude of change.

Changes in Lipid and Glycohemoglobin Measures

From baseline to end-of-study HDL levels increased significantly by 4.0 mg/dL (z=2.044; *P*=.04) and there was a trend toward a reduction in total cholesterol of 10.5 mg/dL (z=-1.784; *P*=.07) and triglycerides of 27 mg/dL (z=-1.478, *P*=.07). There was a baseline to 12-week reduction in LDL of 9.1 mg/dl that not reach significance (z=-1.581; *P*=.11).

Hemoglobin A1C did not change significantly (*P*=.10) although mean values moved in the desired direction (from 5.54 to 5.42%). All patients were in the normal range at baseline and at study end.

Effect size estimates for all lipid and glycohemoglobin measures indicated “medium” magnitudes of change.

Table 2. Baseline and 12-week values for all outcome measures.

Variable		Baseline	12-Week	Z score	*P* value	Effect size (*r*)
Weight and waist measurement						
Body weight (lbs)						
	Mean (SD)	186.3 (15.0)	172.8 (17.0)			-.63
	Median	191.8	177.3	-2.805	.005	
Waist circumference (cm)						
	Mean (SD)	108.3 (6.7)	101.1 (7.7)			-.63
	Median	112.0	104.5	-2.825	.005	
Blood pressure and VO_{2max}						
Systolic BP (mmHg)						
	Mean (SD)	136.4 (15.4)	117.8 (5.9)			-.63
	Median	132.0	118.5	-2.810	.005	
Diastolic BP (mmHg)						
	Mean (SD)	80.9 (5.1)	74.5 (4.0)			-.63
	Median	80.0	74.0	-2.805	.005	
VO_{2max}						
	Mean (SD)	26.7 (2.9)	29.9 (3.8)			.63
	Median	27.6	29.9	2.803	.005	
Total cholesterol (mg/dL)						
	Mean (SD)	191.2 (41.8)	180.7 (38.9)			-.4
	Median	175.5	172.5	-1.784	.07	
Lipid and glycohemoglobin measures						
HDL [a] (mg/dL)						
	Mean (SD)	47.4 (10.5)	51.4 (8.6)			.46
	Median	44.5	51.5	2.044	.04	
LDL [b] (mg/dL)						
	Mean (SD)	114.6 (36.7)	105.5 (30.2)			-.35
	Median	100.0	100.0	-1.581	.11	
Triglycerides (mg/dL)						
	Mean (SD)	145.8 (54.4)	118.8 (65.7)			-.33
	Median	145.0	88.0	-1.478	.07	
Hemoglobin A1C (%)						
	Mean (SD)	5.5 (0.3)	5.4 (0.3)			-.36
	Median	5.5	5.5	-1.630	.10	

[a] High-density lipoprotein

[b] Low-density lipoprotein

Association of App Use and Outcome Measure Changes

Spearman rho correlation coefficients were calculated between two app use variables (levels of exercise achieved, and mean weekly app openings per week) and the difference score from baseline to 12-weeks for each of the outcome measures showing a significant group change (weight, waist, SBP, DBP, Trig, HDL and VO_{2max}). None of the 14 correlations were statistically significant; however, all were in the desired direction (ie, more app use was associated with greater improvement in each health outcome). Actual rho values ranged from 0.109 to 0.442.

Discussion

Principal Findings

Results indicate that while completing a 12-week program utilizing the YouPlus Health mobile coaching platform subjects achieved significant reductions in body weight, waist circumference, systolic blood pressure and diastolic blood pressure, while achieving significant increases in VO_{2max} and HDL. All of these parameters achieved a large effect size except HDL, which had a medium effect size. Decreases in total cholesterol, LDL, triglycerides, and glycohemoglobin trended in the desired direction with a medium effect size, but did not meet statistical significance. Recognizing that the small sample size and restricted range in app use among participants limited the possibility of finding a statistically reliable association between app use and outcomes, each of the 14 associations examined was in the desired direction (participants with more app usage had greater improvements in health outcomes).

Individuals in the study received the entirety of the program via the app. All participants completed the in-app nutrition and fitness tutorials, and answered questions and received in-app feedback. Answering of questions was required to move on in the program, so the percentage of questions answered would be expected to be 100% if the participants were completing levels within the program. All participants completed the minimum number of exercise levels during the study. This would be 7 or more during the 72 day study period, because they were asked to complete a level a minimum of once every 10 days. Given that the usage data confirms that the individuals were using the app to obtain the education and program for the study, it appears the results were obtained secondary to utilization of the app. The lack of a control group cannot completely exclude the possibility that results were enhanced by participants visiting a physician's office to obtain their measurements.

The mean weight loss of 7.3 % from the baseline measurement is generally considered clinically significant and exceeds the 5% the Food and Drug Administration (FDA) considers significant when evaluating the efficacy of weight loss medications [20]. Nearly all (9 out of 10) participants met or exceeded a loss of 5% of body weight during the study. It is notable that the mean weight loss of 13.5 lbs. exceeds the weight loss in the only prospective trial that examined consecutive members of Weight Watchers, which had a weight loss of 9.7 lbs. after 12 weeks for the 33 members (30%) who completed the program for that length of time [21].

The increase in VO_{2max} of 3.13 ml/kg/min is an increase of 0.9 METs. It has been shown that the Framingham Risk Score-adjusted mortality risk decreases by 17% for every 1 MET increase in exercise capacity at baseline [14]. The statistically significant increase in exercise capacity demonstrated in 12 weeks with this intervention would be expected to impact this outcome as well. Improvements in both systolic and diastolic blood pressure, a decrease in waist circumference, and an increase in HDL are also widely accepted as contributing to a reduced risk of disease.

Limitations

Study limitations include a non-randomized, uncontrolled single-arm study design which precludes causal inference of the program to the outcomes. The study was limited by its small sample size, and only looked at females, so applicability of the findings to males is not known.

Conclusions

Results of this study suggest that individuals using the YouPlus Health mobile coaching platform experienced significant reductions in body weight, waist circumference, systolic and diastolic blood pressures, and significant increases in HDL and VO_{2max} in 12 weeks.

Usage data indicates that the participants used the app to receive the education and specific program elements, and were able to understand and follow the program to the degree necessary to achieve significant results in the areas noted. Digital therapeutics in general have the potential to promote health and wellness with a small ongoing cost. These results indicate that the YouPlus Health mobile coaching platform specifically has this potential, and therefore further investigation using a randomized, parallel group, controlled design is warranted.

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Conflicts of Interest

This study was funded by Good Health LLC, a company that has ownership interests in YouPlus Health. SW is the Chief Scientist of YouPlus Health and is a partner in Good Health LLC. JW has no conflicts of interest to declare.

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Abbreviations

A1C: glycohemoglobin
DBP: diastolic blood pressure
FDA: Food and Drug Administration

HDL: high-density lipoprotein
LDL: low-density lipoprotein
MET: metabolic equivalents
SBP: systolic blood pressure
VO2max: maximum volume of oxygen consumption

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Original Paper

A Group-Based Mobile Application to Increase Adherence in Exercise and Nutrition Programs: A Factorial Design Feasibility Study

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Abstract

Background: Novel methods of promoting self-monitoring and social support are needed to ensure long-term maintenance of behavior change. In this paper, we directly investigate the effects of group support in an exercise and nutrition program delivered by an mHealth application called Fittle.

Objective: Our first specific study aim was to explore whether social support improved adherence in wellness programs. Our second specific study aim was to assess whether media types (ePaper vs mobile) were associated with different levels of compliance and adherence to wellness programs. The third aim was to assess whether the use of an mHealth application led to positive changes to participants' eating behavior, physical activity, and stress level, compared to traditional paper-based programs.

Methods: A 2 × 2 (eg, Media: Mobile vs ePaper × Group Type: Team vs Solo) factorial design feasibility study was conducted. A sample of 124 volunteers who were interested in improving eating behavior, increasing physical activity, or reducing stress participated in this study. The study duration was 8 weeks. All groups were self-directed with no ongoing human input from the research team.

Results: Participants in ePaper conditions had higher attrition rates compared to participants in Mobile conditions, χ_3^2=9.96, *P*=.02 (N=124). Participants in Mobile conditions reported their compliance with a much higher frequency closer to the time of challenge activity completion (2-sample Kolmogorov-Smirnov test comparing distributions was highly significant—KS=0.33, *P*<.001 [N=63]). Participants in ePaper conditions had a much higher frequency of guessing while reporting as compared with those in Mobile conditions—χ_1^2=25.25, *P*<.001 (N=63). Together, these findings suggest that the mobile app allowed a more accurate method to report and track health behaviors over a longer period than traditional ePaper-based diaries or log books. There was a significant difference in the overall compliance score for Mobile-Solo (Mean [SD] 0.30 [0.39]) and Mobile-Team (Mean [SD] 0.49 [0.35]) conditions ($t_{50.82}$=1.94, *P*=.05). This suggests that working in a team increased participants' overall compliance within Fittle. Survival analysis showed that participants assigned to Team conditions are 66% more likely to engage longer with mHealth app-based intervention than those assigned to the Solo condition. Overall, participants across all groups reported some positive changes in eating behavior, physical activity, and stress level; however, participants in the Mobile-Solo condition reported higher perceived stress levels at the end of the study.

Conclusions: The team-based Fittle app is an acceptable and feasible wellness behavior change intervention and a full randomized controlled trial to investigate the efficacy of such an intervention is warranted.

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KEYWORDS

mobile phone; app; social support

Introduction

It is no longer news that US health care costs are staggering and that a major driver of these increased costs are unhealthy behaviors such as physical inactivity, increased food intake, and unhealthful food choices [1], which are potentially preventable by health behavior change. In this context, existing formal programs (both primary care and commercial) and one-on-one coaching can be effective in producing behavior change and desirable health outcomes [2]. However, these programs typically have bottlenecks in providing sufficient numbers of expert counselors and personalized day-to-day support to a large population for a long period of time. There is a pressing need to extend the reach of existing health behavior change techniques in areas such as diet and fitness and to intensify and prolong their impact.

Additionally, changing behavior and sustaining it over the long term has been proven to be very difficult and it is suggested that novel methods of promoting self-monitoring and social support are needed to ensure long-term maintenance of behavior change [3]. Social- and group/team-based behavior-change techniques have been shown to be effective in supporting behavior change in areas such as long-term weight loss [4].

Mobile phones may now be providing a platform to scale and disseminate effective group support for sustainable health behavior change [5]. Although eHealth approaches often suffer from the "Law of Attrition" [6] wherein there is a high attrition rate among participants, team identification and interpersonal accountability may ameliorate such attrition. Mobile phones are increasingly prevalent in everyday life and are increasingly used for multiple forms of online social interaction. In this study, we sought to directly investigate the effects of team-based social support in a nutrition and exercise program delivered by an mHealth application called Fittle.

Social Support in Behavior Change Interventions

Social support may potentially help sustain engagement with health behavior change interventions and consequently increase efficacy. An observational study of more than 80,000 users in the context of a Web-based health promotion intervention [7] revealed that increased social ties within this challenge community directly predicted online engagement and activity completion [8]. In order to systematically characterize the role of social support in enhancing the efficacy of the intervention, a recent study compared a structured physical activity intervention comprising education, activity monitoring, and online social networking via a Facebook group versus an education-only control [9]. Despite the lack of difference between intervention and control groups in physical activity levels post-intervention, the authors did find that the attrition levels for participants in the online intervention group were significantly lower than that of the education-only control group at 12 weeks. Likewise, in another study, it was found that weight loss in a 6-month, remotely delivered weight-loss intervention was strongly associated with engagement within an online Twitter-based social network wherein participants provided each other with informational support [10]. Similar results were found in a Web-based weight-loss program where social networking and personalized recommendations did not demonstrate additive effects for user weight loss or retention, but these features increased the average number of days that a user engaged with the system [11]. More recently, Pechmann et al [12] studied the effectiveness of automatic messages delivered to small online groups via Twitter on abstinence from smoking. They found that specific tweet content about quitting was strongly related to abstinence along with high engagement from users over a period of 100 days.

The concept of social support has also been incorporated into many commercial mobile phone-based health behavior change applications, such as MyFitnessPal, WeightWatchers. In these apps, social support is usually built around the user's personal social network, such as Facebook or Twitter friends. However, it is not clear whether a social community of this kind is the one best suited for health behavior change. While family and friends might be a good source of emotional support, they might not necessarily have the same level of motivation to engage in health behavior change programs, and they might also not be able to provide the kind of quality informational support that is an important factor in successful behavior change programs [10].

Further, although social support has health benefits in its own right [13] and increases participation in exercise programs [14], building successful groups to support health-related interventions is not automatic. For example, in an effort to test the effects of an online community for helping people to quit smoking, researchers gave 684 people access to an online community in addition to the informational website Smokefree.gov. However, so few people used the online community features that the researchers were not able to report on its effectiveness [15]. There are a few previous studies that aimed to understand the effects of a social network [16] and the potential of a social mobile phone application in improving physical activity level [17]. However, both of these studies focused more on the usability aspects of the behavior change systems and no data on the effects of social support were reported.

In this study, instead of forming social groups from a person's existing social network, we aim to explore the feasibility of creating an effective behavior-change social group by randomly grouping people who are interested in healthy behavior-change programs into a "team."

Mobile Phone-Based Behavior Change Interventions

Mobile phone-based self-monitoring applications have been found to be effective in improving adherence. For example, My Meal Mate (MMM), a mobile weight-loss app developed on Android, allows users to set goals, self-monitor diet and activity, and receive feedback via a weekly text message. In that study, adherence to the mobile phone-based intervention was found to be the highest [18], as compared to paper or Web-based interventions.

However, most of the behavior change content in existing formal programs (both primary care and commercial) and one-on-one coaching are still paper-based. Previous research has shown that a mobile diary was slightly more preferred, but the inability

to backfill missing entries resulted in a large prevalence of missing data [19]. However, the sample size of that study was very small (N=12). Thus, a secondary aim of this study was to better understand how the mobile phone-based functionality of an mHealth application differed from a usual-care approach of providing paper-based content and requiring paper journaling. In this study, a PDF version of the program is sent to participants in the paper conditions. They can choose to either view the PDF file on their computers or print it out. In this study, we call it "ePaper" journaling.

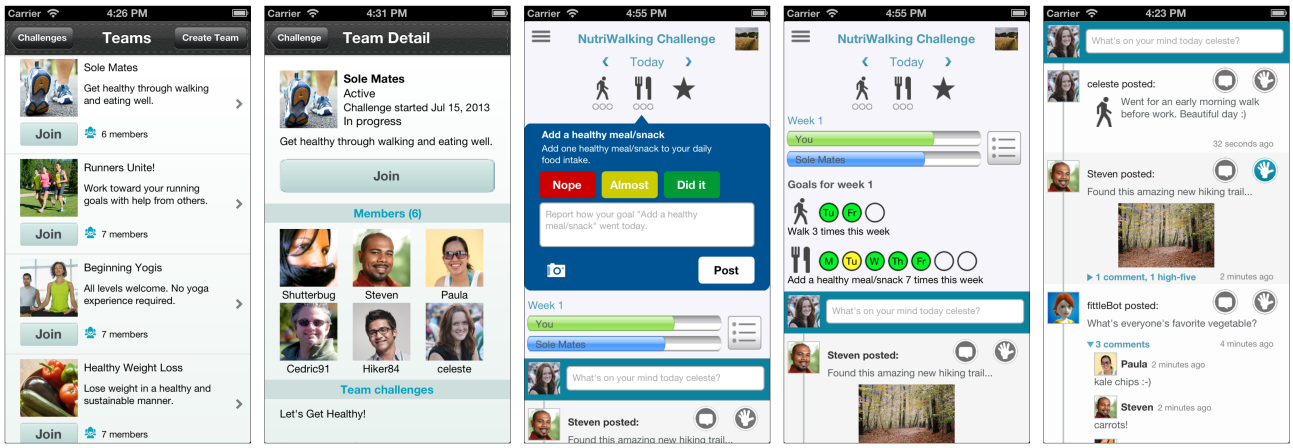
Earlier work [20] reported on a mobile phone-based app, Fittle, which includes functionality to promote online group-based support for individuals to progress through behavior-change programs called "challenges." The challenges are designed to help people master one health-improving habit after another, in a way that builds on previous achievements. Fittle provides a built-in, private social networking feature that allows users to work and engage with their team members so that they can support each other as they learn and adopt new, healthier habits (details about the application are described below). Fittle incorporates a number of evidence-based techniques that are motivated by the theory of planned behavior and social cognitive theory to positively impact health behavior change. Moreover, these interventions can be delivered at low cost because the scaffolding for individual success is either automated or provided through peer support.

The study in Du et al [20] was not designed to systematically study the effects of having team support as all participants were assigned to teams. However, hierarchical regression analyses, including team as a mediating factor, and post-hoc analyses of the impact of team interactions on outcomes were both strongly suggestive of an association between teams, program adherence, and health outcomes. In this current feasibility study, we specifically aimed to compare the Fittle mobile phone-based health behavior change program administered in a solo versus group environment. We hypothesized that using a theory-guided, group/team-based behavior change mobile app (Mobile-Team condition) will result in higher adherence, more improved eating habits, reduced stress, and improved fitness level compared to Mobile-Solo, ePaper-Team, and ePaper-Solo conditions.

Fittle

Fittle is implemented as a client-server architecture running on both iOS and Android. Figure 1 shows several screens of Fittle. The initial experience starts with a presentation of a selection of available challenges. These challenges are either conversions of existing programs that have been developed over the years or new programs created by professionals. The app platform is designed to support open content creation by anyone (under some quality control review process). After challenge selection, a user can either join an existing team (Figure 1a) or create a new one and invite teammates via email. The selection of a challenge and membership in a team opens the primary Fittle dashboard (Figure 1c).

Figure 1. Fittle mobile application screens: (a) teams available, (b) the details of a team, (c) activity information, (d) overall goals for this week, and (e) the team-based social activity feed.



Activities in Fittle

The Fittle dashboard consists of 3 parts. The top portion shows the activities (or goals) as part of the challenge that the user should complete on that given day (ie, today). An icon represents each of these goals with a completion status shown below as a set of circles similar to a horizontal traffic light. Tap selection of the activity icons (as shown in Figure 1c) opens up the title, basic reminder details, the ability to substitute the task for another, a link to more detailed information about the activity that is presented as an electronic card (which may include video demonstration, images, detailed instructions, substitution suggestions, background information, external reference links, links to other related Fittle cards, and more), and the ability to self-report completion and submit a multimedia-enabled post to the team activity feed related to the selected activity. Users can also navigate back and forth in time by tapping the arrows associated with the day display. Users may update reports on past activities, but not on future scheduled activities.

Progress Tracking

The middle section of the dashboard provides visual analytics showing the user's and the team's goal accomplishment for the current week. A details button next to the progress bars opens a weekly activity set view, as illustrated in Figure 1d, showing the user all activities that Fittle will schedule for them in the coming week with visual completion details.

Team Interaction

An activity-posting bar is always present in the dashboard and provides a means for the user to share multimedia posts with the team at any time (Figure 1e). Text whispers (ie, the faint text that appears in text entry fields before the user enters anything) in all open text fields invite the user to share information with the team. Users may also communicate directly with each other through a peer-to-peer messaging system.

All teams also include an artificial intelligence agent as a member, named "FittleBot." FittleBot provides daily tips to the team relevant to their activities, previews the activities for the week, and comments on the daily activities of the team members as a group.

Challenges

In this feasibility study, we featured 2 8-week challenges developed in collaboration with 2 certified experts in personal training and nutrition consulting. These challenges promoted 3 classes of behavior: nutrition, walking, and stress relieving workouts [20].

The challenges consisted of a beginner-level program to get people moving more called "NutriWalking" and a workout focusing on relieving stress called "StressBusting." Both challenges contained 4 nutrition activities: eat slowly, add a serving of vegetables (or a different vegetable if a vegetarian), add a small healthy meal while reducing the others, and keep a food diary. These activities were offered for 2 to 3 weeks each with overlap in the transition week from one habit to the next.

NutriWalking focused on getting participants to walk more, starting with 15 minutes 3 times a week on flat surfaces and ramping up to 45 minutes 5 times a week on inclined surfaces with some exercises (eg, jumping jacks) or short jogging sessions added to the walk. For off days, stretching was suggested. The system dynamically adjusted a user's schedule and recommendations if he or she deferred certain activities and/or substituted walking days.

StressBusting focused on 3 scheduled workouts during the week. Mondays comprised an upper body workout consisting of 5 exercises with easier alternatives that focused on strengthening the upper body and core (eg, chest presses, push-ups, high planks, rows). Wednesdays focused on a full body workout consisting of 5 exercises with easier alternatives that focused on muscle endurance (eg, goblet squats, rotation push-ups, jumping rope, mountain climbers, burpees). Finally, Fridays comprised a lower body workout consisting of 5 exercises with easier alternatives that focused on strengthening the lower body and core (eg, deadlifts, squats, supine hip exercises, lunges, ball chops). Tuesdays, Thursdays, and Saturdays were recovery days where participants were asked to engage in a fun and nonstressful activity to get them moving. Sundays were complete rest days. This program was designed on a schedule with the caveat that if a day was missed, it would not be a big deal and there was no need to make it up—users were just asked to keep moving forward without any worry or stress.

Study Hypotheses

We had 4 research hypotheses (RHs) concerning participants' compliance, adherence, and the effectiveness of Fittle.

RH1: Higher Compliance in Mobile Conditions

The fact that the Fittle app is always available to people on their mobile phones should induce greater compliance. Compliance is defined as the percentage of activities that have been reported as "completed" or "partially completed." For example, if 100 activities were recommended to a user and 90 of the activities were reported as "completed" or "partially completed," the compliance rate is 90%.

RH2: Higher Compliance in Team Conditions

Participants in team conditions should have higher levels of compliance due to increased social interactions.

RH3: Greater Adherence in Team Conditions

Participants in team conditions should have greater adherence to the program due to increased social interactions. Adherence is measured by the number of weeks before a participant becomes inactive (not report any activities for an entire week) in Fittle. For example, if a user always reported some activities from week 1 to week 3, and in week 4 the user did not report any activities, the adherence of this user is 3 weeks.

RH4: Superior Outcomes in the Mobile-Team Condition

Participants in the Mobile-Team condition should show the greatest improvements on our 3 outcome measures (eg, stress reduction, improved eating habits, and increased physical activity) due to higher compliance and greater adherence.

Methods

We designed a 2 × 2 (Mobile vs ePaper × Team vs Solo) factorial design feasibility study to compare the compliance, adherence, and outcomes impact of the team-based (as opposed to solo), mobile app-administered (as opposed to ePaper) health behavior modification challenges.

We will run a 2 × 2 (Mobile vs ePaper × Team vs Solo) analysis of variance (ANOVA) analysis to test RH1 and RH2. For RH3, we will conduct a survival analysis to test the hypothesis that participants assigned to teams (Mobile Team) have greater adherence to the program, controlling for their perceived system usability and attitudes toward the system. To test RH4, we will run a series of 2 × 2 (Media: ePaper vs Mobile × Group Type: Solo vs Team) mixed effects analyses of covariance (ANCOVA). The challenges (StressBusting or NutriWalking) will be modeled as random effects and participants' attitude toward the Fittle program is modeled as a covariate.

Recruitment Strategy

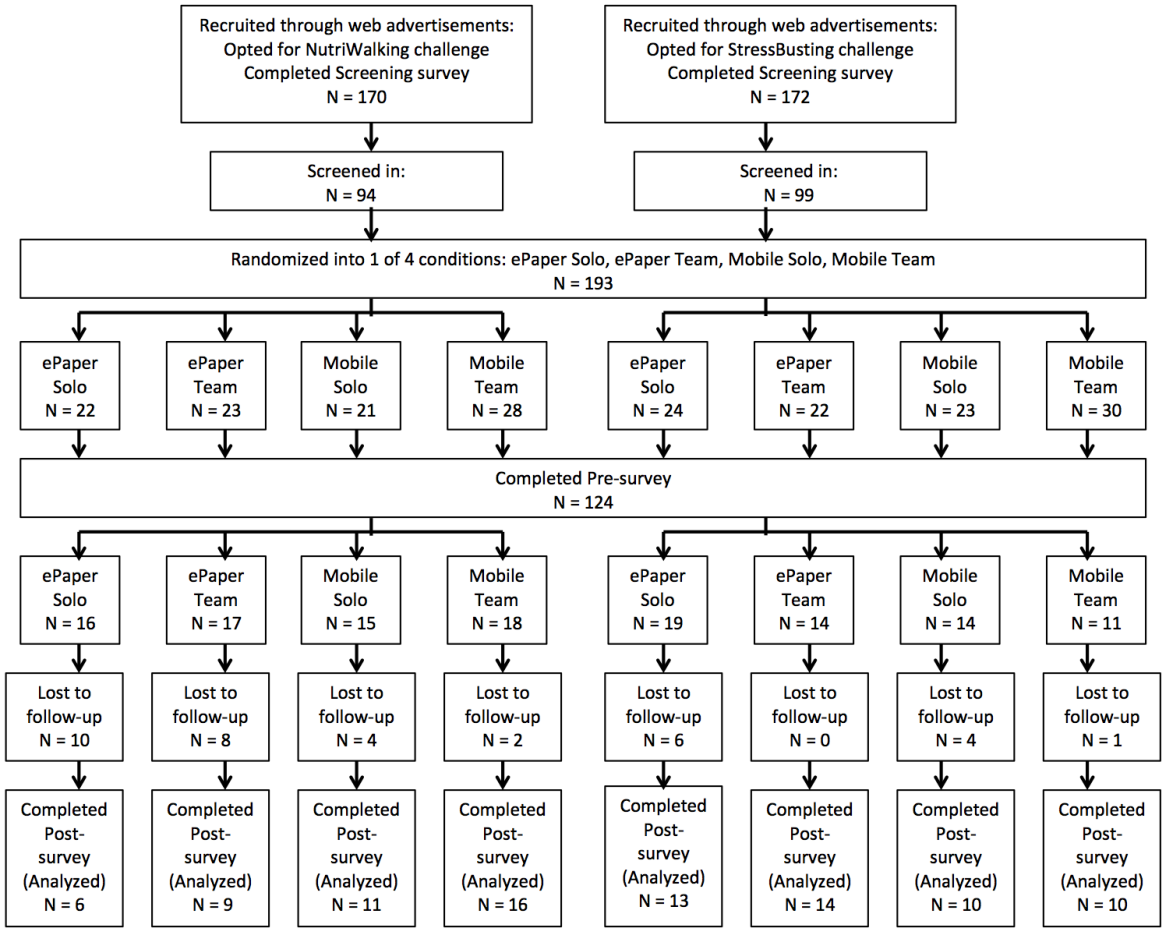
As in Heffner et al [21], participants were recruited using Web-based recruitment methods by advertising through Craigslist, Mechanical Turk, Google Adwords, Reddit, and Facebook, separately for the NutriWalking and StressBusting challenges. Advertising material encouraged participants to visit the study information website (NutriWalking or StressBusting study website), which included a brief overview of the study.

Individuals interested in the study (challenge) then filled out a screening survey on this website. Individuals were eligible for this study if they: (1) were aged 18 or older, (2) were physically capable of performing the exercises in this study (ie, answered yes to all questions on the Physical Activity Readiness Questionnaire) [22], (3) had either an Apple iPhone or an Android phone, (4) resided in the United States, and (5) were willing to commit the necessary time and effort to the study. Participants who completed the pre- and post-surveys were compensated with a US $20 Amazon gift card.

Procedure

Individuals who passed the initial screening were randomly assigned into 1 of the 4 conditions (eg, ePaper Solo, ePaper Team, Mobile Solo, and Mobile Team) using randomizer.org [23]. Individuals assigned to the ePaper Team and Mobile Team conditions were further randomly assigned into different teams. The teams were created by researchers and were designed to be 12-person groups. Next, participants were emailed a pre-survey. Individuals who completed the pre-survey were included in the study. However, not every individual completed the pre-survey after they were assigned into teams; thus, team sizes ended up being unequal. The final sample consisted of 124 participants (N=66 in NutriWalking; N=58 in StressBusting). Participants were blind to the condition they were in and were not informed that there were different conditions. Figure 2 shows the overall flow of the study.

Figure 2. Study flow.



ePaper Solo Condition

Participants in the ePaper Solo (total N=35; N=16 in NutriWalking; N=19 in StressBusting) condition were emailed a PDF version of the wellness program.

ePaper Team Condition

Participants in the ePaper Team condition (total N=31; N=17 in NutriWalking; N=14 in StressBusting) were emailed the same PDF version of the wellness program. There were 3 groups in each of the challenges and the final sizes of the groups ranged from 3 to 7 participants. An introductory group email was sent to participants in the same groups and they were encouraged to communicate with each other via email. The groups were then left to their own recognizance.

Mobile Solo Condition

There were 29 participants (total N=29; N=15 in NutriWalking; N=14 in StressBusting) assigned to the Mobile Solo condition. Participants were pre-assigned into a 1-person team.

Mobile Team Condition

There were 29 participants in the Mobile Team condition (total N=29; N=18 in NutriWalking, N=11 in StressBusting). There

were 3 groups in each challenge and the sizes of the groups range from 3 to 9 participants.

For participants in the ePaper conditions, the challenge programs were emailed to them in PDF. Daily activities were listed in the document. The same experts that created the mobile version of the programs prepared this content, which included a daily logging table at the end of the program. Participants were instructed to log their daily compliance and submit the logging table back to the research team at the end of the study.

For participants in the Mobile conditions, the challenge programs were incorporated into the Fittle mobile app. Daily activities were listed on the main page of the Fittle app.

Figure 3. A sample of the logging table in the ePaper conditions.

Week	Day	Activity	Nope	Almost	Did it
1	1	Eat Slowly	○	○	◉
1	1	Upper body and core workout	○	○	◉
1	2	Eat Slowly	○	○	◉
1	2	Recovery	○	○	◉
1	3	Eat Slowly	○	○	◉
1	3	Full Body Conditioning	○	○	◉
1	4	Eat Slowly	○	○	◉
1	4	Recover	○	○	◉
1	5	Eat Slowly	○	○	◉
1	5	Lower body and core workout	○	○	◉
1	6	Eat Slowly	○	○	◉
1	6	Recovery	○	○	◉
1	7	Eat Slowly	○	○	◉
1	7	Complete rest	○	○	◉

Data Collected

Progress Reports

We collected daily progress reports from participants, allowing us to assess compliance. Participants in the Mobile conditions reported their daily progress within the Fittle app, and participants in the ePaper conditions recorded their daily progress on a logging table (Figure 3) and submitted it to the research team at the end of the study through email or postal mail (2 participants printed the logging table and mailed them to the researchers and the others submitted their reports via email).

Presurveys and Postsurveys

Both challenges were designed to help participants improve eating habits, reduce stress, and increase their physical activity level. The following 3 measures were administered in both pre- and post-surveys.

1. Healthy Eating: A 50-item, 5-point scale adopted from Schlundt et al [24] was used to assess participants' pre- and post-program eating behavior patterns. A lower score indicated healthier eating habits.
2. Perceived Stress Scale: A 10-item, 5-point stress level scale was adapted from Cohen et al [25] to measure participants' pre- and post-program perceived stress levels. A lower score suggested less perceived stress.
3. Metabolic Equivalent of Task (MET): This was calculated from gender, age, body mass index (calculated from weight and height), resting heart rate, and participants' usual pattern of daily physical activities as a measure of a person's cardiorespiratory fitness [26]. A higher value denoted a higher fitness level.

To exclude possible confounds, at post-test we measured perceptions of system usability (for participants in the Mobile Solo and Mobile Team conditions) and the participants' general attitude toward the program [20].

Attitude

A 3-item, 7-point scale (Cronbach's alpha = .95) was used to measure participants' general attitude toward the program.

Usability

For participants in the mobile condition, a 10-item System Usability Scale (SUS) was used to measure the usability of the Fittle app [27].

Perceived stress scale and SUS scales have all demonstrated good psychometric properties such as discriminant and

convergent validity and test-retest reliability in multiple populations [28].

In the post survey, we also asked participants an open-ended question about their experience in the program.

Results

First, we analyze the baseline characteristics of the participants. We then present analysis of user-generated reports to examine compliance and adherence, followed by pre- and post-test survey results to determine effects on outcomes measures.

Table 1 shows the baseline characteristics of this feasibility study participants by group. Of the 124 participants enrolled, 64.5% (80/124) were female and 86.3% (107/124) were white. The mean age of participants was 36 years (SD=9). A chi-square test was used to determine whether there was a significant difference between ePaper participants and Mobile participants in the education level. As much as 81.82% (54 out of 66) of the participants in the ePaper conditions have at least a college degree, whereas only 63.79% (37 out of 58) of the participants in the Mobile conditions have at least a college degree. This difference was statistically significant, χ_1^2=5.14 (N=124), *P*=.03. There were no statistically significant differences found among the groups for the factors balanced at minimization: Gender (*P*=.55) and Age (*P*=.65).

Table 1. Characteristics of the participants by conditions.

Characteristics	ePaper Solo (N=35)	ePaper Team (N=31)	Mobile Solo (N=29)	Mobile Team (N=29)
Age in years, mean (SD)	37.63 (8.90)	36.87 (9.0)	35 (8.68)	35.66 (9.85)
Females, n (%)	23 (65.7)	17 (54.8)	19 (65.5)	21 (72.4)
Caucasian, n (%)	31 (88.6)	27 (87.1)	27 (93.1)	22 (75.9)
College degree, n (%)	27 (77.1)	27 (87.1)	17 (58.6)	20 (69.0)
Attrition, n (%)	16 (45.7)	8 (25.8)	8 (27.6)	3 (10.3)
Nonreporters, n (%)	18 (51.4)	9 (29.0)	2 (6.8)	3 (10.3)

Attrition: At the end of the study, participants were emailed a post survey. A total of 89 participants responded to the post-survey. Participants (N=35) who did not complete the post-survey were considered dropouts. Table 1 shows the attrition rates in the 4 conditions. Participants in ePaper conditions had higher attrition rates compared to participants in Mobile conditions, χ_3^2=9.96 (N=124), *P*=.02. The ePaper Solo condition had the highest attrition rate (45.7%, 16/35), while the Mobile Team condition had the lowest attrition rate (10.3%, 3/29).

Non-reporters: Participants who did not report any progress data were considered non-reporters. There were more non-reporters in the ePaper conditions than in the Mobile conditions, χ_3^2=21.21 (N=124), *P*<.001. This is not surprising given that it took more effort for people in the ePaper conditions to submit their progress report back to the research team.

Attitudes Toward the Programs

A 1-way ANOVA with Tukey post-hoc comparisons revealed that participants in the ePaper conditions held more positive attitudes toward the program than participants in the Mobile conditions ($F_{3,46.97}$=5.84, *P*=.001, partial η^2 =.13, Table 2). Specifically, this analysis showed that participants in the ePaper Solo condition reported significantly more positive attitudes (mean [SD] 6.37 [0.87]) than did people in the Mobile Solo condition (mean [SD] 5.05 [1.27], *P*=.01) or marginally significantly more positive than did people in the Mobile Team condition (mean [SD] 5.33 [1.64], *P*=.06).

Table 2. Average compliance and attitudes and SD by conditions.

	Mobile Solo	Mobile Team	Paper Solo	Paper Team
Compliance	0.30(0.39)	0.49(0.35)	0.95(0.07)	0.87(0.25)
Attitude	5.05(1.27)	5.33(1.64)	6.37(0.87)	6.04(1.40)

Some insights into this finding were gained by analyzing participants' responses to the open-ended question about their experience with the program in the post survey. Participants in both the ePaper and Mobile conditions appreciated the progressive nature of the challenges, and found the self-monitoring, bookkeeping part boring, or felt that they did not get enough team support (if they were in a team). Participants in the Mobile condition felt (1) the design of the app was not easy to understand, (2) the challenge team was confusing, (3) did not know how to navigate to different features in the app, and (4) did not feel that they made progress because the app did not give them an easy way to review their progress in the program.

Social Interactions in Team Conditions

Participants in the Mobile Team condition only interacted with other team members within Fittle while participants in the Paper Team condition used traditional communication channels more often. In the post survey, on a 5-point Likert scale (1: Never, to 5: Every day), participants in both Mobile Team and Paper

Team conditions were asked how often they interacted with other team members using email, SMS, or phone calls. Participants in Paper Team conditions (M=2.07, SD=0.94) used these traditional channels more often than those in the Mobile Team conditions (mean [SD] 1.12 [0.22], t_{23}=4.58, P<.001).

Analysis of the server log data showed that on average each participant in the Mobile Team condition interacted with other team members 10 times (SD=14.97), with interactions in the form of posting status updates, comments, or high fives.

Research Hypotheses Analyses

RH1: Higher Compliance in Mobile Conditions

Participants' average weekly compliance rate was calculated. Average weekly compliance scores were subjected to a 2-way analysis of variance having 2 levels of group types (eg, Solo and Team) and 2 levels of media types (eg, Mobile and ePaper).

The main effect of media type yielded an $F_{1,88}$ = 60.82, P<.001, indicating that the mean average weekly compliance was significantly greater for participants in ePaper conditions (mean [SD] 0.91 [0.2]) than for those in Mobile conditions (mean [SD] 0.39 [0.38]). The main effect of group type yielded an $F_{1,88}$ = 3.24, P=.08, indicating that the mean average weekly compliance was not significantly different between Solo (mean [SD] 0.55 [0.44]) and Team conditions (mean [SD] 0.67 [0.46]). The interaction effect was significant, $F_{1,88}$ = 4.53, P=.04. Participants in the Mobile Team condition reported higher average weekly compliance score than participants in the Mobile Solo condition. However, participants in the ePaper Team condition reported lower average weekly compliance score than participants in the ePaper Solo condition (Table 2).

Secondary Analysis on RH1

Given that participant compliance to the Fittle wellness challenge was self-reported, we further probed how accurately participants reported their compliance in both conditions (ie, via Fittle versus ePaper workbooks). In order to do this, we surveyed the responders (ie, completers of the post-survey, N=89). Participants were asked questions in a short follow-up survey to help characterize their reporting behaviors in terms of various time frames relative to challenge activity completion (ie, same day, next day, within 1 week, more than 1 week, and end of study). Participants indicated at which time points they reported/recorded their activity completion, how confident they felt about their report at each of those time points (measured on a 5-point Likert scale, with responses ranging from Very Unsure to Very Sure), and whether they guessed while reporting (measured with a simple yes/no response). Out of 89, N=63 participants completed this survey; N=33 in ePaper and N=30 in Mobile conditions. It is important to note that this survey was specifically agnostic to medium of reporting and did not prime participants in any way about that factor.

As seen in Figure 4, a clear dissociation between participants in the Mobile and ePaper conditions emerged, as participants in Mobile conditions reported their compliance with a much higher frequency closer to the time of challenge activity completion (2-sample Kolmogorov-Smirnov (KS) test comparing distributions was highly significant; KS (N=63) = 0.3254, P<.001). On the contrary, participants in the ePaper condition appeared to report their compliance with a constant frequency regardless of temporal proximity to challenge activity completion.

Further, when probed about their confidence in their own compliance report, participants in the Mobile condition again clearly differentiated themselves from those in the ePaper condition (Figure 5). Their confidence progressively decreased, as the time of reporting grew distant from the challenge activity completion time point, which could be indicative of honesty in their reporting behaviors. In contrast, participants in the ePaper condition appeared to have relatively high confidence throughout all time points of reporting regardless of when challenge activity was completed. A Kruskal-Wallis test comparing medians at each of the 5 time points (α=0.01 adjusted for multiple comparisons) was highly significant for the later time points, namely less than 1 week, χ_1^2 = 13.14 (N=63), P<.001); more than 1 week, χ_1^2 = 12.64 (N=63), P<.001); and end of study, χ_1^2 = 10.99 (N=63), P<.001.

Finally, when participants were probed about whether they guessed while they reported compliance, the division between participants in the Mobile and ePaper conditions was further solidified (Figure 6). Participants in the ePaper condition had a much higher frequency of guessing while reporting as compared to those in the Mobile condition (chi-square test was highly significant, χ_1^2 = 25.25 (N=63), P<.001.

Figure 4. Histograms showing time frequency of participants' activity compliance self-report in the Mobile and ePaper conditions; frequency distributions were significantly different (Kolmogorov-Smirnov test, P<.001) between Mobile and ePaper conditions. KEY: Sm Day: Same Day as scheduled activity; Nx Day: Next Day after scheduled activity.

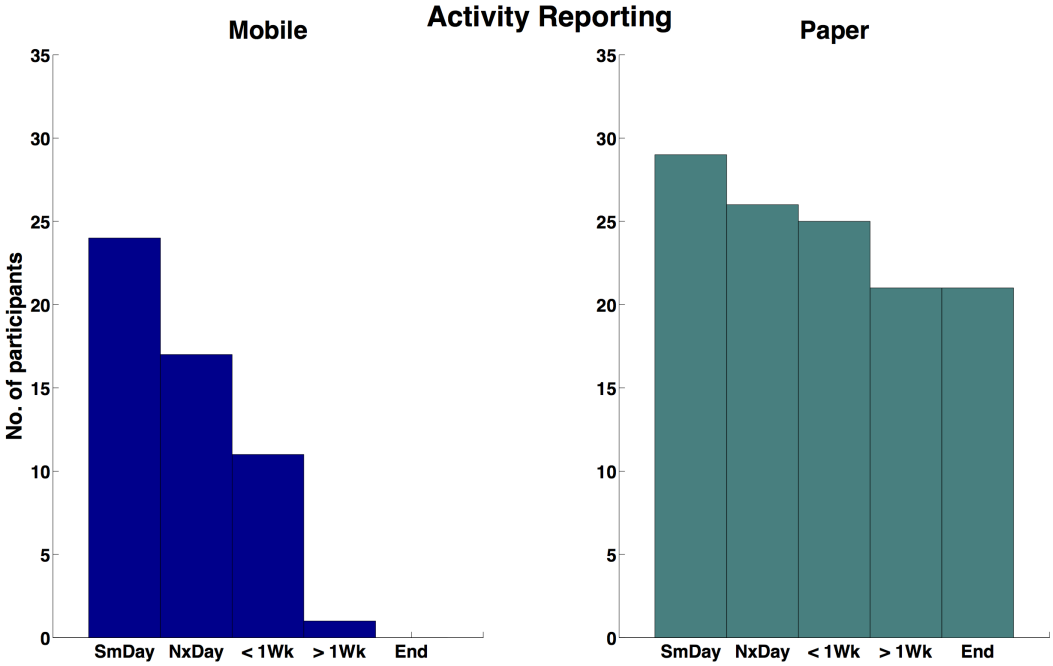


Figure 5. Boxplots showing that confidence in self-report significantly decreased for participants in Mobile condition (Blue) compared to ones in ePaper condition (Black) when self-reporting occurred further away in time with respect to activity occurrence: < 1 week (P < .001), > 1 week (P< .001) and End of study (P< .001). Circles represent medians, boxes represent interquartile intervals and + (Red) represent outliers.

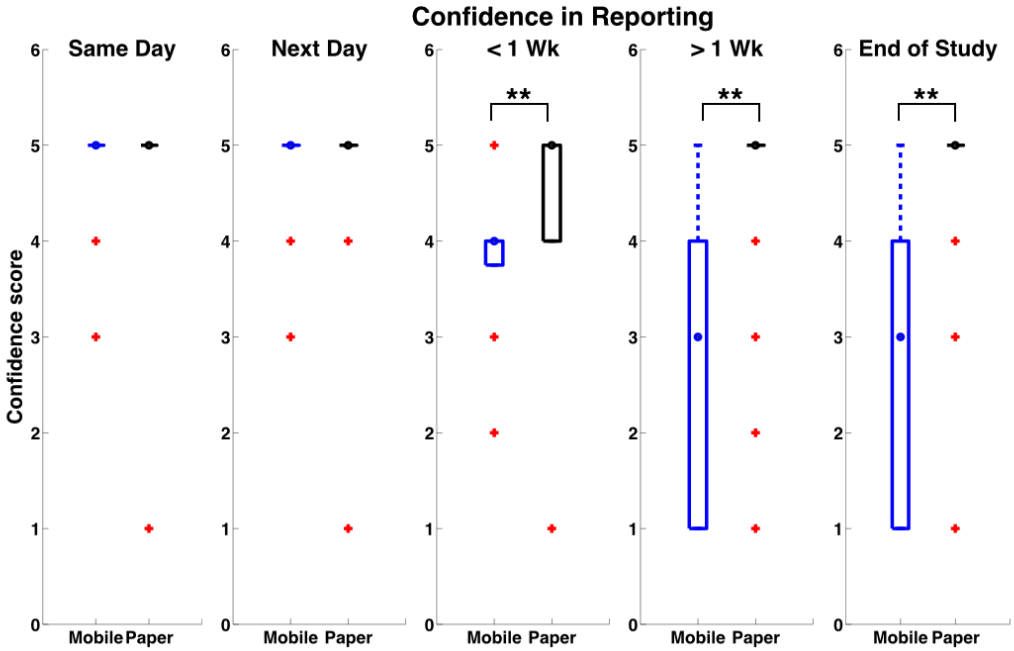
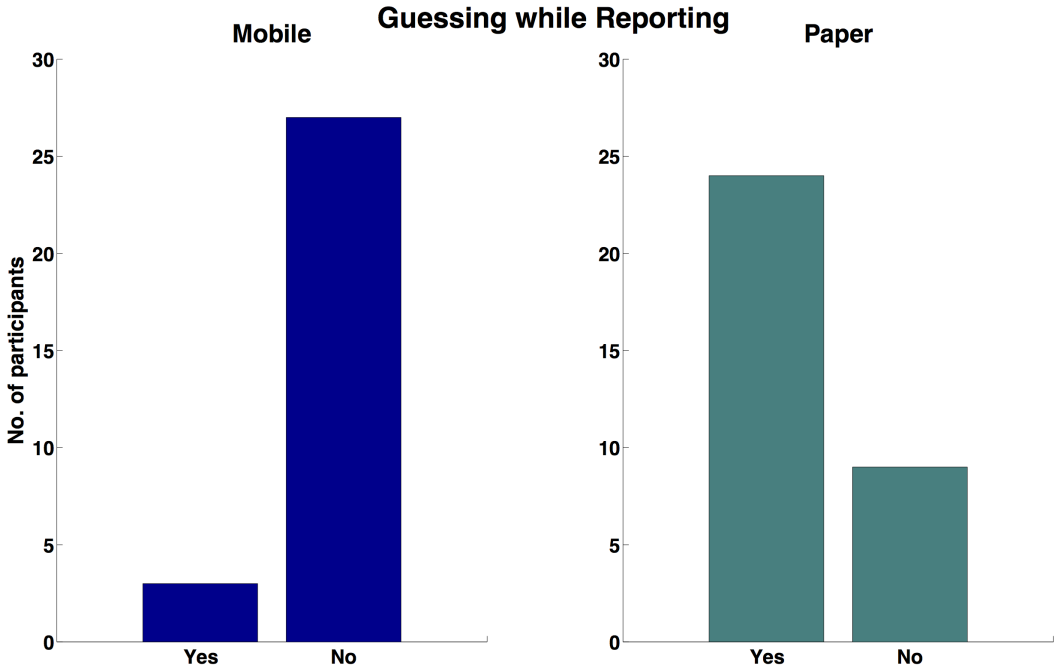


Figure 6. Frequency of guessing during activity compliance reporting.

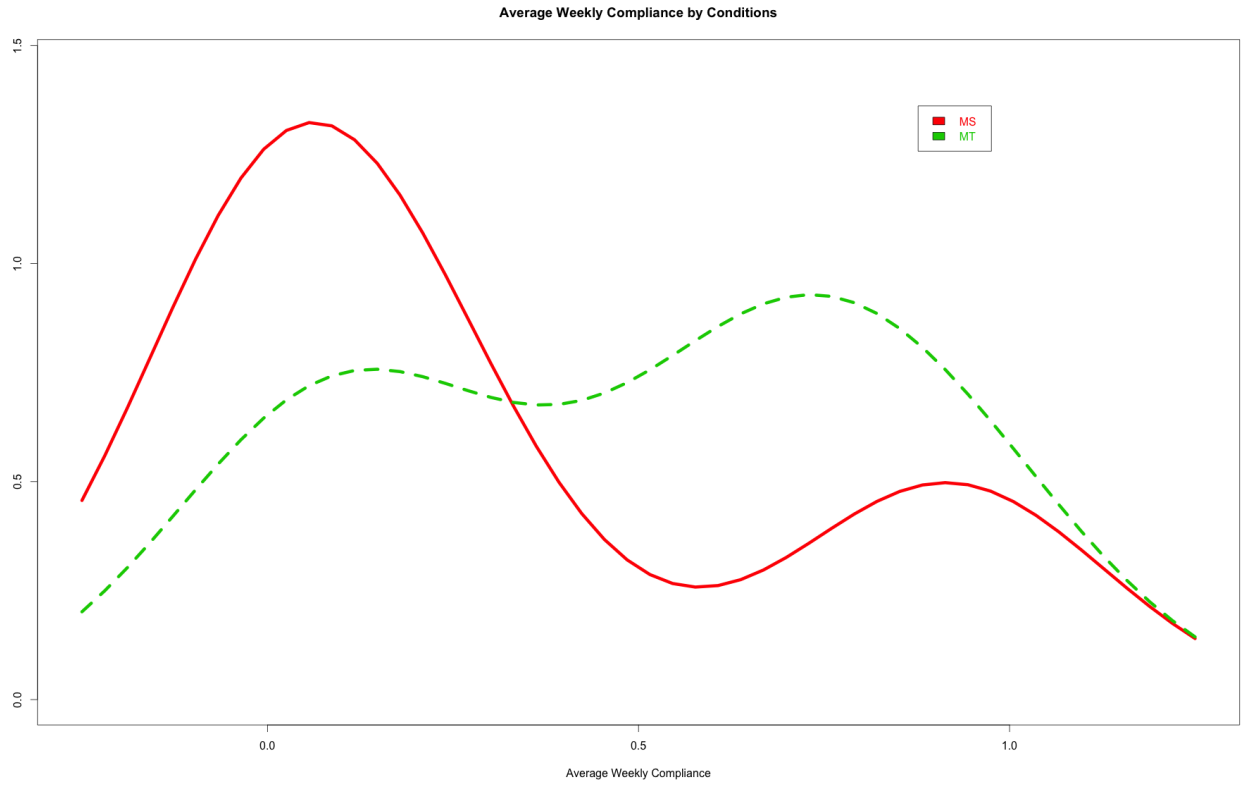


RH2: Higher Compliance in Team Conditions

Given that the accuracy of self-reporting compliance in the ePaper conditions was much lower than in the Mobile conditions, we subsequently focused on analyzing compliance and adherence from the Mobile conditions only. To understand whether being in a team induced higher compliance than being alone, we compared Mobile Solo vs Mobile Team conditions. We first examined the overall compliance between the 2 conditions. Overall compliance was defined as the average compliance across 8 weeks (ie, challenge duration). There was a significant difference in the overall compliance score for Mobile Solo (mean [SD] 0.30 [0.39]) and Mobile Team (mean [SD] 0.49 [0.35]) conditions ($t_{50.82}$=1.94, P=.05). This suggests that working in a team increased participants' overall compliance within Fittle.

We further examined the distribution of the overall compliance in Mobile Solo and Mobile Team conditions. A kernel density plot (Figure 7) showed that overall compliance in both Mobile Solo and Mobile Team conditions interestingly follows a bimodal distribution. Most participants in the Mobile Solo condition had a very low overall compliance (left modal) and very few participants in the Mobile Solo condition had a high overall compliance (right modal). However, in the Mobile Team condition, the proportion of participants whose overall compliance was around the left modal was reduced and most participants' overall compliance was around 0.75 (right modal). This dichotomy in the distribution of overall compliance across Team versus Solo conditions suggests that the team social support-based intervention is more likely to shift individual user compliance closer to the team mean (ie, increase individual compliance). The challenge therefore to design more effective socially based health behavior interventions is to focus on increasing overall mean compliance in teams/groups of participants.

Figure 7. Kernel Density plots of average weekly compliance showing a bimodal distribution for both Mobile-Solo (Red) and Mobile-Team (Green) conditions.



RH3: Greater Adherence in Team Conditions

Based on the self-reported compliance data, adherence of the ePaper groups was high. The average adherence rate of the ePaper Solo group was 0.97 and ePaper Team group was 0.85 (Table 2). However, given the low confidence in the compliance report in the ePaper conditions, we chose to focus the analysis on the Mobile conditions.

We applied survival analysis to test the hypothesis that participants assigned to teams (Mobile Team) have greater adherence to the program, controlling for perceived system usability and attitudes toward the system. In the present study, the event of interest is the time at which a user disengaged from Fittle. This analysis predicted the length of engagement in Fittle based on whether users worked in teams and other control variables.

We considered a participant to have disengaged if they stopped reporting compliance data for an entire week (ie, the compliance of a week is zero). Participants who were engaged until the end of the 8-week study were treated as right censored in the survival analysis.

Table 3 and Figure 8 show the results of the survival analysis. Effects are reported in terms of the hazard ratio. The hazard ratio value for TeamCondition means that participants assigned to Team condition are 66% more likely to engage longer than those assigned to the Solo condition (100% – [100% × 0.34]). The hazard ratio for Attitude indicates that survival rates are 32% higher for those who had a positive Attitude at least 1 standard deviation greater than average, when all other variables were at their average levels. These findings taken together indicate that the team-based intervention, when combined with a positive attitude toward the mobile phone-based program, can positively impact and increase long-term adherence to the program.

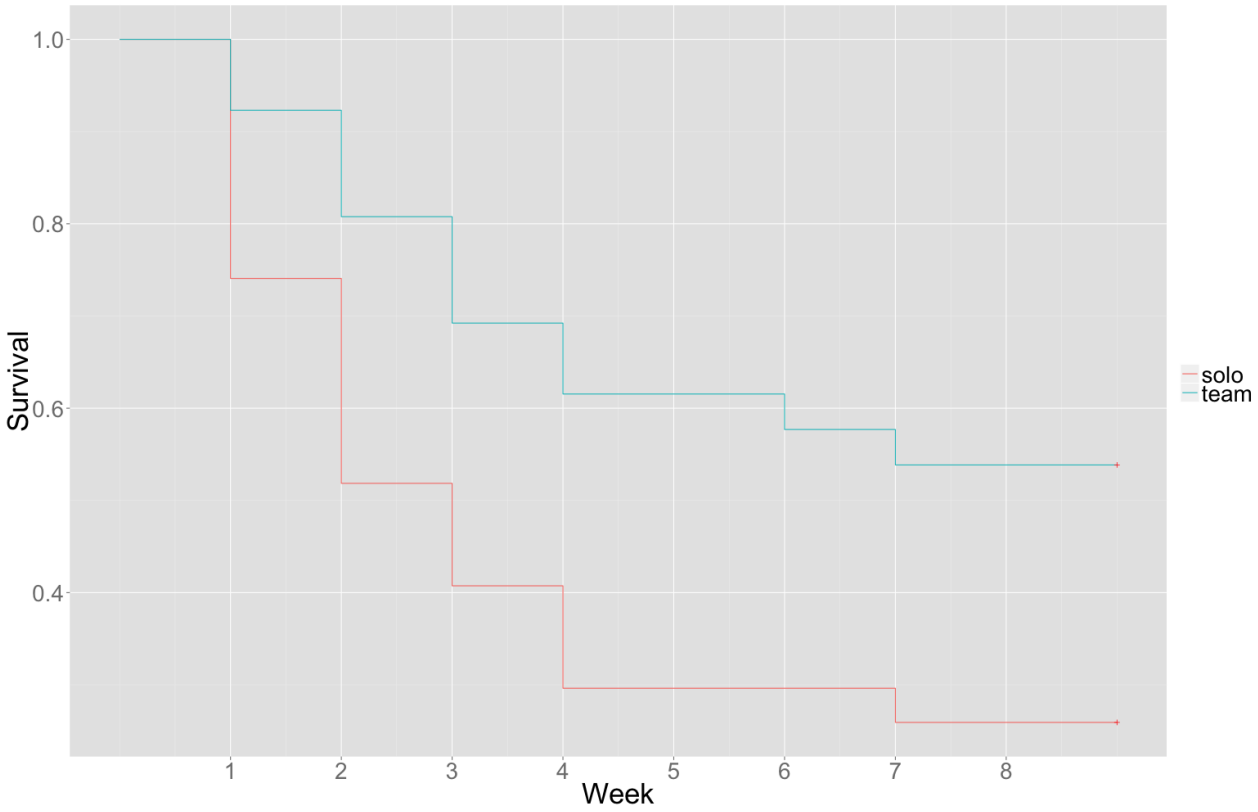
Table 3. Results of the survival analysis.

Variables	Hazard ratio	Lower 95% CI	Upper 95% CI
TeamCondition[a] (0=Solo, 1=Team)	0.34 (*P*=.02)	0.14	0.86
Attitude[b]	0.68(*P*=.02)	0.49	0.95

[a]TeamCondition is a binary predictor variable that describes whether a user was assigned to a Team condition or a Solo condition.

[b]SUS and Attitude are included as covariates to check whether participants' perceived usability of Fittle and their attitude toward the program interfered with the ability to perform and report compliance data.

Figure 8. Survival curves for participants in Mobile-Team (Green) and Mobile-Solo (Red) conditions showing a significantly higher survival rate (ie, "adherence" in the Mobile-Team condition; *P*=.02).



RH4: Superior Outcomes in the Mobile-Team Condition

Table 4 shows participants' average pre- and post-changes (measured by (post-pre)/pre) on Healthy Eating, Perceived Stress Scale, and MET. On average, participants experienced changes in the positive directions (ie, healthier eating habits, lower stress levels, and more physically active) except for participants in the Mobile Solo condition. Participants in the Mobile Solo condition reported higher perceived stress levels at the end of the study.

Table 4. Mean scores of percentage changes in Healthy Eating, Perceived Stress Scale, and MET, and the significance of 2 × 2 ANCOVAs.

	ePaper		Mobile		Probabilities			
	Solo	Team	Solo	Team	Media	TeamType	Attitude	Education
Healthy eating (%)	-0.15 (0.08)	-0.13 (0.11)	-0.06 (0.10)	-0.05 (0.12)	.001	.62	.002	.30
Perceived Stress Scale (%)	-0.27 (0.23)	-0.20 (0.22)	0.18 (1.05)	-0.08 (0.35)	.02	.39	.006	.35
MET (%)	0.04 (0.17)	0.02 (0.09)	0.04 (0.15)	0.05 (0.19)	.59	.85	.04	.38

In order to assess the relationship between media type, team type, and participants' improvements in Healthy Eating, Perceived Stress Scale, and MET, a series of 2 × 2 (Media: ePaper vs Mobile × Group Type: Solo vs Team) mixed effects ANCOVAs were conducted, with a modified *P*-value of .017 (Bonferroni correction). The challenges (StressBusting or NutriWalking) are modeled as random effects and participants' attitude toward the Fittle program and their education level are modeled as covariates.

RH4 was not supported in this study. Table 4 shows the results of the analysis. The influence of Media and TeamType was found to be statistically nonsignificant on participants' changes in Perceived Stress Scale and MET. In terms of participants' improvement in eating patterns (Healthy Eating), participants in ePaper conditions reported more improvements (mean [SD] -0.14 [0.09]) than participants in Mobile conditions (mean [SD] -0.06 [0.11]), which was statistically significant. The strength of this relationship, as indexed by η^2, was .27. Overall, these results suggest that the ePaper-based intervention outperformed the mobile delivery of the intervention in helping participants achieve the health outcomes in this feasibility study.

Discussion

Principal Results

In this project, we studied a novel, low-cost, group-based mobile phone health and wellness application called Fittle. The intervention combined the traditional daily activities suggestions/prompts with real-time, peer-to-peer social support that encouraged discussions consistent with guidelines for behavior change for health and wellness [29,30,31] and online community building [10,12]. More importantly, this application encouraged and helped users to learn and master new, healthier habits progressively over the 8-week period.

Our first specific study aim was to explore if social support improved adherence. Participants in the Mobile Team condition reported higher compliance to the program compared to those in the Mobile Solo condition. Our survival analysis showed that participants assigned to the Team condition are 66% more likely to engage longer than those assigned to the Solo condition. Furthermore, participants' overall attitude toward the program had a significant effect on participants' adherence, which supports the notion that efforts to enhance positive attitudes toward these health behavior change programs can greatly increase their impact.

Our second specific study aim was to assess whether media types (ePaper vs Mobile) were associated with different levels of compliance and adherence to wellness programs. We found that participants in the ePaper conditions reported a much higher compliance score. However, the confidence in the compliance report in the ePaper condition was much lower than in the Mobile condition, while the attrition rate was higher in the ePaper condition. One major factor that could have led to this behavioral discrepancy between the 2 conditions is that the affordance of the Mobile app is much lower to support back-reporting in time, which is not the case with the ePaper workbook. This could have led to possible over-reporting in the ePaper condition precisely due to the easy access of the entire ePaper workbook.

These findings are consistent with those of Stone and colleagues [32] who also found that patients maintaining ePaper medication diaries showed a higher frequency of back-reporting or "hoarding." These results may provide additional support for the use of mobile diaries for patients/users wherein closer tracking of long-term behaviors are required. It also highlights the need for objective measurement of adherence to behavioral treatment regimens, which in the context of physical activity interventions can potentially be achieved with wearable activity trackers.

The third aim was to assess whether the use of Fittle led to positive changes to participants' eating behaviors, physical activity, and stress level. The results revealed that participants all reported some positive changes in Healthy Eating, Perceived Stress Scale, and MET, except that participants in the Mobile Solo condition reported higher Perceived Stress Scale at the end of the study. No significant effects of media or team type were found for the changes observed in Perceived Stress Scale and MET. However, as for Healthy Eating, participants in ePaper conditions reported more improvements than participants in Mobile conditions. The reason for these results is unclear, and it is not explainable given our study design. One possibility is that the higher attrition in the ePaper groups could have been related to less motivated participants dropping out, leaving a more-motivated ePaper cohort to participate for the study duration. On the contrary, the mobile app may have retained a less-motivated cohort who would have otherwise had less compliance and, consequently, these less-motivated participants did not see the expected health benefits.

Limitations

Generalizability of the initial findings from this feasibility study is limited given that the sample was mostly white and female. Moreover, recruitment through online advertisements resulted in a selection bias with more highly educated people being involved in the study, which is in line with the results from previous reviews indicating that mainly higher educated individuals participate in online interventions [33]. This further precludes the generalizability of our study results.

The overall attrition rate of this study was 28.2% (35/124). Missing data may indicate a participant's dissatisfaction with the program. In this study, attrition was not equal among the conditions, with attrition in the ePaper conditions being higher than the Mobile conditions. The attrition rate in the ePaper conditions was about 36.4% (24/66). However, in the mobile conditions (Mobile Solo and Mobile Team), the attrition rate was 18.9% (11/58), which is in line with results from recent reviews that indicated that the average attrition rate in Internet-based physical activity interventions is about 20% [34,35]. However, this is much higher than the 7% attrition rate reported in mobile phone-based interventions [18]. This higher attrition rate may be due to the fact that the Fittle app was a work-in-progress app. Participants held more positive attitudes toward the ePaper-based program than the app-based program. This may have affected participant engagement. Currently, we are working on redesigning these components to improve user experience and accessibility of the health tips-based electronic cards, which could help increase participant engagement in future interventions.

Due to the higher than expected attrition rate, the absolute sample size at the post survey was low, especially for the self-reported compliance, Healthy Eating, Perceived Stress Scale, and MET data. This reduced statistical power could have also partly precluded detection of any intervention effects in the post survey on self-reported Healthy Eating, Perceived Stress Scale, and MET data.

Finally, our initial research design strived to create equal-sized teams. However, not every participant who qualified to participate actually joined the study and the teams ended up having different sizes. In a future clinical trial, the design would need to be altered to address the team size issue and to potentially include analytical approaches to stratify and weight teams based on size while examining intervention efficacy.

Implications and Future Research

The results from this study provide additional evidence to support the role of positive social/group effect on participants'

adherence in mobile phone-based wellness programs. The sizes of the teams range from 3 to 9 participants. However due to the small number of teams, we did not get much insight into the optimal size of the teams. Future studies on the effects of team sizes on adherence and best practices to organize effective teams are necessary.

Moreover, it should be noted that the Mobile conditions received different forms of social interactions and support (ie, interactions with other participants in Fittle, FittleBot-provided daily tips). However, our study design does not allow us to determine whether all components are equally effective and whether their combination is necessary. Future studies should separate the different intervention components in order to assess their individual impact. Furthermore, recent research suggests that prompts via auto-messages to stimulate social interactions within groups helps significantly increase participation in socially based health behavior change interventions [12,36]. Therefore, further research is necessary to help design more targeted prompts within our mobile phone application to most effectively increase participant engagement.

Conclusions

In conclusion, in this initial study examining effectiveness of a group-based mobile phone wellness program, we demonstrated that having people work in teams led to a significantly higher level of adherence and engagement over time. Positive changes in participants' eating patterns, perceived stress, and physical activity levels were reported. We believe that these findings are very promising and should encourage future research to investigate and characterize the role of objective measures of participants' adherence and social support in mobile phone-based wellness programs.

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Conflicts of Interest

The authors developed the Fittle application. Xerox owns full intellectual property of the Fittle app. The researchers developed the application and objectively evaluated it, but have no commercial intent with the app.

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Abbreviations

ANOVA: analysis of variance
ANCOVA: analysis of covariance
CI: confidence interval
MET: metabolic equivalent of task
RH: research hypotheses
SUS: System Usability Scale

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Original Paper

A Mobile Phone App to Stimulate Daily Physical Activity in Patients with Chronic Obstructive Pulmonary Disease: Development, Feasibility, and Pilot Studies

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Abstract

Background: Patients with chronic obstructive pulmonary disease (COPD) demonstrate reduced levels of daily physical activity (DPA) compared to healthy controls. This results in a higher risk of hospital admission and shorter survival. Performing regular DPA reduces these risks.

Objective: To develop an eHealth intervention that will support patients with COPD to improve or maintain their DPA after pulmonary rehabilitation.

Methods: The design process consisted of literature research and the iterative developing and piloting phases of the Medical Research Council (MRC) model for complex clinical interventions and the involvement of end users. Participants were healthy adults and persons with COPD.

Results: The mobile phone interface met all the set requirements. Participants found that the app was stimulating and that reaching their DPA goals was rewarding. The mean (SD) scores on a 7-point scale for usability, ease of use, ease of learning, and contentment were 3.8 (1.8), 5.1 (1.1), 6.0 (1.6), and 4.8 (1.3), respectively. The mean (SD) correlation between the mobile phone and a validated accelerometer was 0.88 (0.12) in the final test. The idea of providing their health care professional with their DPA data caused no privacy issues in the participants. Battery life lasted for an entire day with the final version, and readability and comprehensibility of text and colors were favorable.

Conclusions: By employing a user-centered design approach, a mobile phone was found to be an adequate and feasible interface for an eHealth intervention. The mobile phone and app are easy to learn and use by patients with COPD. In the final test, the accuracy of the DPA measurement was good. The final version of the eHealth intervention is presently being tested by our group for efficacy in a randomized controlled trial in COPD patients.

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KEYWORDS

telemedicine; mobile phones; chronic obstructive pulmonary disease; motor activity

Introduction

Regular physical activity has significant health benefits and contributes to the prevention of non-communicable diseases [1]. Inactivity is estimated to cause 9% of premature mortality worldwide [2]. In older adults, there is strong evidence that regular exercise and participation in physical activity lowers mortality and morbidity [3], and has a significant impact on several psychological and cognitive parameters [4]. Moreover, physical activity has been observed as a behavioral determinant for healthy aging [5].

Physical activity is also a relevant behavioral determinant for patients with chronic diseases, such as chronic obstructive pulmonary disease (COPD), to maintain physical condition [6], and to improve health-related quality of life [7]. COPD is a disabling airway disease with variable extra-pulmonary effects that may contribute to disease severity in individual patients. It mostly affects older adults with a history of tobacco smoke exposure [8]. Patients with COPD demonstrate reduced levels of spontaneous daily physical activity (DPA) compared to healthy controls [9]. This contributes to a higher risk of hospital admission and shorter survival [10].

Pulmonary rehabilitation (PR) generally includes exercise training, education, psychosocial and behavioral interventions, nutritional therapy, and outcome assessment [11,12], and it can help to improve physical capacity. Unfortunately, this effect does not always translate into improved DPA, and when it does, it tends to fade out over time [13-15]. Taking into account the benefits of regular DPA [16], it is important for patients with COPD to improve, or at least to maintain their DPA levels after a rehabilitation program has ended.

Technology-based assistance in health care (eHealth) can help support patients with COPD by improving self-management of the disease. Self-management interventions in patients with COPD have been shown to improve health-related quality of life, to lower the probability of a respiratory-related hospitalization, and to reduce dyspnea [17,18]. It has been postulated that an eHealth intervention might also be beneficial in the self-management of DPA in patients with COPD. An important element for successful implementation of an eHealth intervention is to engage users in the design process because design flaws can affect ease of use, usability, and reliability of the system, which may reduce a user's willingness to use the intervention [19].

The objective of this study is to develop an eHealth intervention to support patients with COPD in improving or maintaining DPA after PR. We investigate what type of interface is adequate and feasible toward obtaining this objective and scored the resultant eHealth intervention in terms of usability and privacy.

Methods

Recruitment

The design process was in alignment with the first two phases (developing and piloting) of the Medical Research Council (MRC) model for complex clinical interventions. The key elements of the development and evaluation process of the MRC model were taken into account throughout the design process [20] (Figure 1). This paper primarily focuses on phases A2 through C. Users were defined as persons suffering from COPD, who were aged 40 years or older, living independently, and had completed a rehabilitation program.

eHealth Intervention and Interface

Based on the literature and our own practice-based experience in the treatment of patients with COPD, the eHealth intervention that we sought to develop had to meet the following requirements: (1) non-obtrusive and easily transportable, (2) objective measurement of DPA, (3) direct feedback and personal DPA, and (4) monitoring and feedback available from a health care professional (HCP).

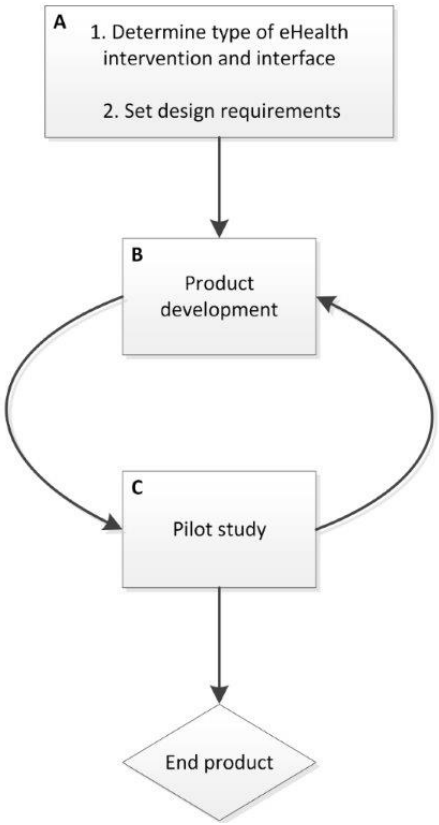
At the time of this study (2010), several eHealth interventions for physical activity engagement in patients with COPD had been described. They were available in various forms, such as wearable sensors [21], television [22], computers [23], a manual input device [24], and mobile phones [25,26].

As an interface, a smartphone with app capabilities met all set requirements. Although the penetration rate of smartphone use among aging adults was estimated to be low at the time, they were expected to become the majority over the next few years [27,28]. Moreover, mobile touch screens are generally easy for the elderly to use [27], and mobile phones are already equipped with an accelerometer that is both accurate and reliable in measuring and quantifying physical activity in a laboratory setting [29].

Although various apps for mobile phones are available that stimulate engagement in physical activity, none of the apps met all the requirements that are needed to fully address our research goal. Therefore, we decided to develop a new app and an associated website for HCPs. This paper focuses on the development of an app for an eHealth intervention.

We encountered 2 types of apps: those developed for mobile phones running on the interactive operating system (iOS) and those developed for mobiles phones running on the Android operating system. Following a comparison of these 2 operating systems, we opted for the HTC HD2 device (HTC). HTC was chosen as the preferred device based on its higher battery capacity, an absence of restrictions in distributing the app, and its affordable price.

Figure 1. Design process.



Pilot Studies

After phases A and B (Figure 1), the product was tested in 3 pilot studies (C1, C2, and C3), and improved through an iterative process. The pilot studies were designed to test the usability of the interface and app, in addition to privacy concerns of the users. The associated website for HCPs was not yet employed in the pilot studies. We also sought to obtain an indication of the accuracy of DPA measurements by the app. Specific sample size recommendations for this type of development and feasibility pilot studies are scarce, as most recommendations are for pilot studies that focus on the feasibility of corresponding RCT studies [30]. The pilot studies were designed to minimize strain on patients with COPD. Therefore, we began the first pilot study with healthy volunteers who had previous mobile phone experience. A subsequent version was then tested in a subset of patients with COPD. Finally, a larger group of patients with COPD were invited to test the final version. We aimed to include 10, 3, and 10 participants in pilot study groups C1, C2, and C3, respectively [31]. The participants in pilot group C1 were recruited from a school, in pilot group C2 they were recruited from a hospital, and in pilot group C3 they were recruited from a rehabilitation center. For inclusion criteria, see Table 1.

Table 1. Characteristics of the three pilot studies in study phase C.

Pilot study	Inclusion criteria	Duration of study	Version application
C1	Healthy persons, experience with mobile phones	1 week	Figure 2
C2	Persons suffering from COPD, aged ≥40 years, living independently, and having completed a rehabilitation program	4 days	Figure 3
C3	Persons suffering from COPD, aged ≥40 years, living independently, and having completed a rehabilitation program (same as pilot C2)	3 weeks	Figure 4

The participants received instructions on the functionalities of the mobile phone and app, and information on the course of the study over a training session lasting 1.5 hours. Thereafter, each participant received a HTC Desire A8181 mobile phone with the app installed, and they were given the opportunity to practice, ask questions, and provide feedback. They were instructed to wear the mobile phones in pouches (with various choices for personalization) on their belts. This location was chosen because the best measurements are achieved by positioning the accelerometer as close to the center of gravity as possible [32,33]. They were also instructed to wear accelerometers (BHC0100 Sensewear PRO armband, Body Media, Pittsburgh, US) that had been previously validated in patients with COPD [34-37], on their right upper arms. The armband and mobile phone were worn during waking hours. The participants were instructed to perform their daily activities as usual.

After each study, a group consultation session was held. The sessions started by asking the participants their general impression of the app followed by writing down 3 positive and 3 negative aspects. The most occurring aspects were written on a flip-over and further discussed. The following topics were each discussed for 5 minutes: wearing the mobile phone, using the app, comprehensibility, navigation, future use, and improvements to the app. Sessions were recorded and minutes were made. Afterwards, the sessions were separately summarized by 3 researchers and the main points were taken into consideration for adjustment of the app. Furthermore, the participants were asked to respond to 3 questionnaires (1) the Usefulness, Satisfaction, and Ease of use (USE) questionnaire on usability [38]; (2) the Florida State University (FSU) mobile device feedback preferences scale; and (3) the FSU physiological monitoring privacy scale (inspired by Beach et al [39] and Kwazney et al [40]). Results of the USE questionnaire were compared within and between pilot studies with independent and dependent *t* tests. All of the participants were required to provide signed informed consent prior to the study. Pilot studies were waived from ethics committee approval by the UMC Utrecht Medical Ethical Research Board (number research protocol 10/259). Correlations between the accelerometers on the armbands and the mobile phones were computed by calculating Pearson's correlation coefficient (*r*) in SPSS version 21. The distinctive characteristics of the pilot studies can be found in Table 1.

An additional pilot study, C4, was performed to provide an extra check on DPA measurement accuracy. This was performed with 10 participants who wore the armband and mobile phone for 1 week. Participants met the same inclusion criteria as in pilot studies C2 and C3. These participants did not take part in a consultation round and did not fill out questionnaires since the development of the app was deemed ready at this point.

In pilot study C1, participants were asked to record their daily activities in diaries, including corresponding times of day and durations. In pilot study C3, 3 randomly selected participants wore accelerometers during the first week.

Figure 2. In version 1, the y-axis provides a measure for activity, while the x-axis provides a measure for intensity. The DPA goal is met when the blue ball (representation of current activity status) is kept in the green circle at all times. The widget shows a current status towards reaching a DPA goal (pilot study C1).

Results

Setting Design Requirements

A list of design requirements for the eHealth intervention was prepared with respect to the general requirements. Some aspects of the existing apps found during the desk research were also added as requirements. Furthermore, since COPD is inversely related to socioeconomic status and mostly affects older adults [41], special attention was paid to readability and comprehensibility. Focus was put on the mobile phone app for the users (Textbox 1).

Figure 3. In version 2, the left axis shows amount of steps, while the right axis gives a measure of intensity. The DPA goal is reached when the open circles (representation of current activity status) are kept in the rising green circles at all times (pilot study C2).

Figure 4. In version 3, the bar on the left side combines amount and intensity of steps. The DPA goal is met when the vertical stripe (representation of current activity status) is kept in the rising rectangle at all times until the green area is reached. Absolute number of steps and current advice on DPA progress are also shown (pilot study C3).

The requirements for the monitoring website for the HCP can be found in Textbox 2. Feedback from HCP on these latter requirements was obtained by consulting with 10 independent respiratory nurses (in a consultation round), and 2 physiotherapists (by phone) who work with COPD patients. Additions to the requirements with regard to privacy and communication were made in response to their feedback.

Product Development

The app and website were created by a small business enterprise that specializes in developing health care apps. Interactive team work sessions were held during this process. The various designed versions of the app that were tested during the pilot studies are illustrated in Figures 2-4. Communication and multimedia design students from Utrecht University of Applied Sciences were employed to assist in improving the design of the app and the widget after pilot study C2.

Pilot Studies

A total of 10 participants took part in pilot study C1, 3 in C2, and 7 in C3, of which 1 (10%), 3 (100%), and 4 (57%) were male, respectively. The mean (SD) age of the participants was 21.5 (2.84), 65 (10), and 60.4 (9.4) years in C1, C2, and C3, respectively. The participants were limited in their DPA due to having COPD and were enrolled in a PR program at the time of the study.

The results from the consultation rounds are shown in Multimedia Appendix 1. In pilot study C2, 1 participant (33%, 1/3) was not interested in the intervention; therefore, the results from the consultation round of this group primarily focused on the remaining 2 participants. This participant did fill out the questionnaires. Eleven subjects were recruited to participate in pilot study C3. After the training session, 4 (36%, 4/11) declined to participate due to the degree of expected effort. On day 3 and 7 of pilot study C3, corrected apps were installed due to discovered errors in the algorithm that caused the app to measure too few or no steps.

The results from the USE questionnaire are shown in Table 2. The usability scores for pilot study C1 were significantly lower than ease of use, learning, and contentment scores ($P<.05$ for all). For pilot study C3, usability scores were significantly lower than for ease of learning ($P<.05$). Ease of learning was significantly lower in patients with COPD compared with healthy participants in pilot study C1 ($P<.004$ for C2; $P=.017$ for C3). The feedback preferences questionnaire in general did not provide added insights to the consultation rounds.

Textbox 1. Users' requirements of the mobile phone-based app.

Software

- Reasonably accurate measurement of DPA
- DPA data are recorded on the mobile phone and available to the user in real time
- Filters out movement produced by riding a car, bus, or train
- Data are available for at least 12 weeks after generation (preferably even longer, such as 6 months to 1 year)
- Data are sent automatically to a secured website for HCP (4-6 times a day)
- Data are only available to users and HCP
- Data are saved when phone runs out of battery
- Data acquisition continues when the mobile phone is in standby mode or is being used for other purposes
- Goal achievement elicits a motivating or complimentary message
- Personal results can be published on social media if desired
- The app uses little energy
- An app-killer is added that can stop all apps except for the intervention
- The app can be used on mobile phones of different brands
- The app can be adjusted in the future

Interface

- DPA is presented in duration, frequency, and intensity
- Data are available in graphs and numbers
- Visual display of progress and goal achievement on screensaver
- Progress is visible in numbers (and percentage until goal is reached)
- Progress is visible based on day, week, and month
- Letters and figures are easily readable (large font and high contrast)
- Navigation is easy and comprehendible; only a few steps are required to reach a desired location
- All text is formulated for persons with low literacy
- The app can be personalized

Textbox 2. Website requirements for the HCP.

Software

- Data are available for at least 12 weeks after generation (preferably even longer, such as 6 months to 1 year)
- Data are only available to the HCP
- SMS text messages (short message service, SMS) or phone calls can be made from the website
- DPA goals can be adjusted from the website
- Goals can be set based on steps, duration, frequency, and intensity
- Goals are individually adjustable

Interface

- DPA is presented in duration, frequency, and intensity
- Data are available in graphs and numbers
- Overview of the activity status of multiple patients
- Progress of each patient is easily visible in an overview (eg, traffic light colors)
- Individual page for each patient with detailed DPA information

Table 2. The mean (SD) scores of the USE questionnaire in the various pilot studies.

Pilot study	Scores, mean (SD)			
	Usability	Ease of use	Ease of learning	Contentment
C1	3.8 (2.0)	5.4 (1.7)	6.6 (0.6)	4.8 (1.7)
C2	3.9 (2.9)	5.1 (2.1)	4.1 (2.9)	5.7 (1.7)
C3	3.7 (2.0)	4.8 (2.2)	5.9 (1.5)	4.4 (1.8)

The correlations between the mobile phones and the armband accelerometers for steps per day are shown in Table 3. The armband of participant 1 (C1) malfunctioned. Participant 2 (C3) only wore the armband for 2 days and was excluded from analysis. The additional pilot study C4 was performed solely to provide an extra check on DPA measurement accuracy. The numbers of valid days for analysis were 8, 4, 8, and 8 for all participants in pilot study C1, C2, C3, and C4, respectively.

Table 3. Correlation between mobile phones and armband accelerometers.

Pilot study, r^a	Participant									
	1	2	3	4	5	6	7	8	9	10
C1	N/A	.94[b]	.96[b]	.76[b]	.71[b]	.76[b]	.64	.61	97[b]	.13
C2	.87[b]	.54	.72[b]	N/A	N/A	N/A	N/A	N/A	N/A	N/A
C3	.45	N/A	.67	N/A	N/A	N/A	N/A	N/A	N/A	N/A
C4	.99[b]	.98[b]	.96[b]	.90[b]	.99[b]	.74	.69	.69[b]	.84[b]	.99[b]

[a]Pearson correlation coefficient.

[b]Significant at $P<.05$

Discussion

Principal Findings

Engaging patients with COPD in active control over their DPA can work as a preventive measure to prevent functional decline [42]. Therefore, our objective was to develop an eHealth intervention that will help patients with COPD to improve or maintain their DPA after a period of pulmonary rehabilitation. The final product consists of two components (1) a mobile phone app (the focus of this study); and (2) a website for HCPs. The app measures DPA as steps per day, measured by the accelerometer of the mobile phone, and shows this information to the patient via the display of a mobile phone. A physiotherapist can monitor the patient via a secure website where DPA measurements are accessible from all patients. DPA goals can be adjusted and text messages sent to inform and to motivate patients. Furthermore, the website of the intervention can help an HCP work in a more efficient way by monitoring all of their patients at once and enabling them to intervene early on in patients who have trouble maintaining DPA.

Use

The mobile phone-based app was found to be easy to learn and use by the participants as well as the patients with COPD. Usability scores were lower than ease of use, learning, and contentment scores. This was significant in pilot study C1 and C3 (for ease of learning). This could be explained, in part, by the fact the app was still in the development phase and still contained some errors, as demonstrated in pilot study C3. Ease of use scores were lower for the patients with COPD, though not significantly. This could be because touch screen pointing performance reduces with age. It is influenced by size, spacing, and location of the target, as well as by size of the device and practice [27,28]. Older people prefer functions that support their declining functional capabilities, and enjoyability is an important determinant of adherence [27]. During the development of the app, attention was paid to all of these aspects. Ease of learning was significantly lower in patients with COPD compared with healthy participants. Proper instruction will greatly influence success in mobile phone usage [43]. Older adults take longer in learning to use mobile phones, and they commit more errors when entering information into mobile phone-based software app [44]. Efforts to overcome these behavioral and attitudinal barriers must include well-designed training that is targeted to older adults to teach mobile phone usage skills as well as creating software with an improved interface and operation [44].

Design

The graphic design of the app was adjusted several times to improve use and to provide a better understanding of the DPA data, as well as to accommodate those with low technology literacy. A combination of qualitative and quantitative feedback proved the best fit.

Privacy

The key aspect, with respect to privacy, is to give the user control over their data distribution. An important element of the intervention is that an HCP has insight into a patient's DPA data. This did not pose a problem for the participants in the pilot studies.

Measurement of DPA

Distance travelled, cycling, strength training, and the intensity of walking stairs were not properly captured by the app. The first two activities could be added by using GPS data, but this

put too much strain on battery life. The accuracy of the measurement varied greatly between participants. Possible reasons for poor correlations include the amount of time spent in a train, bus, or car (participant 7, pilot study C1), unclear diary entries as to whether the mobile phone was worn during exercise (participant 8, pilot study C1), a phone pouch that contained a magnet (participant 10, pilot study C1), using a walker (participant 2, pilot study C2), and using a mobility scooter (all participants of pilot study C3). Using a walker, mobility scooter, or other forms of assistive devices for DPA were added to the exclusion criteria for participants in the randomized controlled trial (RCT). In pilot study C3, the errors in the app in the first week probably also accounted for poor correlations. An additional pilot study (C4) showed a mean (SD) correlation between the armbands and mobile phone accelerometers of r=.88 (.12).

Limitations

During pilot study C3, errors in the algorithm were discovered twice in the distributed app. Although these were swiftly corrected, this could have had a negative impact on the participants' views of the app.

In pilot study C3, there were 4 (36%, 4/11) dropout participants beforehand due to too much expected effort in learning how to use a mobile phone, and in pilot study C2 there was 1 participant (33%, 1/3) that was not interested in, and did not use, the intervention. This participant had trouble understanding how to use the mobile phone. As mentioned before, proper instruction is key in usage success. More extensive instruction might have improved understanding and prevented dropout. The results of the questionnaires in pilot study C2 may have been negatively influenced by this participant.

Battery life posed a major problem while developing the app. Not all desired options, such as GPS-tracking and continuous measurement, were possible due to limited battery capacity. The "5 minutes on and off" configuration was chosen so the battery would last a whole day, which was deemed important for adherence. With the development of mobile phone technology and accompanying batteries with higher capacity, the app could be adjusted back to continuous measurement, and GPS-tracking could be added.

Using a mobile phone to measure DPA is a good way to obtain objective data on this parameter; however, it is not a highly valid and reliable measurement instrument such as that used in research settings. Additional validated accelerometers would provide improved measurement accuracy of DPA, but it was reasoned that (long-term) adherence to the intervention would benefit from the least amount of devices worn. This app can be useful in obtaining an indication of a patient's activity outside of a clinical setting. It will provide much more reliable data compared to a patient's recall [45,46].

Comparison With Prior Work

A review conducted by Bort-Roig et al [47] evaluated 10 studies that described the accuracy of physical activity data as measured by a mobile phone. The participants were mostly overweight or healthy adults. The studies reported measurement accuracy ranging from 52% to 100% in identifying certain activities and postures (eg, walking or standing). As described, there is room for improvement in DPA measurement accuracy when using a mobile phone accelerometer.

This review also found that physical activity profiles, real-time feedback, social networking, expert consultation, and goal setting were identified as key features that facilitated physical activity engagement. Most of these features are also incorporated in our eHealth intervention.

We found one pilot study that similarly focused on physical activity stimulation in patients with COPD [48]. Their intervention consists of a mobile phone app, website, and separate accelerometer. The participants felt encouraged to be more active. The positive effects included an awareness of DPA performance, the stimulating effect of a daily target goal, and a positive effect on self-efficacy. Motivation dropped when technical problems occurred, which is something that we also encountered in pilot study C3.

Conclusions

By employing a user-centered design approach, a mobile phone was found to be an adequate and feasible interface for an eHealth intervention because it is non-obtrusive, can measure DPA objectively, and, by using an appropriate app, direct feedback on DPA can be given. Moreover, by combining the app with an appropriate and secured website, monitoring and feedback by an HCP is possible. The mobile phone and app are easy to learn and use by patients with COPD. Battery life lasted a whole day with the final version, and readability and comprehensibility of text and colors were good. The accuracy of DPA measurement was good in the final test. The idea of providing an HCP with DPA data caused no privacy issues in the participants. The final version of the eHealth intervention is presently being tested by our group for efficacy in a RCT in COPD patients.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Results from the consultation rounds. Data from [28,40,41,42].

[PDF File (Adobe PDF File), 357KB - mhealth_v4i1e11_app1.pdf]

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Abbreviations

COPD: chronic obstructive pulmonary disease
DPA: daily physical activity
FSU: Florida State University
GOLD: The Global Initiative for Chronic Obstructive Lung Disease
HCP: health care professional
MRC: Medical Research Council
PR: pulmonary rehabilitation
RCT: randomized controlled trial
UMC: University Medical Center
USE: Usefulness, Satisfaction, and Ease of Use questionnaire

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Original Paper

Acceptance of Commercially Available Wearable Activity Trackers Among Adults Aged Over 50 and With Chronic Illness: A Mixed-Methods Evaluation

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Abstract

Background: Physical inactivity and sedentary behavior increase the risk of chronic illness and death. The newest generation of "wearable" activity trackers offers potential as a multifaceted intervention to help people become more active.

Objective: To examine the usability and usefulness of wearable activity trackers for older adults living with chronic illness.

Methods: We recruited a purposive sample of 32 participants over the age of 50, who had been previously diagnosed with a chronic illness, including vascular disease, diabetes, arthritis, and osteoporosis. Participants were between 52 and 84 years of age (mean 64); among the study participants, 23 (72%) were women and the mean body mass index was 31 kg/m^2. Participants tested 5 trackers, including a simple pedometer (Sportline or Mio) followed by 4 wearable activity trackers (Fitbit Zip, Misfit Shine, Jawbone Up 24, and Withings Pulse) in random order. Selected devices represented the range of wearable products and features available on the Canadian market in 2014. Participants wore each device for at least 3 days and evaluated it using a questionnaire developed from the Technology Acceptance Model. We used focus groups to explore participant experiences and a thematic analysis approach to data collection and analysis.

Results: Our study resulted in 4 themes: (1) adoption within a comfort zone; (2) self-awareness and goal setting; (3) purposes of data tracking; and (4) future of wearable activity trackers as health care devices. Prior to enrolling, few participants were aware of wearable activity trackers. Most also had been asked by a physician to exercise more and cited this as a motivation for testing the devices. None of the participants planned to purchase the simple pedometer after the study, citing poor accuracy and data loss, whereas 73% (N=32) planned to purchase a wearable activity tracker. Preferences varied but 50% felt they would buy a Fitbit and 42% felt they would buy a Misfit, Jawbone, or Withings. The simple pedometer had a mean acceptance score of 56/95 compared with 63 for the Withings, 65 for the Misfit and Jawbone, and 68 for the Fitbit. To improve usability, older users may benefit from devices that have better compatibility with personal computers or less-expensive Android mobile phones and tablets, and have comprehensive paper-based user manuals and apps that interpret user data.

Conclusions: For older adults living with chronic illness, wearable activity trackers are perceived as useful and acceptable. New users may need support to both set up the device and learn how to interpret their data.

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KEYWORDS

chronic disease; physical activity; sedentary lifestyle; wearables

Introduction

Background

Physical activity levels often decline with age and over two thirds of adults over the age of 60 sit for more than 8.5 hours of their waking day [1]. Physical activity can improve blood pressure, body composition, and overall health, which can prevent frailty and can contribute to a longer independent life [2,3]. Physical activity guidelines recommend adults over the age of 50 to perform moderate to vigorous physical activity for at least 150 minutes/week [4-6]. The guidelines define inactivity as "insufficient amounts of moderate to vigorous physical activity" and Katzmarzyk has noted that this accounts for only 3% of waking hours [4-7]. However, a sedentary lifestyle and physical inactivity are independent risk factors for chronic disease and a shortened lifespan [8-10]. Sedentary behavior is "any waking behaviour characterized by an energy expenditure of 1.5 or less metabolic equivalents while in a sitting or reclining posture" and includes sitting, television watching, computer use, and travel [11].

Home-based physical activity programs have significant potential for encouraging physical activity in older adults [12]. Yet, although sedentary persons can certainly adopt and continue regular long-term physical activity [13], daily adherence to home-based programs is low [14]. Successful interventions are often expensive and time intensive [15]. Programs that build self-awareness may be most amenable to lasting participation [15]. Goal setting has significant promise when it comes to promoting physical and dietary changes [16]. There is evidence that other behavior change techniques, such as self-monitoring, risk communication, and the use of social support can be beneficial additions to change-based interventions [17]. There is also some evidence that tailored feedback and information helps adults adopt physical activity and health-based activities [18-20].

The main challenge to implementing many of the evidence-based physical activity interventions and behavior change techniques is that they are resource intensive. In most cases, often multiple individuals are required to create tailored programs for individual patients, provide education, and then follow-up to promote adherence [21]. Where resources are scarce and demand is high, it would be ideal to have a simple, inexpensive, patient-managed intervention that incorporates behavior change techniques and can help patients improve and maintain activity levels.

Wearable Activity Trackers

Wearable activity trackers are a rapidly growing health-focused industry. There are many terms for the trackers, including *electronic activity monitors*, *fitness trackers*, *wearable activity monitors*, and *wearables*, but generally speaking, wearable activity trackers are devices that use sensors to help users automatically track step counts while aiming for a particular step count or activity goal. Pedometers are simple tools to promote self-awareness and self-monitoring of activity levels. Pedometer-based walking programs improve physical activity, body mass index, and blood pressure, even in adults who are already moderately active [22-26]. Improvements are typically greatest in programs that incorporate goals such as 10,000 steps daily [19].

The newest generation of pedometer is known as the wearable activity tracker. Similar to the behavioral strategies used in walking programs, the new trackers promote goal setting, self-efficacy, and tailored feedback through companion mobile apps and websites. The trackers do this by providing visual representations of activity data (step counts, altimetry, calories, sleep) over days and weeks. Some wearable activity trackers can also be used with social networking sites and other lifestyle apps for diet and stress, such as MyFitnessPal, Weight Watchers, and SparkPeople.

Although the new trackers have been designed as wellness devices rather than health or medical devices, they have considerable potential for use in health care. The BodyMedia FIT and Fitbit Zip trackers have been shown to provide valid measures of daily energy expenditures [27-30]. However, activity trackers may be less accurate for older adults with a shuffling, abnormal, or slow gait caused by conditions such as stroke or Parkinson's disease [31-34]. There is growing evidence that these trackers do improve step count, and while there is acknowledged potential, there is currently little evidence yet that they improve health outcomes such as blood pressure or blood sugar [35-38].

Persuasive Activity Trackers

The following conditions are necessary for persuasive technology to promote a behavior: motivation, physical ability, and an effective trigger [36]. Persuasive fitness technologies are attractive because they "automate" behavior change [39]. They offer convenient data collection, analysis, and storage over long periods with immediate automated feedback. Game-based features also offer points, leader boards, badges, trophies, vibrations, and progress bars to promote self-competition and building support and competitive networks, with the end result of encouraging and increasing physical activity [40,41].

Research has been emerging on the design and evaluation of persuasive technologies to promote physical activity. A matched case-control study with individuals who were members of the 10,000 steps Australia program found that individuals invited to use a website or mobile phone app were four times more likely to log their steps and 20 times more likely to achieve 10,000 daily steps [42]. Mobile phone (and app) developers are also starting to build pedometer functions into devices and using the phones' main screen wallpapers to promote specific behaviors. For example, UbiFit Garden uses images of flowers (activities) and butterflies (goals) on the background screen of a user's mobile phone to promote physical activity [43].

Wearable trackers have been increasingly identified as a tool for helping consumers prevent disease and increase physical activity [44,45]. Wearable activity monitors contain a wide range of behavior change techniques that have been often used in clinical behavioral interventions. In 2014, Lyon et al [46] identified 13 fitness trackers that provided tools for self-monitoring, feedback, and environmental change as well as other common behavior change techniques such as goal setting, self-monitoring, and feedback content that closely matched recommendations from social cognitive theory.

Emerging research into persuasive technology and wearable trackers offers significant promise for improving health and fitness. Research into better understanding how their design affects activity and behavior, how visualization helps both motivate and provide awareness, and how feedback can be better understood and used is a growing field [47-50]. Michie et al [51] discussed the wide range of approaches that can result in behavior change [51]. In 2003, Fogg [52] discussed how persuasive technologies employ a wide variety of strategies that influence behavior and activities, most notably drawing out self-monitoring and conditioning [52]. Self-monitoring is one of the most prevalent persuasive technologies; however, the most successful technologies often employ multiple strategies [53].

To date we know little about how older adults perceive new and emerging mobile health (mHealth) tools that include wearable activity trackers. While some studies conclude that health interventions that use technology are less effective than in-person interventions, there is limited evidence to support this conclusion [54-56]. Therefore, there is great potential in building a better understanding of mobile tools that can help older adults become more active on their own time, in their own space. Our objective was to examine the usability and usefulness of wearable activity trackers for older adults living with chronic illness as a first step to better understand how wearable fitness trackers can help older adults become healthier.

Methods

Design and Setting

Our research design was inspired by a similar study on mobile medication management apps [57]. We used a mixed-methods approach to examine the perceived acceptability of popular wearable technologies designed to promote fitness and healthy living. The research was conducted at the University of Waterloo School of Pharmacy. We qualitatively assessed user acceptance using a thematic analysis, which is reported according to the consolidated criteria for reporting qualitative research [58]. We also developed a technology acceptance questionnaire based on the Technology Acceptance Model (TAM) [59]. We did not develop any of the devices we tested and received ethical approval from the University of Waterloo Office of Research Ethics (Certificate Number 19440).

We made the following assumptions: (1) most older adults are not using wearable activity trackers; (2) many have chronic illnesses that would benefit from increased physical activity; (3) wearable technologies have the potential to improve activity levels; and (4) there are age-related barriers unique to older users. We also assumed that most older adults are not early adopters and we were therefore asking participants to assume the early adopter role for the duration of this study.

Wearable Activity Trackers

To assess acceptability of commercially available wearable activity trackers, we began by identifying all devices available to Canadian consumers as of November 1, 2013. We identified and reviewed 4 devices by Fitbit, 2 devices by Jawbone, and 1 device each from Withings, Misfit, and Nike. The research team selected 4 devices for testing purpose, with each device representing a different feature available with activity trackers (Table 1). All 4 devices used an accelerometer to assess steps (pedometer). We chose the Fitbit Zip because it was inexpensive, could be clipped to clothing, and allowed users to track activity on a simple interactive screen. We selected the Jawbone Up 24 as it could be worn on the wrist and could collect data on sleep quality. We selected the Misfit Shine because it could be worn on the wrist or clothing, was waterproof, and could double as a watch. Finally, we selected the Withings Pulse because it could capture heart rate data.

User Testing

Participants and Sampling Frame

We recruited individuals from local public libraries, community centers, and primary care clinics. We also posted information on community message boards and approached the organizers of public programs (eg, Active Seniors at the Kitchener Public Library) to allow us to make brief presentations at events targeting individuals over the age of 50. The participant characteristics are presented in Table 2.

Table 1. Comparison of the available features of wearable activity tracker devices assessed between January 1, 2014, and May 31, 2014.

	Fitbit Zip	Jawbone Up 24	Misfit Shine	Withings Pulse
Pedometer (steps)	X	X	X	X
Altimeter (stairs)				X
Waterproof			X	
Heart rate				X
Displays number of steps taken on device	X			X
Displays proportion of steps taken toward the total goal			X	
Default activity goal	10,000 steps	10,000 steps	1000 points (equivalent to 10,000 steps)	10,000 steps
Notifies the user of every 2000 steps		X		
Cost	US $60	US $150	US $130	US $100
Apple iOS	X	X	X	X
Android	X	X[a]	X	X

[a]Made available March 2014.

Procedure

Participants started by using a basic pedometer for 3 days. Participants were then provided 4 wearable activity trackers (Fitbit Zip, Jawbone Up 24, Misfit Shine, and Withings Pulse) in random order and were asked to use each device for at least 3 days. Participants received each new device from investigators and we assisted them in setting the device up if needed. Participants were not required to own their own mobile phone or tablet. A total of 12 participants did not own a mobile phone or tablet, and they were lent one from the investigators or shared one with a friend or family member. Participants were instructed to wear the activity tracker as intended by the manufacturer (eg, Fitbit Zip during waking hours, whereas Jawbone Up 24 during waking and sleeping hours). Participants were asked to synchronize the device and their tablet or mobile phone at least once during each trial period and were expected to record their data, specifically the number of steps captured each day. The purpose of collecting step count data was to ensure that participants could access the information rather than to assess the impact of the devices on their activity levels.

Data Collection and Analysis

Prior to testing any devices, a researcher measured each participant's weight, height, resting heart rate, and blood pressure. Participants completed a paper-based questionnaire on demographics and computer experience. Participants self-reported their physical activity using the validated Short Form International Physical Activity Questionnaire, which assesses the duration and frequency of walking, moderate activity, and vigorous activity among adults [61]. High physical activity was defined as either a minimum of 1500 metabolic equivalent of task (MET) minutes/week of vigorous activity or a minimum of 3000 MET minutes/week. Moderate physical activity was defined as a minimum of 600 MET minutes/week, 3 or more days of vigorous activity of at least 20 minutes/day or 5 or more days of moderate activity or walking of at least 30 minutes/day. Individuals who did not meet the criteria for moderate or high activity were classified as having "low activity."

After testing each device, participants completed a questionnaire to describe how they used the device, how satisfied they were with the device, whether or not they would purchase a device, and then rated the devices with a 17-item questionnaire developed using the TAM, which assesses the domains of external variables, perceived usefulness, perceived ease of use, attitude toward using, behavioral intention to use, and actual system use (Table 3) [62-65]. After testing all 5 devices, participants completed a final debrief questionnaire where they ranked the devices according to preference and indicated whether they planned to purchase a particular device. Demographic and clinical information was summarized using descriptive statistics using SPSS (version 22; IBM Corporation, New York, NY, USA).

Table 2. Participant characteristics[a] (N=32).

Characteristic		Number (% or range)
Age		64 (52-84)
Gender		
	Male	9 (28)
	Female	23 (72)
Medical condition(s)		
	High cholesterol	10 (31)
	High blood pressure	17 (53)
	Stroke	1 (3)
	Prediabetes	4 (13)
	Type 2 diabetes	3 (9)
	Osteoarthritis	15 (47)
	Rheumatoid or inflammatory arthritis	3 (9)
	Chronic low back pain	1 (3)
Body mass index (kg/m^2, mean)		31 (21-51)
Blood pressure (mean)		
	Systolic	129 (93-182)
	Diastolic	79 (67-95)
Heart rate (mean)		70 (50-98)
Physical activity (mean)		
	Low	2 (6)
	Moderate	21 (66)
	High	8 (25)
Family history		
	Diabetes before the age of 55	5 (16)
	Heart attack before the age of 55	6 (19)
	Maternal history of hip fracture	2 (6)
Highest level of education		
	High school	6 (19)
	Trade school	2 (6)
	College	7 (22)
	University	7(22)
	Graduate school (MSc, PhD)	7 (22)
	Professional degree (MD, MBA)	1 (3)
Annual household income		
	<CAD $20,000	2 (6)
	CAD $20,000-CAD$49,999	6 (19)
	CAD $50,000-CAD $79,999	12 (38)
	>CAD $80,000	10 (31)
	Prefer not to say	2 (6)
Skill with computers		
	Nonuser	1 (3)

Characteristic		Number (% or range)
	Novice	6 (19)
	Intermediate	19 (59)
	Expert	5 (16)
Use of a computer		
	Daily	28 (88)
	Weekly	2 (6)
	Monthly	0 (0)
	Rarely	0 (0)
	Never	1 (3)
Use a mobile phone or tablet		
	Daily	22 (69)
	Weekly	0 (0)
	Monthly	0 (0)
	Rarely	0 (0)
	Never	12 (31)

[a]Percentages may not add up to 100% due to incomplete surveys or multiple answers.

We included 32 adults over the age of 50 living in southwestern Ontario who had been diagnosed with a chronic disease that could be prevented with physical activity. We excluded individuals who could not speak or read English and who had contraindications to physical activity according to the Physical Activity Readiness Questionnaire [60].

Thematic Analysis: User Perceptions

Focus groups were conducted at the end of each study group. We chose to do a high-level thematic analysis with the purpose of examining and recording the patterns in our data [66]. We chose thematic analysis because it helped us organize the data into themes to offer a rich description of participant experiences. Thematic analysis goes further than just counting phrases or words in a text and works to identify the implicit and explicit ideas of the data [67]. Borrowing from the grounded theory approach, we did not identify any preconceived theories before starting data collection on the usability or usefulness of the wearable activity trackers for older adults with chronic disease [68]. This gave us the opportunity to incorporate fresh viewpoints from the diverse settings of participant lives, rather than from our own perspectives as heavy users of technology. The final dataset used in the thematic analysis included participants' written notes, researcher observations, and the recorded and transcribed focus group discussions.

The TAM identifies two key beliefs as the primary reason for behaviors that encourage computer and technology acceptance: *perceived usefulness* and *perceived ease of use*, with the idea being that if people think that using a technology will make their life easier or think a technology is easy to use, then they will be more likely to adopt the technology [69]. In particular, TAM identifies that using technology, both new and established, is associated with behavioral intention, specifically that people form intentions to use technologies when they have a positive feeling about the technology in question. TAM identified the following areas that can influence adoption: external variables, perceived usefulness (U), perceived ease of use (e), attitude toward using (A), behavioral intention to use (BI), and actual system use. It postulates that BI = A + U and stated that people form intentions about using new technologies based on how they perceive the technology will improve their performance.

Our data were coded and analyzed in NVivo (QSR International) in 3 stages. For the initial stage of analysis, 1 independent researcher (KM) coded data by briefly summarizing each line and then paragraph of data. In the second stage of coding, the codes were combined into themes by 2 researchers (KM and KG). In the third and final stage, each theme was populated by representative quotations (KM and KG).

Results

User Testing

We recruited a purposive sample of 32 participants aged between 52 and 85 years (mean 64 years; Table 2). Participants were included if they were over the age of 50 and self-reported a diagnosis of one of the following: hypertension, hyperlipidemia, diabetes, osteoarthritis, rheumatoid arthritis, and osteoporosis (including a history of non-traumatic fracture of the wrist, spine or hip). We also included participants who had a significant family history of cardiovascular disease or diabetes (a parent, sibling, or child has developed cardiovascular disease or type E diabetes before the age of 55) and a parental history of hip fracture.

Because our goal was to explore acceptability, which is based on participant's perceptions of usability and usefulness, a sample size of 32 was adequate. We also continued sampling until data saturation was reached and no new ideas or issues were identified [70].

Table 3. Participant experience questionnaire (answer averages) evaluating the use of wearable activity trackers.[a]

No	Feedback	Withings	Fitbit Zip	Jawbone	Pedometer	Shine	Average
1	Overall, I was satisfied with the activity tracker.	3.39	3.57	3.33	1.77	3.37	3.09
2	Using the activity tracker helped me set activity goals.	2.90	3.13	2.93	2.55	3.13	2.93
3	Using the activity tracker helped me reach my activity goals more rapidly.	2.81	3.03	2.67	2.19	2.80	2.70
4	Using the activity tracker helped me to be more active.	3.00	3.20	3.10	2.65	3.13	3.02
5	Using the activity tracker made it easier to be more active.	2.84	3.00	2.87	2.35	2.83	2.78
6	Using the activity tracker supported me in managing my disease.	2.61	3.00	2.60	2.23	2.70	2.63
7	I found it easy to learn to operate the activity tracker.	2.84	3.27	3.13	2.84	3.00	3.02
8	I found the activity tracker to be clear and understandable to use.	3.06	3.40	3.07	2.90	2.90	3.07
9	I found the activity tracker to be flexible to work with.	3.00	3.37	3.23	2.42	3.03	3.01
10	Overall, the activity tracker was easy to use.	3.03	3.43	3.43	2.74	2.97	3.12
11	People who influence my behavior would think I should use the activity tracker.	2.65	2.93	2.87	2.68	2.86	2.80
12	People who are important to me would think I should use the activity tracker.	2.74	3.00	2.97	2.68	2.97	2.87
13	I have the technology necessary to use the activity tracker	3.45	3.90	3.43	3.65	3.50	3.59
14	I have the knowledge necessary to use the activity tracker.	3.26	3.67	3.47	3.90	3.33	3.53
15	The activity tracker was compatible with other systems I use.	2.84	3.53	3.23	2.47	3.23	3.06
16	I am very knowledgeable about my physical activity needs.	4.00	4.17	4.03	3.90	4.03	4.03
17	I understand how to use physical activity to manage my health problems.	4.06	4.17	4.03	4.13	4.07	4.09
18	The activity tracker was comfortable to wear.	3.87	4.13	3.70	3.13	4.10	3.79
19	The activity tracker accurately tracked my physical activity.	3.48	3.50	3.67	1.77	3.77	3.24
20	Average by tracker (SD)	3.15 (0.43)	3.44 (0.40)	3.25 (0.40)	2.79 (0.67)	3.25 (0.44)	

[a]Scoring was as follows: 1=strongly disagree, 2=disagree, 3=neutral, 4=agree, and 5=strongly agree.

Of the 32 participants, 30 completed the testing of all devices; 2 users dropped out after testing the pedometer (initial stage), citing acute viral illness. All the wearable activity trackers tested had moderate acceptability, with the standard pedometers having the lowest acceptability to users (Table 4).

In general, all the wearable activity trackers tested had a similar score for each item of the TAM questionnaire and were rated higher than the standard pedometer in all items but 13 and 14, both of which are related to baseline knowledge of the technology. This coincides with the exit interview ratings, where participants constantly rated the standard pedometer as their least preferred option.

The language participants used about wearable activity trackers was also notable. Participants would pick a favorite device, and

stick with that device, even if through later discussion they identified more negatives than positives about that device. The common reasons for liking or disliking a device are how they looked, be it for subtle or fashion-based factors, and ease of use. The participants' perceived comfort level with the devices was another notable aspect of this study that drove how participants ranked the devices. We also found that the wearable trackers performed highest on items assessing ease of use, namely, Item 10 "Overall, the activity trackers were easy to use" and Item 14 "I have the knowledge necessary to use the activity tracker." The highest rated item was Question 16, "The activity tracker was comfortable to wear." This was reflected by low scores for Item 7 "I found it easy to learn to operate the activity tracker" for the Withings and pedometer (2.84) compared with the Fitbit (3.27), Jawbone (3.13), and Shine (3.00), which contributed to decisions to purchase or not purchase (Table 3).

After testing the devices, none of our participants planned to purchase a Mio or Sportline pedometer, whereas 22 of the 30 participants who completed the study said they would purchase a wearable activity tracker. The participants were asked which device or devices they would potentially purchase, and after trying the devices, 30% (N=32) felt they would buy a Jawbone Up 24, 30% would purchase a Misfit Shine, 33% felt they would buy a Withings Pulse, and 40% felt they would buy a Fitbit Zip. At the completion of the study, 73% (22/30) felt they would purchase a tracker and 67% (20/30) felt they would purchase a device for a friend or family member. Those who felt they would not purchase a tracker included reasons of cost, lack of interest, and complexity of the devices. Tables 5 and 6 present the positive and negative associated with individual fitness trackers, respectively.

Table 4. Mean participant acceptance scores from the participant acceptance questionnaire for each wearable activity tracker assessed.[a]

App	Mean score (SD)
Pedometer	55.7 (10.2)
Fitbit Zip	67.6 (15.8)
Jawbone Up 24	65.8 (19.1)
Misfit Shine	64.7 (13.7)
Withings Pulse	62.9 (13.8)

[a]Minimum score was 19 points; maximum score was 95 points (N=30).

Table 5. Positive statement associated with individual fitness trackers.

App	Positive statement
Pedometer	"I just want a step counter, I don't care about the rest of the stuff"
Fitbit Zip	"The Fitbit I still say is the easiest. I actually got an email that tells you your weekly progress, and I really like that."
Jawbone Up 24	"I liked the sleep data a lot, and I found the Jawbone easy to use. I found it really easy, it was light."
Misfit Shine	"I really liked that I could wear it in the water
Withings Pulse	"A lot of people say they don't like the Withings, but I really did, I thought it was great"

Table 6. Negative statement associated with individual fitness trackers.

App	Negative statement
Pedometer	"The very first one, the pedometer was unbelievably off. I would take one step, and it would count 10."
Fitbit Zip	"It was too small, I was scared I would lose it"
Jawbone Up 24	"Jawbone, see look, this is by far the easiest to put on and off but once it's on it can get a little annoying"
Misfit Shine	"The Shine I thought was just the most unintuitive, poorly constructed system"
Withings Pulse	"The reason I didn't choose it is because I was afraid that over time it would all break."

User Perceptions: Thematic Analysis

In this study, 4 overarching themes emerged to describe how acceptable wearable activity trackers are for older adults with chronic disease. The first theme is that new and emerging consumer health technologies are likely to be outside the older user's perceived comfort zone. However, the second theme is that after a brief trial period, users can appreciate that wearable activity trackers improve self-awareness and goal setting. The third theme was that wearable activity trackers are ultimately more useful as motivators than as quantifiers. The final and fourth theme was that older adults are unlikely to adopt wearable activity trackers if the trackers are not sold and managed as health care devices.

Theme 1: Adoption Within a Comfort Zone

There is a perception that the navigation of devices and apps requires technological know-how that is often absent in the older adult and elderly population. Modifications of the TAM have identified technical know-how as a form of self-efficacy that influences a user's *perceived ease of use* and *attitude toward using* [69,71,72]. It was clear that improvements could be made to the devices and associated apps to make them more accessible for older adults. This was reflected by many of our participants in the comments they made about the devices—often relating that they were "not built with us in mind," that they were created "for someone younger," and that devices needed a more "tech-savvy" user. An issue brought up by each group was that there were no instruction manuals, which prevent them from feeling comfortable with the various devices.

> *I wonder if people looking at getting one would see younger people wearing these, but that might be a deterrent, saying "well, that's only for young people."* [Female, 58 Group 2]

> *I think the right person is someone who has patience and a real understanding that this person doesn't get it because they're simple or stupid or whatever, it's only because it is like a foreign language to them. So for our generation, they need to back it up and simplify the steps.* [Female, 60, Group 2]

TAM additionally identifies the lack of instructions as a barrier to a person adopting, because it is a barrier to *actual system use* and can imply to the user that they should be able to use the device and that difficulties are personal failing. In addition to learning to use the device, users must also learn to speak the language of the device, including terms such as "active time," "1000 points," and "link with Bluetooth."

> *If you look at that little Fitbit, it doesn't have any instructions with it. That almost did me in. I waited for a child to come along. But I also had to take into account the feelings, like you don't feel, you feel really limited, you know you feel really badly when you can't figure it out.* [Female, 60 Group 2]

> *I couldn't figure out how to get steps, it kept giving me some percentage of my daily activity and I couldn't figure out how to get the steps. So I was told to go online. Of course that seems so intuitive, but for me it wasn't. The fact that they don't come with written instructions I think is a real downside.* [Female, 58, Group 1]

A more practical consideration is comfort, identified by the TAM as *perceived ease of use*, specifically in this study how the device looks, with some participants preferring wristbands and others preferring to clip devices to a belt or bra. This also goes to *actual system use*—if the participants felt there was a potential to lose or break the device, they were less likely to be comfortable with adopting one.

> *I don't know which I found most comfortable. I might take the Jawbone because it would stay on. As opposed to the Fitbit I'm not sure if the Fitbit, the way it's designed there would stay on, and I had trouble clipping on some of the other ones—I didn't trust they wouldn't fall off.* [Female, 58, Group 2]

> *...[The Jawbone Up 24] was a really beautiful object so you have to kind of get behind that specific look. I like Italian rubber design jewelry so I didn't mind that this is a nuisance to take off and on cause it's a cool look. If I'm looking for what I feel comfortable with wearing, I would like a fashion statement.* [Female, 67, Group 1]

The wearable activity trackers may be less useful for individuals less familiar with mobile technology. For this group, simpler devices with clear displays should suffice.

> *None of my friends [aged] 80-90 that I play cards with would, they were interested in what I was wearing, but they weren't interested in it for themselves, they don't care how many steps they take, they sit most of the time. We read and play cards. We do a bit of exercise, we walk a bit, but as far as wearing one of the simple devices, maybe, but I found those that are more complicated they don't have the iPad, no computer, but they couldn't even use it so, we're out.* [Female, 85, Group 1]

Theme 2: Self-Awareness and Goal Setting: Knowing Where You Are and Where You Want to Be

The greatest advantage to wearable activity trackers is that they help participants become more aware of their activity levels. TAM identifies *behavioral intention to use* as one of the key attitudes to adoption. If a participant wanted to make lifestyle choices, he/she is more likely to identify a *perceived usefulness* of a device, which increased their intention to use it and eventually adopt the technology. In all groups, participants had been asked by a physician to exercise more, and agreed that they needed to be more active.

> *It was more informative than motivating, because I had my own agenda that my doctor set out for me to do.* [Female, 55 Group 3]

> *I'm just interested in the number of steps and exercise really. As far as living healthy, I think we all know what we're supposed to eat, what our blood pressure should be at and all these sorts of things.* [Male, 85, Group 1]

However, even if participants thought they were active, they either wondered or worried that they were not as active as they should be.

> *At least it was telling me something, maybe not what I always wanted to know. I didn't care what it said. I just knew I had it on. So I wanted to try to be more active. I didn't care what the numbers said but I have to admit that when I did see the numbers I was like, wow, or a couple of days it was like, whoa.* [Female, 56 Group 3]

> *I like the interactive part of these. I don't really care about the details, and if I'm gaining or losing 500 steps, because I know now I'm not doing enough steps at all, so I had a eureka moment when I thought I*

need to notch this up and stop being so lazy. [Female, 67, Group 1]

Triggers from the activity tracker such as a vibration to alert the user after a period of inactivity (Jawbone Up 24) also increased awareness more than motivation. TAM suggests awareness as a motivator to adoption, falling closely in line with *behavioral intention to use*, as well as with the lead-in to the TAM, *external variables*. If a person is driven to improve his/her health that influences his/her intentions, it leads to potential openness for adoption. However, this growing motivation does not necessarily translate into increased physical activity.

It's not a motivation, it's an awareness. I had it set to inactivity buzz every 15 minutes and at times I wouldn't get up but it was enough to motivate me to realize I just hadn't moved. [Female, 62 Group 3]

Well it reminded me, but it didn't get me moving. I was working on a computer, and it would buzz, lying down watching a program. I think I had it set for every 20 minutes to vibrate so it lets you know that you're inactive, but what I did after the reminder to move was up to me. [Male, 62, Group 2]

Theme 3: By the Numbers: Purposes of Data Tracking

Participants were less interested in being motivated by the activity tracker than in being motivated by the self-awareness gained from data collected by the tracker. The *perceived usefulness* and *behavioral intention to use* help the users to find clarity around real and perceived activity levels. This clarity was a step toward finding an intrinsic motivation to become more active.

I think the issue is always how do you motivate yourself to do things you know are good for you, so that was part of how I was thinking about it, not just for myself. I've been in a really heavy workload so I've been sitting a lot so it actually shocked me to know I only do 2000 steps a day, so that was super motivating for me. [Female, 67, Group 1]

I was diagnosed years ago with osteoporosis so I've always felt like I need to have at least 3 hours of activity in the bone bank, and once I retired I thought not good enough, I need to have 4 or 5 hours in the bone bank. I found using these helped. That, well, my husband said I was developing obsessive compulsive disorder because I was constantly moving, I'd run up and down the stairs, or I'd dance with a grandchild or something and I'd look down. So it was hugely motivating. [Female, 62, Group 3]

Self-awareness translated into motivation when it made activity a game or competition for some participants. For participants, the "goal" of 10,000 steps seemed to matter less than being aware of how much, or how little activity they got, compared with where they wanted to be.

I was trying to get to 10,000 steps and I did, a few times, it was fun, and you could see most of the different things...you know my activity level is higher at this time and lower at that time, and let's run up and down stairs a couple times, and I got another 2 minutes. It was a lot of fun. [Female, 58, Group 3]

The goal was 10,000 steps. These trackers really let you know how much more than your daily routine you really need to put in to get to that goal. Doing your normal day-to-day thing, you're not even close. [Male, 65, Group 2]

As demonstrated by our oldest user, for users who are isolated in their home, the wearable activity trackers may help users compete against themselves more easily by automatically collecting data and tracking it over days and weeks.

Very definitely, you know you compete with yourself. I have no one else to compete with. This winter has been hard, for going outside and walking. I used to be able to walk, or I used to be a swimmer, and now I've become a couch person...I've done the track in the house, I run up and down the stairs, down to the basement and I walk my driveway a couple of times cause it's long. I try and I compete with myself and I know that I sit or lie down much too long. But when you're over 80 I think that's excusable. [Female, 85, Group 1]

Theme 4: The Future of Wearable Activity Trackers as Health Care Devices

Overall, participants generally enjoyed trying out the wearable activity trackers (Textbox 1). In the exit focus groups, participants were asked what they thought the opportunities were for the future of wearable devices. The responses varied, but one of the statements commonly repeated was the need for the health sector to get involved in promoting physical activity trackers to patients as a possible way to improve their health.

I think the next step should be a handout in consultation with medical groups like pharmacies and in partnership with provincial and federal groups and maybe even activity groups like the YMCA to come up with a really effective comprehensive, simple pamphlet pointing out the importance of what you do in the hours you're awake. I think then we'll need some kind of financial incentive because there are limitations to people being able to afford a tablet and the device. [Male, 78, Group 1]

In Canada, physical activity trackers are not taxed if bought with a prescription. Several of our participants also stated they wished the devices were available in pharmacies because they did not go into the electronics stores where the devices are traditionally sold.

But if someone can guide you through it, I think any of them, once you start using them you would probably use it. But I wouldn't go to Best Buy I wouldn't have thought to go to best buy. If it's for my health, I would think to go to a pharmacy. [Female, 52, Group 3]

There was also a noted desire to learn about the devices from someone in health care. The participants were interested if their doctors or other health care professionals would be interested in the data provided from the devices. There was also a noticed

interest in pharmacies carrying the devices, and having pharmacists able to explain how to use them, similar to how health-monitoring systems such as blood glucose meters or blood pressure meters are explained by pharmacists. Several times a barrier to learning was that the participant asked older/adult children for help using the device, and was met with impatience and frustration.

> *My daughter was no help at all. She just kept saying it's stupid, I don't have time.* [Female, 59, Group 2]

Textbox 1. A brief summary of participants' experience in trying wearable activity trackers in one word.

Negative words:

- Annoying
- Challenging
- Stressful
- Hard
- Frustrating

Neutral words:

- Instructive
- Learning experience
- Interesting
- Informative
- Fine
- Educational
- Life
- Experiential

Positive words:

- Fun
- Exciting
- Motivational
- Comfortable
- Motivational

Discussion

Running from January 2014 to June 2014, our study included 32 older adults living with chronic illness who were trying wearable activity trackers for the first time. We found that the study participants generally enjoyed using the widely available trackers and even preferred them over the standard pedometer. Our participants also found the trackers to be useful in promoting self-awareness and motivation. However, it should be noted that at the time of this study, these trackers were an emerging technology; thus, participants often felt that these devices were too new to be comfortable with. When asked, our participants suggested that wearable activity trackers should be recommended for health care rather than entertainment. To meet this final theme, it was suggested that the devices be available at pharmacies and sold alongside blood pressure and blood glucose meters with the standard health-related tax exemptions or credits.

At the beginning of the study, the initial feedback during recruitment from several older adults and seniors was that they did not use mobile phones and tablets and were unsure whether they were the right choices for the study. Throughout the study, however, we found that these participants were often the ones who had the least trouble adapting to new technology, and many times knew more about new technologies than they thought they did. Frustration often came from the apps during use, and the lack of clear instructions for installation rather than understanding and using the technology.

Research into wearable activity trackers is a new area but it is closely tied to the growing body of research in mHealth. Several previous studies have evaluated the use of mobile phones in supporting health care and public health interventions, particularly in the collection of data for health research [73,74]. The area is rapidly growing, with the number of mobile phone health and fitness apps growing from 7000 in 2010 to over 40,000 in 2013 [75,76]. Studies assessing specific functionality of mobile phones have recently looked at digital diaries in symptom research, short message service texting to manage behavior change, and the use of mobile phone records against traditional paper records in drug trials [77-80]. Free et al [81] identified several key features that give mobile phones advantages over other communication technologies, including

portability, continuous data, and sufficient computing power to support multimedia-based interfaces. Other reviews also offer more information about how to incorporate mobile phones and other small devices in health and clinical practice [82-84].

Traditional pedometers digitally monitor and track basic physical activity. They are essential to programs that recommend a specific daily step count. Many of the participants we interviewed cited comfort and experience with using pedometers because they are appealing to older adults uncomfortable with technology. However, long-term tracking requires manual data entry, which hinders engagement of the user. The wireless transmission of data allows for timestamps, measurement of intensity, frequency and duration ideally without significant input from the user, and then sending the data automatically to devices that report back to the user such as mobile phones, tablets, and computers [85]. It was also clear from our studies, that when given the choice, participants preferred a newer wearable activity tracker over a traditional pedometer.

Some of the most important lessons we learned over the course of this study were related to how our participants were using the new technologies in their daily lives. We heard from several participants that adult children were encouraging them to get a mobile phone or had bought or handed down a tablet. In one case, an adult child had recently gifted a participant with a Jawbone Up 24. We found that often our participants were not aware of how much they used the new apps and technologies, citing that they just used their tablet for email and simple card games. As we spent more time with each participant, we saw them browsing for health information, using tablets to check the stock market, checking Facebook, tracking calories, and playing new games.

More research needs to be carried out to fully understand the best practices for designing wearables for older adult populations. There is significant potential for stakeholders to promote and use wearables as a tool to encourage, motivate, and assist older adults in improving their health. Future wearables could benefit from including a simple paper-based instruction manual that clearly addresses set up, how to use the device. and basic problem solving. This would provide knowledge to older adults in a medium they are familiar with, which has potential to increase adoption. There is also significant potential for designing wearable fitness trackers in a way that older adults can benefit from both on the device itself and in the accompanying app. Displays should consider using large, high-contrast text with large light-on-dark letters and numbers to allow for easier viewing. In addition, allowing access to device knowledge on both a computer and a mobile app would allow older adults to access data in a more familiar way, in terms of comfort with technology and by allowing them to view results on a bigger screen. Waterproof design decreases worry about the fragility of the device if it is forgotten, and accidentally damaged by doing dishes or the laundry, and also allows older adults to use it in the water-based activities that are commonly recommended by health care providers as part of a low-impact way to increase physical activity.

The primary limitation of our study is that we gave participants the devices for a purposely short period, with the goal of getting initial impressions. There is significant opportunity to test wearable devices for longer periods to determine long-term adherence as well as to test the devices with a population that is more universally sedentary. We also purposely ran our study in the winter to spring months, when many of our participants self-identified as less active than they would be in the summer. A key driver of this project was to determine if awareness in their actual activity times would increase or decrease dependent on awareness despite there being challenges to simply “going for a walk.” Given the qualitative nature of our inquiry, we were also careful to not focus on the effects of the wearable activity trackers on step counts.

In conclusion, our goal with this study was to determine the acceptability and usability of the various wearable fitness trackers for adults over the age of 50 and whether the devices may be something these adults would be interested in, acknowledging that we are in an early adopter phase with this technology. We worked with 30 adults (all aged >50) with a chronic illness to determine how they perceive the usability and acceptance of wearable fitness trackers. Overall, we found that there was a meaningful potential in using wearable fitness trackers as a multifaceted intervention to help older adults become more active. If health professionals can help older adults become more aware of wearable activity trackers, there is potential for adoption, and through adoption, for creating more awareness of physical activity levels. The benefits of mHealth technologies, specifically in this case wearable activity trackers, lie in their potential to overcome barriers between patients, clinicians. and researchers through giving users independent insight into the realities of their physical fitness, which translates into their awareness of their active times and arguably most significantly, awareness of user’s own real levels of physical activity.

Conflicts of Interest

None declared.

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Abbreviations

MET: metabolic equivalent of task
TAM: Technology Acceptance Model

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Original Paper

A Mobile App for Hypertension Management Based on Clinical Practice Guidelines: Development and Deployment

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Abstract

Background: Hypertension is a chronic and lifestyle-related disease that requires continuous preventive care. Although there are many evidence-based clinical practice guidelines (CPGs) for hypertension management, applying them to daily management can be difficult for patients with hypertension. A mobile app, based on CPGs, could help patients with hypertension manage their disease.

Objective: To develop a mobile app for hypertension management based on CPGs and evaluate its effectiveness in patients with hypertension with respect to perceived usefulness, user satisfaction, and medication adherence.

Methods: The hypertension management app (HMA) was developed according to the Web-Roadmap methodology, which includes planning, analysis, design, implementation, and evaluation phases. The HMA was provided to individuals (N=38) with hypertension. Medication adherence was measured before and after using the HMA for 4 weeks. The perceived usefulness and user satisfaction were surveyed in the patients who completed the medication adherence survey.

Results: Of the 38 study participants, 29 (76%) participated in medical adherence assessment. Medication adherence, as measured by the Modified Morisky Scale, was significantly improved in these patients after they had used the HMA (P=.001). The perceived usefulness score was 3.7 out of 5. The user satisfaction scores, with respect to using the HMA for blood pressure recording, medication recording, data sending, alerting, recommending, and educating about medication were 4.3, 3.8, 3.1, 3.2, 3.4, and 3.8 out of 5, respectively, in the 19 patients.

Conclusions: This study showed that a mobile app for hypertension management based on CPGs is effective at improving medication adherence.

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KEYWORDS

mobile health; clinical practice guideline; hypertension; self-management

Introduction

Hypertension is a disease that can lead to myocardial infarction, cerebral infarction, and heart failure [1], and its prevalence rate is 29.2% among males and 24.8% among females [2]. Controlling blood pressure is essential in hypertension care.

The two main branches of hypertension care are lifestyle improvement and drug treatment. According to the 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults of the Eighth Joint National Committee [1], lifestyle management is the first step in hypertension care for patients older than 18 years. The second step is setting a blood pressure target based on the patient's age, presence of diabetes mellitus, and chronic renal disease status, and reaching that target through drug treatment. This indicates the importance of helping patients with hypertension to maintain lifestyle

improvements and drug treatments in order to keep their blood pressure in check by fostering self-management skills.

The use of mobile health care is becoming increasingly popular in the self-care of chronic diseases such as hypertension. Mobile health care refers to the delivery of health care services via mobile communication devices [3]. The widespread availability of mobile phones with app capabilities means that they can be used to facilitate mobile health care via various types of interventions. According to an analysis of the current state of mobile health care, mobile phones can now be used to provide health care intervention strategies, such as tracking patient data, providing tailored self-management, leveraging social influence, and utilizing entertainment [4].

This expansion of mobile health care led to approximately 20,000 commercial health care apps appearing on the iPhone App Store in 2013 [5]. The main functions of most hypertension management apps are measuring blood pressure and managing records. Providing users with more clinically helpful functions requires the use of evidence-based knowledge when developing apps. For this purpose, a paper-based clinical practice guideline (CPG) needs to be converted into a computer-interpretable guideline and applied to the delivery system. In other words, hypertension management, through mobile health care, requires the development of an app that provides tailored information and recommendations on lifestyle management based on accurate evidence while also improving the hypertension medication adherence of the user. The development and correct utilization of such an app could help patients with hypertension improve their lifestyle and increase their medication adherence through drug education and medication reminders.

The aim of this study is to develop and evaluate a mobile app for hypertension management based on CPG knowledge, and then apply the developed hypertension management app (HMA) to patients with hypertension and evaluate its effects with respect to perceived usefulness, user satisfaction, and medication adherence.

Methods

The HMA was first developed based on CPG knowledge, and evaluated by experts. The HMA was then applied to patients with hypertension to investigate the perceived usefulness and user satisfaction, while its effect on medication adherence was evaluated using a one-group pre- and posttest design.

Development of the HMA

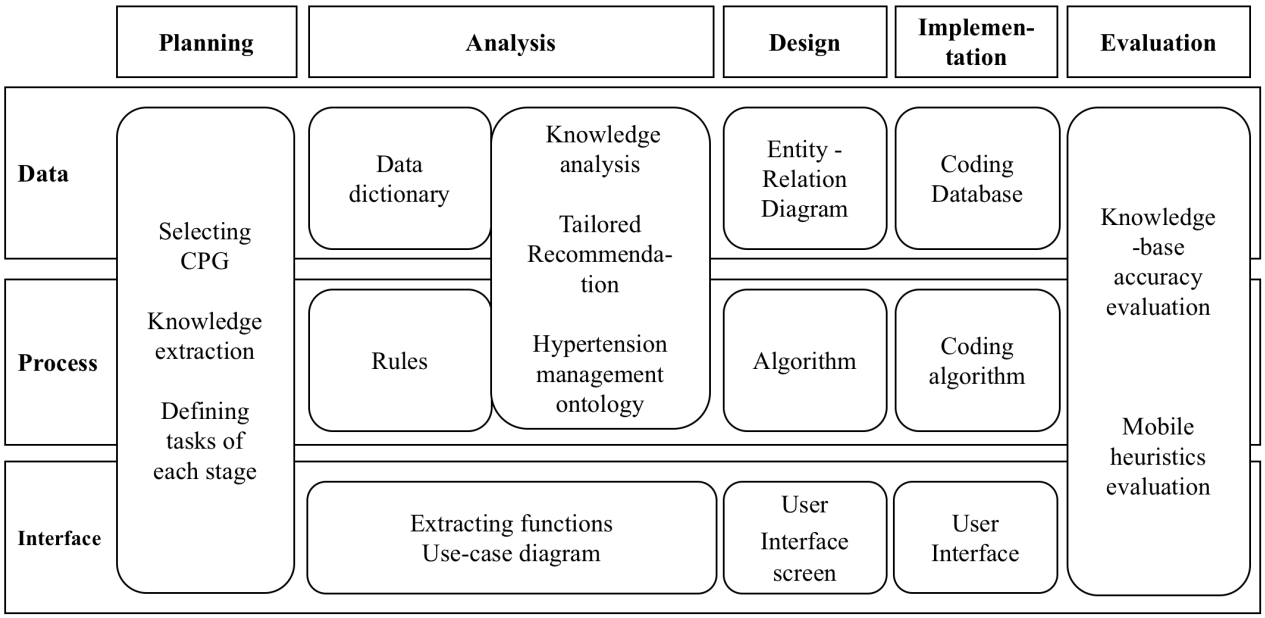
The HMA was developed using the planning, analysis, design, implementation, and evaluation phases of the Web-Roadmap methodology of information science [6].

Phase I: Planning

The CPGs for providing the evidence for hypertension management were selected in consultation with experts whilst also considering the credibility of the publisher, year of publication, and inclusion criteria of the information. After selecting each CPG, knowledge was extracted from it that would improve the adherence to treatment for hypertension management.

The Web-Roadmap methodology of information science [6] was used as a reference to define the data, process, and interface domains of the planning, analysis, design, and implementation phases, which in turn were used to plan the tasks and products of each phase (Figure 1).

Figure 1. Development stages of the HMA.



Phase II: Analysis

In the data domain, the data necessary for the system were extracted from the CPG and grouped. Data dictionaries were developed for each item.

In the process domain, rules to serve as judgment criteria for each intervention were identified and summarized. These rules were later used for algorithm development. In addition, extracted data and rules were organized into the hypertension management ontology to apply the content of hypertension management according to the nursing process. Data and rules were also used to compile a list of tailored recommendations to make to patients with hypertension.

In the interface domain, the required functions of the HMA were extracted by analyzing the requirements of the HMA. The requirements for the user interface were presented in a use-case diagram.

Phase III: Design

In the data domain, an entity-relation diagram was created to design a database for the data extracted in the analysis phase. Data entities of the system were identified and presented in tables with their attributes then connected with lines based on their relationships. This procedure revealed the data organization of the system.

In the process domain, knowledge extracted in the analysis phase was elaborated in algorithmic form for use in system operations. In the interface domain, the layout of the user interface was designed to implement essential functions extracted in the analysis phase.

Phase IV: Implementation

In the implementation phase, the database, algorithms, and user interface were realized through coding.

Phase V: Evaluation

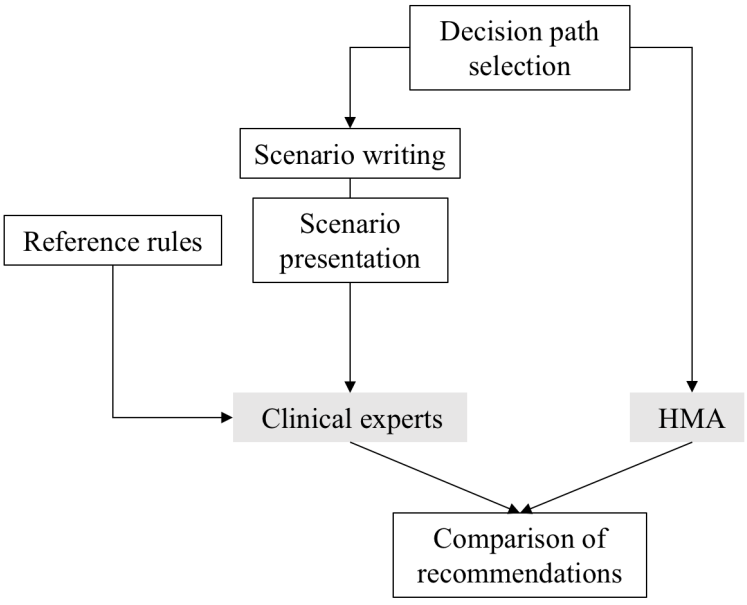
The HMA was first evaluated on the accuracy of the knowledge base and then mobile heuristics. The system development stage was completed by reflecting the evaluations of experts in revising the app.

Accuracy of the Knowledge Base

The degree of consistency between recommendations provided by experts and by the HMA was evaluated based on a previous study [7]. This evaluation was performed by 3 nurses, holding doctor of philosophy degrees (PhDs) in adult health nursing, and who have a special interest in chronic diseases. The accuracy of the knowledge base was evaluated using the process depicted in Figure 2.

Seven scenarios were created to ensure that all possible judgments in decision-making nodes appeared at least once. Knowledge extracted from the CPG was documented as reference rules and provided to experts. Scenarios were presented to the evaluators, who were then asked to write recommendations in a free-text format. The same data were entered into the system, and the recommendations produced by the system were compared with those of the clinical experts and checked for inconsistencies. If inconsistencies between the recommendations or their details were found, the opinions of the experts were used to improve the system.

Figure 2. Process used to evaluate the accuracy of the knowledge base.



Mobile Heuristics Evaluation

The expert evaluations of the usability of the HMA were performed by applying mobile heuristics evaluation. In accordance with Nielsen's recommendation to involve 3-5 experts [8], 5 evaluators took part in the mobile heuristics evaluation. The evaluators were experts with at least a PhD in nursing informatics and medical informatics, and with prior experience in medical system development. The mobile heuristics was evaluated using the 8 principles of mobile heuristics [9], which is a modification of the 10 principles of heuristics evaluation [8] modified appropriately for assessing mobile software. Each evaluation item was scored on a severity ranking scale to diagnose the number and distribution of flaws

in the software and the opinions of the evaluators. The Korean version of the tool was used for this study [10]. The eight principles of mobile heuristics evaluation were introduced to the evaluators, who were provided with Android-based mobile phones that included the HMA. After using the HMA, the experts were asked to freely comment on any issues about usability pertaining to items on the heuristics, and evaluate the severity of each problem on a scale from 0 to 4. Items were indicated as faulty if 2 or more people scored them as 1 point or higher on the severity ranking scale. Any items that received 4 points were considered to have major usability problems and required revision. The system was revised for these items.

Deployment of the HMA

Subjects

The minimum number of subjects for this study was found to be 38 based on the requisite for a *t* test with an effect size of 0.55, alpha of .05, and a power level of .95, as proposed in a previous study [11]. All calculations were performed using the software G*Power. Patients with hypertension visiting cardiovascular clinics at tertiary hospitals in Seoul, South Korea who were taking 1 or more antihypertensive drug(s) were recruited in person. Those who possessed a mobile phone, were able to use a mobile app without outside help, understood the purpose of this study, and volunteered their participation were chosen as subjects.

Procedure

The study participants were briefed on its purpose and their initial medication adherence was examined in person. The researcher installed the HMA on the participant's mobile phone, and then taught the participant how to use it. The study participants were then asked to use the HMA for 4 weeks. The perceived usefulness, user satisfaction, and final medication adherence were then examined via a phone call or in a face-to-face interview. The participants kept following their treatment plans as advised by health care providers during the study period.

Measurement Scales

Perceived Usefulness

The perceived usefulness of the HMA was evaluated using 6 questions pertaining to perceived usefulness from Davis' perceived usefulness and perceived ease-of-use measurement scales [12]. Cronbach alpha for the 6 perceived usefulness items was .98. There were significant correlations of .63 and .85 between perceived usefulness and self- reported current usage and self-predicted future usage, respectively [12]. The Korean version of the tool [13] was used. Perceived usefulness was measured on a scale from 1 ("strongly disagree") to 5 ("strongly agree"). The final score for usefulness was defined as the mean of the scores for all of the questions.

User Satisfaction

User satisfaction was evaluated with respect to using the HMA for blood pressure recording, medication recording, data sending, alerting, recommending, and educating about medication, on a scale from 1 ("very dissatisfied") to 5 ("very satisfied"). Cronbach alpha for the 6 user satisfaction items in this study was .78. The score for each question was defined as the user satisfaction for the relevant function.

Medication Adherence

Medication adherence was measured using the Modified Morisky Scale (MMS) [14]. MMS has two factors: motivation subscale items (factor 1), and knowledge subscale items (factor 2). Cronbach alphas for the two factors were .722 and .691, respectively, in a previous study [15]. The scale is composed of 6 questions using a yes-or-no survey, with 0 or 1 point assigned to each choice. The final MMS score was the sum of the answers to these 6 questions.

Statistical Analysis

The obtained data was analyzed using Microsoft Excel and SPSS. Subjects' demographics and hypertension characteristics were analyzed using real numbers, percentages, means, and standard deviations, while the perceived usefulness, user satisfaction, and MMS scores were analyzed using means and standard deviations. The one-group pre- and posttest MMS scores for medication adherence were measured via a non-parametric Wilcoxon signed-rank test.

Ethics and Informed Consent

This study was approved by Samsung Medical Center Institutional Review Board (IRB No. 2014-03-130-005), where the participants were recruited. The informed consents contained the purpose, procedure, and measurement scales of this study. They were obtained at cardiovascular clinics of Samsung Medical Center in Seoul, South Korea, by paper. For safety and security reasons, personal identifiers were encoded and collected data were kept in a secured storage location to restrict access.

Results

Development of the HMA

Phase I: Planning

Selection of CPGs

The hypertension CPGs were selected by searching well-known CPG search websites such as the National Guideline Clearinghouse [16], the Guidelines International Network[17], and the National Institute for Health and Care Excellence [18], using the following keywords: "hypertension management," "hypertension," "hypertension treatment," and "high blood pressure." Consulting with an expert group majoring in nursing informatics and considering the publisher's credibility, year of publication, and inclusion criteria, 5 CPGs were selected (Table 1).

Extraction of Hypertension Management Interventions

Of the 5 CPGs, 4 (80%) included a hypertension diagnosis by the physicians and principles of anti-hypertensive drug prescriptions. These were omitted from the present study because they were not under the purview of the HMA. What interventions the HMA could provide in terms of nursing and self-management were used to extract intervention categories and items for hypertension management (Table 2) and the target systolic blood pressure for hypertension treatment (Table 3).

Table 1. CPGs selected for the HMA.

CPG	Publisher	Country	Date	Reference
2014 Evidence-based guideline for the management of high blood pressure in adults	American Medical Association, The Eighth Joint National Committee	United States	2014	[1]
2013 Hypertension guideline of the Korea Society of Hypertension	The Korea Society of Hypertension	Republic of Korea	2013	[19]
European Society of Hypertension (ESH) and European Society of Cardiology (ESC) guidelines for the management of arterial hypertension	European Society of Hypertension and European Society of Cardiology	Members of the European Union	2013	[20]
The clinical management of primary hypertension in adults	National Institute for Health and Care Excellence (former National Institute for Health and Clinical Excellence)	United Kingdom	2011	[21]
Nursing management of hypertension	Registered Nurses' Association of Ontario	Canada	2005	[22]

Table 2. Intervention categories and targets [20,22].

Category		Target
Lifestyle intervention		
	Diet	Sodium intake of 65-100 mmol/day
	Body weight	Body mass index(BMI) <25 kg/m^2
		Waist circumference <102 cm (men)
		Waist circumference <88 cm (women)
	Exercise	Dynamic exercise (more than moderate effort) for >30–60 min 4-7 times/week
	Alcohol	Maximum of 2 standard drinks/day or 14 standard drinks/week (men)
		Maximum of 1 standard drink/day or 9 standard drinks/week (women)
	Smoking	Smoking cessation
	Stress	Susceptibility scale score <30[a]
Medications		Obtaining users' medication history
		Providing education about medications that are prescribed for users
Monitoring and follow-up		Receiving appropriate follow-up
Documentation		Documenting and sharing information with the user and health care team

[a]To learn how to cope with stress effectively.

Table 3. Target systolic blood pressure [1].

Characteristics of the patient	Target systolic blood pressure
Age <60 years	140 mmHg
Age ≥60 years with underlying disease[a]	140 mmHg
Age ≥60 years without underlying disease	150 mmHg

[a]Diabetes mellitus and/or chronic renal disease.

Phase II: Analysis

Data Domain

A total of 41 data items were extracted for hypertension management in the planning phase. The extracted data were categorized into two groups: input data and calculated data. Data dictionaries of each data item were developed by specifying the type, values, and unit.

To facilitate obtaining data on sodium intake and stress level from the users, 2 questionnaires that were not part of the CPGs

were used as replacements for the criteria listed in Table 2. For sodium intake, a diet behavior questionnaire [23], with 12 items, was developed in order to classify groups with high and low sodium intakes. Whereas for stress level, the Brief Encounter Psychosocial Instrument, Korean version (BEPSI-K) scale [24], containing 5 items, was used.

Process Domain

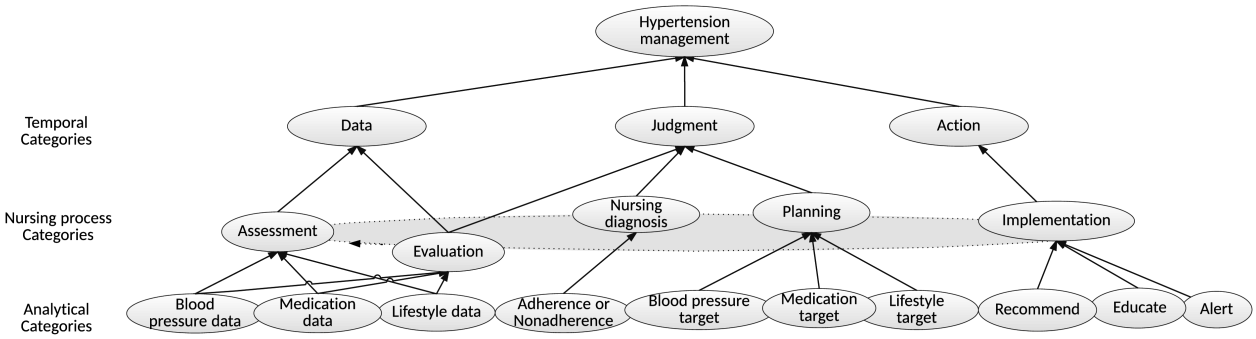
For the process domain, rules were extracted from the CPG to provide tailored recommendations for each participant. For setting the targets for each hypertension management item according to the participant's demographic data, 8 rules were extracted (Table 4), and 20 rules were extracted for tailored recommendations based on preset target and input data.

Hypertension Management Ontology and Tailored Recommendation List

To allow the hypertension management flow of the HMA to be visualized by linking concepts with the nursing process, an ontology for hypertension management (Figure 3) was developed based on a previous study [25]. The ontology is made up of three levels where concepts of the analytical level are linked to the nursing-process-categories level according to their roles in the HMA. Nursing process categories are linked to data, judgment, and action concepts, which constitute the hypertension management concept of the HMA.

A tailored recommendations list was developed based on CPG knowledge by combining data extracted from the data domain and rules extracted from the process domain. This process produced 17 tailored recommendations including one maintenance recommendation and one modification recommendation each for the 7 target items of blood pressure, sodium intake, exercise, alcohol, smoking, body weight, and waist circumference, as well as 3 recommendations for low, moderate, and high stress levels. In addition, optional detailed recommendations were made for subgroups of each recommendation when necessary. Each tailored recommendation comprises the following 3 parts: (1) informing the target of the item, (2) providing the evaluation result, and (3) providing the recommendation. The evaluation-result sentence provides the result of input data analysis, and the recommendation sentence provides evidence and recommendations from the clinical guidelines.

Figure 3. Hypertension management ontology of the HMA.



Interface Domain

Forming an expert group and extracting the functions necessary for the HMA yielded 9 functions, which are presented in a use-case diagram (Figure 4) and are described in Textbox 1.

The use-case diagram shows the actors, use cases, and their relationship in the HMA. The 3 actors outside of the system are the system database, the knowledge database, and user. The system contains 9 use cases that are connected to actors according to their interactions.

Textbox 1. Description of HMA function.

1. Visit: visit from the system
2. Register: register the user to the system
3. Input data: input user’s initial, medication, blood pressure, and lifestyle data
4. View data: view patient’s saved data as a chart, calendar, and graph
5. Send data: send patient’s saved data via e-mail
6. Set alert: set an alert for a medication time or hospital visit date
7. Alert: alert about a medication time or hospital visit date
8. Recommend: give user targets and recommendations
9. Educate: provide education about the medication

Figure 4. Use-case diagram of the HMA.

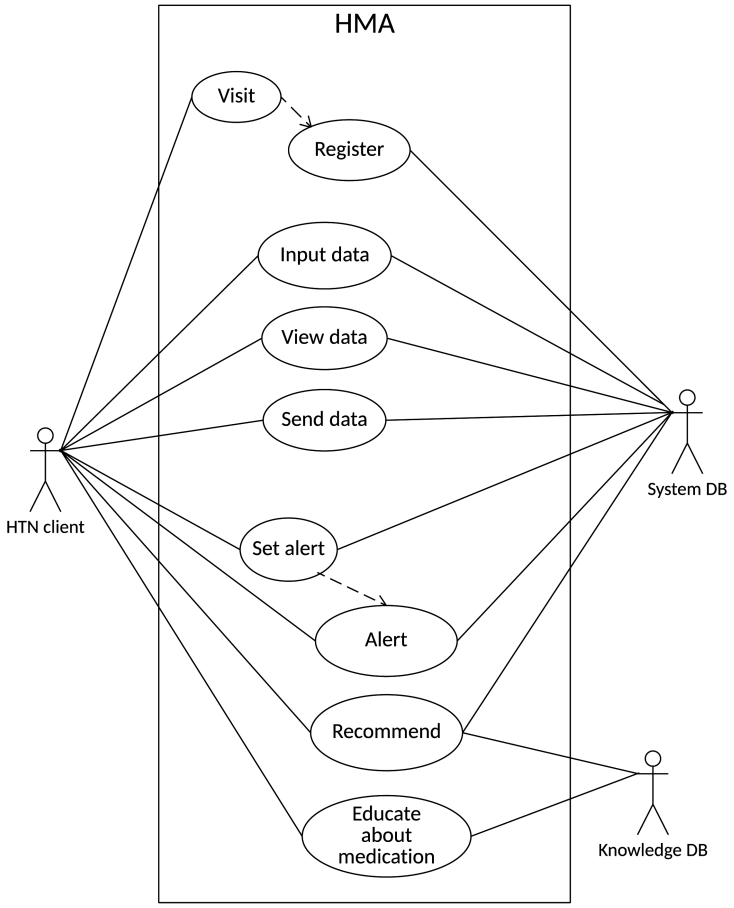


Table 4. Rules of setting targets of the HMA [20,22].

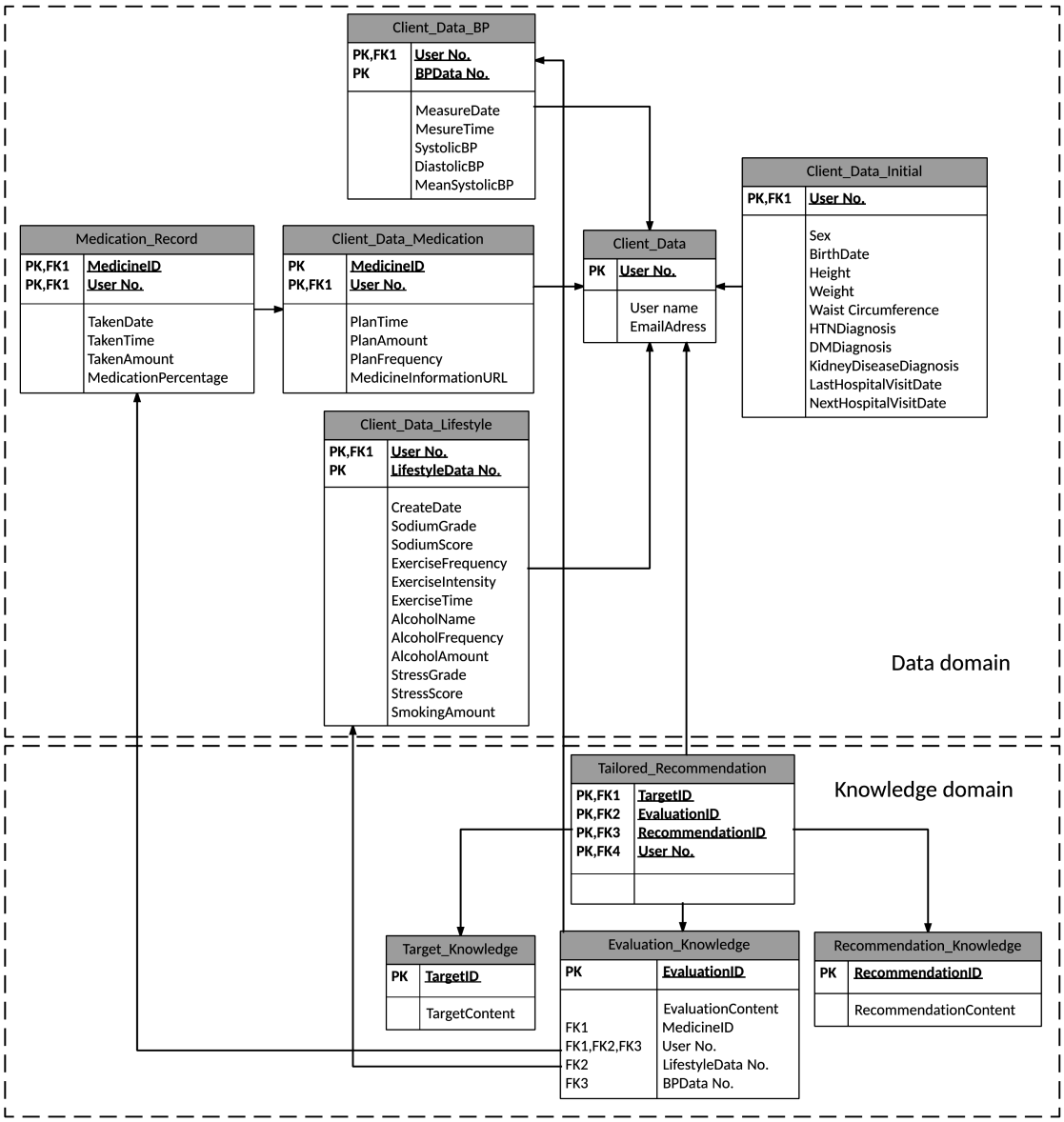
Target category	Rules for set targets
Blood pressure	If ≥60 years with no underlying disease, then systolic BP <150 mmHg
	Else systolic BP <140 mmHg
Sodium intake	Diet behavior score <5
Body weight	Body weight (kg) <25 × height^2 (m^2)
Alcohol	If male and weight ≥60 kg, then alcohol intake ≤2 glasses/day and ≤14 glasses/week
	Else alcohol intake ≤1 glasses/day and ≤9 glasses/week
Smoking	<1 cigarette/day
Stress	Brief Encounter Psychosocial Instrument, Korean version score ≤1.6
Waist circumference	If male, then waist circumference <102 cm
	Else waist circumference <88 cm
Exercise	Exercise frequency >4 times/week, exercise duration >60 min, exercise intensity >moderate effort

Phase III: Design

Data Domain

The data structure is documented in an entity-relation diagram (Figure 5). Separate tables were prepared for the data and knowledge domains, and the data domain tables were further divided according to the change cycle of data values.

Figure 5. Entity-relation diagram of the HMA.

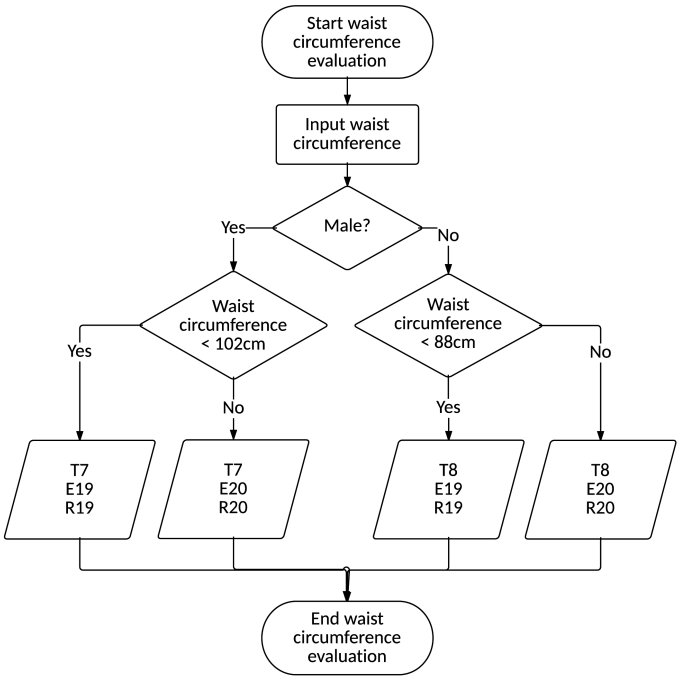


Process Domain

By linking the 8 rules for setting the target and the 20 rules for tailored recommendations, 8 algorithms were developed. The algorithms were used to set targets for each intervention item and provide tailored recommendations based on the target and input data. As an example, the algorithm for evaluating the waist circumference is shown in Figure 6. When a user inputs his/her waist circumference, depending on the user's sex and target waist-circumference evaluation (T7 or T8), the evaluation result (E19 or E20) and recommendation (R19 or R20) will be presented to the user.

In the case of a female user whose waist circumference is 92 cm, a recommendation composed of T8 ("Your target waist circumference is 88 cm"), E20 ("Your waist circumference is 92 cm, 4 cm over the target"), and R20 ("For a hypertension patient, maintaining the proper waist circumference is necessary to lower blood pressure. Reduce your waist circumference to 88 cm") will be received.

Figure 6. Algorithm for waist-circumference evaluation.



Interface Domain

The user interface screens were designed around a menu containing essential functions extracted in the analysis phase. In total, 34 user interface screens were designed.

Phase IV: Implementation

System Environment

The HMA was developed using the Android SDK Platform 4.4.2 Java Development Kit and Eclipse. The database management program was developed using MYSQL. The system works on mobile phones running the Android operating system versions 2.3 to 4.4.

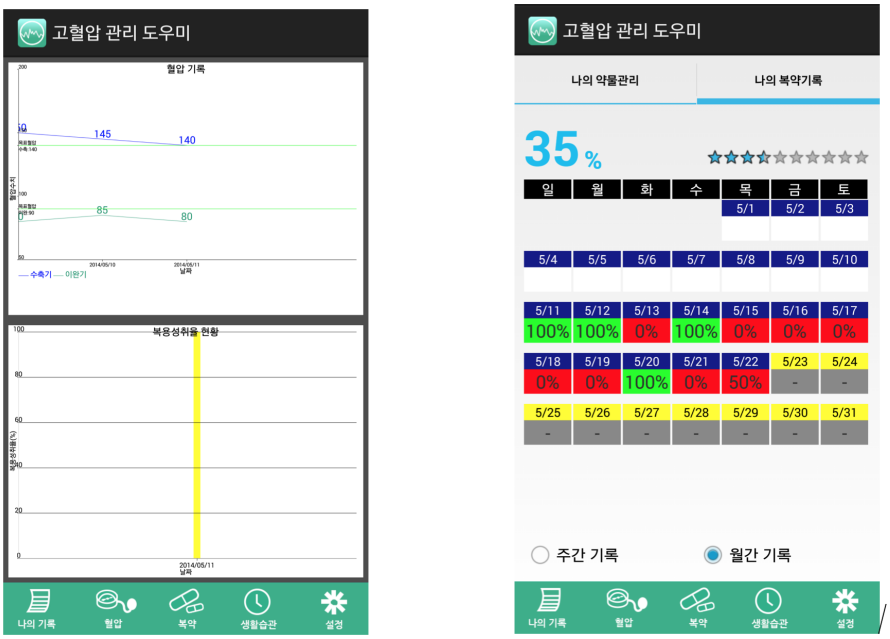
System UI Implementation

The HMA developed in this study was implemented with 5 basic menus at its core (Textbox 2).

Textbox 2. The five basic menus of the HMA.

1. *My records*, which shows the most recent blood pressure and hypertension medication usage records in a graph (Figure 7).
2. *Blood pressure management*, which can be used to check the target blood pressure, makes input blood pressure measurements, receive tailored blood pressure management recommendations, and review blood pressure records.
3. *Medication management*, which can be used to browse for the user's hypertension medication information, enter the medication schedule to be provided with reminders, record the taking of medication, and review the adherence on a weekly and monthly basis (Figure 7).
4. *Lifestyle management*, which provides tailored recommendations in response to the user's answers to questions regarding the 7-lifestyle management items (ie, sodium intake, body weight, waist circumference, exercise, alcohol, smoking, and stress). This menu displays a pop-up window once a month to alert the patients to input lifestyle data.
5. *Settings*, whose basic functions include information management, alert settings, password settings, and data sending via e-mail.

Figure 7. User interfaces of the "my records" (left) and "medication management" (right) menus.



Phase V: Evaluation

Knowledge-Base Accuracy Evaluation

In this evaluation, 2 assistant professors teaching adult health nursing and 1 senior nursing researcher participated. All 3 evaluators had more than 10 years of clinical practice experience. There were no inconsistencies in the broader recommendations produced by the evaluators and the HMA. However, the evaluators proposed the following three additional detailed recommendations: (1) adding the option to input the daily amount of alcohol intake in addition to the existing weekly amount of intake, (2) more specific comments on sodium intake, and (3) adding “get advice from a professional” to stress management. These three recommendations were added to the HMA.

Mobile Heuristics Evaluation

The mobile heuristics was evaluated by 5 nursing informatics, medical informatics, and computer programming experts with PhDs. They flagged 33 usability-related problems related to the mobile heuristics items, of which 3 problems that were related to a severity score of 4, and 7 problems that were flagged by more than 2 evaluators were revised after reflecting on the evaluators’ comments.

Deployment of the HMA

Demographics of Study Subjects

Initially 38 study participants were recruited, of which 29 (76%) participated in the medication adherence survey and 19 (50%) participated in the perceived usefulness and user satisfaction surveys. The mean age of the subjects was 56.0 years, with the highest percentage (48%, 14/29) of them being in the age group of 50-59 years. Most (66%, 19/29) of the participants were male, 62% (18/29) were educated to higher than a bachelor’s degree, 62 % (18/29) were employed full-time, 62% (18/29) were religious, 93% (27/29) were married, and 72% (21/29) were living with their spouse and children.

Hypertension-Related Characteristics of Study Participants

Hypertension-related characteristics of the study participants are presented in Table 5. A mean of 106.2 months had passed since the participants were diagnosed with hypertension, and 101.2 months since they had started taking hypertension medication. Most of the participants (79%, 23/29) reported taking a hypertension medication, and 90% (26/29) took medication once a day. Of the participants, only 5 (17%, 5/29) experienced side effects of hypertension drugs, 55% (16/29) had a family history of hypertension, and 66% (19/29) had previously received education about hypertension. The two main sources of hypertension information were hospitals (52%, 15/29) followed by the Internet (28%, 8/29).

Table 5. Hypertension-related characteristics of the study participants (N=29).

Characteristic	Number or response	n (%)
Number of antihypertensive drug taken per day	1	23 (79)
	2	2 (7)
	3	4 (14)
Medication frequency per day	1	26 (90)
	2	3 (10)
Number of pills taken per day	1	23 (79)
	2	2 (7)
	3	4 (14)
Experience of side effects	Yes	5 (17)
	No	24 (83)
Prior education about hypertension	Yes	19 (66)
	No	10 (34)
Source of hypertension information	Hospital	15 (52)
	Community health center	1 (3)
	TV, radio, newspaper	4 (14)
	Internet	8 (28)
	Book	2 (7)
	Other sources	3 (10)
	Non-response	2 (7)

Survey Results

Perceived Usefulness

The overall mean perceived usefulness score was 3.7 out of 5. The items with the highest score (3.9) and lowest score (3.4) were “I would find the HMA useful in my hypertension management” and “Using the HMA in my hypertension management would increase my productivity,” respectively. The mean score for perceived usefulness of each item is listed in Table 6.

User Satisfaction

The mean user satisfaction scores for 6 functions were (1) 4.3 for blood pressure recording; (2) 3.8 for medication recording; (3) 3.1 for data sending; (4) 3.2 for alerting; (5) 3.4 for recommending; and (6) 3.8 for educating about medication.

Medication Adherence

The mean (SD) MMS scores increased significantly (P=.001) between before and after using the HMA, from 4.2 (1.3) to 5.2 (1.1), respectively.

Table 6. Perceived usefulness score by item.

Number	Item	Mean score
1	Using the HMA in my hypertension management would enable me to accomplish tasks more quickly	3.5
2	Using the HMA would improve my hypertension management performance	3.8
3	Using the HMA in my hypertension management would increase my productivity	3.4
4	Using the HMA would enhance my effectiveness in hypertension management	3.8
5	Using the HMA would make it easier to manage my hypertension	3.8
6	I would find the HMA useful in my hypertension management	3.9

Discussion

Development of the HMA

In the knowledge extraction phase, it was necessary to decide from which CPG, and to what extent knowledge needs to be extracted, in order to form the knowledge base for the HMA. After selecting multiple CPGs, knowledge on hypertension diagnosis and drug therapy required for health care providers to make decisions was excluded. Instead, the following knowledge relevant to a patient’s self-management of hypertension was included: target blood pressure, lifestyle management intervention, and evidence for tailored recommendations.

The system development stage involved converting the knowledge extracted from the CPG into a computer-interpretable form so that it could be applied to the system. Data and rules were extracted from the text-formatted CPG, then coded so that both the user and the system could understand them. The process of making the CPG knowledge understandable to computers requires cooperation between clinical experts and computer developers [26]. This process would be more efficient if a knowledge modeling tool and system development methodology, specialized for the development of a CPG-based mobile system, are developed.

The evaluation of the knowledge-base accuracy indicated that the recommendations proposed by the experts were more detailed than those suggested by the HMA. Since the accuracy of the knowledge base was evaluated after the HMA had been developed, coding needed to be performed twice to reflect this change. This extra coding step could be avoided if the expert evaluation of the knowledge base was performed in the algorithm development stage.

In the mobile heuristics evaluation, diverse expert opinions were sought from evaluators with diverse backgrounds, such as nursing, medical informatics, and computer programming. The various evaluators made different numbers of comments on different heuristics items. Since the capability of each evaluator acts as an important variable in mobile heuristics evaluation [27], including diverse experts from several fields facilitated the identification of usability problems.

Deployment of the HMA

The users found the HMA useful. According to Davis [12], there is a positive correlation between system acceptance and perceived usefulness. Although system acceptance was not directly measured in the present study, we assume that users will have a positive attitude toward using an app for measuring hypertension.

Users rated that they were highly satisfied with the HMA's blood pressure and medication recording functions. This is in accordance with a previous study on a chronic disease management mobile app [28], which found patients suffering from chronic diseases to be very interested in its recording functions. Recording functions are especially useful for those who need to record and monitor their health information on a chronic basis.

The education provided about medicine information also received a high score of 3.8 in the user satisfaction survey, which is attributed to the HMA being connected to an external database and provides the latest information on hypertension medicine in real-time, including visual information. The quality of information is an important factor in determining the success of information systems [29]. This is consistent with the present study where users were satisfied with the well-constructed knowledge base because it provided quality information on medicine.

On the other hand, users showed a lower user satisfaction for the data sending function. The purpose of this function was not only to store, but also to send the users' records to the users' health care providers for feedback. However, because the HMA manages the users' blood pressure records, provides tailored recommendations, and offers analysis of their medications, the users may have not found it necessary to send their records to their health care provider, resulting in a lower score for the data sending function. The HMA was rated as useful but inefficient for hypertension care in the survey of the perceived usefulness. The users were satisfied with the monitoring functions themselves (eg, blood pressure and medication recording), but rated the efficiency aspect of the HMA poorly due to the additional act of recording, since the users previously did not have to do this.

This study found that the HMA improved medication adherence. However, an attrition bias [30] may have been present since 9 of the 38 participants (24%) dropped out during the 4-week study period. Those who answered the posttest survey may have represented a high-adherence group, and thus not representative of the entire survey cohort. Results that are more accurate are likely to be obtained in a future study that includes both control and experimental groups with similar initial adherence rates.

Limitations

Implications of the study findings are limited, as we did not measure the direct effects of the HMA on parameters such as actual medication adherence, lifestyle improvement, and change in blood pressure. A future study should measure the actual medication adherence using digital adherence measuring equipment [31], and evaluate lifestyle improvements and blood pressure changes over the long term. A future app with wireless medical sensors and technologies for better data collection and transmission will allow this future study possible.

There is the possibility that those with low medication adherence refused to participate in the survey. Thus, it is necessary to explore the reasons for the withdrawals to evaluate selection bias on the medical adherence survey. In addition, it is arguable that the 4-week intervention was too short and the number of participants involved was not sufficient to measure the effectiveness of the HMA. This will certainly introduce bias in the measurements. A future study with a longer intervention period and a larger study cohort is recommended.

Finally, we did not assess patient engagement and use of the HMA for their hypertension management, which should be taken into consideration in future studies.

Conclusions

This study describes the development of a mobile HMA based on CPGs that allows patients with hypertension to conduct appropriate self-management. CPGs were used as the knowledge base of the HMA, and critical functions were constructed to aid 2 factors of hypertension management: lifestyle improvement and drug treatment. The developed HMA was evaluated based on the accuracy of the HMA's knowledge base and its mobile heuristics, was applied to a cohort of patients with hypertension patients, and evaluated for its perceived usefulness and user satisfaction. The HMA scored 3.7 out of 5 for perceived usefulness, and with respect to user satisfaction, it scored 4.3 for blood pressure recording, 3.8 for medication recording, 3.1 for data sending, 3.2 for alerting, 3.4 for recommending, and 3.8 for educating about medication. The findings also

demonstrated that medication adherence increased significantly after using the HMA (P=.001).

This study is significant not only in that it developed a mobile app for hypertension management based on CPGs, but also evaluated the developed system and its effects on patients with hypertension over a 4-week period. Further studies are necessary to determine the direct effects of the HMA on patients with respect to actual medication adherence, lifestyle improvement, and change in blood pressure.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

BEPSI-K: Brief Encounter Psychosocial Instrument, Korean version
BMI: body mass index
CPG: clinical practice guideline
HMA: hypertension management app
MMS: Modified Morisky Scale

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Original Paper

Design Considerations for Smoking Cessation Apps: Feedback From Nicotine Dependence Treatment Providers and Smokers

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Abstract

Background: Hundreds of smoking cessation apps are commercially available, but most are not theory-based or designed to take advantage of mobile technology in ways that could make them more engaging and possibly more effective. Considering input from both clinical experts (who understand best practice nicotine dependence treatment requirements) to inform appropriate content and from smokers (the end users) to express their preferences is important in designing these programs in the future.

Objective: To assess and compare the opinions of nicotine dependence treatment providers and smokers regarding the design of future smoking cessation apps.

Methods: We surveyed providers (n=264) and smokers who own smartphones (n=40) to assess their opinions on the importance of 21 app design features. Features represented 5 domains: cost, reputation, privacy and security, content and user experience, and communication. Domains were chosen to reflect best practice treatment, leverage mobile technology to support smoking cessation, and elicit important user preferences. Data were collected between June and July 2015.

Results: Most providers agreed that mHealth apps hold promise for helping people quit smoking (203/264, 76.9%) and would recommend them to their clients/patients (201/264, 76.1%), especially if the app were empirically validated (236/264, 89.4%). Few providers believe effective cessation apps currently exist (112/264, 42.4%). Few smokers (5/40, 13%) had ever downloaded a smoking cessation app; of the ones who had not, most said they would consider doing so (29/35, 83%). Both respondent groups indicated the following features were very to extremely important to include in cessation apps: free or low cost, keeps information private, matches individual needs and interests, adapts as one's needs and interests change, helps to manage nicotine withdrawal symptoms and medication side effects, and allows users to track their progress. Providers and smokers also indicated gaming and social media connectivity were less important than other features. Despite these similarities, the groups had significantly different opinions about the relative importance of various features. In particular, providers rated privacy as the most important feature, whereas smokers rated low cost and the ability to adaptively tailor content as the most important features.

Conclusions: Smoking cessation apps hold great promise as intervention tools but only if they engage users and appropriately treat nicotine dependence. Intervention development should take into consideration the perspectives of both treatment experts and smokers. This paper highlights important perspectives from each of these groups to be considered when designing future app-based smoking cessation programs.

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KEYWORDS

tobacco use cessation; smoking; mobile health; smartphone

Introduction

According to the World Health Organization, mobile Health (mHealth) technologies have the potential to transform the face of health service delivery [1]. mHealth interventions, particularly smartphone apps, offer many treatment benefits such the relatively low cost of intervention and wide potential reach. Smartphones are increasingly the device with which lower income and minority populations access the Internet [2], making smartphone apps an important public health tool and an obvious modality for delivering population-based smoking cessation interventions. In the United States alone, 64% of adults own a smartphone [3], and 17% are current smokers [4]. Thus, there is great opportunity to create mHealth tobacco cessation programs.

Other benefits of mHealth smoking cessation programs include accessibility, personalization, and convenience—content can be viewed on-demand 24/7. Content delivered through an app or mobile-enabled website can be dynamically updated in response to user-provided content on changing needs, interests, or situations (eg, nicotine withdrawal symptoms, cravings to smoke, or medication side effects). In addition, mobile apps can capitalize on the strengths of social media to allow interaction with other smokers trying to quit, share knowledge and experiences, and create a sense of community. As a result, cessation apps may be more acceptable and engaging than other population-level interventions such as written materials or tobacco quitlines, resulting in a higher therapeutic exposure and greater impact on treatment outcomes.

To date these benefits are largely hypothetical and untested. A recent review of commercially available products concluded that most smoking cessation apps are simplistic and not particularly "smart" [5] in that their designs do not take advantage of the technological capacities of smartphones to do things such as adaptively tailor content or allow 2-way interactions between users or users and clinicians. In fact, most existing commercial cessation apps do not even include best practice treatment. For example, most address only 2 of the 5 A's (ask, advise, assess, assist, and arrange follow-up) considered to be core aspects of appropriate nicotine dependence intervention [6,7]. Other studies have found that only a handful of publicly available cessation apps recommend the use of approved stop-smoking medications, and none recommend users seek additional counseling from a tobacco quitline [8,9], an evidence-based, free treatment resource available to smokers in almost all US states. In other words, most existing cessation apps seem to have been developed without an understanding of the complexities of nicotine dependence treatment.

Moreover, most apps appear to have been developed without taking into consideration user needs. In fact, few user-centered studies have focused specifically on cessation app design [10,11] as opposed to the design of other mobile-delivered cessation interventions via short message service (SMS) text messaging or social media. To date no large scale randomized effectiveness trials of cessation apps have been published. In contrast to the robust body of literature examining text messaging for smoking cessation [12-30], research on apps has been limited to preliminary pilot studies with small samples or short follow-up periods [11,12,31-33] and protocols of trials in progress [34-37].

Despite the limitations noted above, cessation apps are being developed and sold at a rapid pace [38]. Hundreds of cessation apps are available on the popular iPhone and Android platforms; downloads have exceeded a million per month for some apps [5,8,39]. Consumers are purchasing these apps with the hope of increasing their chances of quitting smoking, but this may not be the case given the apps' basic designs, lack of theoretical grounding, and failure to include best practice treatment elements. Furthermore, the popularity of these programs clearly speaks to smokers' interest in these programs, but we know little about what content and design features are most appealing to users [10,22,40]. This is important since appeal may translate to use, and programs must be used to be effective.

Not much is known about treatment provider knowledge, attitudes, and beliefs about smoking cessation apps. For example, do providers think these tools hold promise for treatment? Will they recommend them to clients/patients? What content and features do they believe are most important? The latter is critical because in the absence of empirical data on which content and design features make smoking cessation apps more engaging and effective, it is necessary to rely on alignment of user preferences with the clinical knowledge and practical experience of treatment providers to guide app development. We are unaware of any prior research that has surveyed the relative perspectives of these two key stakeholder groups about these issues. Prior studies have reported on the content of existing cessation apps [5,8,9,41] and the extent to which content is theoretically grounded [39], but none have presented preferred or recommended content from the perspectives of both treatment providers and smokers.

We address this important gap in the literature in this paper. We surveyed clinicians who routinely provide smoking cessation counseling or other nicotine dependence treatment services to assess their knowledge and attitudes about smoking cessation apps as well as their opinions about which key content and design features should be included in the future. We contrast provider perspectives with perspectives of smokers who own and use smartphones and tablets and represent the target audience for smoking cessation apps. These results can more fully inform how best to leverage the technological capacities of mobile devices in future app development to help people stop smoking.

Methods

Setting and Review

All research activities were conducted at the Group Health Research Institute and approved by the Group Health Institutional Review Board.

Participants

Providers were recruited through the professional LISTSERVs of the Society for Research on Nicotine and Tobacco, the Association for the Treatment of Tobacco Use Disorders, and the Society for Behavioral Medicine. Counselors from the largest US tobacco quitline service provider were also invited to

participate. Respondents were eligible if they routinely assisted clients/patients to quit smoking and, on average, treated at least 5 smokers every 3 months. Assistance was defined as providing counseling, support and/or pharmacotherapy; persons who simply provided advice to quit and/or treatment referral were not eligible. Participants had the option to receive a $25 Amazon gift card as a thank you or to remain anonymous. Survey completion was limited to one per person and enforced by allowing only one survey submission per IP address. We also monitored names and email addresses provided to ensure there were no duplicates.

Smokers were recruited via online ads (eg, craigslist, SuperSeattleAds, ClassifiedAds), flyers posted around the Seattle area, and invitation letters mailed to members of Group Health Cooperative (a nonprofit health care system in Washington state) who lived in the Seattle area and were likely smokers. Interested smokers were invited to provide feedback on their attitudes and preferences for mHealth smoking cessation tools. Individuals were eligible if they were at least 18 years old, a current smoker interested in quitting smoking or actively trying to quit, could read and write in English, and owned a smartphone or tablet computer which they used to access the Internet at least occasionally. Eligible smokers attended a one-time focus group during which they completed a written survey and were asked to react to a hypothetical smoking cessation app. Data presented in this paper were collected via the written survey; qualitative reactions to the hypothetical app are presented elsewhere and not discussed here. Smokers received $50 for their participation.

Survey

Both participant groups provided information about their demographics, education, smartphone use, and use of mobile devices and apps. We also surveyed provider attitudes and beliefs about smoking cessation apps and their comfort using smoking cessation apps and electronic communication with clients/patients using a 5-point scale (completely disagree, somewhat disagree, neutral, somewhat agree, and completely agree). Finally, both providers and smokers rated the importance of 21 hypothetical app design features. Features were categorized into the following domains: cost, reputation, privacy and security, content and user experience, and communication with others. Individual features were chosen to (1) reflect technology-based strategies for implementing best practice treatment recommendations (eg, addressing use of pharmacotherapy, providing social support, and offering cognitive behavioral–based content), (2) reflect ways to leverage other smartphone capacities to make these programs more engaging (eg, gaming), (3) assess perceived limitations of mHealth tools (eg, security and privacy), or (4) understand other user preferences which may inform future program development (eg, cost, reputation). Each feature was rated using a 4-point Likert scale (not at all important, somewhat important, very important, and extremely important). Providers were asked to rate how important each feature would be to them as a clinician if they were recommending a cessation app to their clients/patients. Smokers were asked to rate the importance of each feature if they were considering downloading or using a smoking cessation app.

Provider data were collected online with SurveyMonkey online survey software between June and July 2015. Smokers were surveyed in person in June 2015. All participants provided informed consent and could choose to decline to respond to any survey item.

Analysis

Descriptive statistics were calculated with Excel 2011 (Microsoft). Comparisons between ratings reported by providers and smokers were analyzed in R version 2.15.1 statistical computing software (The R Foundation) with Mann Whitney U tests. We report mean ratings and *P* values for group comparisons. All respondents were included in the sample denominators, but participants who declined to respond to individual items were excluded from the group comparisons as noted in table footnotes.

Results

Provider Characteristics

Of the 344 providers responding to the survey, 264 were eligible and were included in the respondent sample. Providers ranged in age from 21 to 85 years (mean 44, SD 13). They were predominantly female (203/264, 76.9%), white (211/264, 79.9%), and not Hispanic or Latino (239/264, 90.5%). Of the providers responding, 30.7% (81/264) had a doctorate degree (MD, PhD, PsyD, PharmD), 37.5% (99/264) had an advanced practice degree (MA, MS, ARNP, PA), 26.9% (71/264) had a college degree, and 3.0% (8/264) had a high school degree. The vast majority (244/264, 92.4%) had received formal training in nicotine dependence treatment; 73.1% (193/264) considered themselves very knowledgeable about best practice smoking cessation treatment, and 25.0% (66/264) considered themselves somewhat knowledgeable. Practice settings included a tobacco quitline service provider (79/264, 29.9%), primary care setting (58/264, 22.0%), specialty medical care setting (34/264, 12.9%), mental health clinic (29/264, 11.0%), pharmacy (1/264, 0.4%), and other settings as specified by respondents (59/264, 22.3%). The latter predominantly included inpatient, outpatient, and work-place practice settings. Most owned smartphones (231/264, 87.5%) and had previous experience downloading apps (230/264, 87.1%).

Smoker Characteristics

A total of 40 current smokers were surveyed (average cigarettes per day, 12; SD 12). Participants were predominantly white (25/40, 63%) and not Hispanic or Latino (36/40, 90%); half were female. Smokers ranged in age from 20 to 58 years (mean, 38; SD 12). Most did not have a college degree (26/40, 65%), and 70% (28/40) had an annual household income of $50,000 or less. Of the 40 smokers surveyed, 60% (n=24) owned an Android phone, 30% (n=12) an iPhone, and 10% (4/40) another brand of smartphone. The most common tablet computer owned was an iPad (7/40, 18%), but 55% (22/40) did not own a tablet. More than half (24/40, 60%) primarily accessed the Internet via their smartphone. Nearly half (19/40, 48%) had downloaded a health-related app to their phone, and 13% (5/40) had downloaded a smoking cessation app. Among those who had

not downloaded a smoking cessation app, 83% (29/35) said they would consider doing so.

Provider Attitudes and Beliefs About Smoking Cessation Apps

Provider attitudes and beliefs about mHealth cessation apps are summarized in Table 1. Most agreed (somewhat or completely) that mHealth apps hold promise for helping people quit smoking (203/264, 76.9%) and would recommend them to their clients (201/264, 76.1%), especially if the program were empirically validated (236/264, 89.4%). Most respondents also agreed they would use an app that allowed them to track their clients'/patients' progress (187/264, 70.8%). Relatively few respondents agreed that effective cessation apps currently exist (112/264, 42.4%) or that there is good empirical evidence that apps can help people quit smoking (81/264, 30.7%).

Table 1. Provider attitudes and beliefs about smoking cessation apps (N=264).

	Completely disagree[a] n (%)	Somewhat disagree[a] n (%)	Neutral[a] n (%)	Somewhat agree[a] n (%)	Completely agree[a] n (%)
Many of my clients or patients use mHealth apps to manage their health.	23 (8.7)	88 (33.3)	65 (24.6)	74 (28.0)	4 (1.5)
mHealth apps hold promise as a tool to help people stop smoking.	2 (0.8)	10 (3.8)	38 (14.4)	126 (47.7)	77 (29.2)
There is good empirical evidence that stop-smoking apps can help people quit.	26 (0.3)	30 (11.4)	134 (50.8)	69 (26.1)	12 (4.5)
As a clinician, I would recommend a stop-smoking app to my patients or clients trying to quit.	2 (0.8)	12 (4.5)	38 (14.4)	137 (51.9)	64 (24.2)
Effective stop-smoking apps are widely available for smokers.	11 (4.2)	46 (17.4)	84 (31.8)	90 (34.1)	22 (8.3)
If there were an app that allowed me to track my client/patients' progress quitting smoking, I would use it as a clinician.	10 (4.2)	21 (8.0)	35 (13.3)	113 (42.8)	74 (28.0)
If there were an empirically validated stop-smoking app, I would recommend it.	5 (1.9)	2 (0.8)	10 (3.8)	69 (26.1)	167 (63.3)

[a]Nonresponders ranged from n=10 to n=13 across items and are not reflected in table.

Table 2 summarizes provider comfort using electronic communication with clients/patients. Less than half agreed (somewhat or completely) they were comfortable exchanging text messages or emails with their smoking clients/patients (95/264, 36.0%). However, the majority agreed they would be comfortable communicating electronically if it were through a secure system compliant with the Health Insurance Portability and Accountability Act (HIPAA) (221/264, 84%).

Table 2. Provider comfort using cessation apps and electronic client/patient communication (N=264).

	Completely disagree[a] n (%)	Somewhat disagree[a] n (%)	Neutral[a] n (%)	Somewhat agree[a] n (%)	Completely agree[a] n (%)
I am comfortable exchanging text messages or emails with my patients/clients.	68 (25.8)	46 (17.4)	45 (17.0)	53 (20.1)	42 (15.9)
I would be comfortable communicating electronically with my patients/clients if it were through a secure HIPAA-compliant system.	7 (2.7)	8 (3.0)	18 (6.8)	98 (37.1)	123 (46.6)

[a]Nonresponders (n=10) are not reflected in table.

Perceived Importance of Select Features for Smoking Cessation Apps

Figure 1 compares providers' and smokers' ratings for importance of 21 potential content and design features for smoking cessation apps. All features except gaming and social media were considered at least somewhat important by both groups.

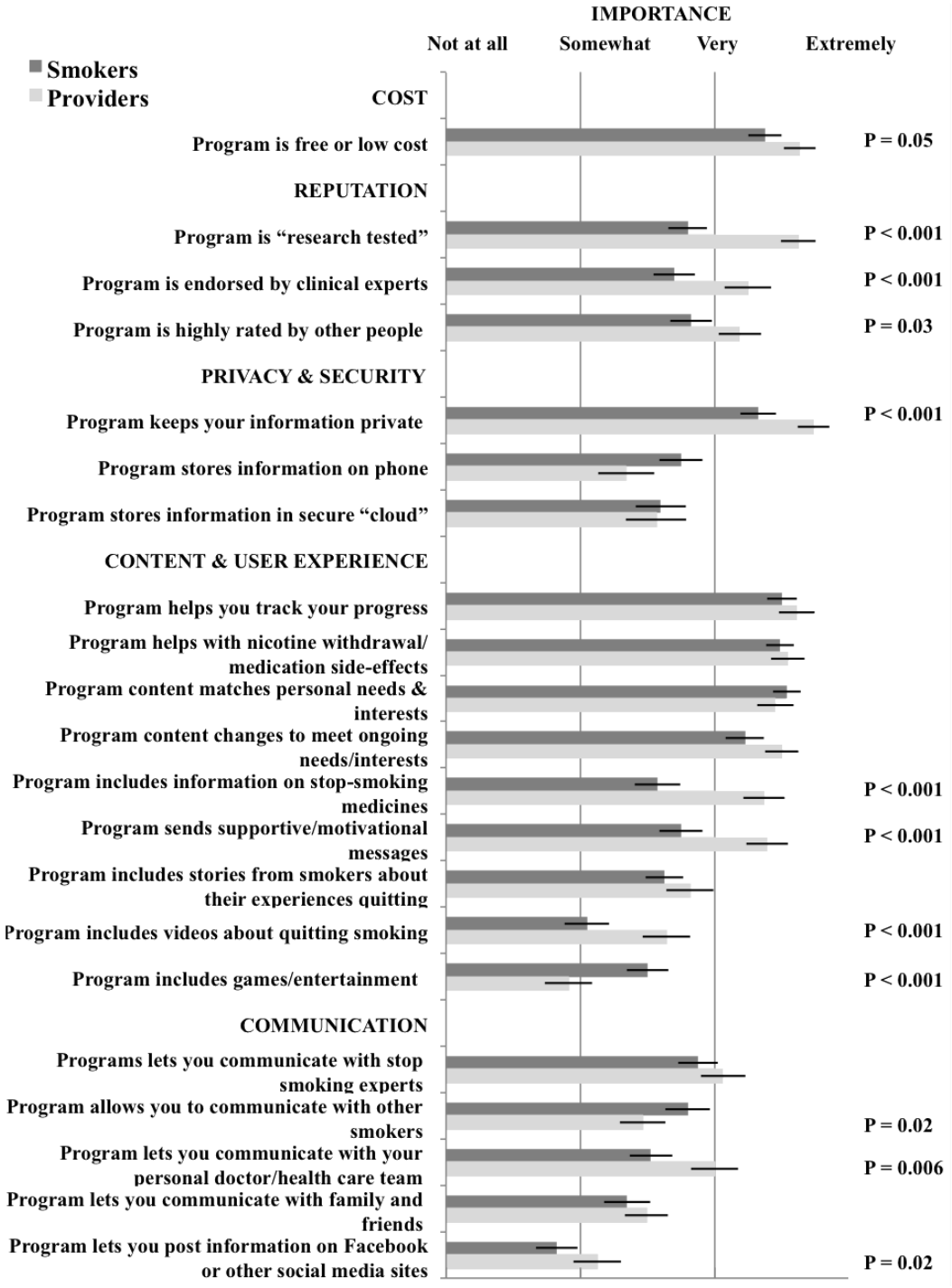
While the mean ratings differed between providers and smokers for many features, on average both groups agreed that the following were very to extremely important as evidenced by a mean rating of 3.0 or greater: the program is free or low cost (providers, 3.6 [SD 0.6] vs smokers, 3.4 [SD 0.8]; P=.05), the program keeps your information private (3.7 [SD 0.5] vs 3.3 [SD 0.8]; P<.001), the program content matches individual needs and interests (3.5 [SD 0.6] vs 3.5 [SD 0.6]; P=.36), the program content adaptively changes as one's needs and interests

change (3.5 [SD 0.6] vs 3.2 [SD 0.9]; *P*=.11), the program helps with managing nicotine withdrawal symptoms and medication side effects (3.5 [SD 0.6] vs 3.5 [SD 0.6]; *P*=.49), and the program allows users to track their progress (3.6 [SD 0.6] vs 3.5 [SD 0.7]; *P*=.32). Although both groups considered programs that are low cost and keep information private important, providers rated their importance significantly higher than smokers.

Both groups considered gaming features or connecting with social media such as Facebook less important than the other features, but the relative importance between groups based on their mean scores differed. Smokers were more likely than providers to rate games or entertainment features at least *somewhat* important (2.5 [SD 1.0] vs 1.9 [SD 0.8]; *P*<.001), but providers were more likely to rate social media connectivity at least *somewhat* important (2.1 [SD 0.8] vs 1.8 [SD 1.0]; *P*=.02) and to believe it is important to include videos about quitting smoking (2.6 [SD 0.8] vs 2.1 [0.9], *P*<.001). Both groups also agreed it was important that apps allow smokers to communicate with experts about their progress (3.1 [SD 0.8] vs 2.9 [SD 0.9]; *P*=.30), allow communication with family and friends about their progress (2.5 [SD 0.8] vs 2.4 [SD 1.1]; *P*=.35), and include stories from other smokers' experiences quitting (2.8 [SD 0.8] vs 2.6 [SD 0.9]; *P*=.16). The groups also agreed it was at least *somewhat* important that apps store information directly on the smartphone (2.3 [SD 1.0] vs 2.8 [SD 1.0]; *P*=.20) or in a secure cloud (2.6 [SD 1.1] vs 2.6 [SD 1.1]; *P*=.89), but no clear preference was expressed for one over the other in either participant group.

Providers and smokers largely disagreed on the importance of the remaining features. For example, providers thought it was more important than did smokers that apps be highly rated by users (3.2 [SD 0.7] vs 2.8 [SD 0.9]; *P*=.03), endorsed by clinical experts (3.2 [SD 0.8] vs 2.7 [SD 1.0]; *P*<.001) and research tested (3.6 [SD 0.6] vs 2.8 [SD 0.9]; *P*<.001). The providers also believed it was more important that these programs provide supportive motivational messages by text or email (3.4 [SD 0.7] vs 2.8 [SD 1.0]; *P*<.001), include videos about quitting smoking (2.6 [SD 0.8] vs 2.1 [SD 0.9], *P*<.001), include information on stop-smoking medications (3.4 [SD 0.7] vs 2.6 [SD 1.8]; *P*<.001), and allow users to communicate with one's personal doctor or health care team (3.0 [SD 0.8] vs 2.5 [SD 1.0], *P*=.006). In contrast to providers, smokers said it was more important that they are able to communicate with other smokers about their progress (2.5 [SD 0.8] vs 2.8 [SD 1.0]; *P*=.02) and that programs include games or entertainment (1.9 [SD 0.9] vs 25 [SD 1.0]; *P*<.001); but smokers did not rate either of these features highly.

Figure 1. Comparison of providers' and smokers' ratings of important features.



Discussion

Principal Findings

This paper represents the first known survey of smoking cessation treatment providers and smokers to assess and compare their attitudes and opinions about important design features for future smoking cessation apps. While smokers represent the target user group for these programs, clinicians understand the complexities of nicotine dependence and the treatment components this requires. Thus, it is important for mHealth designers and developers to take into consideration the perspectives of both groups when developing smoking cessation apps.

We found that both smokers and clinicians are receptive to using or recommending smoking cessation apps, although clinicians were more open to recommending programs that have been empirically proven to be effective. Smokers rated it as less important that a program be research tested and were also less concerned about the reputation of a program as indicated by user ratings or endorsements by clinical experts. This appears consistent with prior research showing nearly 78% of smoking cessation app users did not check on the credibility of the app publisher before downloading it [42]. The latter may also explain

the popularity of existing commercially available cessation apps in the absence of sound empirical support for these programs. Nevertheless, empirical validation is important for smoking cessation apps since these are fundamentally treatment programs.

Features that are low cost, match their personal needs and interests, and help them address nicotine withdrawal and medication side effects and track their progress are rated most highly by smokers. Participants were not asked to delineate what these features mean to them, but matching content to personal needs suggests that adaptively tailored features will help them cope with physiological or environmental cues to smoke. Tracking progress typically takes the form of tracking cigarettes smoked but could also include calculating money saved by not smoking.

Providers rated cost, assistance with withdrawal symptoms and medication side effects, and personalization as important, but they rated privacy as the most important feature for cessation apps. This is not surprising given clinicians' need to comply with federal privacy laws such as HIPAA. It is notable, however, that 84% said they would be comfortable communicating with clients/patients through a secure, HIPAA-compliant system if it were integrated into the app. Further, both smokers and providers rated the ability to communicate with stop-smoking experts through the program as fairly important (3.1 vs 2.9, P=.30). While most mHealth cessation apps do not currently provide this functionality, this evidence supports allowing smokers to have bidirectional communication with stop-smoking experts using systems designed to be HIPAA-compliant. From a technical standpoint, this can be accomplished via a hybrid app which allows users to log into a secure Web portal through the app interface. Information can then be shared, accessed, and stored in the Web portal as opposed to being resident on the mobile device or in an email message. We are currently testing this functionality in our research and expect to see more apps using secure messaging in the future to encourage communication between patients and care providers.

Also of note, smokers seemed to favor communication with tobacco treatment specialists (2.9) over communication with their own health care providers or health care team (2.5), but the ability to communicate with treatment specialists (2.9) was only rated slightly higher than the ability to communicate with other smokers (2.8).

Perhaps as interesting as what providers and smokers rated as most important are the features they viewed as least important: games/entertainment; videos about quitting smoking; communication with friends, family, personal doctor, and health care team; and social media connectivity. Providers tended to give higher ratings, but neither group considered the features critical. These findings may be a cautionary tale for developers. For example, many researchers and developers are working on apps that focus on social media or "gamify" the process of quitting smoking. While these features leverage the technological capabilities of mHealth devices and may appeal to subpopulations of game or social media users and may be novel, they may not ultimately be the most appealing features to smokers on a population level or be viewed favorably by content experts who are in a position to recommend programs to their clients/patients.

Information on stop-smoking medications was not rated highly by smokers but was considered very important by providers. Appropriate pharmacotherapy is a critical component of any best-practice, comprehensive treatment program for nicotine dependence [6,43], and developers are advised to place greater weight on the feedback of providers when considering this feature.

Strengths and Limitations

This work has several notable strengths. To our knowledge, this is the first research to survey clinical providers' and smokers' opinions about smoking cessation apps and one of the first to assess user-centered preferences for smoking cessation apps as opposed to other forms of mHealth intervention (ie, via SMS text messaging or social media platforms). By presenting and contrasting smokers' and clinicians' opinions, we provide a richer insight into the relative importance of the reviewed design features than might be gleaned if either group were surveyed in isolation. Another important contribution of this study is that it describes the importance to users of existing design features relative to features that may be considered in future apps. Next, our provider group includes clinicians ranging from physicians, psychologists, nurses, and pharmacists with advanced specialty training to lay counselors working at tobacco quitlines or community-based stop smoking programs. As such, the perspectives may be more representative of the overall provider community than if we had focused on doctorate or masters level professionals only.

This research has several limitations. Our sample reflects the opinions of US treatment providers and may not be generalizable to other populations. Second, it is not clear whether the opinions of the smokers in our sample will generalize to other smokers (US or non-US) because the sample is relatively small (n=40). However, the sample demographics reflect a lower socioeconomic status, racially diverse group of US smokers who were interested in quitting smoking, so the findings are expected to generalize best to this important target group for intervention.

Conclusion

In summary, smoking cessation apps hold great promise as intervention tools, but current programs are not designed to reflect best practice treatment or take advantage of the full technical capabilities of smartphones and tablet computers. Addressing the latter could make these tools more engaging and more effective. The feedback provided by smokers and providers in this paper offers insight into which content and features researchers and developers should consider in the future. Features rated highly by both groups should receive particular attention, as they are informed by both clinical expertise and user preference. Differences of opinion are notable, as well. In this case, developers should balance user preferences with provider knowledge of best practice treatment. This paper offers insights into this important area of research.

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Conflicts of Interest

None declared.

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Abbreviations

HIPAA: Health Insurance Portability and Accountability Act
mHealth: mobile Health
SD: standard deviation
SMS: short message service

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Original Paper

Automated Behavioral Text Messaging and Face-to-Face Intervention for Parents of Overweight or Obese Preschool Children: Results From a Pilot Study

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Abstract

Background: Children are 5 times more likely to be overweight at the age of 12 years if they are overweight during the preschool period.

Objective: The purpose of this study was to establish the feasibility, acceptability, and preliminary effects of a cognitive behavioral intervention (TEXT2COPE) synergized with tailored mobile technology (mHealth) on the healthy lifestyle behaviors of parents of overweight and obese preschoolers delivered in a primary care setting.

Methods: Fifteen preschooler-parent dyads recruited through primary care clinics completed a manualized 7-week cognitive behavioral skills building intervention. Beck's Cognitive Theory guided the TEXT2COPE intervention content and Fogg's Behavior Model guided the implementation. The intervention employed a combination of face-to-face clinic visits and ecological momentary interventions using text messaging (short message service, SMS). To enhance the intervention's relevance to the family's needs, parents dictated the wording of the text messages and also were able to adapt the frequency and timing of delivery throughout program implementation.

Results: Self-reported findings indicate that the program is feasible and acceptable in this population. The intervention showed preliminary effects with significant improvements on parental knowledge about nutrition (P=.001) and physical activity (P=.012) for their children, parental beliefs (P=.001) toward healthy lifestyles, and parental behaviors (P=.040) toward engaging in healthy lifestyle choices for their children. Effect sizes were medium to large for all variables. The timing, frequency, and wording of the text messages were tailored to the individual families, with 69% of parents (9/13) increasing the frequency of the tailored SMS from being sent once weekly to as many as 5 times a week.

Conclusions: Utilizing a cognitive behavioral skills intervention with SMS has great potential for supporting clinical care of overweight and obese preschool children and their families. Further exploration of the potential effects on health and behavioral outcomes is warranted.

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KEYWORDS

Child; Obesity; Overweight; Health Behavior; Text Messaging/SMS; Mobile Health; Parents; Psychology; Behavior Therapy; Telemedicine

Introduction

Background

The preschool age group is a priority for surveillance and intense intervention because obesity trends in this group are a predictor of trends in older children and adults [1-3]. Children are 5 times more likely to be overweight at the age of 12 years if they are overweight during the preschool period, and 60% of overweight preschoolers are overweight at the age of 12 years [4]. Yet, challenges arise as parents perceive use of the term obesity to be stigmatizing and blaming [5,6], and a sizable number of pediatricians, pediatric nurse practitioners, and registered dietitians perceive themselves as having low proficiency in behavioral management strategies and parenting management techniques related to obesity [7]. Feasible and acceptable interventions to promote healthy lifestyle choices are greatly needed, particularly for young children prior to the formation of poor lifestyle choices and associated illness.

Evidence suggests that parents desire personalized information relevant to their child and are enthusiastic about receiving text messages (short message service, SMS) endorsed by their child's primary care provider [8]. mHealth interventions show promise based on evidence using SMS to remind and cue participants to act [8-12]. Interventions using SMS can be successful as reminders about disease management behaviors (ie, medication adherence, blood glucose monitoring) and tailored, interactive, and family-centered interventions can be supplemented with mobile technology to facilitate behavior change [13]. Yet, there are very few studies aimed at promoting behavior change in conjunction with text messaging (SMS) in pediatric populations [13].

Therefore, the purpose of this study was to establish the feasibility, acceptability, and preliminary effects of a 7-session cognitive behavioral intervention combined with tailored and adaptive SMS regarding healthy lifestyle beliefs, perceived difficulty, and behaviors of parents of overweight and obese (OW/OB) preschoolers (aged 3-5 years) delivered in a primary care setting. The first aim was to examine the feasibility and acceptability of the intervention as determined by rates of participant retention, adherence to the study protocol, and response to participant evaluation. The second aim was to evaluate preliminary effects of the intervention on parental self-reported nutrition/physical activity knowledge, healthy lifestyle beliefs, perceived difficulty, and healthy lifestyle behaviors determined by pretest-posttest scores and effect sizes.

Theoretical Framework

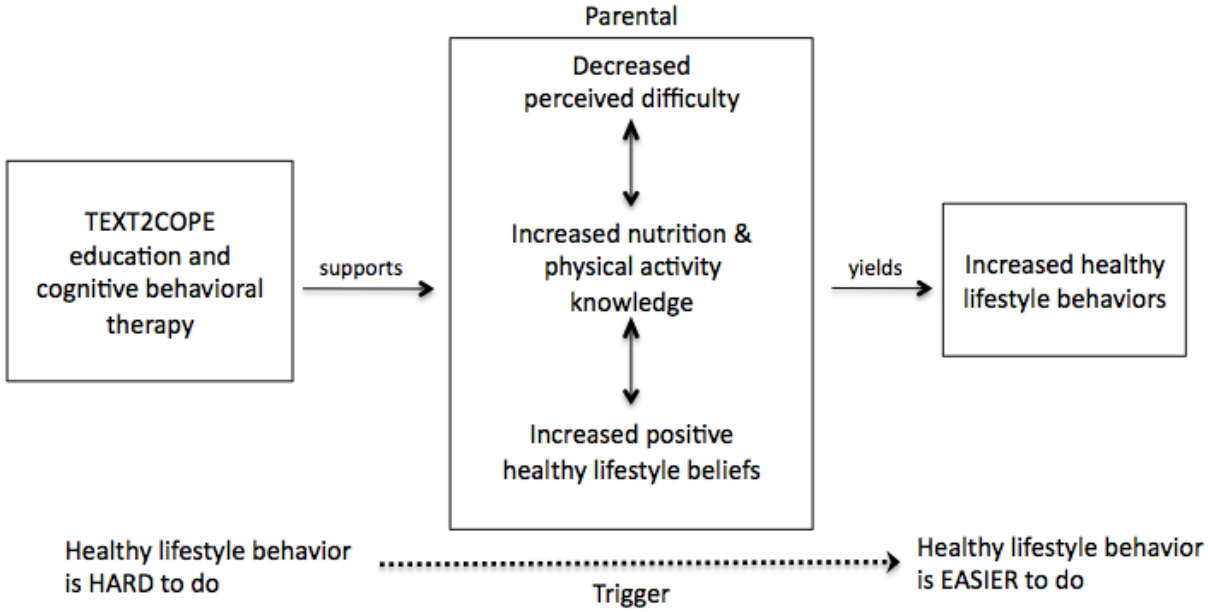
Previous evidence [14,15] suggests that individuals who cognitively appraise healthy lifestyle choices as more difficult are less likely to have intentions to make these choices and engage in healthy lifestyle behaviors. The effects of negative cognitions about oneself are profound when there are skill deficits (eg, poor problem-solving skills, cognitive distortions, and failure to attribute positive outcomes to one's behavior) [15]. Cognitive behavioral therapy (CBT) emphasizes short-term, problem-focused cognitive and behavioral intervention strategies derived from the science and theory of learning and cognition [16]. Using these guiding principles, the TEXT2COPE intervention was adapted from the COPE/Healthy Lifestyles Thinking, Emotion, Exercise, and Nutrition (TEEN) Intervention Program [15,17-19], and a combination of the Be Beary Healthy [20] and the Parents Lead Active Youth (PLAY) programs [21]. The content manual was created following recommendations for developing print-based tailored interventions [22,23]. Through a 7-session manualized intervention, participants were educated about healthy nutrition, physical activity, and building cognitive and behavioral skills to facilitate healthy lifestyle choices. Cognitive Theory (CT) [24-26] provided the foundation for the selection of study variables (parental knowledge, perceived difficulty, beliefs, and behaviors). With an emphasis on how thinking affects behaviors and emotions, the intervention content comprised problem-solving skills, methods to overcome barriers, goal setting, positive self-talk, and restructuring negative thoughts (Table 1).

Table 1.

TEXT2COPE Intervention Program Cognitive Behavioral Skills Content	Session Mode
Healthy lifestyles and the thinking, feeling, behaving triangle; basic recommendations for nutrition & physical activity in preschoolers; goal setting	Session 1 Face-to-face AND text messaging
Information on physical activity and nutrition, including appropriate portion sizes, healthy eating, and food groups	Session 2 Self-study AND text messaging
Barriers to goal progression and overcoming barriers through problem solving and cue recognition	Session 3 Face-to-face AND text messaging
Positive thinking and self-talk related to healthy lifestyle behaviors	Session 4 Self-study AND text messaging
Cognitive reframing—with an emphasis on physical and emotional responses to stress and how positive beliefs can help to reframe cognitions and promote positive coping	Session 5 Face-to-face AND text messaging
Effective communication, stress, and coping	Session 6 Self-study AND text messaging

Aspects of Fogg's Behavior Model (FBM) informed the overarching strategy for the study [27,28]. In FBM, 3 principal elements (motivation, ability, trigger) are emphasized to better understand the process of behavior change. Triggers serve to facilitate, spark, or signal an action through external or routine stimuli [28]. Triggers that spark, motivate behavior; triggers that facilitate, make a behavior easier; triggers that signal, remind [28]. In this study, a *trigger* was restricted to the purpose of identifying a concept that prompts or calls a person to act. This prompt may be tailored to the target user's context [27,28]. Text messaging was selected as a tool to trigger skills to promote positive cognitive reframing and subsequent healthy lifestyle behavior choices due to its simplicity, broad user base, and ability to be individualized to the user. Fogg describes triggers as *hot* and *cold* [27]. Hot triggers are presented when users can take action (eg, walking in the kitchen and getting something from the fridge). Cold triggers are presented when users cannot take action at that moment (eg, getting a text message while driving a car). Utilization of hot triggers is more closely associated with a behavioral response [27]. FBM highlights a shift in behavior moving from *hard to do* to *easy to do* [27,28]. The intent of the SMS was to reinforce positive skill enactment and to disrupt repeated negative actions. The blended CT and FBM conceptual model guiding this study is depicted in Figure 1, and offers one approach to healthy lifestyle behavior change for parents of OW/OB preschoolers.

Figure 1. Conceptual model of the TEXT2COPE program.



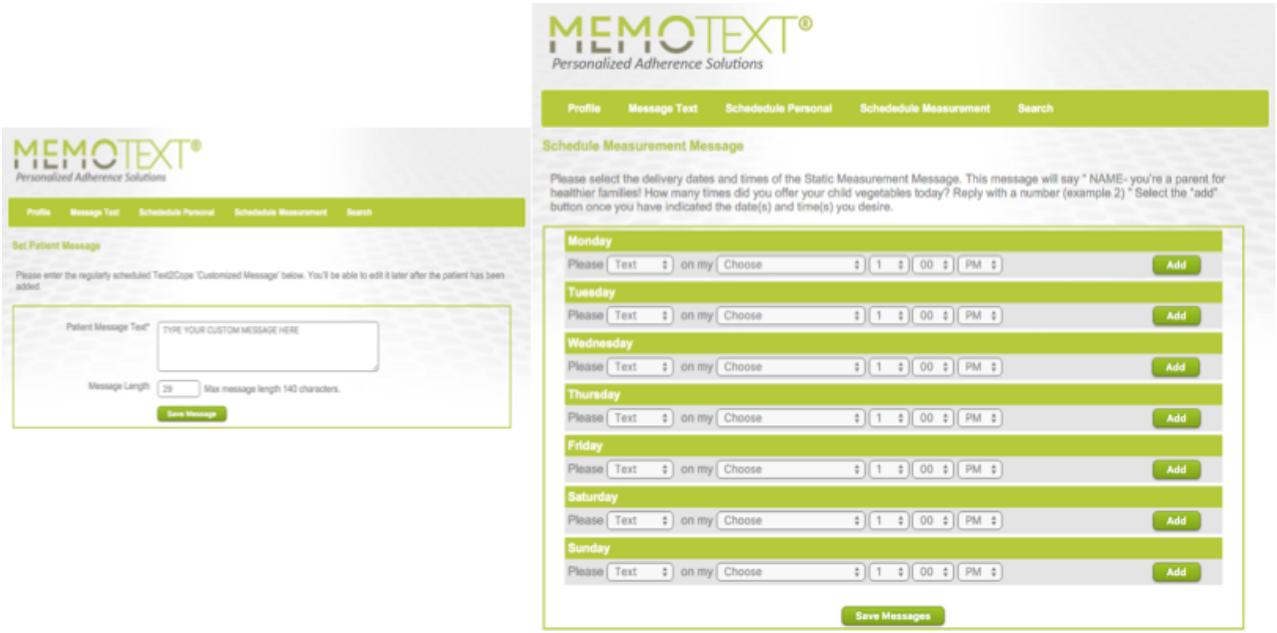
Methods

Design and Sample

This pilot study used a one-group pre and posttest preexperimental design approved by the Arizona State University Institutional Review Board. Participants were recruited from 3 pediatric primary care practices. To be included, the primary caretaker (hereafter referred to as the *parent*) of an OW/OB preschooler aged 3 through 5 years had to (a) have a preschooler with a medical diagnosis of OW/OB, defined as a BMI percentile of 85% or above; (b) possess an active mobile phone with text-messaging capability; (c) be between the ages of 18 and 45 years; and (d) give consent for participation.

The principal investigator (PI) partnered with MEMOTEXT Corporation to develop software specific to this project for delivering/receiving SMS data. Participant confidentiality was secured through MEMOTEXT's privacy policy and data were used in accordance with all applicable laws and the Personal Information Protection and Electronic Documents Act. Per the study protocol, no personal health information was communicated via SMS. Both static and tailored messages were entered into the SMS application used for this project. A sample of the software shown in Figure 2 highlights the simplicity of scheduling both a series of tailored and static of messages.

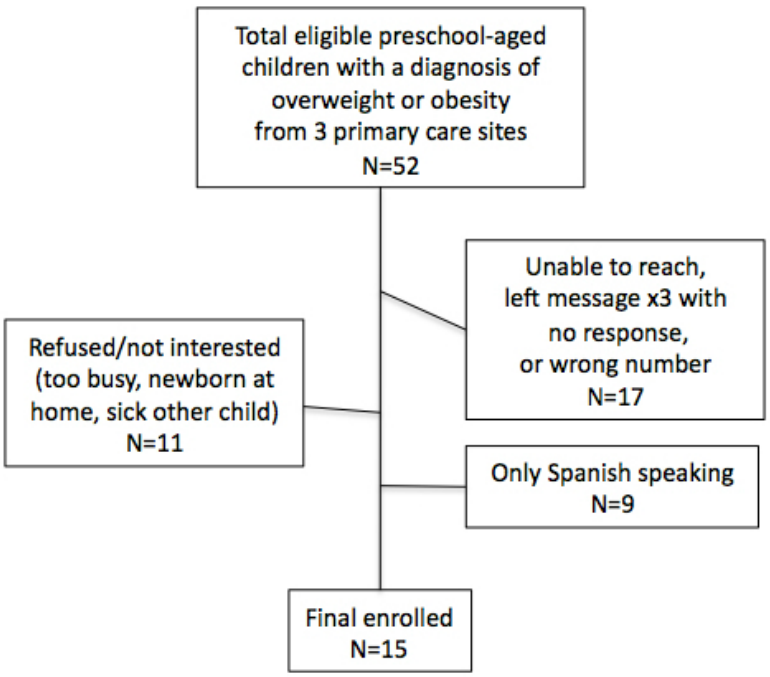
Figure 2. TEXT2COPE-Memotext application



Recruitment and Enrollment

The clinics preferred a combination of burst and serial recruitment efforts. In all of the offices, a support staff member (eg, medical assistant, receptionist) was identified to serve as a recruitment facilitator. The clinic staff member phoned and/or mailed a scripted recruitment letter to all participants identified as having a diagnosis of OW/OB based on provider referral or billing code, and who met eligibility criteria. Recruitment occurred from March to November 2013. Figure 3 depicts participant recruitment. A convenience sample of 15 parent-preschooler dyads (13 parents, 15 preschoolers; 2 families had 2 children who met inclusion criteria) gave consent and were enrolled. This sample size allowed for preliminary analysis. In appreciation of participants' time and associated costs for text messages, upon completion of baseline instruments, a $10 gift card to a local grocery store was given. Similarly, upon completion of the posttest, a gift card in the amount of $20 was presented.

Figure 3. Flow diagram of participant recruitment.



Intervention

The intervention implementation consisted of 4 key strategies: (a) face-to-face visits (covering educational information and cognitive behavioral skills), (b) reminders, (c) triggers, and (d) reinforcements. Table 2 details the content covered in each session relevant to the needs and knowledge base of the families. Two families had two children enrolled in the study. However, skills and goals were family-centered versus child-centered, so this did not pose any challenges. Skills and education training occurred during the face-to-face clinic visits. After baseline data were collected, all parents were given a hard copy and an audio compact disc (CD) of the TEXT2COPE manual. The manual served as a reminder of the cognitive behavioral skills and was used to keep the principal investigator (PI) and parents on task. The text messages were designed to trigger the skill or new behavior. Lastly, homework reinforced skills and was reviewed during clinic visits.

Table 2. TEXT2COPE intervention implementation.

Session	TEXT2COPE Intervention Program Cognitive Behavioral Skills Content	Mode
1	Healthy lifestyles and the thinking, feeling, behaving triangle; basic recommendations for nutrition & physical activity in preschoolers; goal setting	Face-to-face AND text messaging
2	Information on physical activity and nutrition, including appropriate portion sizes, healthy eating, and food groups	Self-study AND text messaging
3	Barriers to goal progression and overcoming barriers through problem solving and cue recognition	Face-to-face AND text messaging
4	Positive thinking and self-talk related to healthy lifestyle behaviors	Self-study AND text messaging
5	Cognitive reframing—with an emphasis on physical and emotional responses to stress and how positive beliefs can help to reframe cognitions and promote positive coping	Face-to-face AND text messaging
6	Effective communication, stress, and coping	Self-study AND text messaging
7	Putting it all together; integration of knowledge and skills	Face-to-face

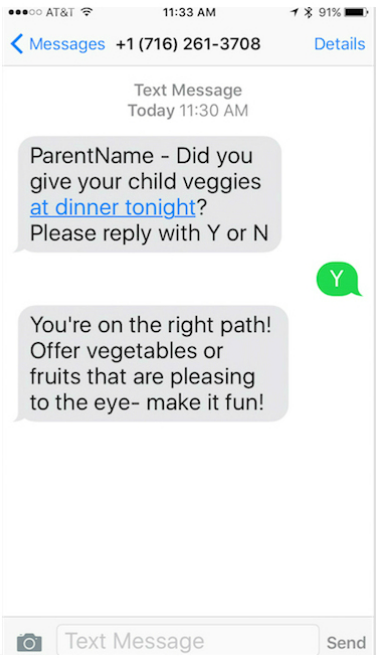
Text Message Support

Participants responded to static test messages sent twice weekly. For simplicity, because of related health benefits, and evidence indicating that most preschoolers do not eat the recommended daily serving of vegetables, the authors collectively decided to use vegetable consumption as the topic of the static text messages. The use of 2-way weekly text messages (sent/received) is consistent with previous literature [29-34]. Upon sending a response to the static text message, parents received immediate automated SMS feedback generated from a library of text messages developed using *if, then* algorithms. The content of the SMS library of responses was derived from the TEXT2COPE manual used during the face-to-face and self-study components of the intervention. For instance, when the text message “[Parent name] did you give your child veggies at dinner tonight, please reply with Y or N” is sent, an “N” response may elicit the automated skill-building response, “Fear of new foods is common in children—try offering the same vegetable many times in different ways.” Conversely, if the parent responded “Y” to offering veggies, the library would generate a message to reinforce positive behaviors, such as “Be proud of yourself, you’re getting your child off to a healthy start!” Figure 4 illustrates a sample static text message, participant response, and automated support.

To enhance SMS support, parents were taught the difference between hot and cold triggers. At the end of each face-to-face visit, each parent developed a custom text message intended to hot trigger a skill at home. By having participants select the skill to work on, the general verbiage of the prompt, and the day(s) and time each week that they would like to receive the prompt, parents were able to reflect on their own family needs and tailor the intervention content accordingly. The goal was to customize the text message to the families and deliver it at just the right time. Parents were encouraged to create a text message that would “speak to them” regarding that week’s skill or goal. If a parent was unable to articulate a text message, the PI reviewed the session content with the participant until the parent was able to verbalize comprehension and subsequent SMS content. Test messages varied depending on the participant and included the following: the parents’ own words, a mixture of PI and parent words (up to 140 characters), examples from the manual tailored by participants, and a combination of a tip with a page reference from the manual for further information. Examples of the text messages crafted by parents included, “Run, laugh, chase the little guy around. Keep moving!!! Repeat it, BELIEVE IT! You’ve got this!!!!” or “Kick your own butt for 2 minutes! Follow your exercise plan and believe in yourself, now go!” “Wake up sleepy head - you'll regret it if you don't. RUN RUN RUN! you're the Role Model. Don't hit snooze!”

Since the individual ultimately chose the SMS content, each text message took on the tone preferred by the participant (ie, funny or authoritative).

Figure 4. Static text message and support.



Manipulation Checks and Fidelity

Homework from the previous session was reviewed at each face-to-face visit. To ensure reception and comprehension, parents were asked to respond to the static text messages. An additional log for each text message sent and received was maintained throughout the study. Two of the authors reviewed all text messages.

A subset of the SMS data reflected a quality control population. Outside of the iterative testing phase of the MEMOTEXT-TEXT2COPE software, the PI included a confederate participant to receive text messages at the same time the MEMOTEXT system was *live*. This was done to explore the system's delivery and response to potential aberrant text messages from participants. For instance, when one of the tailored text messages was sent, the respondent replied, "Who is this?" This text message was then flagged by the MEMOTEXT staff and then emailed to the PI within 24 hours of being sent. Similarly, for the static text messages, when participant responses occurred outside of *Y* and *N*, the MEMOTEXT staff responded by forwarding an email with the response to the study PI within 24 hours. MEMOTEXT was able to confirm sending text messages. However, unless text message delivery was verified from an aberrant response, delivery was confirmed by self-report at face-to-face visits. This quality control provided information about the logistics built in by the software company to handle such situations and subsequent communication. These features were critical to explore when considering the evidence needed to implement such technology into clinical practice.

Measures

Measures used in this pilot study assessed parental demographics and child anthropometric measures, parental nutrition and physical activity knowledge as it related to their child [35,36], parental healthy lifestyle beliefs [36,37] and behaviors [36,38] with respect to their child, perceived difficulty towards making healthy lifestyle choices for their child [38], and a parent evaluation form. Table 3 provides a summary of data collection.

Table 3. Summary of data collection.

Construct	Instrument	Validity	Reliability[a]	Data Collection
Demographics	Demographic Questionnaire		NA	T1[b]
Parent Evaluation	Exit Interview		NA	T2[c]
Healthy Lifestyles Beliefs Scale	Healthy Lifestyles Beliefs Scale	Content, Construct	.86	T1, T2
Perceived Difficulty	Perceived Difficulty Scale	Content, Construct	.92	T1, T2
Knowledge	Nutrition Knowledge	Content, Construct	.74	T1, T2
Knowledge	Physical Activity Knowledge	Content, Construct	.52	T1, T2
Healthy Lifestyle Behaviors - Parent	Healthy Lifestyle Behaviors Scale	Content, Construct	.78	T1, T2

[a] Cronbach's alpha

[b] T1: Time 1

[c] T2: Time 2

Statistical Analysis

All analyses were conducted using SPSS 21. For normally distributed data (nutrition knowledge, perceived difficulty, healthy lifestyle behaviors), paired sample *t* tests were used to evaluate change over time. Effect size measured with Cohen's *d* for paired samples determined the effect of the intervention. Given the small sample size, two of the outcome variables (activity knowledge, healthy lifestyle beliefs) were nonnormally distributed per the Shapiro-Wilk and Kolmogorov-Smirnov tests. Neither a reflected $\log_{10}$ nor a reflected square root transformation corrected the distribution. Therefore, the Wilcoxon signed-rank test for nonparametric data was used to evaluate change over time. The effect size of the Wilcoxon signed-rank test is reported using r code.

Results

Demographics

Mothers were predominant study participants and caregivers, consistent with other family-based interventions [14,20,34,39]. Anthropometric data were not obtained for one preschooler who did not attend any face-to-face visits. The mean age of preschool participants was 54.47 months, with a mean BMI of 19.48. Half of the preschoolers met criteria for a diagnosis of overweight (7/14, 50%), and half of the sample met diagnostic criteria for obesity (n=7/14, 50%). Of the 7 children diagnosed with obesity, 6 had BMI percentiles greater than the 99th percentile. Table 4 highlights the demographic data.

Table 4. Descriptive characteristics of TEXT2COPE parents and preschoolers.

Participant	Characteristic		n (%)
Parent (n=13)	**Age (years)**	18-24	3 (24)
		25-34	5 (38)
		35-44	5 (38)
	Gender	Female	13 (100)
		Male	0 (0)
	Race/Ethnicity	Caucasian	4 (31)
		African American	1 (8)
		Hispanic/Latino	8 (61)
	Education	Less than high school	1 (8)
		General equivalency diploma/high school	5 (38)
		Some college	3 (23)
		4-year college	3 (23)
		Master's degree	1 (8)
	Annual Income	Less than $10,000	5 (38)
		$10,000-$19,000	4 (31)
		$20,000-$29,000	1 (8)
		$40,000-$49,000	1 (8)
		$70,000 or more	2 (15)
	Public Assistance	Yes	11 (85)
		No	2 (15)
Child (n=15)	**Age**	3 years	2 (13)
		4 years	5 (33)
		5 years	8 (54)
	Gender	Female	5 (33)
		Male	10 (67)

Feasibility, Acceptability, and Preliminary Effects

Parents reported the program to be helpful 100% of the time and 100% of parents indicated that they would recommend TEXT2COPE to other parents of preschoolers. Qualitative feedback included, "The program doesn't just tell you to be healthy, it shows you how," and participants noted that it included messages to "Keep trying, don't give up," and "Keep pushing towards my goals." Thematic saturation occurred for goal setting (10/13, 77%) as the most-liked content of the program. No saturation occurred for topics least liked.

Paired *t* tests indicated that parents in the TEXT2COPE program significantly improved scores for nutrition knowledge (95% CI

for mean difference -4.33 to -1.54, *P*=.001) and healthy lifestyle behaviors (95% CI for mean difference -9.34 to -0.24, *P*=.04), but not perceived difficulty (95% CI for mean difference -9.56 to 1.87, *P*=.168). Using Wilcoxon signed-rank test for nonparametric data, parental beliefs about their ability to engage in a healthy lifestyle significantly increased from pre to posttest (95% CI for mean difference -16.78 to 1.31, *P*=.001). A Wilcoxon signed-rank test showed significant effects for activity knowledge (*Z*=-2.507, *P*=.012, *R*=0.46) and healthy lifestyle beliefs (*Z*=-3.317, *P*=.001, *R*=.61). Collectively, there were significant gains for 4 out of 5 outcome measures (nutrition knowledge, activity knowledge, healthy lifestyle beliefs, healthy lifestyle behaviors). Effect sizes were medium to large for all study variables.

Table 5. Self-reported cognitive and behavioral outcomes for the TEXT2COPE group.

Instrument	Pretest Mean (SD)	Posttest Mean (SD)	Effect Size	*P* Value
Nutrition Knowledge	14.60 (3.46)	17.53 (1.73)	1.07[a]	.001
Activity Knowledge	9.93 (1.58)	11.00 (1.07)	.45[b]	.012
Parental Healthy Beliefs	79.53 (8.10)	83.00 (7.63)	.61[b]	.001
Parental Healthy Behaviors	46.20 (8.37)	51.00 (7.83)	.59[a]	.040
Perceived Difficulty [c]	38.46 (11.33) [a]	42.31 (10.94) [a]	.50[a]	.168

[a] Effect size for Cohen's *d* (parametric): .2 small, .5 medium, .8 large

[b] Effect size for R code (nonparametric): .1 small, .3 medium, .5 large

[c] Higher scores on the Perceived Difficulty scale indicate less perceived difficulty (easier to do)

Retention and Attrition

Parent participants were defined as completing the program if all of the content in the 7 TEXT2COPE sessions were covered and parents completed pretest and posttest measures. Findings reflect a 100% retention rate. Although missed or canceled appointments did occur, participants were able to continue the program through provider understanding, rescheduling of appointments, and counseling on the benefits of healthy lifestyle habit establishment relevant to the family's needs. It is believed that customization of the content relative to the family, routine follow-up in person, and supplemental text messages facilitated patient engagement.

Program Adherence

The 4 face-to-face visits, which lasted approximately 20-30 minutes to mimic the length of a standard office visit in primary care, were conducted during an outpatient visit at the child's primary care office. As in other studies [21,39], parents in the TEXT2COPE program attended visits with or without their child; however, they were strongly encouraged to practice and model the skills at home with their child. All participants had to reschedule at least one clinic visit. Reasons for rescheduling included: (a) work schedule, (b) sick child, (c) forgot about the appointment/lost track of time, or (d) lack of transportation. Participants completed the face-to-face visits over the course of 3 to 7 weeks, with 5 being the median number of weeks needed to go through the course content. The PI hosted a *make-up* session lasting 40-60 minutes to cover additional materials.

Tailored and Adapted Text Messages

A total of 291 text messages were sent to parents: 138 tailored text messages, 105 static text messages, and 53 automated feedback text messages. The number of text messages sent to each participant varied from 7 to 39, with a mean of 22.31 (SD 9.47). Tailored text messages per participant ranged from 3 to 20 (mean 10.62, SD 5.45). The number of static text messages sent to each participant ranged from 4 to 12 (mean 8.00, SD 2.42). Overall, 69% of parents (9/13) changed the frequency of tailored text messages, increasing delivery from once weekly to as many as 5 times a week. Timing (when the message was delivered) was evaluated by dividing the day into 3 segments: morning (6:01 am-12:00 pm), afternoon (12:01 pm-6:00 pm), and evening (6:01 pm and later). Parents favored receiving tailored text messages in the afternoon (58.8% of the time), coinciding with parents' perceived need for support (and when the message would most likely serve as a hot trigger). Peak timing occurred during the hours when children were home from school, the workday ended, and dinner/afterschool activities coincided. All parents reported SMS frequency to be "just right," while 85% felt the timing of delivery was "perfect" (n=11/13).

None of the tailored text messages were used strictly as a reminder. All of the tailored text messages incorporated an aspect of the cognitive behavior skills associated with that week's session. For example, parents were encouraged to make a plan and set SMART (specific, measurable, attainable, realistic, and timely) goals. After learning about that skill, a participant used the SMS to trigger physical activity with the message, "[Parent name]- Make a plan; schedule a SMART goal for family fun exercise; Remember- set yourself UP for SUCCESS! Believe you can do anything!" This message was delivered twice in one week, during the afternoon hours when the parent could make a plan and act on it. As parents advanced through the program, it appeared that they became more aware of how SMS content, timing, and frequency could cue them to act (or highlight an inability to act). It also became apparent that participants liked having a reminder of content covered in the face-to-face visit and corresponding section of the manual/audio CD to help them work on skills. For instance, one participant reported having the television on when her son was home in the afternoon, but wanted to work on increasing

physical activity. She developed a combination text message with a reminder of where in the manual she could find help (Chapters 5 and 6), but also a tip on how she could build in a skill to meet her goal. At 4:30 pm, on a specified day, her text message was sent stating, "You're near the finish line. This wk 5&6! Decrease TV time or family exercise challenge on commercials! Who will win?"

Static Text Messages

Parents reported not responding to the static text messages because they "thought it was a reminder" or "didn't know to respond back." The initial response rate was only 26% (15/58) for the static text messages. Subsequently, verbiage of the static text messages was made shorter and simpler, while topic and response algorithms remained unchanged. The response rate improved to 80% (38/47) with this change, ranging from 0%-100% response per participant (mean 49%, SD 36.2%). Overall, 87% of parents reported offering their child vegetables at dinner. Messages were confirmed delivered. The sociodemographic variability of the small sample was a factor in two-way SMS. At least two families had very limited SMS data plans. As a result, they could continue to receive text messages, but could not send them. Therefore, one participant did not respond to any of the static text messages (yes/no questions). Another parent circumvented her data plan by using a free software application to send outgoing text messages. While the service was free, it altered every outgoing message with a tag line advertising their service (eg, "Y -Sent free from TextNow.com"). This tag line was not part of the TEXT2COPE if/then algorithm, and subsequently fell into an aberrant response category. As a result, that participant did not receive immediate automated feedback to her response.

Discussion

Principal Findings

The results of this study indicate that a cognitive behavioral skills program, synergized with mobile messaging, is feasible and acceptable in a primary care setting with parents of OW/OB preschool-aged children. The preliminary short-term effects of this research show great potential for promoting healthy lifestyle choices in this population. There are a number of key points to be learned from this research. Using recommendations from Bowen [40], feasibility for this study was framed in several focus areas: (a) acceptability, (b) demand, (c) implementation, (d) practicality, (e) adaptation, and (f) integration.

Acceptability

Parents reported high satisfaction with the TEXT2COPE program and expressed intent to continue using the skills learned in the program. The skills covered in the intervention align with previous research and perhaps shed light on retention and acceptance rates as well as preliminary effects. Better parental compliance with behavior strategies (eg, targeting specific behaviors, self-monitoring, goal setting, stimulus control/environmental cues, positive parenting strategies) is predictive of better outcomes for the child [7]. One parent commented that she copied (ie, cut and paste) the content from her TEXT2COPE text messages and programmed them into her electronic calendar so that her messages would continue to trigger the skills she wanted to practice. While the face-to-face visits allowed for detailed discussion on how to problem solve and set realistic goals, text messaging allowed for brief, real-time snippets of support. Parents desired a *strong message* that was *short* and *easy to read*. These findings parallel aspects of Fogg's work suggesting that simplicity changes behavior [28], and effective behavior change is possible through smaller, habit-changing steps [41].

The use of static text messages warrants further exploration. The static text messages performed a multitude of functions. First, they served as a data collection tool with a varied response rate. The automated response built from the if/then algorithm served as reinforcement. Some parents viewed the text messages as reminders and did not respond. It is difficult to assess if response rate was a function of (a) the change in verbiage, (b) the way it was presented, or (c) characteristics of the participants responding. Predetermined delivery timing and vernacular could have contributed to the variability in response.

Demand

Demand for innovative programs in the primary care setting reflects two domains: demand from the organization and demand from the patients. Office managers, providers, and staff welcomed the TEXT2COPE program as an innovative resource to treat OW/OB. However, partnering with primary care clinics was difficult. Administrative affiliations warranted lengthy negotiations between the PI and the organizations and required academic institutional review board approval, legal review, and/or third party reviewers. Parents stated that they welcomed the SMS communication from their providers. However, outside of the TEXT2COPE program, we were unaware of any direct communication between clinic and patients, outside of traditional phone calls or appointments. One clinic had an established Facebook page, yet, the clinic was unaware of how many families subscribed to their page or received updates. Parents also voiced an interest in learning more about how to help their child, but often lacked the resources. Parents reported feeling more proactive in their family's health while using clinic time to address skills that could promote behavior change. Supplementing these new skills with text messaging provided additional support for parents in their home environment.

Implementation

The intervention was manualized to facilitate reproducibility. A health care provider or lifestyle coach could deliver the content. With regards to SMS, sending weekly text messages took less than 5 minutes per participant, per text message. Automating text message delivery using machine learning techniques or learned user preferences is possible with advances in mHealth. From a logistical perspective, the use of text messages may require additional software, which would be either independent or programmed into existing electronic health record (EHR) software.

Practicality

Practicality was explored when resources, existing means, and time were constrained in some way. Given the nonacute nature of healthy lifestyle behaviors, parents often requested to

reschedule appointments. Parents often reported that some habits were more difficult to change than others. Mothers commonly reported that positive self-talk and "believing is achieving" was not something they commonly practiced; however, after reviewing this content more, mothers appreciated how this could affect the way serve as a role model to their children. Equally as impressive was that mothers welcomed content about topics such as overcoming barriers, problem solving, and goal setting. Positive reactions indicated parents favored an emphasis on "*how to* be healthy" versus being told, "you need to be healthier." Parents were able to carry out those activities that were relevant to their needs. Congruent with the theoretical framework and previous research [8], this appeared crucial to participant interest.

Adaptation

The user determined the number of weeks needed for content delivery, timing, and frequency of text message delivery. Most reflected parents' routines around primary care use and their daily demands. However, adapting the schedule, content, and utilization of parent-driven text messages enhanced relevance to the user. Taveras and colleagues [42] reported that African American, Hispanic/Latino, and Asian parents rated the quality of nutrition and physical guidance received from health care professionals as poor to fair. Yet, cultural sensitivity is important to factor into the design of programs targeting healthy beliefs and behaviors. Therefore, content was designed and reinforced to incorporate the parent's own words and build on parental understanding and use of the skills. The content manual provided a basis for knowledge about healthy lifestyle behaviors, while prior knowledge was incorporated into the face-to-face sessions as a starting point for discussion. For the pilot study, the manual was offered in print and audio format; future studies could offer a Web-based version of the manualized content for added flexibility.

Integration

In terms of perceived fit, perceived sustainability, and costs to organizations and policies [40], the program was robust. The PI for this study also served as the interventionist, but was not a health care provider at the clinic sites. However, providers, support staff, and lifestyle coaches have the potential to implement this intervention. Providers could work within practice limitations, delivering the intervention in a typical 30-minute outpatient visit, and still provide evidence-based care, analogous to findings from Lusk and Melnyk [43,44]. Tailored SMS software can be integrated into existing EHR platforms and sustained over time. With the implementation of the Affordable Care Act, organizations have the opportunity to share in Medicare savings created through demonstrated quality performance [45]. Integrating the TEXT2COPE program can facilitate: (1) getting timely care and information, (2) how well your providers communicate, (3) patient ratings of providers, (4) health promotion and education, (5) shared decision making, and (6) health status.

Strengths and Limitations

Strengths

This research sheds light on programs aimed at families with OW/OB preschoolers in a primary care setting, which have been sparse in the literature to date. Using a dynamic (versus static) design, the research supported participants as they progressed toward their goals. Parents want specific, action-oriented advice to achieve goals rather than general information on healthy behaviors [8]. While the sample was small, it was ethnically varied. The program was also designed to build skills relevant to the user's goals, one skill and one goal at a time. The combination of text messages and clinic visits allowed for enhanced support through both small bursts of contact and traditional face-to-face time. The face-to-face visits were helpful when more detailed discussion was warranted about, for example, how to do something such as incorporate exercise into their daily routine. The text messages provided nontraditional support during times when the health care provider could not be there. By incorporating SMS, another channel of communication was opened with their child's health care provider, a figure whom parents perceived as having a voice of authority [8].

Limitations

Although novel in approach, the findings must be tempered due to some limitations. First, the lack of an attention control group threatened the internal validity. Secondly, although fathers were encouraged to attend, the small sample size of only mothers (roughly 47% reported being single) limits the generalizability of the study findings. Perhaps a larger sample size and varying recruitment methods targeting dad's groups could help to strengthen participation. Thirdly, measures were self-reported, wherein bias or human error can be introduced. Parent anthropometric measures would have been useful to obtain, as evidence suggests that one of the strongest predictors of childhood obesity is parental obesity [46]. Child anthropometric measures were collected at baseline; however, it may have been difficult to assess anthropometric changes over such a short period and those identified may not have accurately reflected the skills taught and changes observed in behavior. A longitudinal design incorporating parent and child anthropometric changes over time would be beneficial in future research.

Conclusion

Mobile technologies, in conjunction with clinical care, have the potential to expand care and reduce costs. This new delivery method is poised to reinvent health care delivery, as it is superior to other technologies due to high demographic penetration, an omnipresent nature, fluidity of use, and a broad range of capabilities [47,48]. Feedback messages may play a pivotal role in goal attainment, through behavioral principles such as reinforcement and correction, and serve as a compass enabling individuals to stay on course [49]. However, there is strong potential for discord between patient/family desire for mHealth services and actual use in pediatric populations due to the scarcity of pediatric mHealth programs and evidence to successfully support clinical practice.

Future research should involve a full-scale randomized controlled trial to determine the short- and long-term efficacy of this intervention with families who have OW/OB preschool children. Technology also lends itself to alternate research methods such as adaptive interventions. Highly adaptive sequential multiple assignment randomized trials (SMART) have been used to inform the best sequencing of treatments when individuals are not responding, and the best time to transition from more to less intensive or maintenance therapy [50-53]. Adaptive interventions may be ideal for families attempting to change behavior amid already hectic schedules. *Crunch time* (3:00 pm to bedtime during the work week) was found to be a major contributor to unhealthy habits for millions of American children [54]. While 95% of parents polled believed that it is important for their kids to eat healthy and exercise, more than half of the parents (60%) said their children ate or drank something unhealthy during *crunch time*, did not get enough physical activity, and reported eating out 6 or 7 nights in the past week (48%) [54]. Similarly, in the TEXT2COPE study, most tailored text messages were requested to trigger a response in the late afternoon hours. Perhaps SMS delivery reinforced acceptability of the program by providing participants with support during times when support was needed the most. Previous research demonstrates that interventions may be more effective if the process of behavior change is emphasized, rather than the health-related outcomes [55]. In this study, during the face-to-face sessions and in subsequent messaging, some parents focused on the actual habit (ie, exercise), while some focused on the actual skill (ie, problem-solving, goal-setting). It would be interesting to further test the specific effects of cognitive versus behavioral training on healthy lifestyle related outcomes. With continued efforts, proof of concept and proof of efficacy studies will provide insight into mHealth strategies used in the field of pediatrics.

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Conflicts of Interest

Bernadette Melnyk is the founder of COPE 2 Thrive, an LLC that distributes the COPE intervention.

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Abbreviations

CBT: cognitive behavioral therapy
CT: Cognitive Theory
FBM: Fogg's Behavior Model
OW/OB: overweight/obese
SMS: short message service

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Original Paper

Smartloss: A Personalized Mobile Health Intervention for Weight Management and Health Promotion

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Abstract

Background: Synonymous with increased use of mobile phones has been the development of mobile health (mHealth) technology for improving health, including weight management. Behavior change theory (eg, the theory of planned behavior) can be effectively encapsulated into mobile phone-based health improvement programs, which is fostered by the ability of mobile phones and related devices to collect and transmit objective data in near real time and for health care or research professionals and clients to communicate easily.

Objective: To describe SmartLoss, a semiautomated mHealth platform for weight loss.

Methods: We developed and validated a dynamic energy balance model that determines the amount of weight an individual will lose over time if they are adherent to an energy intake prescription. This model was incorporated into computer code that enables adherence to a prescribed caloric prescription determined from the change in body weight of the individual. Data from the individual are then used to guide personalized recommendations regarding weight loss and behavior change via a semiautomated mHealth platform called SmartLoss, which consists of 2 elements: (1) a clinician dashboard and (2) a mobile phone app. SmartLoss includes and interfaces with a network-connected bathroom scale and a Bluetooth-connected accelerometer, which enables automated collection of client information (eg, body weight change and physical activity patterns), as well as the systematic delivery of preplanned health materials and automated feedback that is based on client data and is designed to foster prolonged adherence with body weight, diet, and exercise goals. The clinician dashboard allows for efficient remote monitoring of all clients simultaneously, which may further increase adherence, personalization of treatment, treatment fidelity, and efficacy.

Results: Evidence of the efficacy of the SmartLoss approach has been reported previously. The present report provides a thorough description of the SmartLoss Virtual Weight Management Suite, a professionally programmed platform that facilitates treatment fidelity and the ability to customize interventions and disseminate them widely.

Conclusions: SmartLoss functions as a virtual weight management clinic that relies upon empirical weight loss research and behavioral theory to promote behavior change and weight loss.

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KEYWORDS

weight loss; app; eHealth; mHealth; SmartLoss; telehealth; mobile website; mobile phone

Introduction

In the United States, over two-thirds of the adult population is classified as overweight or obese [1] and over 140 million US adults are eligible for weight loss treatment [2] based on the treatment guidelines published in 2013 [3]. Gold standard weight management programs are intensive, employ at least 14 in-person contacts in a 6-month period, and include: (1) a

specific dietary goal or prescription, (2) self-monitoring of health indicators such as weight change, (3) individualized counseling that facilitates programmatic success in both the short-term (weight loss) and long-term (weight-loss maintenance), and (4) individualized feedback based on body weight change and dietary intake [3].

Intensive programs for weight management when delivered in-person have several limitations, including financial and geographical barriers, and can be cost prohibitive for many people. A less obvious but no less important barrier is that in-person interventions typically do not provide timely treatment advice to clients, which affects weight control. For example, a cornerstone of effective weight management is self-monitoring behaviors that track diet, physical activity, and weight. Behavior change and learning theory indicate that feedback by counselors that is both temporally contiguous and closely aligned with the client data being monitored produces superior behavior change and improved weight control [4]. Above all, in-person intensive programs for weight management deemed successful in large clinical trials have limited scalability. Dissemination of intensive in-person interventions to large numbers of individuals is costly and would significantly strain the health care system. Innovative and cost-effective treatment approaches for weight management that are grounded in behavior change theories need to be developed and tested.

With the insurgence of electronic and Internet-enabled devices available to consumers, the development of "online" or Internet-based programs for health improvement are more readily available. For weight management, mobile health (mHealth) interventions are particularly advantageous because, if designed appropriately, mHealth weight management programs overcome barriers for participation in traditional clinic-based treatments and thereby can reach many more consumers needing treatment. Indeed, Internet-based weight management interventions that are intensive (ie, include counselor support and individualized recommendations) produce clinically significant weight losses [5-8] that are comparable to intensive in-person interventions [9]. More scalable and automated programs, however, have produced much less weight loss.

Weight management programs delivered via remote devices (ie, mobile phones and tablets) are new to the mHealth technology domain. Mobile phones provide a platform for the collection of objective data from onboard or peripheral sensors and delivery of automated feedback, as well as counselor-driven feedback. The ability to rely on embedded communication platforms (eg, texting, phone calls) fosters synchronous rather than asynchronous feedback and communication. Mobile phones and tablets are nearly ubiquitous and allow people to be mobile yet stay connected to the Internet [10]. The number of devices doubles every 5 years [11]; in 2015, there were 3.5 devices for every person on the planet [12] and, by 2020, it is estimated that there will be approximately 50 billion devices worldwide [11]. Importantly, mobile phone-based programs present a promising approach to effectively reach individuals with limited access to health care. For example, underrepresented minorities are the most frequent users of mobile Internet [10] and households with low incomes are more likely to rely solely on mobile devices for Internet access rather than a computer [13].

In summary, given the increasing prevalence of overweight and obesity and the need for large numbers of individuals to be enrolled in effective treatment programs, cost-effective alternatives to intensive in-person programs need to be developed and tested. The aim of our work is to develop a virtual weight management program that can be deployed via mobile phones that: (1) provides individualized treatment goals; (2) allows for the collection of objective data from the client, as well as the input of self-reported data; (3) provides personalized feedback and treatment recommendations in near-real time; (4) delivers health information in a systematic fashion to foster healthy behavior changes; and (5) allows for remote monitoring of individuals by health care providers.

Methods

The SmartLoss Virtual Weight Management Suite

The SmartLoss Virtual Weight Management Suite includes 2 system components: a mobile application for mobile phones or tablets (the SmartLoss app) and a clinician dashboard. The SmartLoss app allows the end user to quickly receive information about their adherence to a prescribed diet and/or exercise goal, receive health information, enter data if needed, and foster synchronous communication with a health care professional.

The SmartLoss clinician dashboard is Internet-based and securely accessible by 3 levels of users: (1) administrators, (2) health care or research professionals, and (3) clients. Individual login IDs and passwords are required to access the SmartLoss clinician dashboard. Administrators have rights to: (1) create weight management programs for a clinic or group of clients; (2) assign a weight management program to a health care or research professional; (3) assign clients to a health care or research professional; (4) enter health materials for delivery during the weight management program; (5) enter delivery schedules for health information and the frequency of automated feedback; (6) view client data; and (7) generate reports that summarize client data at the level of the whole clinic/program, health care or research professional, or the individual client. Health care or research professionals have rights to: (1) view and enter weight and exercise (step) data for clients assigned to them, (2) generate client reports across all clients and also for a given individual, and (3) enter health materials and personalized feedback for delivery to clients. Clients have rights to view and enter only their own weight and step data, and to view health information specific to the weight management program or clinic. The SmartLoss clinician dashboard promotes treatment fidelity by providing real time access to intervention data.

The Theoretical Framework of SmartLoss

Despite the ubiquity of mobile phones and peripheral devices to record health data, there is limited evidence that these devices and the information that they provide results in behavior change [14]. There are hundreds of weight management apps and, despite excitement over their promise [15,16], only a minority

(15%) of apps incorporate evidence-based weight control methods [17]. Also, there is limited evidence for the efficacy of mHealth weight loss interventions [18-20] and the Guidelines for the Management of Overweight and Obesity in Adults [3] conclude that there is a low quality rating in the strength of evidence for mHealth interventions. Nonetheless, efficacy has been found for mHealth interventions such as SmartLoss and others that incorporate behavior change theory, self-monitoring, tracking of objective body weight data, and skills training [21-23].

SmartLoss is an ecological momentary intervention (EMI) or a program that delivers treatment to clients in their natural environment. EMIs rely on communication technology to deliver treatment, which clients find acceptable and effective at tracking progress toward objective goals [24]. SmartLoss utilizes remote devices to collect body weight and exercise information objectively and in near real time to facilitate timely behavior change. Specifically, learning theory [4] postulates that temporally contiguous feedback based on objective individual level data results in superior behavior change and fosters engagement of a client in treatment. Additionally, SmartLoss relies on the theory of planned behavior and the theory of reasoned actions [25] by fostering an environment conducive to behavior change where clients' behavioral goals are clearly defined, self-efficacy is promoted, and behavior can be regulated through the presence of objective behavioral data. Clinic-based weight management interventions also rely on these theoretical frameworks, in addition to social cognitive theory [26]. SmartLoss incorporates aspects of social cognitive theory by reinforcing behavior change and fostering personal agency, clear outcome expectations, and goal setting, yet opportunities for modeling behaviors and vicarious learning are limited.

Development of weight loss and exercise goals is a collaborative process between the health care or research professional and the client, which facilitates client ownership of the behavioral goals. Further, the health care or research professional helps the client to develop positive attitudes and the intention to change behavior by providing specific behavioral changes that, if achieved, will result in a desired and expected outcome. Perceived behavioral control and self-efficacy are built as the client exerts self-control, makes behavioral changes, and experiences the positive consequences of behavior change (eg, weight loss, higher energy levels, compliments from others about weight loss, etc). Additionally, praise from the health care or research professional and automated feedback indicating that the client is on track to achieve established goals fosters behavior change, though intrinsic motivation increases over time as goals are internalized and self-efficacy and perceived behavioral control of the client is bolstered. It is recognized that motivation and perceived behavioral control naturally fluctuate during the course of treatment and health care or research professionals are able to utilize motivational interviewing [27] techniques, though such techniques are deployed remotely. As detailed below, the delivery of personalized treatment recommendations are based on objective data and are guided by an algorithmic approach that relies on a toolbox strategy, similar to those used in highly effective clinical trials of weight management [28-30].

The SmartLoss Lifestyle Intervention

Tracking Body Weight as a Measure of Dietary Adherence

The SmartLoss lifestyle intervention approach is grounded in the ability to (1) determine the weight maintenance energy requirement for an individual, (2) establish realistic weight loss and dietary intake goals, (3) objectively quantify the adherence of an individual user to this weight loss and dietary prescription goal, and (4) from the individual data being inputted (ie, body weight) provide immediate and personalized feedback and treatment recommendations. Using data from adults in the National Health and Nutrition Examination Survey and adults who have completed highly controlled clinical trials that led to weight loss [31,32] or weight gain [33,34], we developed and validated dynamic differential equations based on the energy balance model [35-37]. We have demonstrated that these equations allow energy requirements of individuals to be accurately predicted from basic demographic and anthropometric data and, most importantly, the equations generate a prediction for the change in weight over the course of weight loss interventions that include an energy restricted diet and moderate levels of exercise. The model-predicted weight changes are then displayed graphically, which provides a guide for weight change throughout a given program. We further extended these mathematical models to provide accurate estimates of energy intake during weight change by inputting body weights over time [38]. Finally, we developed and validated a model that predicts weight change secondary to high levels of exercise only, and we developed and validated separate models that predict weight change during programs that include both an energy restricted diet and high levels of exercise [39]. The models form the cornerstone of the SmartLoss virtual weight management suite since, based on observed body weights, they provide the ability to quantify adherence to energy balance prescriptions induced by changing dietary intake and/or exercise behaviors.

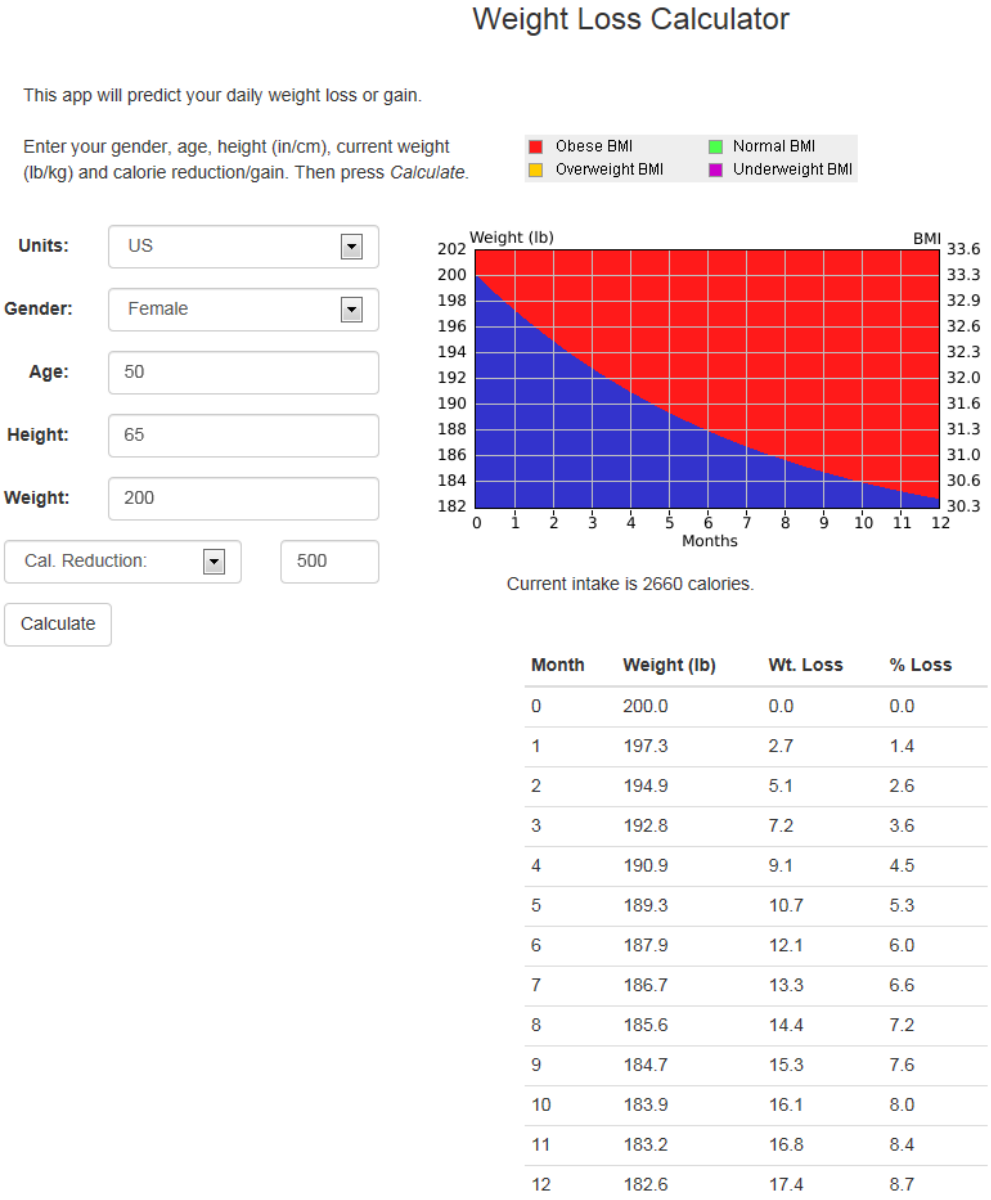
The functionality of the mathematical models is demonstrated on the Weight Loss Calculator website (Figure 1) [40]. As shown in Figure 1, to use the models the user is required to enter sex, age, weight, and height. The user then can elect to either reduce or increase their calorie intake to view the effect of the energy balance prescription on their body weight. The example in Figure 1 is for a 50-year-old female who is 65 inches tall, weighs 200 pounds, and wishes to reduce her intake by 500 kcal/day. This example is for a client wishing to diet and not dramatically increase levels of exercise, yet exercise-only interventions and interventions that include both energy restriction and high levels of exercise can be accommodated, as detailed in the following section. In such cases, the weight graphs provide a proxy measure of adherence to the energy balance prescription, which promotes an energy imbalance of a specified size through changes to diet and exercise behaviors. As demonstrated in the output, this patient's weight will decrease by 17.4 pounds or 8.7% over 12 months if adherent to her new energy intake level. This website is free to use, and the SmartLoss intervention relies on these mathematical models to generate a SmartGraph, which shows the predicted course of

weight change for the individual as well as the acceptable upper and lower limits of the projected weight change for the chosen energy intake target. As demonstrated in Figure 2, the upper and lower bounds of the weight loss projection present a proxy for adherence to the energy balance prescription, which, in our example, is induced by reducing energy intake. The individual is considered adherent if, throughout the course of the weight management program, the change in body weight falls between the upper and lower bounds, which is termed the "weight zone" or "zone of adherence." Intervention strategies, including personalized feedback, are delivered based on the actual weight of the individual in relation to this zone [21]. One of the strengths of this approach is the ability to objectively quantify adherence to diet and exercise recommendations based on observed body weight. As described herein, the SmartGraph is automatically created by SmartLoss and updated with new weight data in near real time, and it is viewable by the client and health care or research professional on the SmartLoss clinician dashboard and the app.

SmartLoss relies on weight data that can be automatically imported from commercially available devices. For example, SmartLoss is presently programmed with the Body Trace bathroom scale application program interface (API) to directly import body weight data. The bathroom scale synchronizes with the Internet via a cellular card, and body weight information is automatically and wirelessly transmitted to a server. The SmartLoss system retrieves weight data from the server in near real time and weight is plotted on the SmartGraph (Figure 2), which is available immediately via the SmartLoss app or the SmartLoss clinician dashboard. Additionally, weight data can be hand entered by clients via the mobile phone application or dashboard, or a health care or research professional can enter weight data into the SmartLoss clinician dashboard. Should a client weigh multiple times during the day or enter multiple daily weights, SmartLoss is programmed to plot only the first recorded weight of the day. It is also programmed to eliminate weights not obtained from the client (ie, weights that deviate by +/− 5% from the last available weight). The system is adaptable and the programming logic can be manipulated should a health care or research professional wish to evaluate weight fluctuations throughout the day, for example.

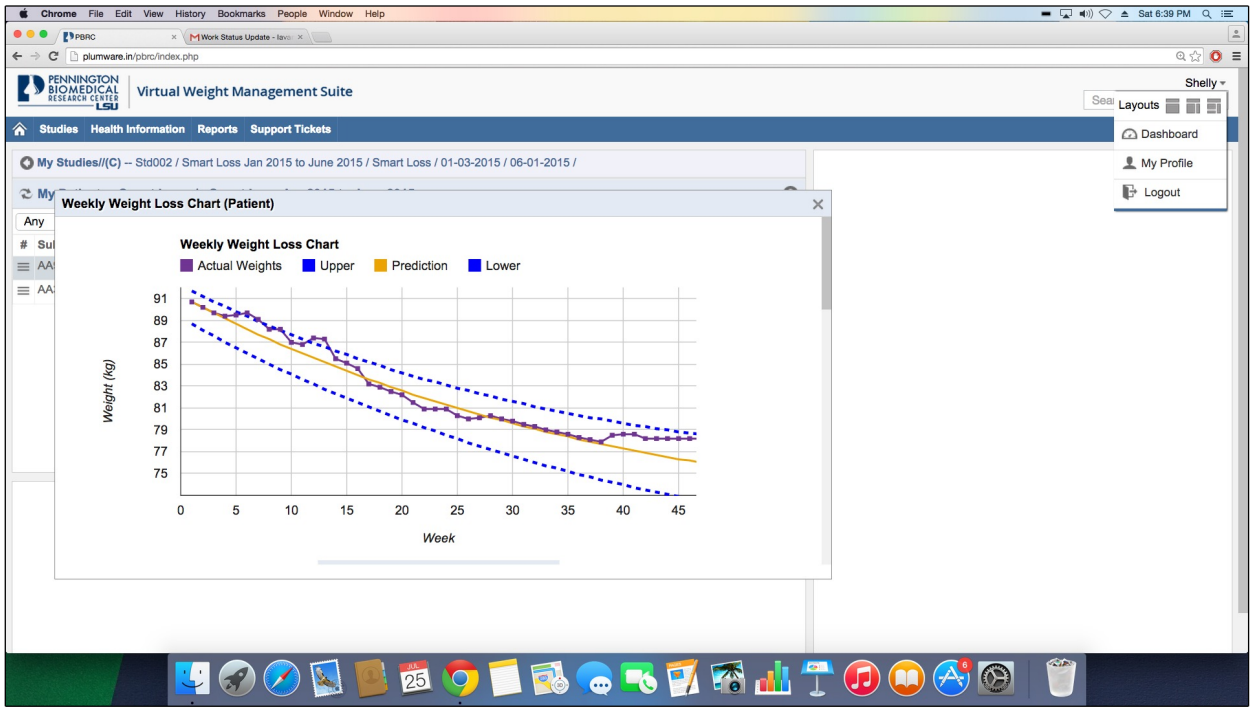
SmartLoss can transmit automated feedback to clients at prespecified intervals or based on weight change characteristics. For example, if the weight of a client is changing as expected (ie, is within the zone of adherence), the feedback includes a congratulatory message and a tip to encourage continued success. Via the clinician dashboard, the health care or research professional can have further interaction with clients by initiating additional personalized feedback messages and treatment advice. The collection of objective weight data (and exercise data, as described below) by clients, the integration of those data into personalized behavioral goals, and the delivery of both automated feedback and customized feedback generated by health care or research professional are illustrated in Figure 3. SmartLoss also provides instantaneous feedback to clients regarding the change in weight relative to the zone of adherence. The program automatically generates color-coded flags indicating if the weight of the client is: (1) within the zone of adherence (green flag); (2) within the zone but plateauing or approaching the upper edge of the zone (green/yellow flag); (3) out of the zone (red flag); or (4) above of the zone but decreasing at a rate that reflects adherence to the energy intake target (red/green flag) and, consequently, if continued will result in the client being back in the zone on the weight graph. If weight exceeds the target and is out of the zone for a given period of time (eg, 3 of 5 days), the client is provided with supportive treatment recommendations to modify energy intake and/or physical activity and foster adherence based on a toolbox approach, which is described below.

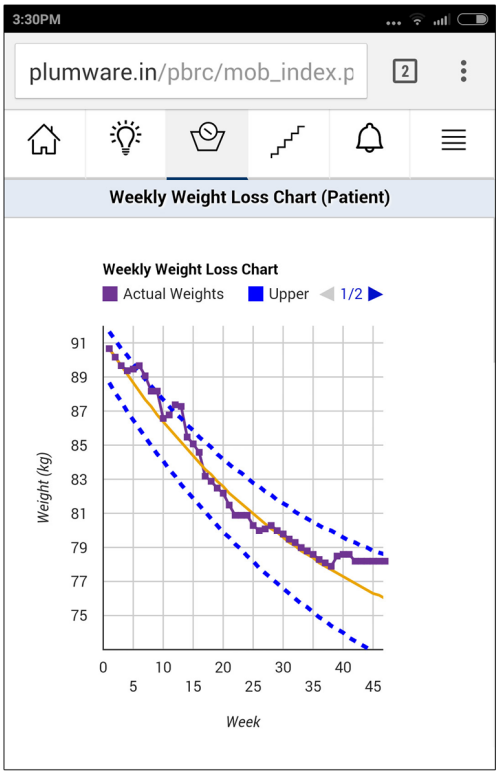
Figure 1. Predicted weight change based on mathematical models of energy balance and an energy intake target that reduces intake by 500 kcal/day. This example was created at http://weight-loss-predictor.appspot.com/weight for a hypothetical 50-year-old female who is 65 inches tall, weighs 200 pounds, and wishes to reduce her intake by 500 kcal/day, which would result in weight loss of 17.4 pounds or 8.7% over 12 months if adherent to the new energy intake level.

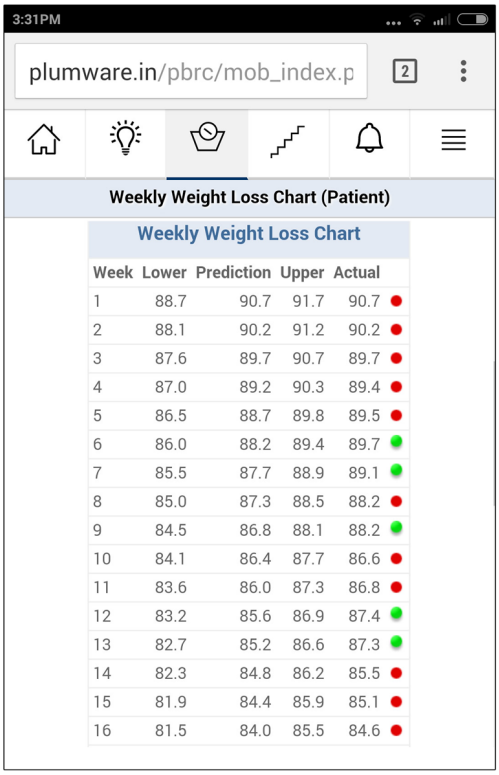


Month	Weight (lb)	Wt. Loss	% Loss
0	200.0	0.0	0.0
1	197.3	2.7	1.4
2	194.9	5.1	2.6
3	192.8	7.2	3.6
4	190.9	9.1	4.5
5	189.3	10.7	5.3
6	187.9	12.1	6.0
7	186.7	13.3	6.6
8	185.6	14.4	7.2
9	184.7	15.3	7.6
10	183.9	16.1	8.0
11	183.2	16.8	8.4
12	182.6	17.4	8.7

Figure 2. Panel A: A screenshot from the clinician dashboard for a hypothetical client. The SmartLoss intervention generates a SmartGraph that shows the predicted course of weight change for an individual assuming adherence to the energy intake target (yellow line), which can be either an increase or decrease in daily energy intake. The upper and lower bounds around the predicted weights (dashed blue lines) create a "weight zone" or "zone of adherence" and participants are considered adherent if their body weight (purple line) falls within the zone over time. Also, intervention strategies are delivered based on the participant's actual weight in relation to this zone, and the graph is available to participants and health care or research professionals at any time via the clinician dashboard and app. Panel B: The SmartGraph is automatically delivered to participants smartphones at regular intervals (e.g., once per day, after a new body weight is received by the dashboard). Panel C: A "details view" in the app allows participants to see their weights over time in addition to their predicted weights, the weights associated with the upper and lower bounds of the adherence zone, and a color coded flag denoting if they were in or out of the zone (these same data are also available via the clinician dashboard).

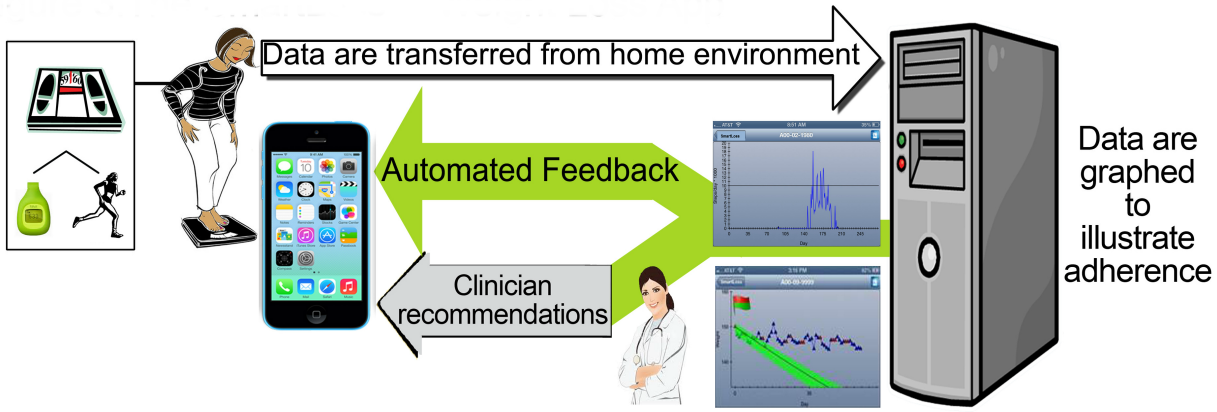






Week	Lower	Prediction	Upper	Actual
1	88.7	90.7	91.7	90.7
2	88.1	90.2	91.2	90.2
3	87.6	89.7	90.7	89.7
4	87.0	89.2	90.3	89.4
5	86.5	88.7	89.8	89.5
6	86.0	88.2	89.4	89.7
7	85.5	87.7	88.9	89.1
8	85.0	87.3	88.5	88.2
9	84.5	86.8	88.1	88.2
10	84.1	86.4	87.7	86.6
11	83.6	86.0	87.3	86.8
12	83.2	85.6	86.9	87.4
13	82.7	85.2	86.6	87.3
14	82.3	84.8	86.2	85.5
15	81.9	84.4	85.9	85.1
16	81.5	84.0	85.5	84.6

Figure 3. The overall concept of the SmartLoss Virtual Weight Management Suite: objective weight and exercise data are obtained, those data are integrated into personalized behavioral goals, and both automated and customized feedback based on client data and their relation to preestablished goals are transmitted to the client.

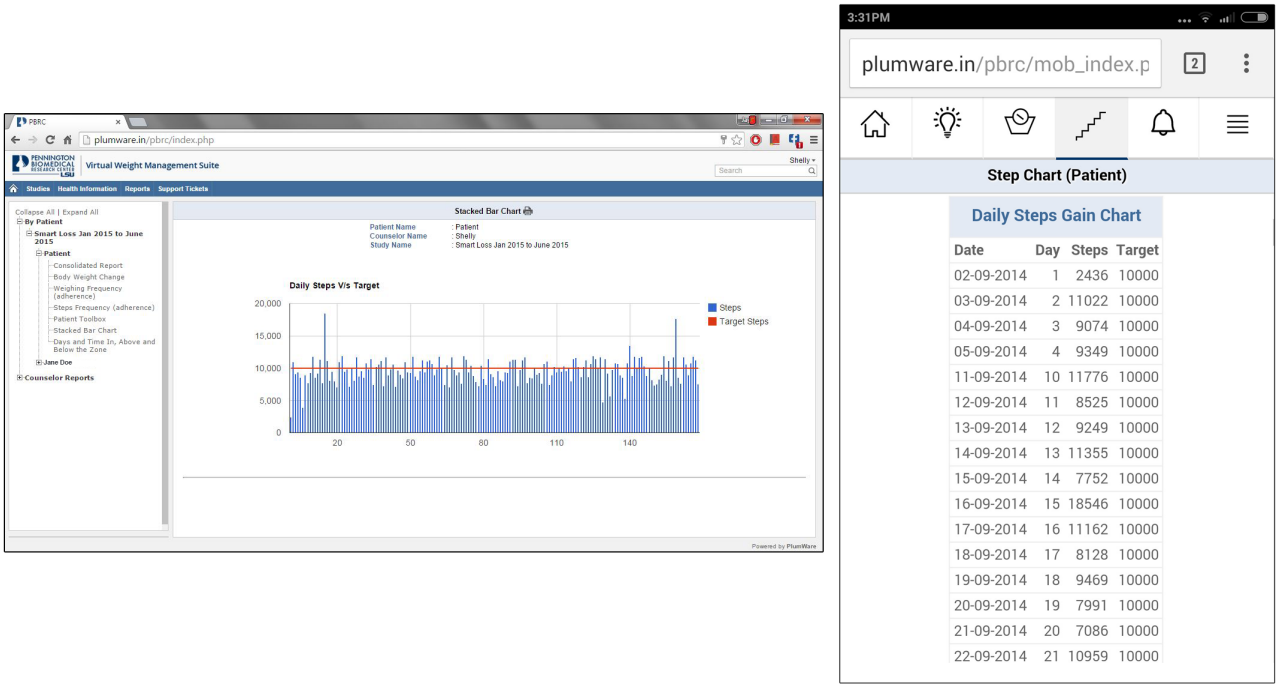


Tracking Client Adherence to Activity or Exercise Goals

SmartLoss is programmed to automatically receive activity information from the FitBit API twice per day. Additionally, step data can be hand entered by participants via the SmartLoss app or dashboard, or a health care or research professional can manually enter weight data into the dashboard. After receiving activity data, the SmartLoss program summarizes the activity goal of the client and current steps per day on a SmartSteps graph for immediate viewing within the mobile phone app and clinician dashboard (Figure 4).

Adoption of a regular program of physical activity is important for weight management and exercise was considered when developing the energy balance models that predict weight loss; hence, the models include a term for activity [35-37]. The model currently used by SmartLoss produces weight loss predictions that are valid for individuals engaging in light to moderate levels of physical activity at the federally recommended level of 150 minutes per week [41]. Should an intervention rely only on higher levels of exercise, a different model that relies on a modified Forbes curve would be used to predict weight change [39]. Similarly, if an intervention promoted a combination of higher levels of exercise and an energy-restricted diet, an alternative model would be used to predict weight change that includes inputs for exercise and restriction of energy intake.

Figure 4. Panel A: A screenshot of the SmartSteps graph from the clinician dashboard, which is also delivered to clients' mobile phones once per day. Panel B. The details view of a client's step data on the smartphone app.



The physical activity component of SmartLoss is designed to encourage individuals to adopt a regular program of physical activity with the goal of increasing their daily steps by 3000 to 4000 steps per day above baseline [42], which results in 7000 to 8000 steps per day [41,43] and is consistent with federal guidelines of 150 minutes per week of moderate intensity activity. Since very few activity monitors provide valid estimates of caloric expenditure, the focus of the exercise goals in

SmartLoss is steps per day. Similar to feedback of weight data, individuals receive automated feedback messages about daily adherence to the physical activity goals. Long-term weight loss maintenance is promoted by higher levels of exercise [41,44], and elevated levels of exercise can be promoted and monitored over the long-term through SmartLoss, particularly after weight is lost and clients enter a weight maintenance phase.

SmartTips

SmartLoss can deliver a comprehensive set of health materials called SmartTips to educate clients on strategies for effective behavior change and weight management. A key feature of intensive in-person sessions is the receipt of health information to motivate and inform lifestyle change. During in-person interventions, these materials are generally printed and a health care or research professional reviews this information with clients in group or individual sessions and works with clients to apply the material to their own situation in an attempt to facilitate and maintain behavior change. The content of the SmartTips can be customized for different groups of individuals (eg, post-menopausal women, young men, lactating women) or with a focus toward a particular type of diet (ie, DASH diet, Mediterranean diet, etc). The interval at which the SmartTips are delivered can be customized for individual clients or programs, but participation in intensive intervention programs generally warrants receipt of health information weekly at the onset of the program and can taper off to biweekly and then monthly as the program progresses.

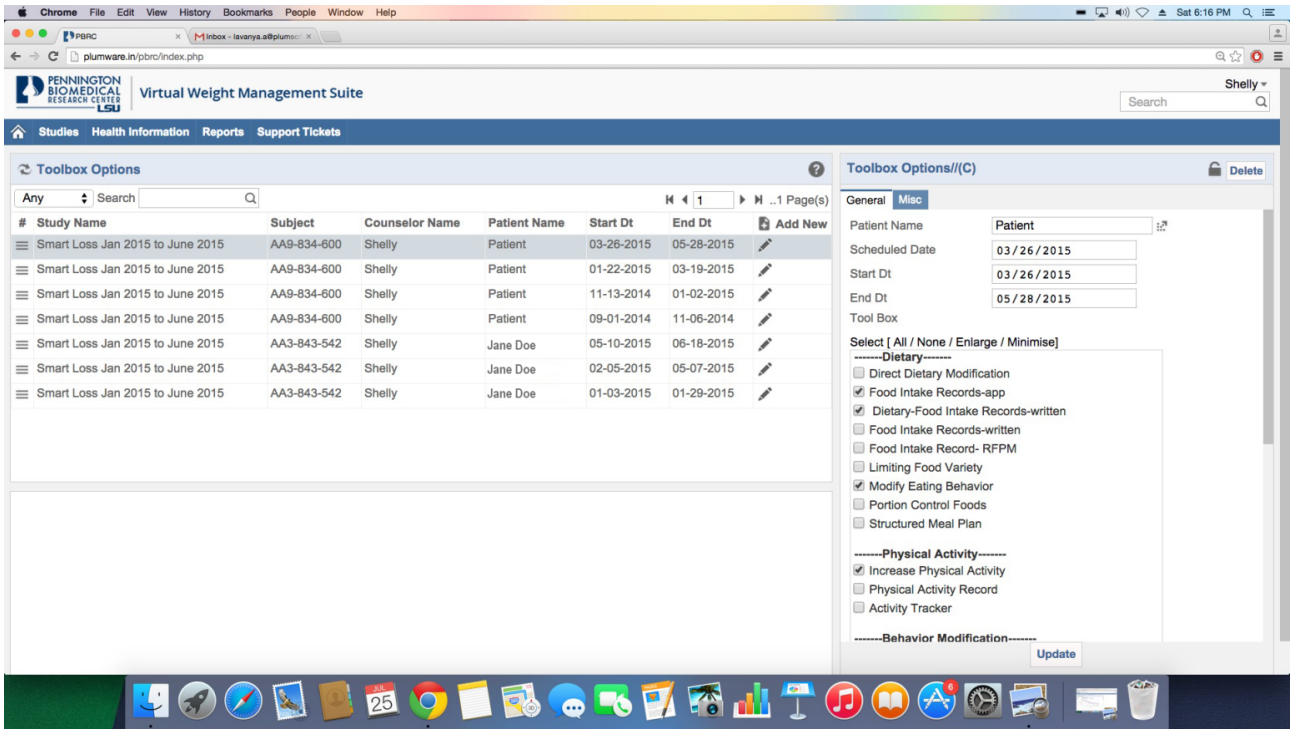
The SmartTips also provide a platform to reinforce and facilitate the use of strategies that effectively promote weight management. For example, use of portioned-controlled foods is an effective strategy in weight management programs and links can be embedded in the SmartTips to direct clients to credible websites where information on a variety of portioned-controlled foods can be obtained. The SmartTips are also interactive, requiring input from the client that acknowledges comprehension of the content. SmartTips also reference the SmartGraphs and recent weight change of the client. SmartLoss is therefore adaptable to many different intervention approaches, from purely automated delivery of SmartTips to the delivery of SmartTips with a counselor remotely reviewing the material with the client via a mobile phone's multimedia capabilities. Thus, similar to in-person intensive lifestyle interventions, SmartLoss provides a platform for health care or research professionals to customize intervention delivery to the needs of individual clients and facilitate behavior change on an individual level. Further, SmartLoss provides a platform for researcher professionals to test the effects of remotely delivered interventions that include counselor support versus interventions that are fully automated but otherwise identical. Such research is needed, as SmartLoss and similar interventions that have been found to be efficacious were also fairly intense [21-23], while less intense and less directive interventions have produced less weight loss [45,46].

Toolbox Options

When body weight is repeatedly outside the zone of adherence, it serves as an objective indicator to the client and health care or research professional that more intensive treatment strategies are needed. Different treatment strategies to increase the intensity of the weight management program are maintained in the SmartToolBox. Examples of these strategies include the use of portion controlled foods, increased frequency of contact with the assigned health care or research professional, increased activity or exercise, adoption of a plan to self-monitor food intake, etc. This toolbox approach is similar to the strategy used in the Comprehensive Assessment of Long-term Effects of Reducing Intake of Energy (eg, the CALERIE study) [30,47] and other studies (eg, LookAhead) [28], and it provides a systematic and algorithmic method to improve adherence to diet and weight goals.

When using this approach, the client and health care or research professional are prompted by the SmartLoss app and dashboard to first select less intensive strategies from the toolbox, followed by more intensive and frequently more expensive strategies if the less intense strategies fail to result in the desired outcome (usually weight loss) over a given period of time (eg, 2 weeks). Treatment strategies provided within the SmartToolBox are specified by the clinic and customized for the type of weight management program being delivered and to meet the needs of individual clients (Figure 5). Use of the toolbox is tracked and quantified by the clinician dashboard. One aim of the toolbox approach is to build self-efficacy as selection of toolbox strategies is a collaborative process between the client and their healthcare or research professional, particularly early in treatment. Options are personalized to meet the individual client's needs based on their current circumstances and abilities. As treatment progresses, the client learns to identify potential problems, evaluate and select a strategy to overcome the problem, and track the success of the strategy. This framework follows an active problem-solving approach and builds accountability and self-efficacy since the client is actively involved in choosing methods to improve adherence, evaluating the effectiveness of the chosen solution, and selecting an alternative solution if needed.

Figure 5. Screenshot of the SmartToolbox section of the clinician dashboard. SmartToolbox options are utilized when clients require additional support to meet their goals. Less intense and usually more affordable options are used first and progress is tracked to determine if improvement occurred. If not, more intense and usually more costly options are utilized and progress is similarly tracked. The clinician dashboard automatically tracks toolbox use and reports can be generated to demonstrate which options were utilized, as well as change in weight and exercise levels during use of the different toolbox options.



Usage Tracking and Report

The clinician dashboard allows users with administrator and healthcare or research professional rights to generate reports that summarize data on usage of the SmartLoss app, as well as reports showing weight and exercise data at the individual and group level. Usage data includes: (1) the number of days that body weight and step data were recorded, (2) the number of days clients were enrolled in the program, (3) the percent of days with weight and step data, (4) the number of times participants viewed the weight and step graphs, and (5) the number of times and which SmartTips were viewed. Reports can also be generated that summarize the following body weight data: (1) client body weight over time, (2) the target/goal weight and the upper and lower bounds of the zone of adherence, (3) client weight change (pounds and percent) over time, and (4) the number of days and percent of time that clients were in, below, or above the zone of adherence. Finally, reports can be generated that summarize SmartToolBox use and weight change and step counts during the time that different toolbox options were utilized. All reports can be viewed within the clinician dashboard and the raw data can be downloaded into other software packages for analysis.

Results

Evidence of the efficacy of the SmartLoss approach has been reported previously [21]. The present report provides a thorough description of the SmartLoss Virtual Weight Management Suite, a professionally programmed platform that facilitates treatment fidelity and the ability to customize interventions and disseminate them widely.

Discussion

Mobile phones and similar Internet-enabled devices (eg, tablets) are virtually ubiquitous and provide the opportunity to deliver weight management and health promotion programs to people with limited access to health care. Nonetheless, the preponderance of mobile phones and peripheral devices that provide objective health information to the user and, frequently, their clinician has failed to result in a large number of efficacious mHealth weight management interventions. SmartLoss is an EMI that quickly provides participants with feedback about their adherence to energy intake and activity goals via graphical displays. Importantly, adherence to the weight management program is quantified based on actual changes in client body weight and validated mathematical models of energy balance, and SmartLoss relies on the established behavioral theories to initiate and sustain behavior change.

SmartLoss and similar interventions [22,23] address shortcomings identified through earlier research, including the need to incorporate behavior change theory, self-monitoring, tracking of objective body weight data, and skills training. Based on the literature, it appears clear that more intense mHealth interventions such as SmartLoss are more efficacious at reducing body weight while more passive interventions are not as effective [45,46]. An unanswered question is the extent to which efficacy can be maintained during longer-term weight management interventions that increasingly rely on automated feedback versus feedback and treatment recommendations from a health care or research professional who delivers treatment remotely. Additionally, it seems likely that tracking objectively measured body weight during treatment is important, yet it is

unclear to what extent interventions can maintain efficacy and rely on self-reported data. The ability of mHealth interventions to promote long-term weight loss maintenance also is not known and research on their efficacy and cost-effectiveness at promoting weight loss maintenance is warranted.

In conclusion, the SmartLoss Virtual Weight Management Suite provides health care providers and researchers with the ability to deliver weight loss and weight maintenance treatment plans to individuals remotely via a mobile phone app and an Internet-based clinician dashboard. It is hoped that this and similar theoretically-based mHealth interventions will facilitate the delivery of effective health promotion programs to populations who are typically underserved or who face barriers to engaging in high intensity programs offered in urban clinical settings.

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Conflicts of Interest

Drs Gilmore, Apolzan, and Myers report no conflicts of interest. SmartLoss is a registered trademark of the Louisiana State University System; the trademarked approach was developed by Drs Martin, Thomas, and Redman. There are no direct benefits to the authors for publication of this manuscript. Drs Martin, Thomas, and Redman have no financial affiliations with the companies who conducted the work to develop the SmartLoss Virtual Weight Management Suite. Any licensing of SmartLoss could financially benefit LSU-Pennington Biomedical Research Center, Montclair State University, and Drs Martin, Redman, and Thomas.

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Abbreviations

API: application program interface
EMI: ecological momentary intervention
mHealth: mobile health

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Original Paper

Development of a Weight Loss Mobile App Linked With an Accelerometer for Use in the Clinic: Usability, Acceptability, and Early Testing of its Impact on the Patient-Doctor Relationship

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Abstract

Background: Although complications of obesity are well acknowledged and managed by clinicians, management of obesity itself is often difficult, which leads to its underdiagnosis and undertreatment in hospital settings. However, tools that could improve the management of obesity, including self-monitoring, engagement with a social network, and open channels of communication between the patient and doctor, are limited in a clinic-based setting.

Objective: The objective of our study was to evaluate the usability and acceptability of a newly developed mobile app linked with an accelerometer and its early effects on patient-doctor relationships.

Methods: From September 2013 to February 2014, we developed a mobile app linked with an accelerometer as a supportive tool for a clinic-based weight loss program. The app used information from electronic health records and delivered tailored educational material. Personal goal setting, as well as monitoring of weight changes and physical activity combined with feedback, are key features of the app. We also incorporated an interactive message board for patients and doctors. During the period of March 2014 to May 2014, we tested our mobile app for 1 month in participants in a hospital clinic setting. We assessed the app's usability and acceptability, as well as the patient-doctor relationship, via questionnaires and analysis of app usage data.

Results: We recruited 30 individuals (18 male and 12 female) for the study. The median number of log-ins per day was 1.21, with the most frequently requested item being setting goals, followed by track physical activities and view personal health status. Scales of the depth of the patient-doctor relationship decreased from 27.6 (SD 4.8) to 25.1 (SD 4.5) by a Wilcoxon signed rank test (P=.02).

Conclusions: A mobile phone app linked with an accelerometer for a clinic-based weight loss program is useful and acceptable for weight management but exhibited less favorable early effects on patient-doctor relationships.

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KEYWORDS

mobile apps; electronic health record; weight reduction programs; physician-patient relations

Introduction

In South Korea, management of obesity remains challenging within the current health care system [1,2] despite the existence of numerous guidelines [3-5] and effective treatments [6,7]. Although the consequences of obesity, such as hypertension, type 2 diabetes, or knee osteoarthritis, are promptly evaluated and managed by clinicians in the hospital setting, the core disease itself is frequently underdiagnosed and undertreated. A retrospective analysis [8] found significant disparities between the reported and true prevalence of obesity in outpatient departments, such as orthopedics (3% vs 25.1%), cardiology (4% vs 30%), and rheumatology (5% vs 20.2%).

Given obesity's negative impact on premature death [9], socioeconomic costs [10-12], and quality of life [13], it is important to manage obesity in hospital settings via a coordinated and multidisciplinary approach with a comprehensive lifestyle program [3] that includes implementing a low-calorie diet, increasing physical activities through the use of behavioral strategies, and providing additional support from pharmacotherapy or surgical treatment in certain patients [14]. However, there are several limitations to managing obesity in a clinic-based setting. From a patient's perspective, clinic visits are time consuming and costly, and these problems are exacerbated by inadequate patient-doctor interaction time. Behavioral intervention strategies [15], including self-monitoring of weight, diet, and physical activities, are key components of successful weight management. However, the tools required for self-monitoring and interactive feedback with clinicians are often limited in a clinic-based setting. Educating patients [16] concerning the risk of obesity and their active participation remains the cornerstone of weight loss programs, which require a repetitive and considerable effort by the clinicians. Moreover, a patient's social network, social influence, and social support [17,18] are important aspects to consider, and these factors are typically lacking in the clinical management of obesity.

Recently, given the exponential spread of mobile phones, the Internet and mobile apps have become widely accessible, anytime and anywhere. Mobile apps in health care [19] have been regarded as a potential tool for altering patients' behavior and improving pretreatment regimens.

Particularly in a clinic-based weight loss program, a mobile phone app can be a great resource for both patients and clinicians. To a patient, self-monitoring and self-regulation via a mobile app may be a more effective method than a paper-based monitoring system [20,21]. A mobile app can also serve as a tailored and customized educational tool for individualized services [22] and as a social support and social engagement tool [23] for weight loss. Considering the positive association [24] between the patient-doctor relationship and treatment adherence, with better patient satisfaction and outcomes [25-27], a mobile app has the potential to strengthen the patient-doctor relationship by making clinicians more focused on the patient's concerns and consequently spending less time obtaining or providing basic information. In general, patients are more likely to be actively involved in the management of their disease if they perceive that they are engaged in a good-quality interpersonal exchange and have increased out-of-office contact with their physician [24]. Moreover, a mobile app may allow patients to play a more active role in the medical decision-making process, thus minimizing the knowledge gap between physicians and patients [27].

Despite an enormous number of available health care apps, most apps are underused [19], with limited approaches for user engagement, limited adoption of evidence-based behavioral-change strategies or frameworks [28], and limited evidence of clinically significant benefits derived from using the app [29]. Results of previous studies of a mobile app for weight loss were controversial regarding weight changes. One study of a mobile phone app for intervention [30] compared weight changes over 6 months between mobile app users and a control group. This study did not find significant weight loss in the intervention group, and a 42% dropout rate was noted within the first month. Another pilot study assessed a mobile phone app with a wearable monitoring device and compared the use of the app with a health education control group [31]. A significant meaningful weight reduction was noted in the monitoring device group.

Only a few studies have examined the use of mobile apps in hospital- or clinic-based weight loss programs and assessed how these apps may have affected the patient-doctor relationship. In our study, given that the app was developed for supportive use in a clinic-based weight loss program, we decided to link an accelerometer to the app. Therefore, our study aims were to develop a mobile app linked with an accelerometer for a clinic-based weight loss program and to test its usability, acceptability, and early effects on the patient-doctor relationship.

Methods

Development Process of the Mobile App Linked With an Accelerometer

One aim of this study was to describe the development process of a mobile app linked with an accelerometer for a clinic-based weight loss program. This study was part of a project to develop a personalized media service using a device-cloud interconnection for improving patient-doctor communication, which was funded by a grant from the Korean Evaluation Institute of Industrial Technology Research Fund. The development of the mobile app was planned and organized by a multidisciplinary team, including a team from Xeron Healthcare Corporation (Seoul, Republic of Korea), app designers, and teams from the hospital staff (family physicians and dietitians with a research coordinator; Seoul National University Bundang Hospital, Seongnam, Republic of Korea) between September 2013 and February 2014.

Theoretical Basis

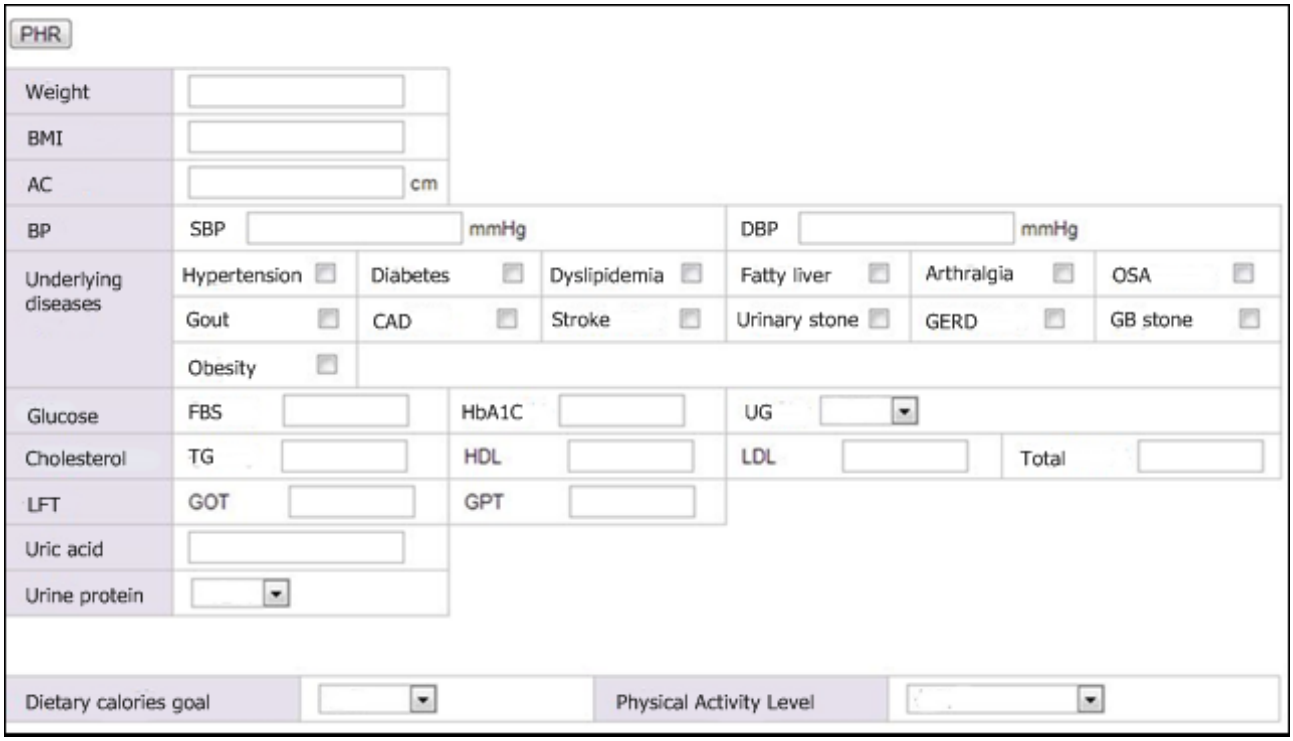
The theoretical concept for this mobile app was mainly derived from social cognitive theory [32], which has played an important role in many weight loss clinical trials [33]. Weight management involves numerous lifestyle changes, including diet and exercise, which must be sustained for a long time. For such changes to be achieved and maintained over the course of an individual's life, participants should believe in the value of weight loss and that their desired outcome is achievable through implementation of the required behavioral changes. Furthermore, those changes can be made through a key mediator [34]; self-regulation skills, such as goal setting, self-monitoring of behaviors (such as dietary intake or physical activities), or target outcomes (such as weight); and social support from important others [35].

Other important behavioral strategies have been noted to aid weight loss [36], such as time management, stimulus control, self-reward, relapse prevention, and emotion-focused strategies or cognitive strategies, which are all important components of successful weight management. However, the aim of our mobile app was to support weight management in clinic-based settings. Therefore, we adopted four main features in our app: (1) increased knowledge by providing personalized educational materials, (2) personal goal setting for weight loss, (3) self-monitoring of weight and physical activity linked with an accelerometer, and (4) online social support from a peer group as well as Web-based communication channels with their clinicians.

Definition of Obesity-Related Problems and Development of a Web-Based Interface Using Information From Electronic Health Records in a Clinic-Based Weight Reduction Program

For the clinic-based weight loss program, we assessed patients and categorized their obesity-related problems [37,38] into subclinical states, symptomatic physical dysfunction, and established obesity-related diseases. We developed a Web-based interface for the mobile app to provide obesity-related information based on electronic health records (EHRs) to provide patients with tailored content and assessment tools, as Figure 1 shows. From EHRs we obtained anthropometric measurements, such as height, weight, age, abdominal circumference, and blood pressure, as well as laboratory measurements, including blood glucose, uric acid, triglyceride levels, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol. A family physician input information regarding obesity-related comorbidities, such as coronary artery disease, stroke, hypertension, diabetes, dyslipidemia, nonalcoholic steatohepatitis, arthritis, gout, obstructive sleep apnea, and reflux esophagitis, from the initial assessment. Participants consulted with dietitians and were prescribed a weekly sample menu of a low-calorie diet consisting of 1200 to 1800 kcal/day that was based on their age, sex, activity level, and target weight. Moreover, in accordance with the target weight and prescribed daily calories, participants were advised to achieve a target level of physical activity each day.

Figure 1. Screenshot of the Web-based interface through which the physician can input obesity-related information from the patient's electronic health record. AC: abdominal circumference; BMI: body mass index; BP: blood pressure; CAD: coronary artery disease; DBP: diastolic blood pressure; FBS: fasting blood sugar; GB: gallbladder; GERD: gastroesophageal reflux disease; GOT: glutamate oxaloacetate transaminase; GPT: glutamic pyruvate transaminase; HDL: high-density lipoprotein; LDL: low-density lipoprotein; LFT: liver function test; OSA: obstructive sleep apnea; PHR: patient health record; SBP: systolic blood pressure; TG: triglyceride; UG: urine glucose.



Delivery of Tailored Educational Materials Via a Web-Based Interface Using Information From EHRs

We considered the delivery of tailored educational materials about diseases and the specific weight loss target for each person as an important function of the app. We developed educational videos (see Multimedia Appendix 1 for the educational video for angina pectoris) for each obesity-related disease as part of the tailored educational materials. The educational videos featured a fictional scenario pertaining to a patient and an explanation of the mechanisms of the disease, as well as possible suggestions for weight loss. We set a target for the total running time for each video to be no greater than 1 minute and 30 seconds.

Participants could monitor their corresponding diseases through the app, and each disease was linked with educational videos that ran on their app. Additional educational materials could be viewed and downloaded on mobile phones running the Android operating system (Google) linked with the study app called My Health Diary. Within the app, each disease was also linked with corresponding nutritional information and recommendations. We provided general nutritional information about macronutrients, a low-salt diet, and low-calorie tips for shopping or dining out. We also provided dietary guidelines for specific diseases, such as dyslipidemia, diabetes, fatty liver, and hypertension, to patients in need (Figure 2). We presented sample menus of healthy meals for 1week in accordance with the calorie targets prescribed by a dietitian (Figure 2).

Figure 2. My Health Diary screenshot: the patient's laboratory results, sample menus for the meal plan, and dietary guideline for obesity-related diseases.

Personal Goal Setting, Self-monitoring, and Automatic Feedback on Weight and Physical Activities Using an Accelerometer

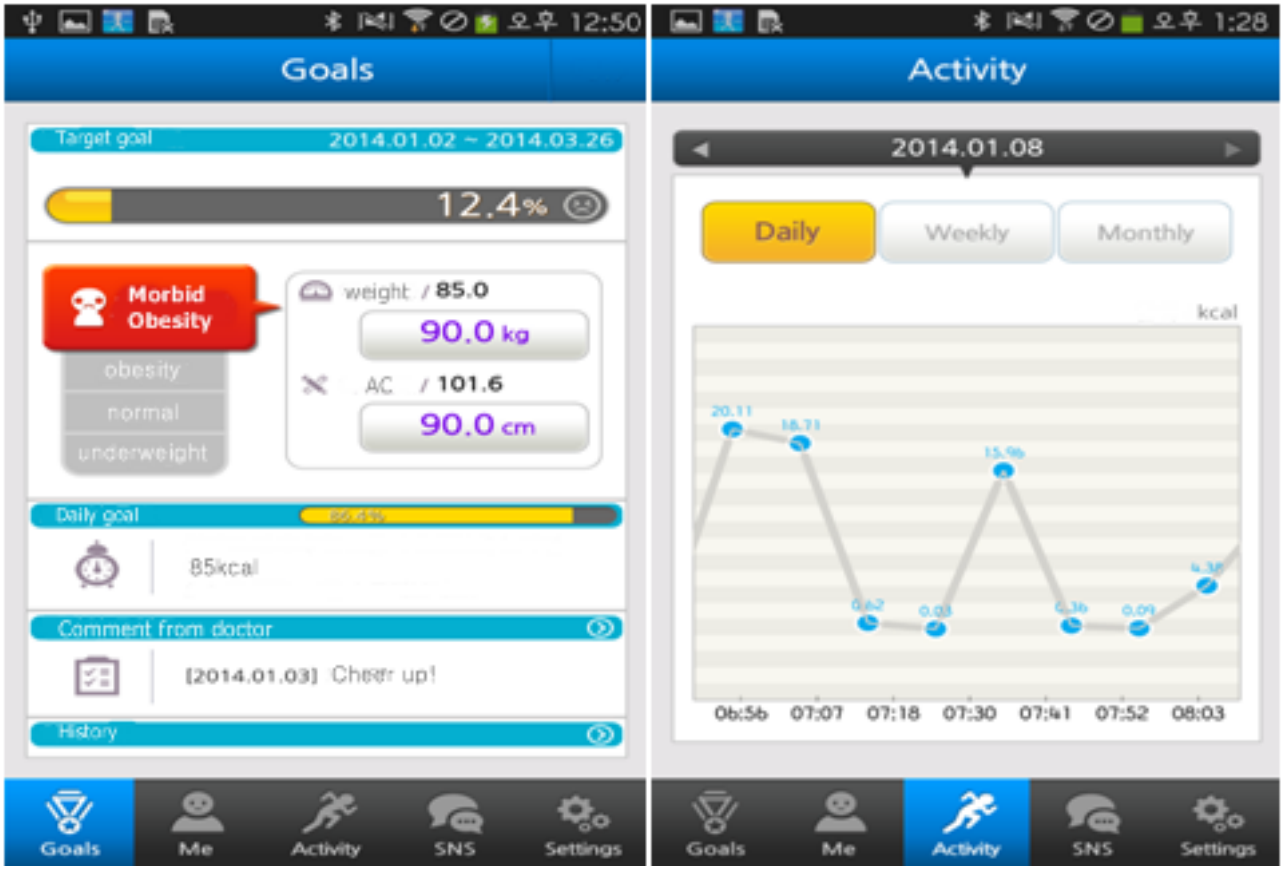
Participants could set their final weight goal and monthly weight goal. If they did not enter their goal, a default set of goals was automatically chosen: 10% reduction of their current weight as the final goal and a 2-kg reduction as the monthly goal. If the monthly goal was >5% of their current weight, information regarding the risk of rapid weight loss and advice for adjusting the target goal was provided.

If participants set their goal, the difference between their current weight and their target weight was automatically calculated in calories. Assuming participants adhered to their prescribed calorie targets, the app suggested daily and weekly target activity calories. Participants could select the target activity calories within a 10% range.

A wristband-type, 3-axis accelerometer (LG LifeGram, LG Electronics, Seoul, Republic of Korea) monitored the patients' physical activity. This accelerometer analyzes the number of steps, distance, activity time, and intensity of the activity and calculates the calories burned by each activity on the basis of patients' personal information, such as height, weight, age, and sex. We chose this accelerometer because it allowed us to use the database directly linked with the study app. Unfortunately, no studies regarding the validity of the LG LifeGram have been published.

Physical activities were monitored daily by the accelerometer, which synchronized with the mobile app. Automatic feedback messages were sent to patients in accordance with the protocols based on their monthly target weight loss goal, which included the recommended calorie consumption per day, target calories burned by activities, and previous physical activity records. If the accelerometer and the mobile app were not synchronized over a 24-hour period, an automated reminder message was sent to patients. Self-reporting of daily weight was encouraged. If no weight was reported for more than 2 days, an automated reminder message was sent to patients. As Figure 3 shows, weekly graphical reports provided weight and physical activity summaries with messages of encouragement and assigned the goals for the next week.

Figure 3. My Health Diary screenshot: regular monitoring reports include weight changes, weight goals, physical activities undertaken, and encouraging messages.



Development of a Web-Based Communication Channel Between Patient and Doctor

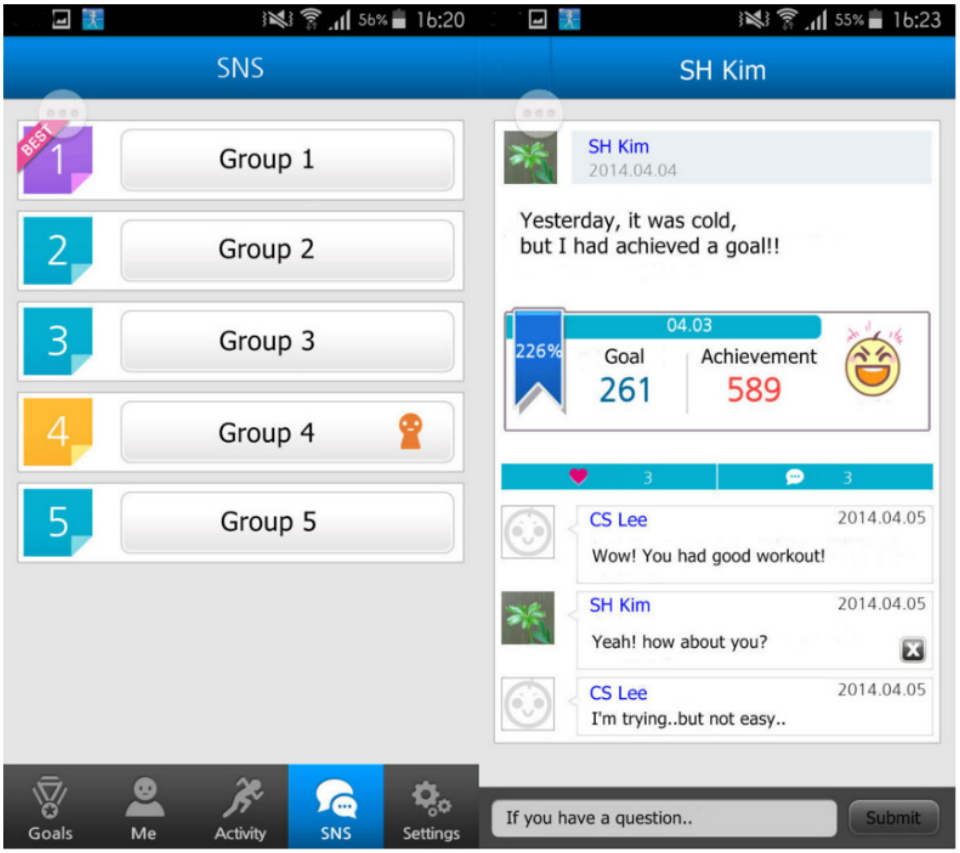
We developed an interactive messaging board between doctors and patients. If a patient asked questions regarding their health status or condition via the message board, doctors received an automated message as Figure 4 shows. The message board was developed to promote effective and efficient communication, which would supplement the short interview time available during clinic visits. Doctors had a choice of answering questions either via the mobile app or directly during a scheduled clinic visit with patients. Doctors could also leave encouraging messages or target goals on the message board, and messages were sent to the corresponding patient's mobile app. The message board was developed for one-to-one chatting with each patient's doctor, and patients could not see the contents of other participants' messages. On the doctor's app screen, the message board looked like a list of emails from participants, but only one-to-one communication was possible so that the participants' sensitive medical information remained secure.

Peer Support Group Using a Social Network Service

We set up a peer support group using a social networking service that was incorporated into our mobile app (Figure 5) that the participants could join. Participants could view each other's physical activities and the percentage of their goals that they had completed, and they could communicate with each other via a peer-to-peer messaging system. Participants' physical activities with their achievement goals were linked with the social networking service and viewable by other people by default. The default option was that only the username generated by each participant was visible in the social network service, but it was possible for the participants to upload their photo.

Figure 4. My Health Diary screenshot: message board between doctors and patients.

Figure 5. My Health Diary screenshot: social networking service for peer support group. (Fictional names entered for demonstration purposes.).



Study Design

During the period of March 2014 to May 2014, we applied a pre-post single-group design to evaluate the usability and acceptability, as well as the early effects on patient-doctor relationship, of our newly developed mobile app, which was linked with an accelerometer. Usability assessments measured the technical effectiveness of the mobile app by asking whether the users could easily follow the steps without making any errors. We assessed acceptability by the users' overall experience in using the mobile app, their perceived confidence in the information, and their satisfaction with the experience. Our aim was to implement a mobile app that runs on mobile phones as a clinical program. We did not provide telephone numbers, emails, or Web-based portal services to patients. A Web-based portal was only used for researchers to summarize participant's anthropometric measurements, laboratory measurements, and corresponding obesity-related problems.

Flow of the Clinic-Based Weight Loss Program

We briefly outline the clinic-based weight loss program as follows.

If a patient came to the clinic, either on their own or referred from other departments, a family physician obtained the patient's medical history, health behaviors, previous attempts at losing weight, preferences, and goals. Then, the patient was scheduled for a meeting with a dietitian and was evaluated regarding obesity-related problems, including screening questionnaires for depression and eating disorders, body composition measurements, and laboratory examinations, such as tests for glucose, cholesterol, liver function, and kidney function. The patient could be referred to specialists in accordance with the problems identified in their initial assessment. The patient then received a treatment program consisting of lifestyle-focused interventions, including a nutritional plan, targeted behavioral changes, and an exercise program. The patient was also provided with pharmacotherapy or was referred to a bariatric surgical team if their body mass index (BMI) was >35 kg/m^2 with comorbidities, they had previously attempted lifestyle modification and pharmacotherapy without success, and they were interested in surgical treatment. A follow-up meeting with the physician was typically scheduled at 2- to 4-week intervals for the first 3 months.

Study Population

We recruited 30 participants from patients who visited our clinic for weight loss programs. The World Health Organization's Regional Office for the Western Pacific Region defines obesity in Asians as those with a BMI ≥25 kg/m^2 [39]. The Korean government officially uses this definition when defining and implementing health policies regarding obesity in Korea.

If patients met the following criteria, they were eligible for participation: BMI of ≥25 kg/m^2, possession of an Android mobile phone, and between 20 and 70 years of age. Patients were excluded if they had been admitted to a hospital due to a cardiovascular disease in the previous 6 months, being immobile due to surgical procedures in the previous 3 months, being pregnant, having experienced weight fluctuations of >10% in the previous year, or having a history of alcohol use disorder, an eating disorder, or of using weight loss pills in the previous 3 months.

Patients who were eligible were identified and informed about the study. On their second visit to the clinic, patients were invited to participate and discuss their results from the initial assessment. If a patient agreed to participate and provided written informed consent, he or she was scheduled to contact a research staff member for instructions regarding the process of downloading, authenticating, and using the app, as well as other pertinent information, including receiving manuals and explanations for the accelerometer. Moreover, patients were followed up 4 weeks after downloading the study app.

We also explained the delay of pharmacotherapy or surgical treatment for the 1 month of the study period so that we could perform pilot testing of the app's effect on weight changes. Patients received the equivalent of US $20 per visit as reimbursement. The study was approved by the Institutional Review Board of Seoul National University Bundang Hospital (B-1402-238-005).

Outcome Measures

The primary outcomes measured were the acceptability of our mobile app linked with an accelerometer and changes in the patient-doctor relationship after the intervention. We measured the usability of our mobile app linked with an accelerometer via a 5-point Likert scale by asking whether the users could easily follow every step without making errors and successfully complete all steps. We analyzed usage information of each module in our mobile app as follows. (1) mean number of log-ins per day: the mean number of log-ins to the mobile app per day during the study period, which represented how often a participant used the app in a day, (2) use of each module: the number of clicks per specific module divided by the total number of clicks in the mobile app during the study period, which represented how often a participant used a specific module in this app, (3) mean exercise calories per week: the mean exercise calories per week was recorded by an accelerometer during the study period, which represented the actual exercise activities recorded by an accelerometer in a week, (4) mean percentage of weekly exercise goals achieved: the mean percentage of actual exercise calories divided by suggested exercise goals per week, which represented the amount of exercise a participant achieved in a week, (5) total numbers of messages posted on the social network services: the numbers of messages, including replies participants posted on the social network services, which represented how frequently a participant used the social network services.

We evaluated the patient-doctor relationship by the scores of the Patient-Doctor Depth-of-Relationship Scale [40]. This scale is an 8-item self-completed questionnaire for measuring 4 elements: knowledge, trust, loyalty, and respect. The survey instrument has good reported reliability (Cronbach alpha=.93).

The secondary outcomes were changes in weight and abdominal circumferences from before to after the study. A research nurse measured these when patients visited the clinic.

Protecting Patient Privacy and Security When Using the Mobile App

According to the Personal Information Protection Act in Korea, unique identifiers, social security numbers, and bioinformation should be safely encrypted when they are intended to be transferred via a network or subsidiary storage devices. In our mobile app, we stored all individual information on the internal server, where a firewall was installed to block unauthorized access. We also incorporated an additional layer of authentication using an email address and a password.

Statistical Analysis

We used descriptive statistics to summarize the baseline characteristics of the study participants. We analyzed the information on use for each functional category in our mobile app along with the proportion of patients who achieved their first month's target goal. For the acceptability tests, we present the percentages for each response. Changes in weight and abdominal circumferences were calculated using a paired *t* test, and changes in the patient-doctor relationship scales were tested using a Wilcoxon signed rank test. We performed all statistical analyses using Stata version 12.1 (StataCorp LP) and considered $P<.05$ to be statistically significant.

Results

Baseline Characteristics of Study Participants

A total of 30 individuals agreed to participate in the study. At 1 month, 93% (28/30) of participants completed their follow-up surveys. Although 2 participants used the mobile app for 1 month, they were unable to attend their 1-month follow-up visit. Among the 30 participants, 60% (18/30) were male. Participants had a mean age of 49.07 (SD 8.84) years and a mean BMI of 27.64 (SD 2.14) kg/m^2; 60% (18/30) of participants had dyslipidemia, 27% (8/30) had hypertension, and 10% (3/30) had diabetes mellitus. (Table 1)

Mobile App Use Information During the Intervention Period

All study participants used the mobile app at least once during the study period even if they did not complete the follow-up visits. Table 2 presents usage information.

Participants used the study app for a median of 1.21 log-ins per day with a maximum of 6.38 log-ins per day. The most frequently used module was goal setting (median 199 times, 74%), followed by tracking of physical activities (median 30 times, 13.5%) and viewing of personal health status (median 34.5 times, 10.8%).

Most study participants achieved more than their recommended exercise; the median percentage of target exercise goals achieved per week was 125.9%. The mean number of messages posted on the social network service was 1 during the entire study period, and only 6 patients used the social network service.

Usability of Mobile App After 1 Month of Intervention

With regard to the app's ease of use, participants reported a high rate of positive responses for the log-in process (25/28, 89%) and goal setting process (23/28, 82%), as presented in Table 3. However, the rate of positive responses for the message board was low, including posting (11/28, 39%) and replying (10/28, 36%) on the social network service. Additionally, the positive response rate for the educational videos was 46% (13/28).

Acceptability of the Mobile App and Patient-Doctor Relationship Scales

As Table 4 shows, regarding participants' satisfaction with each module of the mobile app, setting personal goals had the highest positive response rate, at 75% (21/28). Ratings of satisfaction with the monitoring and feedback on physical activities were also highly positive. However, satisfaction with the social network service, educational videos, problem solving in case of errors, and reliability of the contents was approximately 50% (14/28, 14/28, 15/28, and 15/28), which was low relative to other modules. Nonetheless, most users (26/28, 93%) responded positively to receiving help with managing weight from the mobile app. Specifically, 75% (21/28) of users were willing to recommend this app to their family or friends, and 79% (22/28) (expressed interest in continuing to use this app for weight management.

Scales measuring the depth of the patient-doctor relationship decreased during the 1-month period from 27.6 (SD 4.8) to 25.1 (SD 4.5) by a Wilcoxon signed rank test ($P=.02$).

After the 1-month study period, the mean weight change was –0.1 kg (95% CI –0.6 to 0.8) and we observed no significant changes. However, abdominal circumference was significantly reduced by a mean of –1.84 cm (95% CI –3.3 to –0.4) (see Multimedia Appendix 2).

Table 1. Baseline characteristics of study participants (n=30).

Variable	Result
Male, n (%)	18 (60.0)
Age in years, mean (SD)	49.07 (8.84)
Weight in kg, mean (SD)	76.82 (8.38)
Abdominal circumference in cm, mean (SD)	93.55 (4.92)
BMI[a] in kg/m^2, mean (SD)	27.64 (2.14)
Systolic blood pressure in mmHg, mean (SD)	111.07 (39.85)
Diastolic blood pressure in mmHg, mean (SD)	70.70 (25.40)
Fasting glucose in mg/dL, mean (SD)	86.87 (37.24)
Triglyceride in mg/dL, mean (SD)	121.90 (80.08)
HDL[b] cholesterol in mg/dL, mean (SD)	42.8 (20.17)
LDL[c] cholesterol in mg/dL, mean (SD)	102.97 (56.05)
Uric acid in mg/dL, mean (SD)	5.20 (2.59)
Hypertension, n (%)	8 (26.7)
Diabetes mellitus, n (%)	3 (10.0)
Dyslipidemia, n (%)	18 (60.0)
Ischemic heart disease, n (%)	1 (3.3)
Cerebrovascular disease (n, %)	1 (3.3)
Gastroesophageal reflux disease, n (%)	7 (23.3)
Obstructive sleep apnea, n (%)	5 (16.7)

[a]BMI: body mass index.

[b]HDL: high-density lipoprotein.

[c]LDL: low-density lipoprotein.

Table 2. Study participants' use of each module of the mobile app for weight management in the clinic (n=30).

Aspect of use	Minimum	25th percentile	Median	Mean	75th |percentile	Maximum
Mean number of log-ins per day[a]	0.03	0.73	1.21	1.88	2.65	6.38
Numbers of clicks on each module, n (%) [b]						
Goal setting	24.0 (36.0)	151.0 (61.5)	199.0 (74.4)	217.13 (71.3)	290.0 (77.9)	549.0 (98.8)
My personal health status	1 (0.6)	21.0 (8.9)	34.50 (10.8)	40.83 (12.3)	52.0 (16.0)	136.0 (33.7)
Educational videos and nutritional information	0.0 (0)	2 (0.9)	5.5 (1.9)	6.6 (2.1)	10.0 (2.8)	19.0 (6.7)
Tracking my physical activities	1 (0.6)	20.0 (9.6)	30.0 (13.5)	55.7 (14.3)	69.0 (18.4)	285.0 (31.9)
Mean exercise calories per week[c]	46.0	1740.0	2575.0	2612.8	3211.5	7125.5
Mean percentage of weekly exercise goals achieved (%)[d]	3.4	87.9	125.9	141.1	167.1	601.7
Total numbers of messages posted on patient-doctor communication board	0	0	0	0.5	1	3
Total numbers of messages posted on social network service[e]	0	0	0	1	0	10

[a]The number of days that patients logged into the mobile app at least once during the study period.

[b]Usage rate of each module is calculated as the percentage of the number of clicks on each module divided by the total number of clicks on all mobile app menus during the study period.

[c]The mean calories expended in exercise per week recorded by the accelerometer during the study period.

[d]The mean percentage of actual exercise calories divided by suggested exercise goals per week.

[e]The numbers of messages including replies that participants posted on the social network service.

Table 3. Number of responses regarding usability of a mobile app for weight management in the clinic (n=28).

Aspect of usability	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Log-in process	7	18	1	1	1
Goal setting	6	17	3	1	1
My personal health status	3	15	9	1	0
Educational videos and nutritional information	1	12	11	3	1
Tracking my physical activities	4	13	10	1	0
Posting comments on social network	1	10	15	2	0
Replying to comments on social network	2	8	16	2	0
Sharing information regarding physical activities through social network	3	11	13	1	0
Ease of learning each function	2	17	8	1	0

Table 4. Number of responses regarding acceptability of a mobile app for weight management in the clinic (n=28).

Aspect of acceptability	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Satisfaction					
Goal setting	4	17	6	1	0
Educational videos	1	13	12	2	0
Nutritional information	3	13	12	0	0
Social network service	3	11	13	1	0
Tracking physical activities	7	13	7	0	1
Feedback on physical activities	6	14	5	2	1
Contents in mobile app	8	13	7	0	0
Convenience in using mobile app	5	15	8	0	0
Integration of each function	2	13	11	2	0
Font size and styles	4	15	8	1	0
Response to problems with using the app	2	13	12	1	0
Reliability of contents	3	12	13	0	0
Helpfulness in managing weight	9	17	2	0	0
Likelihood of recommending this app to family or friends	7	14	7	0	0
Continuous use	10	12	5	1	0

Discussion

To our knowledge, this was the first study to test the usability and acceptability of a mobile app linked with an accelerometer for a clinic-based weight loss program, and was also the first to evaluate such an app's early effect on the patient-doctor relationship. Most participants used our mobile app during the 1-month study period, and the goal setting function with self-monitoring of physical activities linked with an accelerometer was the most frequently used module. As this was a pilot study for the purpose of further improving our mobile app, we focused on the usability and acceptability of our app, as well as on the preliminary findings concerning the patient-doctor relationship.

Development of a Mobile App Linked With an Accelerometer for a Clinic-Based Weight Management Program

In contrast with many other weight loss apps that target the general population as a health and fitness tool, our mobile app was targeted to the population that participates in a clinic-based weight management program. Our choice of target population was based on several factors that are particular to hospital settings.

Numerous different phenotypic presentations [41,42] and risks that affect obesity-related mortality have been noted [43], even within the same BMI. Therefore, recognizing obesity-related comorbidities and functional status is essential for treatment planning, as well as for prescribing exercise or nutrition. These evaluations are typically possible only in a clinic or hospital setting with a multidisciplinary health care team. Hence, management of weight loss should not only target weight loss itself but also aim at controlling obesity-related health problems. Consequently, a commercially available weight loss app cannot deliver tailored information to each patient. We attempted to incorporate medical information from EHRs to deliver the appropriate information to each patient in need via tailored education videos and nutritional information. Moreover, bariatric surgery continues to be the most effective method for initiating significant improvement in obesity-related comorbidities [44,45], and the need for multidisciplinary weight management is increasing in hospital settings for both pre- and postoperational care. Therefore, mobile technology can contribute to a precise assessment of obesity-related comorbidities, thereby enhancing the medical and surgical treatments.

Given that informed, active patients, or patients who have the motivation, knowledge, skill, and confidence, play a large role in improving their own health outcomes [46], as well as reducing health care costs [47], our mobile app could have potential use as a tool for supporting patient activation in hospitals by providing tailored education along with self-management skills.

A mobile app linked with an accelerometer could be a good resource for clinicians for monitoring patient behaviors or physiological signals. In addition, if such information is recognized and used during a clinic or hospital visit, high-quality doctor-patient exchanges both inside and outside of the office visit can be achieved, which could favorably influence patients' behavior and attitude [24].

Although our study did not use EHR-linked personal health records, our methods can be applied to incorporating them in chronic disease management, where patients require constant care and regular follow-ups.

Usability and Acceptability of the Mobile App

Based on app usage data, the most frequently used module was goal setting, as well as the monitoring of and feedback on physical activities, which was concordant with the subjective satisfaction measures reported in the questionnaires. The median number of log-ins per day was 1.2, and all participants used our app over the course of the 1-month intervention period. Furthermore, participants achieved more than their suggested activity amount. We linked an accelerometer to our mobile app automatically, which potentially contributed to its frequent use and the successful achievements within our app. The self-regulation function was the main feature of our program, and participants evaluated this feature as the most comfortable and helpful through both objective and subjective measurements. These results were consistent with other studies [48,49], which further validates the benefit of mobile health apps in increasing physical activity. This increase may also result in a reduction in the abdominal circumferences of study participants by the end of the study period.

Conversely, we only provided nutritional guidelines that matched with the metabolic profiles of each participant, and we did not track nutrition, which may have affected the weight loss outcomes. Although abdominal circumferences were reduced by a mean of -1.84 cm during the study period, we noted no weight change. Research has demonstrated that frequent recording of dietary intake can contribute to weight loss [50]. However, recording food intake has been the most laborious and challenging work in mobile phone apps or websites for weight loss [51]. Healthy diet education via a mobile app did not affect weight loss. However, eliminating the food diary, which is time consuming, might also lead to a low attrition rate for mobile apps. Furthermore, a food recording function that is user friendly and less time consuming is necessary for achieving desirable outcome in a clinic-based weight loss program.

The satisfaction rate was low for the personalized mobile education module. We attempted to provide the study participants with tailored educational videos. Most participants did not download the educational videos from an Android operating system even if they received instructions on how to download the videos. The size of each educational video was between 31.8 and 52.4 MB. Therefore, the process of downloading and viewing educational videos may have been too difficult or too time consuming, or patients may have simply been in an area with no Internet or network connection.

Moreover, only a few participants used the social network service. Although social networking has been used extensively in intervention approaches, including those targeted at weight loss, no clear effect of social networking on weight change has been reported in randomized controlled trials [52]. However, participants received more encouragement from the community in many weight loss intervention programs that used social network services [52]. The low usage of this module combined with low satisfaction among our study participants may be attributed to several factors. The patients were all new users to our social network service, and no one had adequate experience to act as a facilitator. They study intervention period was only 1 month long, hindering the formation of a strong support group. Given the age and sex of our study participants, patients might not have been exposed to online social networking in general. The contents of the online networking in this study app might not have met participants' needs, or the usability might not have been optimal, which is important for both user engagement and behavioral change [53]. However, research into the theory and function of online social networking and its impact on health outcomes is still in early development, and more studies regarding the actual usability combined with the contextual factors of social networking are needed. According to a systematic review [54], most studies reported that online social networking in attempts to change health behavior had poor retention and engagement.

Patient-Doctor Relationship Scales

Our mobile app had a unique feature: an interactive message board that was used to help patients share information with their doctors. However, according to the usage analysis, only a few participants used the interactive message board for communication. Family physicians in charge of patients left at least 2 messages for all participants under their care: 1 at the beginning of the study period to encourage behavioral change, and the other 2 weeks later to address questions about the weight loss program or process. Only 2 patients sent messages to their doctors: 1 pertained to how to take care of high blood pressure measured at home, and the other pertained to medication for controlling diabetes. Doctors replied to the participant's question via the message board, but the participants were informed that the doctor's reply may be instant or provided at the time of their scheduled session. Such misinformation may have inhibited the participants from using the interactive message board.

In our study, scales measuring the depth of the patient-doctor relationship decreased during the 1-month study period. This effect could reflect several aspects related to using the mobile app in a clinical setting. First, the doctor's passive participation in the app, particularly in the interaction with a patient, might have been a factor in the decreased depth in the patient-doctor relationship. Second, the doctor's encouragement or feedback regarding app usage might not have been recognized during the clinic visit, or the doctor's feedback might not have been sufficiently positive. According to one survey regarding information technology and its impact on doctor-patient communication [55], panelists, including both medical professionals and patient advocates, expected improvement in the relationship. However, the lack of acceptance by doctors and issues of data security and monetary costs were regarded as barriers. Third, patient-doctor relationship scales might not adequately reflect short-term changes. Patient-doctor relationship scales were designed to measure the quality of the relationship in the context of continuity of care, whereas our study period was only 1 month. Fourth, empowering patients with self-management skills could make the patient-doctor relationship more complicated, and this phenomenon could have a negative effect on the short-term patient-doctor relationship if a doctor did not exhibit a supportive attitude toward using the apps. Moreover, cultural aspects of the relationship between a patient and his or her doctor in Korea may have played a role in preventing any improvement [56].

Study Limitations

This study had several limitations. It was a pilot study of a single group that used a pre-post intervention design, which only demonstrated the possibilities for further improvement and clarification of the app's design and treatment functions. The research was performed in 1 clinic for a limited time using a small number of participants, which may not reflect the diverse population of patients with weight problems. We attempted to implement the function of self-monitoring of physical activity by synchronizing the accelerometer with the app, but LG LifeGram has not published its validity test, which might affect the usage pattern for this study app.

However, to our knowledge, this study is one of the first to demonstrate the usability and acceptability of a mobile app linked with an accelerometer for a clinic-based weight loss program and its potential impact on the doctor-patient relationship. The mean age of the study participants was 49.07 years, which is generally older than other mobile app studies [30,57] with a greater proportion being male participants. This finding could potentially indicate that these were less-active users for a mobile weight loss app. However, all participants used the mobile app during the study period, achieved their suggested physical activity goals, and reported a high rate of satisfaction with the self-regulation function. One study [58] suggested that men would be willing to use Web-based self-monitoring tools delivered by mobile phones if interventions were easy, quick, and simple to use but showed little interest in using the social networking service. Our study results confirm these observations to some degree. Further studies identifying a mediating effect of age and sex will be needed to deliver a tailored intervention through a mobile app.

This mobile app has the potential for furthering improvements in achieving weight loss if it includes more strategies for reaching dietary goals, improvements in pattern monitoring and stress management techniques [59], and improvements in its structure, ease of use, personalized features, and accessibility in technology and design [60]. Further studies with a larger representative population and longer duration are needed.

Conclusions

In this study, we evaluated a mobile app linked with an accelerometer for a clinic-based weight loss program. Mobile health apps have the potential to be integrated into a clinic-based weight management program by empowering patients with self-regulation tools that enhance physical activity.

An easier method for recording daily food intake should be incorporated into the mobile app for better weight loss outcomes. Further reflection of the user's needs with regard to the online social network and the patient-doctor relationship should also be considered.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

The educational video for angina pectoris.

[MP4 File (MP4 Video), 43MB - mhealth_v4i1e24_app1.mp4]

Multimedia Appendix 2

Changes in weight and abdominal circumference after a 1-month intervention.

[PDF File (Adobe PDF File), 29KB - mhealth_v4i1e24_app2.pdf]

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Abbreviations

BMI: body mass index
EHR: electronic health records

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Original Paper

Preferred Tone of Nutrition Text Messages for Young Adults: Focus Group Testing

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Abstract

Background: Young adults are a particularly hard to reach group using conventional health promotion practices as they do not see nutrition messages as personally relevant to them. Text messaging (short message service, SMS) offers an innovative approach to reaching young adults to support and promote dietary behavior change.

Objective: The aim of this study was to develop and test tonal preferences for nutrition text messages among young adults using focus groups.

Methods: A total of 39 young adults aged 18-30 years residing in Perth, Western Australia participated in four focus groups. Participants briefly discussed their perception of healthy eating and their responses to messages about increasing fruit and vegetables, and reducing “junk food” and alcohol intake. They ranked their preference for 15 nutrition messages across 3 dietary behaviors (fruit and vegetables, junk food, and alcohol) with 5 different message tones (authoritative, empathetic, generation Y, solutions, and substitutions) and identified the messages most likely to persuade young adults to change their diet. A 5-point ranking of the nutrition messages was from the most likely to least likely to persuade (1-5). The focus groups were conducted by a trained facilitator and observer and were recorded. Data driven content analysis was used to explore themes. Tonal preferences and potential motivators were collated and frequencies presented.

Results: Participants ranked offering substitutes (29%, 11/39) and using empathy (22%, 9/39) as the most persuasive message techniques in improving diets of young adults, with low responses for Generation Y (17%, 7/39), solutions (17%, 7/39), and authoritative (15%, 6/39) tones. Females were more likely to consider substitution messages persuasive (35%, 7/20) compared with males (22%, 4/19). A greater proportion of males compared with females considered authoritative messages persuasive: (22%, 4/19) compared with (7%, 1/20). There is a strong preference for a substitution tone for fruit and vegetable messages (52%, 20/39), and no overall message tone preference for junk food and alcohol messages. Substitutions were viewed as helpful and practical. Empathy was liked as it acknowledged previous efforts. Responses to authoritative tone were mixed with some feeling guilt while others found them informative. Acceptability of the solutions depended on the behavioral change and acceptability

of the solution proposed. Generation Y tone had some support for junk food and alcohol messages, and if favored, was considered casual, humorous, catchy, and motivational.

Conclusions: Substitutions and tone of empathy were favored as the most likely execution styles to motivate nutrition behavior change across all participants. There is no "one size fits all" with different tones preferred by individuals for different dietary behaviors. Although text messaging provides instant message delivery direct to the individual, these results demonstrate the complexity of developing motivational nutrition message for young adults. These findings reveal the importance of considering the tone and content and pretesting messages for health promotion text message interventions.

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KEYWORDS

text messages; tone of voice; nutrition messages; fruit; vegetable; junk food; alcohol; communication

Introduction

Dietary guidelines established from scientific evidence provide credible and reliable nutrition information for health professionals and policy makers to underpin nutrition interventions [1,2]. Public health nutrition priorities include encouraging populations to increase their fruit and vegetable intake, decrease their energy dense nutrient poor (EDNP) food and beverage intake, and reduce alcohol consumption [3,4]. The challenge is how to translate this complex information into messages that consumers find relevant. Health authorities have embraced social media tools, such as text messaging (short message service, SMS), to expand the reach of health communications, foster engagement, and increase access to credible, science-based health messages [5,6]. Message development, implementation, and evaluation should be viewed as central to any campaign designed to influence health behavior [7]. Message persuasiveness is related to the source of the message, recipient characteristics, and context as well as the particular desired outcome (eg, attitude, intention or behavior) [8].

Commercial companies, public sector bodies, and charities use a brand "Tone of Voice" (ToV) in their communications to engage people with messages regarding their products and services [9]. The ToV conveys the nature of the brand personality in a way that is accessible and liked by consumers, for example, a friendly or official tone. The strength of the message recipients' impression of the brand can be related to message expressions describing feelings or actions that are used to engage the audience and are largely based on recipients taking action. Companies strive for distinct brand values developed through linguistics; for example warm, expert, and friendly. However, other than through sales and awareness, little is known about the impact of message ToV on the message recipient in terms of health behavior change. The impact of the message ToV for the specific target audience is important because it can vary and evoke differing responses [8].

Young adults are a particularly hard to reach group using conventional health promotion practices as they do not see nutrition messages as personally relevant to them and may be less likely to take notice of conventional health promotion approaches [10]. Text messaging may better engage young adults; however, the messages need to be short and to the point, with 140-160 characters the recommended message length [5]. The advantage of text messaging is that it is delivered directly to the individual and is likely to be read within minutes of receiving [6]. To date, health-related text messages have been used in physical activity, weight loss, and smoking interventions [11-16] but have not been fully evaluated in population-based approaches in nutrition [17]. Text messaging interventions to encourage better nutrition have the potential as a cost-effective rapid communication method with high population reach.

Achieving the correct tone, content, and length of messages for text message delivery is challenging and the complexity of message development needs to be considered [18]. A criticism of physical activity text messaging interventions is that the majority of studies failed to provide information on how the text messages were developed [15]. Prior to conducting a text messaging intervention, important steps are needed to carefully construct the messages and undertake pretesting to avoid potential unintended effects [14].

Young adults aged 18-30 years were the target for the Connecting Health and Technology (CHAT) randomized controlled trial (RCT) to improve nutrition behaviors using mobile devices and tailored text messaging in young adults, desribed in full elsewhere [19]. In brief, young adults were the target as they had particularly poor intakes of fruit and vegetables, a high intake of energy dense nutrient poor food, and an excessive alcohol intake due to binge drinking. There was some evidence of misconceptions relating to what constituted a healthy diet among young adults and at the time, little was known about the best approach to motivate dietary change in this group. The mobile phone application for dietary intake measurement addressed issues of respondent burden and increased engagement in this traditionally hard-to-reach population who are high users of mobile phones. The ultimate goal of the CHAT RCT was to deliver messages that were persuasive and motivated dietary behavior change. The objective of this study was to develop and test tonal preferences for short nutrition messages among young adults using focus groups as formative evaluation for the CHAT RCT.

Methods

Participants

Young adults aged 18-30 years were recruited through social media (Facebook), emails sent to workplaces, and snowballing techniques in October to December 2010. They were invited to take part in a 90 minute focus group discussion about food and eating at an advertising agency in an accessible central

metropolitan location. Those responding to the advertisements were screened for eligibility and booked into a focus group. Exclusion criteria were focus group participation in the previous 6 months and studying or working in advertising, marketing or health-related industries. After conducting four focus groups, the facilitator and observer assessed that no new information was emerging. Focus groups were segmented by gender and age (18-22 years, 23-30 years) to facilitate discussion and identify any gender and age group differences as well as to minimize social desirability bias. All participants received written information about the study and signed individual consent forms. The Curtin University Human Ethics Committee approved the study.

Message Development

Short motivational messages were developed by the investigators, who are accredited practicing dietitians and health promotion experts, to persuade behavioral changes in 3 areas (to *increase* fruit and vegetable consumption and to *decrease* alcohol and EDNP [or junk food] intake). Each message was 2-3 sentences long to make it suitable for delivery via a text message. Next, an advertising agency copywriter applied 5 different tonal executions to each of the 3 areas based on ToV approaches used in commercial advertising. The 5 tonal executions were authoritative, substitution, solution, empathetic, and generation Y (Gen Y). Table 1 provides an explanation of each ToV. The number of messages was limited to 15 as this was the maximum number that time would permit for in-depth discussion during the focus groups. The 15 final "test" messages applied the 5 ToV approaches to a message to increase fruit and vegetables, reduce junk food, and reduce alcohol intake. These final messages were ranked by participants on their potential to motivate behavioral change. Tone and content preferences were explored through focus group discussions.

Table 1. Definitions used for five different tonal executions of messages explored in the focus groups.

Five tone of voice	Definition
Authoritative	An all-knowing nutrition expert, telling them what and what not to do with educational reasoning
Empathetic	Sympathetic tone that says you understand the struggles and indulgences they have and are just trying to be informative and helpful
Gen Y engaging	Speaking in their language using peer-to-peer slang, as if you are their best buddy telling them cool news or insights on a personal one-to-one level to develop affinity with the subject
Solutions based	Providing tips and ideas to encourage them to eat more healthy food, by showing them how
Substitution based	Tips and ideas or showing how to choose a healthier option (swap, don't stop)

Focus Groups

The investigators prepared focus group outlines to test general influences on diet, preferred ToV and content for text messages. A female facilitator and male observer with extensive advertising experience moderated the focus groups. The investigators had no contact with participants other than during screening and observed the focus groups from another room via a video screen. Focus groups were held in the evening to enable those working to attend. All groups were audiotaped with participants informed that they were being observed and recorded. The facilitators explained the research aims and informed the participants that the investigators were planning to use text messaging to motivate people to change their diet. The discussion started with broad questions about what participants thought people their age ate, their motivations for food choices, and what would make them change their food choice. This first set of questions is referred to as general influencers of food choice and message preference in the results section.

To assess message tone, each participant was asked to rank their preference regarding the persuasiveness of 5 messages in each of the 3 nutrition behavioral change areas. For each behavioral change area, they were provided with the message in the 5 tonal executions resulting in a list of the 15 messages as shown in Table 2. The facilitator then handed out the list of messages in the 5 different ToV. Participants individually ranked the 5 tonal messages according to their potential to persuade young adults to change their diets from 1 (favorite) to 5 (least favored) for each behavior change area. An in-depth discussion about the messages took place following the ranking. The preference for words or phrases used in the messages and suggestions for alternatives were noted during focus groups.

Table 2. Focus group participants rating of behavior change persuasiveness of tonal messages, n=39.

Nutrition behavior change area	Tone of voice	Message and abbreviation	Rated as most likely to persuade change (%)
Fruit and vegetables	Authoritative	You need lots of fruit and vegetables to stay healthy. If you're not getting 2 serves of fruit and 5 serves of veg every day, you are just not looking after yourself. (FVAut)	11
	Empathetic	Two fruit and five veg every day sounds like hard work, but when you get into it, you'll find it's easy. You'll be less likely to snack on junk, and you'll feel great! (FVE)	21
	Gen Y	Fruit and veg make awesome healthy snacks, and they stop you craving nasty fatty stuff. The guys in white coats reckon 2 serves of fruit and 5 serves of veg every day is the go. (FVGY)	5
	Solution	Do a daily fruit and veg shop, and you'll never go without. You'll always have something healthy to whip up in the kitchen, and you'll eat less junk. (FVSol)	11
	Substitution	It's not hard to work in more fruit and veg every day. Swap fruit for other snacks, roast veggies for chips, and have a fruit salad for breakfast. (FVSub)	52
Junk food	Authoritative	Junk food is high fat, salt, and sugar and low in nutrition. So avoid it. (JFAut)	10
	Empathetic	We're all tempted by a "quick-fix" of junk food now and again. You really should be strong and say NO! (JFE)	23
	Gen Y	It's called junk food coz it's no good for you! It's all bad. You know you feel better if you leave it alone.(JFGY)	18
	Solution	Make sure you've always got a few days' fresh food in the house. You won't get caught out and end up eating junk food if you're prepared for a healthy diet.(JFSol)	28
	Substitution	There's always a tasty alternative to junk food. Swap an apple for a piece of cake, veggies for chips, have salads for snacks, and a yummy sanger instead of that burger.(JFSub)	21
Alcohol	Authoritative	Not only is alcohol full of useless energy that can make you fat, it is harmful even in the smallest amounts. Listen to the health experts and avoid alcohol, or if you insist on drinking, limit your intake.(AAut)	23
	Empathetic	Most people like a drink now and again, but unfortunately alcohol is a killer when it comes to weight gain. Try and remember the empty calories when someone offers you a drink.(AE)	21
	Gen Y	You booze-you lose. Unfortunately not weight though. Alcohol is packed with totally pointless calories. It's also pretty damn bad for you.(AGY)	28
	Solution	If you're trying to maintain a healthy weight drop the drink. Alcohol is deceptively fattening. Drink less and try and acquire a taste for mineral water!(ASol)	13
	Substitution	Alcohol is full of pointless calories so slow down when you go out. Drink less and swap alcoholic drinks for mineral water or juice.(ASub)	15

Data Analysis

The audio recordings were transcribed and combined with the observers' detailed notes. Themes were identified in accordance with the method described by Owen [20]. Data-driven content analysis was used to explore the findings with 3 researchers identifying themes independently. The investigators and facilitators reviewed the responses and confirmed the main themes and specific phrases that demonstrated them. Quantitative data on tonal preference ranking were collated and frequencies reported. For the purpose of reporting, each topic area was given an abbreviation code relating to the message content: Junk Food (JF); Fruit and Vegetables (FV); and Alcohol (A); Authoritative (Aut); Substitution (S); Solution (Sol); Empathetic (E); and Generation Y (GY). The abbreviation for the message and the tone were combined to assist the reader in identifying individual messages by tone, eg, the authoritative fruit and vegetable message is (FVA). A list of abbreviations is given in Table 3.

Table 3. List of message tone abbreviations.

Abbreviation	Description
FVAut	Fruit and vegetable authoritative
FVE	Fruit and vegetable empathetic
FVGY	Fruit and vegetable Gen Y
FVSol	Fruit and vegetable solution
FVSub	Fruit and vegetable substitution
JFAut	Junk food authoritative
JFE	Junk food empathetic
JFGY	Junk food Gen Y
JFSol	Junk food solution
JFSub	Junk food substitution
AAut	Alcohol authoritative
AE	Alcohol empathetic
AGY	Alcohol Gen Y
ASol	Alcohol solution
ASub	Alcohol substitution

Results

Participants

Four focus groups were conducted with a total sample of 39 participants (19 males and 20 females). Each group comprised 9 or 10 participants. Participant characteristics are shown in Table 4. The majority were in paid employment and had either completed or were enrolled in tertiary studies. The results are presented in four sections: the first section was a general discussion on influencers on food choices and text messages to promote nutrition; the second section provides a short summary of the ranking of likelihood for message tone to motivate change, shown in Table 5; the third, presentation of the major themes regarding response to the tone and potential influence of each message; and the last section is the summary of preferences for words and phrases, Table 6; and final messages developed for the intervention, Table 6.

Table 4. Characteristics of young adults participating in focus group sessions.

Demographics		n (%)
Gender		
	Males	19 (%)
	Females	20 (%)
Employment status		
	Not working/unemployed	3 (7.7)
	Working	26 (66.7)
	Student	10 (25.6)
Level of education		
	Completed secondary school or less	9 (23.1)
	Completed university (or currently completing)	30 (76.9)
Household income		
	≤US $60,000 per annum	7 (17.9)
	≥ US $60,000 per annum	32 (82.1)
Sample		
	Sample total	n=39
	Mean age in years (SD)	23.2 (2.9)

Section 1: General Influencers of Food Choice and Message Preference

Convenience, Price, and Feelings

When discussing general influences on young adults' food choices, convenience, price, and feeling or emotions were mentioned as the main influencers. Convenience was important as participants described competing demands on their time. The struggle to fit in both work and study left limited time to prepare food. Healthier food was also considered more expensive than junk food.

> *...Unhealthy fast food is a lot cheaper than the healthy food I like, I could go for a salad, but it's probably quicker and cheaper to buy something junky.*

Feelings influenced food choice; it just depends on how they feel on that day and what they want to eat. There was a general view that message credibility depended on who delivered the communication, with government health departments and nongovernment health organizations (eg, Cancer Council or Heart Foundation) considered credible sources of nutrition information. Most participants were aware of health recommendations regarding alcohol, fruit and vegetables, and body weight. Specific action communications, (eg, "avoid weight gain, avoid junk food") and those with additional explanation were favored. The issue of alcohol intake and weight gain was particularly salient for younger women but only a few men.

Unrealistic Alcohol Recommendations, but Want to Know More

Alcohol drinkers viewed current alcohol recommendations as unrealistic for their lifestyle "When you go out to drink you drink a lot more." The motivators for drinking were considered very different than those described in the messages, "All of these miss the point, we don't drink for nutrition." and "it's fun, makes you feel good or better." Social norms and peer pressure were seen as the main barriers to cutting down on alcohol consumption, "drinking is normal–socially impressive."

Identifying motivators to change drinking habits was challenging but "feeling ill the next day" appeared to resonate overall as did the use of memorable slogans, and health statistics highlighting the consequences of drinking too much. Many were interested in the long term harm associated with excessive alcohol intake.

Text Messages Mode Appreciated, but Length and Tone Important

Delivering messages via a text was appreciated, but the timing and tone was important, (eg, "common knowledge but good to have in this form"). Some messages were "too long" and "preachy" but agreed the content was true. Tone was also important, "sounds like a message from mum". Message timing was considered crucial to curb junk food intake, (eg, "If it comes too late you will have already bought the junk food").

Tonal Preferences

Across the board participants ranked offering substitutes (29%, 11/39) and using empathy (22%, 9/39) as the most persuasive message techniques in improving diets of young adults, with low responses for Gen Y (17%, 7/39), solutions (17%, 7/39), and authoritative (15%, 6/39) tones. Females were more likely to consider substitution messages persuasive (35%, 7/20) compared with males (22%, 4/19). Also, a greater proportion of males (22%, 4/19) compared with females (7%, 1/20) considered authoritative messages persuasive.

Table 5 shows that there was no clear overall tonal preference across all messages with the exception of the substitution ToV which was ranked as most likely to motivate change in fruit and vegetables by 52% of participants. The preferred tone for junk food and alcohol messages were more diverse, 28% chose the solution tone for junk food and the same proportion chose Gen Y for alcohol messages. The main themes emerging from the focus group discussions on message feedback are reported by ToV with examples relating to the specific messages identified with the abbreviations shown in Table 3.

Authoritative Tone

Condescending yet Provoking, a Good Reminder and Informative

There were mixed reactions to the authoritative messages. Some considered them condescending, boring or even offensive, provoking feelings of guilt or a defensive response. Yet most said they were informative and made them listen. The intensity of reaction to the authoritative tone depended on the nutrition message.

The authoritative FVAut message reinforced known health authority messages and was viewed as "Positive" and an effective reminder "Makes you want to eat 2 fruit and 5 veg." For others, FVAut was considered strong but informative "A bit harsh. It is needed but it can also offend" or "True, makes you think I guess". Some had the same opinion for authoritative alcohol AAut, "Good info but might offend people".

Junk Food Tone Strong

For some, junk food, authoritative JFAut was stating the obvious but not necessarily effective, "We know this but it doesn't stop us." For others it was "straight to the point", "informative" or as having "shock value" reminding them about how bad junk food was. The "so avoid it" wording was effective and led some participants to ask for some clarification and more information about the health consequences, "Being told to eat less is a powerful message" and "The first sentence is effective but should finish with an outcome, eg, Prolonged use will cause…[what?]".

Alcohol Tone Offensive yet Informative

Some responded negatively to the AAut message, "Feels like someone is telling you off, I would ignore this one.", and clarity was needed by some "Does it want us to stop or limit?" A common view was that although the message might make people realize that alcohol was not good for them, it would not stop them drinking but may help limit their intake, "If it said limit their intake then I would be more inclined to adhere to it." There was poor knowledge and disbelief about the harmful health effects of drinking alcohol and some participants requested more medical information. One participant defended the benefits of

"some" alcohol, "Even the smallest amount? People would argue about red wine."

Men particularly viewed AAut as reliable and persuasive. The comprehensiveness of the messages and the content resonated, "Gives you the whole picture," particularly for alcohol and weight gain, as some men did not know the connection, "Can make you fat? Strong message." There was a general caution that "Recognize that people will always drink, but give a reason to cut down."

Substitution Tone

Helpful and Practical if Equivalent Substitutions

The substitution tone was generally seen as helpful and practical, particularly when there were specific examples given. There was a preference for "easy" and "simple." And substitutions needed to be equivalent in terms of time, effort required, and cost, "Alternatives are okay but take more effort." Fruit and vegetables FVSub were well-received and accepted, "helpful, give specific ideas, seems achievable."

Some participants were just grateful to be reminded of alternative options in the JFSub message, "Tasty alternative gives us hope that we can still enjoy food." Others said the substitutions themselves were not acceptable, plausible or appropriate, "Offering ideas makes me consider them. But apples for cake? Need viable options." And the notion that healthier food could be tasty was not acceptable for some, "Not true! In many cases the healthy option is far less tasty."

The effort required for substitution needed to be equivalent to resonate, "You can have an apple, cake or burger, but salads are too much effort for a snack."

Alcohol Substitution Realistic, but Say Limit Not Stop

The alcohol substitution tone message ASub was appreciated as it was viewed as a realistic reminder to "limit intake" or strive for "moderation" rather than "stopping" drinking. Although most reacted favorably to the substitution tone, one woman said "while this statement is encouraging it is quite negative, makes me feel defensive."

Men were likely to perceive the tone as appropriate but the content unreasonable, particularly the suitability of replacing alcohol with nonalcoholic beverage, "Do not ever offer me a mineral water instead of alcohol!" and there was a suggestion to consider the reasons for drinking, "A better vibe it still doesn't address the reasons are drinking."

Empathetic Tone

Empathy Resonates If It Acknowledged Previous Attempts

The empathetic tone was liked because it was achievable, true, about feelings, and not too forceful. All groups indicated that they liked being acknowledged, encouraged, and supported for their efforts. However, the relevance of the acknowledgement was important. For example, for fruit and vegetables FVE, "I like how it emphasizes feeling good, not just an unseen long-term health goals."

JFE was seen as provoking and effective, "It challenges you not to follow the crowd" and "If I got this message, I would think twice about what I was eating." The use of the capitalized word "NO!" in text gave a feeling of external support, "The capitalization of the word NO! is good as it motivates us to be strong." and "Will make me think twice, feels like I have someone with me." Others wanted a substitute suggestion rather than just a straight out NO!

Acknowledgment and recognition of previous attempt was appreciated, "Appeals to my conscience, I find myself in this position where I typically give in."

Saying "Stop" to Junk Food Provoked a Defensive Reaction

Some reacted negatively to the JFE because they were already trying to cut down and thought it meant "never" to eat junk food and some defended the right to eat junk food, while some saw it as patronizing, "People can't be strong all the time, I don't like them saying every now and again." and defended the right to have junk food, "There's no harm in having junk food occasionally" or "Don't tell me what to do."

Thought Provoking but Not a Motivator for Alcohol

There was a general feeling that the empathetic alcohol message AE also needed substitutions. The factual content made it thought provoking and a good reminder, but not necessarily a motivator, "Gets me thinking about what I drink but probably wouldn't stop me."

Although many responded to the reference to losing weight, the "empty calorie" reference was difficult to understand and weight gain was not what people thought about when drinking, "Weight gain would stop me drinking as much." Males aged over 25 years said people think about exercise not calories, "I wouldn't decline drink due to calories."

Solutions Tone

Acceptability

The solutions message tone acceptability was dependent on the behavior change proposed. The fruit and vegetables FVSol message was considered unrealistic, impractical, effortful, and costly, particularly the shopping, "Daily is unrealistic, weekly is better."

Realistic and Helpful for Junk Food

The junk food solution JFSol was considered realistic, salient, practical, helpful, and good advice. It was liked because they encouraged preplanning meals with laziness, business, and forgetfulness the reasons given for not being prepared. Participants identified with message scenario, "I do get caught out. This one speaks to me." The distinction was made between solutions and authoritative tones, "More of a healthy tip than an order."

Should Encourage "Slowing Down" Not Stop Drinking

Participants were divided on the appropriateness of the alcohol solution ASol message, some people liked the mineral water substitution, but others, mostly men, thought it was boring or inappropriate. "Slowing down" rather than stopping was

preferred as an appropriate solution, "Good, encourage slowing down, not completely stopping."

Focus on "Maintaining" Not "Gaining or Losing" Weight

The "deceptively fattening" terminology motivated some women to think twice about drinking alcohol or to choose mineral water, but not so for men. The subtle orientation to weight status in the ASol message was acknowledged, "I like to focus on maintaining a healthy weight rather than not gaining or losing weight."

The Food or Alcohol Calorie Trade-Off

More information was requested regarding alcohol solutions (eg, how the caloric content of alcohol compares to other junk food). Some men considered ASol interesting, effective, and providing good options while others did not like it. There also appeared to be a trade-off between eating healthy and alcohol intake, "If you are already trying to eat healthy then you don't need to worry about this."

"Gen Y" Tone

Either Friendly and Informal or Belittling

The Gen Y tone was considered least persuasive for fruit and vegetables FVGY, but had reasonable support for junk food and alcohol messages (Table 2). Depending on the behavior targeted, the Gen Y tone was seen as casual, friendly, humorous, catchy, and motivational with good ideas that made people stop and think. Some cautioned that Gen Y messages were at risk of trying too hard to be funny, being too colloquial and patronizing, particularly the reference to the white coat in the FVGY, "Belittling, feel I'm five years old!" Although the least favored tone to motivate fruit and vegetable intake, FVGY was valued as the "Use of informal tone stops it from sounding preachy."

Either Defensive or Appreciative for Junk Food

Participants said the motivators for eating junk food were different to those for eating fruit and vegetables and there was a feeling that the JFGY was taking away small pleasures, "I don't always feel bad and I don't enjoy having to watch everything I eat" and "It [this message] takes the fun out of life."

Some reacted negatively to the junk food JGY as they thought it was telling them how they felt or what to do, "I didn't like you telling me how I feel" or "I feel like I have been smacked like a child. I would prefer to be spoken to on an adult level." The discussion led to expressions of the need for freedom of choice, "While this is true it doesn't really hit home, junk food is a personal choice."

Even though the JFGY message tone was thought to be strong, "Strong message telling me not to, straight to the point" many liked it as they related to and believed it, "We do feel better when we leave it and eat healthy foods" and "We all know the TRUTH here, you do feel worse after junk!" Others wanted more information as they thought the recommendation to eat less junk food only related to people who need to lose weight, "Why is it bad? Not specific enough."

Junk Food and Alcohol Gen Y Tone Strong but Resonated for Some

The directive message content for alcohol AGY was liked by some, "Nice and blunt" and "Like the reminder a friend would give" and others found it a "little rude" and were put off. It was seen by some as patronizing, "Sounds too much like it's trying to imitate teenagers." There were gender differences to the message, "You booze you lose is great!" or "I like it, it uses a well-known statement and adds a twist" from women whereas, "Stupid and misses the point" from males.

Wording Preferences Across All Messages

Throughout the focus group discussions wording preferences and recommendations for incorporation into text messages for young adults were recorded, Table 5 presents the summary. The messages were then revised for use in a text messaging intervention and are outlined in Table 6 [19].

Table 5. Language suggested and preferred for nutrition messages by young adult focus group participants.

Language preferences	Fruit and vegetable	Junk food	Alcohol
Generally liked phrases	You need lots of fruit and vegetables to stay healthy	High fat, sugar and salt	Swap alcohol for juice
	Looking after yourself	We're all tempted	Drink less
	You'll find it's easy	Quick fix	Alcohol is deceptively fattening—drink less
	You'll feel great!	You really should be strong and say NO!	Limit your intake
	Healthy snacks	You know you'll feel better if you…	Most people like a drink now and again
	It's not hard	A few days' fresh food in the house	Alcohol is a killer
	Swap roast veggies for chips	You're prepared	You booze you lose
	Have a fruit salad for breakfast	Salads for snacks	
Generally disliked phrases	If you're not getting…you are just not….	So avoid it	Useless energy
	Awesome	Coz	Pointless calories
	Nasty fatty stuff	It's all bad	Empty calories
	The guys in white coats	Leave it alone	Health experts
	Daily	Make sure	If you insist on drinking…
		Always	…Offers you a drink
		Swap an apple for a piece of cake	drop the drink
		Swap vegges for chips	...Swap alcohol for mineral water

Discussion

General Influences

Participants described their food choices as being influenced by the following factors: the competing demands of work and study commitments leading to a desire for quick and convenient meals; the high cost of healthy food; and their feelings or emotions.

In terms of message content, they liked being acknowledged for steps already taken to improve their diet and did not like being asked to make unreasonable changes. Although there was awareness of, and in some cases disregard for, existing health recommendations and messages, there was a strong interest in the health consequences of dietary choices, particularly for excess alcohol and junk food consumption. Overall there was a preference for short, informative, and direct nutrition messages.

Substitution Techniques and Empathetic Tone Favored Overall

Overall the technique of substitution and tone of empathy were favored as the most likely execution styles to motivate nutrition behavior change. Females were more likely to rate substitution messages persuasive compared to males; however, they disliked message content that implied restriction or failed to acknowledge previous attempts to change behavior. Males were more likely than females to favor the authoritative messages although it was not because of their tone but due to the rational reasoning within the message content. Positive, supportive or directive message tones appeared to be preferred overall. This is consistent with previous research which highlights the importance of message framing and that positively framed messages were generally favored [18,21].

Message communication research suggests that message persuasion potential is related to the message source, context, and the particular desired outcome [8]. This research found that there were differences in the preference for message techniques depending on the sought after nutrition behavior.

Table 6. Revised message for mobile phone intervention based on the findings of focus group with young adults.

Nutrition behavior change area	Target audience	Message
Fruit and vegetables	All	When you're hungry you want to grab the closest thing in the fridge, so make sure it's something healthy. Just cook up a bulk meal with veggies and freeze it. Something healthy ready when you are.
	All	Fitting veggies into your day can seem tricky, but why not just add some frozen peas or corn to your meal! It's easy.
	All	Veggies can taste great if you know how to cook them. Try a quick and easy…
	All	Buying loads of veggies is great, but they're not much use at the back of your fridge. Check out some of our quick, easy recipes that'll get them out of your fridge and onto your plate.
	All	It's easy to reach for unhealthy snacks when you're hungry, but fruit makes great, quick snacks too. Keep some handy for when those hunger pangs hit.
Junk food	All	When you're hungry, you need food now! But grabbing the nearest bit of junk food won't do you any favors. Take a few minutes to find a tasty wrap or salad sandwich and you'll feel much better.
	All	There's never time to make lunch when you're running late, and eating out often means eating junk. But a chicken salad or a fresh deli sandwich can be quick and healthy.
	All	If you haven't sorted out your lunch for the day, healthy food is harder to find. So try planning ahead and pre-making something simple the night before to grab on your way out the door.
	All	We're all tempted by fast food, even though we know it's bad for us. If you can't say no completely, just drop the chips or choose the meal with salad.
	All	One minute you want junk food but the next you wish you hadn't. Eat regular healthy snacks and keep the cravings at bay.
Alcohol	All	Everyone likes a few drinks with friends, but too much alcohol and you'll stack on the weight. So try and slow down your drinking.
	Women only	You've worked hard to fit into that party dress. But a (glass of wine has the same amount of kilojoules as a …). So try space your alcohol with water and keep looking great.
	Women only	Everyone deserves a fun night out. Just remember that alcohol's high in kilojoules. By slowing your drinking you're keeping in shape.
	Men only	Lots of people drink on the weekend, but drinking too often can make you feel slow and sluggish. Cutting out beers during the week is an easy way to feel more energetic.
	Men only	Every big drinker's done something they're embarrassed about. They might not remember it, but Facebook will. So try to slow down the drinking and space your drinks with water. It could save your reputation.
	Men only	Want to catch up with friends after work? Swap the pub for some sport. You'll burn off the kilojoules instead of drinking them.

Favored Tones Depended on Desired Behavior

Substitution was favored as the most persuasive message technique to encourage increasing fruit and vegetable intake. Messages for fruit and vegetables, known to the target group are likely to result in intention to comply [22,23]. The Department of Health in Western Australia, considered a credible and reliable information source, conducted high profile population based fruit and vegetable social marketing campaigns since 2000 [23]. When discussing the fruit and vegetable messages, the prescriptive *Go for 2&5* campaign message was often mentioned, confirming the high awareness of the recommendation reported elsewhere [23,24]. All communication executions for the *Go for 2&5* campaign were friendly, humorous, and a quirky, eg, advertisements with animated characters conducting cooking demonstrations offering quick and easy recipe suggestions and ideas [23]. The focus group discussions and message ranking showed preference for the communication style and ToV.

For junk food, offering solutions and empathic tone were favored as the most likely message techniques to encourage reduced intake. There was no clear message technique favored to reduce alcohol intake, in fact, the messages to limit or reduce intake did not appear to resonate. However, the discussions revealed that there was an interest in more specific information and statistics regarding longer-term health consequences and that the Gen Y and authoritative tones resonated.

There were gender preferences for ToV and message content for alcohol and weight control components. This finding is consistent with previous work that found obesity-related health messages may be perceived as stigmatizing and instilling less motivation to take action [22].

Alcohol and Junk Food Tones Offensive yet Informative

There was confusion about junk food and alcohol recommendations and a feeling that the current health authority advice was either too strict, aspirational or missed the point.

Participants were less certain of the negative impact, short or long-term, of consuming junk food or alcohol, and were interested in knowing more. The need for more information regarding the consequences of dietary change was a similar finding to formative evaluation undertaken for the *Go for 2&5* campaign, which found that young adults wanted to understand why they should eat more fruit and vegetables [24]. There appears to be a similar need for information to assist young people to make informed choices regarding junk food and alcohol.

Messages recommending action may need to explain why the action is important [5]. Prescriptive and/or descriptive information regarding recommended consumption and the health consequences of excessive intake of alcohol or junk food may be of value for young people, particularly as there was confusion about recommendations. Previous research suggests that information on the sugar content and potential health impacts of various beverages should be delivered in modes that are acceptable to young people [25]. The focus group discussions suggest that communications should focus on raising awareness and increasing knowledge and acceptance of the health risks of excessive junk food or alcohol consumption to change attitudes, possibly prior to any specific behavior change communication [7].

Individuals responded differently to message framing and content. Our current findings suggest that the empathetic tone would be most helpful when challenging young people to eat less junk food or limit drinking. Negative or defensive reactions to messages advising to limit or not consume alcohol or junk food were similar to previous Australian research testing text messages with obese adolescents [16]. Identifying and avoiding inferior or potentially counterproductive messages and tones may be as important as identifying the messages that are more likely to be effective. For many the advice was to frame alcohol and junk food messages to "limit" rather than "stop" and to focus on "maintaining" weight rather than "losing it". Participants wanted to know "why" to drink less alcohol, but at the same time did not like to be told to "stop" drinking alcohol or eating junk food all together with support to help resist the "temptation to eat junk food" or drink too much.

Inform and Suggest Appropriate Action to Engage

The message source, context, and personal relevance as well as the specific steps to changing dietary behavior were shown to be important. Overall, our findings are consistent with the CDC suggestions that in order to quickly engage the reader, messages need to be clear, give important information first, be action-based and easy to understand [5]. Personally relevant information is more systematically processed than less salient information, and attentive processing is required for effective health communications [10,26]. People are more likely to change their diets following personalized and specific nutrition messages [27,28]. This is evidenced by initial success in a mobile phone application providing automatic personalized messages to improve the user's nutrition and physical activity behavior [29]. It is likely that short factual nutrition text messages and quizzes would be well-received with this audience, as they were with teenagers in the United States [17].

Message Tone and Content Should be Tested for Each Behavior

Preference for message tone does not necessarily reflect its potential impact on attitudes or behavior as some of the least liked messages created the most interest, often a pre-requisites for behavior change [30]. The authoritative tone was the least liked but may be used to convey serious communications. Research suggests that over-simplifying plain language can be perceived as condescending by some consumer groups [9]. Although the Gen Y tonal messages were perceived as unusual, quirky, and fun by some, they were not viewed favorably by others. Social distance can be created or reduced based on language [9]. A conversational, informal position can come across as inauthentic and false, which appeared to be the case with the Gen Y ToV for some.

Message Tone and Content in Whole Diet Context

Dietary behavior changes are not made in isolation, eg, when trying to decrease junk food intake, it would be likely that nutritious snacks such as fruit might be suggested as an alternative. The young adults in this study wanted practical, realistic, convenient, and low cost suggestions to support their dietary change. This is consistent with previous Australian research which found that when attempting to influence health behavior, time scarcity was a stress associated with limited economic resources [31]. These current findings reinforce that there is not a "one size fits all" healthy eating message that would motivate change across the population. The appropriateness and preference for the message tone differed with the nutrition behavior being addressed, readiness to change, perceived barriers, gender specific differences and individuals within groups responded differently. There is unlikely to be one nutrition message suitable for the general population as these types of differences between individuals rarely disappear [32]. However, the warm and approachable empathetic tone of voice should be considered in communications challenging current nutrition behaviors [9].

Recommended Approach to Dietary Message Testing

The nutrition text message development was based on the framework for health campaigns proposed by Matterson et al as we (1) convened nutrition experts to agree on evidence that needs to be communicated; (2) convened health communication specialists to establish strategy and conduct formative research of message process; (3) implemented the findings; and (4) corrected the messages based on the outcomes for use in an intervention trial [7]. Table 6 presents the corrected messages which are to be used as part of a randomized controlled trial to improve eating behaviors via a mobile phone text messaging intervention [19].

The personal relevance of nutrition text messages influences their acceptability [5]. An unexpected finding was the similarity in opinions expressed between the genders, with the exception of discussion relating to alcohol messages or gender specific weight loss suggestions, for example about "fitting into that party dress". Further research is needed to explore and quantify gender specific responses to messages challenging alcohol and junk food intake and weight status.

The findings of this research were part of formative evaluation for an intervention specific to young adults residing in Perth, Western Australia. Therefore, caution would be needed when using these with other groups. A limitation of the current study is that the ToV message testing was only applied to 3 nutrition messages, 15 messages in total, as time did not permit further messages being assessed or discussed. The focus group methodology enabled in-depth discussion and responses to these 15 messages and the approach provided insights into audience reactions to the message tone, content, and external factors influencing behavior change. We recommend that further work is conducted to specific nutrition behaviors (eg, to reduce confectionary intake or take away food). The approach of using a combination of qualitative and quantitative research to test dietary messages before conducting an intervention was useful. We plan to further develop and test the messages in a text messaging intervention with a wider audience [20].

Conclusion

Text messaging communications deliver health messages direct to individuals with the challenge of delivering salient and persuasive nutrition message content in 2-3 sentences. This research provided insights into the appropriate message ToV and content for text messages to promote dietary change for young adults. The technique of substitution and tone of empathy were favored as the most likely execution styles to motivate nutrition behavior change. Message development research is important for effective interventions and public health practitioners need to pay close attention to how the message will be received by the recipient.

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Conflicts of Interest

None declared.

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Abbreviations

A: alcohol
Aut: authoritative
AAut: alcohol authoritative

AE: alcohol empathetic
AGY: alcohol Gen Y
ASol: alcohol food solution
ASub: alcohol food substitution
E: empathetic
EDNP: energy dense nutrient poor
FV: fruit and vegetables
FVAut: fruit and vegetable authoritative
FVE: fruit and vegetable empathetic
FVGY: fruit and vegetable Gen Y
FVSol: fruit and vegetable solution
FVSub: fruit and vegetable substitution
Gen Y: generation Y
GY: generation Y
JF: junk food
JFAut: junk food authoritative
JFE: junk food empathetic
JFGY: junk food Gen Y
JFSol: junk food solution
JFSub: junk food substitution
Sub: substitution
Sol: solution
ToV: tone of voice

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Original Paper

Unpacking the Black Box: A Formative Research Approach to the Development of Theory-Driven, Evidence-Based, and Culturally Safe Text Messages in Mobile Health Interventions

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Abstract

Background: Mobile-cellular subscriptions have increased steadily over the past decade. The accessibility of SMS messages over existing mobile networks is high and has almost universal availability even on older and unsophisticated mobile phones and in geographic settings where wireless coverage is weak. There is intensive exploration of this inexpensive mobile telecommunication technology to improve health services and promote behavior change among vulnerable populations. However, a neglected area of research is the documentation and critical analysis of the formative research process required in the development and refinement of effective SMS messages.

Objective: The objective of this qualitative research study was to identify major factors that may impact on the effectiveness of evidence-based SMS messages designed to reduce health inequities in hypertension management in low resource settings, including Aboriginal populations in high-income countries and rural populations in low-income countries. Specifically, we were interested in uncovering the range of mediators that impact on appropriate message content transmission and, ultimately, on health behavior improvements in a range of these sociocultural settings.

Methods: Collaborative qualitative research with Canadian Aboriginal and Tanzanian participants was conducted to deconstruct the content and transmission of evidence-based health information contained in SMS messages in the context of an international research project designed to address health inequalities in hypertension, and to develop a grounded theory of the major factors that mediate the effectiveness of this communication. We also examined the interrelationship of these mediators with the three essential conditions of the behavior system of the Behavioral Change Wheel model (capability, opportunity, and motivation) and cultural safety.

Results: Four focus groups with a total of 45 participants were conducted. Our grounded theory research revealed how discrepancies develop between the evidence-based text message created by researchers and the message received by the recipient in mobile health interventions. These discrepancies were primarily generated by six mediators of meaning in SMS messages: (1) negative or non-affirming framing of advocacies, (2) fear- or stress-inducing content, (3) oppressive or authoritarian content, (4) incongruity with cultural and traditional practices, (5) disconnect with the reality of the social determinants of health and the diversity of cultures within a population, and (6) lack of clarity and/or practicality of content. These 6 mediators of meaning provide the basis for sound strategies for message development because they impact directly on the target populations' capability, opportunity, and motivation for behavior change.

Conclusions: The quality of text messages impacts significantly on the effectiveness of a mobile health intervention. Our research underscores the urgent need for interventions to incorporate and evaluate the quality of SMS messages and to examine the mediators of meaning within each targeted cultural and demographic group. Reporting on this aspect of mobile health intervention research will allow researchers to move away from the current black box of SMS text message development, thus improving the transparency of the process as well as the quality of the outcomes.

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KEYWORDS

Aboriginal people; behavioral change wheel; cultural safety; grounded theory; mobile phone; semiotics; SMS; Tanzania; text messages

Introduction

Mobile-cellular subscriptions have increased steadily over the past decade with current subscription rates ranging from 69.3 per 100 inhabitants in the African region to 140.6 per 100 inhabitants in Communist Independent States [1]. The accessibility of SMS (short message service) over existing mobile networks is high. It has almost universal availability even on older and unsophisticated mobile phones and in geographic settings where wireless coverage is weak. The high penetration of SMS texting in low- and high-resource settings has resulted in intensive exploration of this inexpensive mobile telecommunication technology as a promising application in interventions to improve health services and promote behavior change among vulnerable populations [2]. Other attractive features of text messaging for health interventions include the potential for scalability of an intervention, option to tailor messages based on age, gender, and ethnicity of a target group, and ability to send time sensitive information [3].

SMS-based health intervention messages delivered to personal mobile phones have been applied to disease prevention interventions, disease treatment interventions, disease surveillance, and to track adherence [4]. Systematic reviews have found that SMS messages can positively impact on personal health behaviors including diabetes self-management, weight loss, physical activity, smoking cessation, medication adherence for antiretroviral therapy, as well as on chronic disease management and prevention in low- and middle-income countries (LMIC) by addressing access, coverage, and equity gaps in low resource settings. Much of the current research has focused on the effectiveness of mobile health interventions as a whole with respect to behavior change and clinical outcomes, but more research is required on the unique characteristics and components of interventions [5-8].

The SMS message development process in particular is a component that is commonly hidden within a black box, lacking deconstruction of the steps involved in creating messages as well as rigorous evaluations of the quality of the health communication messages. Based on their review of the literature on SMS interventions, Fitts Willoughby and Furberg conclude that text message development and pretesting should follow best practices similar to those used for health communication messages delivered through other channels like mass media [9]. They further stress that pretesting should be conducted with the target audiences and that the associated findings should be reported.

Lim and colleagues have also emphasized the need for quality, rigor, careful development and evaluation of these brief messages [10]. After careful crafting of the messages, they argue that pretesting of the messages is necessary to ensure that they are relevant and have the expected impact on the target population. Gurman and coworkers agree that the pretesting of messages should be a priority in order to understand the needs of the target audience [2]. Accordingly, published formative research has already demonstrated audience preferences for specific types of messages such as positive, encouraging, practical and concise messages [11,12].

Clearly, a neglected area in the published literature is the documentation and critical analysis of the formative research process required in the development and refinement of messages [13]. To improve future research and program implementation, this research should be accessible for scientific scrutiny, including a description of the development of the SMS content, the theoretical basis of the messages, cultural adaptation to the target population and context along with an analysis of how the content is received by users [14]. Ideally, reporting should include a rationale for the chosen theory of behavioral change, the quality of the evidence on which the messages are based, as well as the fit of the messages within the culture and context of the targeted groups [15].

We address this gap in the literature by reporting on our research process on the development and refinement of SMS messages for an international research project designed to address health inequalities in hypertension entitled DREAM-GLOBAL (Diagnosing hypeRtension - Engaging Action and Management

in Getting LOwer Bp in Aboriginal and LMIC). In the DREAM-GLOBAL study, SMS messages are designed to impart evidence-based health knowledge related to hypertension management in patients in culturally and geographically diverse, low resource environments, including diverse, rural and remote Aboriginal communities in Canada and rural communities in northern Tanzania.

The objective was to conduct qualitative research to identify major factors that may impact on the effectiveness of evidence-based SMS messages designed to reduce health inequities in hypertension management in low resource settings, including Aboriginal populations in high-income countries and subsistence farmers in low-income countries. Specifically, we were interested in uncovering sociocultural factors that mediate effective communication of content, influence behavioral responses, and ultimately impact on health behavior changes in these settings.

This paper describes the formative research process applied in DREAM-GLOBAL to develop messages, their theoretical grounding, and the sociocultural mediators that had to be considered to ensure optimal effectiveness of the transmission of the content of messages and optimize their potential to encourage healthy behaviors.

Methods

The DREAM-GLOBAL project approach is defined by community-based participatory research (CBPR) principles that include a commitment to community collaboration in all phases of the research, acknowledging the value of practical knowledge, building on existing community strengths, and integrating research and knowledge exchange to address inequalities [16-17].

All communities participating in the DREAM-GLOBAL study were invited to participate in the formative research on the development of culturally safe SMS messages. As part of the CBPR approach, recruitment of participants in each community was led by community health staff who invited a representative group of community members with hypertension or at risk of hypertension and who had recently accessed services at the local clinics. Incentives included a luncheon and modest financial compensation to cover expenses such as travel and childcare.

The Aboriginal communities within Canada were culturally, linguistically and geographically diverse and included rural and remote locations. Testing the messages in each of the three Aboriginal communities was therefore deemed to be essential. In Tanzania only one community was able to participate at the time of the formative research, however the two communities participating in DREAM-GLOBAL were culturally, linguistically and geographically quite similar. This suggested to us that one focus group would be sufficient to represent the major views and attitudes that exist in the two communities. Member checking of the emerging themes with local Tanzanian research assistants confirmed that the emerging themes represented community attitudes and realities among the subsistence farmers and small business owners in both communities very well.

Drafting a Set of Evidence-Based Messages

As a starting point, the content of the messages was informed by the Canadian Hypertension Education Program [CHEP] clinical practice guidelines, which include healthy eating messages from the Dietary Approaches to Stop Hypertension [DASH] diet [18]. The comprehensive set of messages was created by clinician researchers (ST, KY, ZT) with excellent knowledge of the hypertension clinical practice guidelines and extensive dietetic counseling experience within the target population in Canada (ZT). The message content focused on both drug therapy and health behavior changes.

Shaping Evidence-Based Content Into Meaningful, Culturally Safe Text Messages

A process was designed (1) to develop a grounded theory of cultural and contextual factors that may mediate the effective transmission of the evidence-based content coded into SMS messages for target audiences in Canadian Aboriginal and Tanzanian partner communities [19]; and (2) to adjust the messages through dialogue until the content of the SMS text coded by researchers and the meaning received by the target audience was highly congruent based on the focus group discussion.

To achieve this, focus groups were conducted by experienced qualitative health researchers (MB, MM, ZT), audio recorded and transcribed verbatim. In each session, participants who had some knowledge and awareness of hypertension, were shown a total of approximately 50 text messages. In Canada, focus group discussions were conducted in English. In Tanzania, however, all messages were first translated into Swahili and then presented to community members. Focus group discussions were also translated from Swahili to English, and English to Swahili in real time with the help of two skilled translators. The transcripts were back-translated by an independent translator to ensure accuracy of the translated content prior to analysis.

We applied grounded theory to guide our analysis. Grounded theory is a qualitative research approach designed to produce new substantive theory grounded within the collected data instead of analyzing the data through a predetermined theoretical framework [20]. Grounded theory is therefore particularly useful when little is known about the studied phenomenon, as was the case in our study of the major factors that mediate the effectiveness of SMS health communication with Aboriginal people in Canada and Tanzanian villagers. NVivo 9 Qualitative Research Software was used to code the data. Consistent with grounded theory, coding categories were grounded in the focus group data instead of trying to force the data into preconceived theories or categories [20]. During early analysis, the emerging themes were formally discussed with Canadian and Tanzanian project staff and collaborators as a form of member checking to ensure research rigor and culturally relevant interpretation. Final focused code categories were developed through consensus between two of the researchers (LB, MM).

Theoretical Frameworks That Guided the Formative Research

The text messages in this project were developed for eventual application in diverse cultural environments. An important

question was whether or not the content of the evidence-based messages would be received by the target population as intended by the clinical researchers. We therefore explored text message construction from a semiotic perspective (ie, an analysis of how meanings are created) in order to improve our understanding of the meaning that participants would actively construct from the evidence-based hypertension management messages transmitted to them. During focus groups, we invited participants to discuss their interpretation of content of the message. This included their perception of potential positive and negative characteristics of each message based on their knowledge of the sociocultural realities and perspectives within their community.

In addition to exploring the meaning that participants created from the messages, we were also interested in how the communication of advice in each message would influence the message receiver's behavior. To conceptualize the basic conditions that influence behavioral change, we applied the behavioral change wheel (BCW) as our theoretical model to explain the relationship between the emerging themes in our qualitative research and health behaviors required for hypertension management [21]. Briefly, the BCW is a theory- and evidence-based tool designed to analyze the nature of health behaviors as well as the mechanisms, supports and policies required to bring about behavioral change. We focused on the 3 essential internal and external conditions of the behavior system necessary to bring about behavioral change in the BCW. These conditions are capability, opportunity, and motivation [21]. The qualitative researchers on this project integrated conversational prompts to inquire about the capability, opportunity, and motivation of community members to follow the advice provided by each of the messages. In focus group discussions, the terms capability, opportunity, and motivation were used consistently with descriptions used in the theoretical model of the BCW [21]:

> *Capability is defined as the individual's psychological and physical capacity to engage in the activity concerned. It includes having the necessary knowledge and skills.*
>
> *Opportunity is defined as all the factors that lie outside the individual that make the behavior possible or prompt it.*
>
> *Motivation is defined as all those brain processes that energize and direct behavior, not just goals and conscious decision-making. It includes habitual processes, emotional responding, as well as analytical decision-making.*

To explore these essential conditions from the participants' perspective, focus group facilitators invited a dialogue about (1) the participants' beliefs about the meaning of the health behavior messages (and if it matched or diverged from the scientific evidence), (2) how well participants perceived the behaviors suggested in the messages to be accepted within their community, and (3) if potential participants would have sufficient control over their circumstances and motivation to enact the suggested behavior.

In our discussions, we also explored the concept of cultural safety. Cultural safety encompasses reflection on social, political, and historical contexts to health care and an awareness that power relations need to be addressed to improve health and that science and medicine are laden with culture [22-23]. We invited focus group participants to explore these concepts in relationship to the suggested behaviors in the messages during the focus groups. This concept helped to expand our engagement with the concept of culture in DREAM-GLOBAL from a simplistic listing of cultural differences to an examination of social processes and actions that influence inequities in health.

Ethics

The study is based on community-based participatory research and had to be formally presented to, and approved by decision-making bodies in all participating communities through Village Council approvals in Tanzania and Band Council Resolutions in First Nations in Canada. The study protocol was reviewed by the following university and community-based research ethics review boards: The National Institute for Medical Research in Dar el Salaam, Tanzania (approved March 19, 2014); Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board, Kingston, Ontario (DMED-1603-13 approved June 21, 2013); Sunnybrook Health Sciences Centre Research Ethics Board, Toronto, Ontario (#182-2013, approved May 31, 2013); the Cree Board of Health and Social Services of James Bay, Ontario (approved September 11, 2013); Manitoulin Anishinaabek Research Review Committee (MARRC), Ontario (approved October 7, 2013).

Results

Four focus group sessions were conducted, with a total of 45 participants (see Table 1).

Table 1. Focus group sessions.

Focus group	Number of participants	Gender of participants	
		Female	Male
First Nation A	12	9	3
First Nation B	10	8	2
First Nation C	8	4	4
Tanzanian Village A	15	10	5
Total	45	31	14

Our qualitative analysis focused on the identification of major factors that may mediate the effectiveness of the transmission of the content of evidence-based health knowledge and therefore result in divergent or shared meaning between the sender (the researchers) and the recipient (the research participants) of messages. The focus group transcripts provided sufficient data to reach saturation of categories. The analysis revealed that the main categories of these mediators were discussed in the First Nations focus groups in Canada as well as in Tanzania, although some distinctions were noted within subthemes. The major thematic categories of the impact experienced by participants in response to messages are discussed below.

Feeling Persuasiveness in Positively Framed Advocacies

Participants in all focus groups repeatedly stressed that a positively framed message was more persuasive than negatively framed messages. Discussing a message that instructed patients to "keep taking their medication as instructed", one participant noted:

> *There's no positive (in this message). You need a positive first. Even though you are having a bad day (in terms of hypertension management), it should still be something in regards to saying well maybe you can do better. Say: hope you're having a good day. Have a good day and don't forget to take your pills. (The message needs to be) encouraging and positive.* [First Nation Community A]

For those messages where positive and negative aspects are discussed, such as the benefits of pharmacotherapy and the drawback of potential side effects, participants felt the order of the information is important:

> *Maybe reverse the message—talk about the benefits before you talk about the symptoms. Because you are putting the bad before the good, maybe you should put the good before the bad—people would respond a bit better.* [First Nation Community A]

Messages sent to participants in response to healthy blood pressure readings within the desired range were thought to best provide positive personal feedback such as "You are doing a good job of managing your blood pressure!" Participants perceived this kind of positive and affirming feedback as a key motivating factor:

> *This would encourage me. It would say "Something is working for me!"* [First Nation Community B]

Participants in Tanzania also stressed the importance of understanding the linguistic variations of the Swahili dialect in the region to avoid words with local negative connotations when crafting messages. This is particularly important when explaining side effects of medication.

> *Certain words might have a very negative connotation which was not intended, for example the word "dalili" means: "a negative effect… it will harm you". It also means "symptoms", but it has a very negative meaning. It is better to exchange it with "madhara" which means "mild effect".* [Tanzanian Village A]

Experiencing Incapacitation in Response to Fear- or Stress-Inducing Messages

Participants in all focus groups expressed the belief that life in their communities subjected them to a lot of stress because many day-to-day necessities were beyond their direct control. One message specifically designed to inform patients of the heart relaxing properties of medication was regarded with skepticism. A participant questioned how this medication could possibly work if patients still feel stress after taking their medication. This may be pointing to a more holistic view of health compared with western medicine, a view which closely links emotional discomfort such as stress with physical disease:

> *How can (the medication) make you more relaxed when you are always worried about something?* [First Nation Community C]

Participants also asked that care should be taken not to unduly alarm people with fear-based messages which would cause even more stress. For example, the phrasing of messages to act urgently on a high blood pressure reading prompted participants to caution that community members may not be able to act quickly due to a lack of access to services. Instructions to hurry may therefore be counterproductive:

> *It would scare me—"you have to hurry" (to have your blood pressure checked and managed)". I know it's a fact, they need to scare you. But if somebody's scared it will just freeze them up, (make them) panic.* [First Nation Community B]

Similarly, sternly worded warning messages about skipping medications were also perceived as stress-inducing. Instead, reminders were preferred:

> *If you get busy and you forget then this message gets you worried. It would flip me out. Better to say: "did you take your meds today?"* [First Nation Community C]

Furthermore, fear-inducing words like "bad outcomes" in English or "kapooza" in Swahili (a graphic description of stroke in the Swahili language) were also discouraged as participants believed it would simply scare people instead of encouraging positive health behaviors:

> *What about removing the word "bad" and just say "outcomes such as stroke". Everybody knows stroke is bad. It's too scary (otherwise).* [First Nation Community B]
>
> *Take the word" kapooza" out and put just "stroke"—everyone understands that (English) word because in the past there was no Swahili word for stroke.* [Tanzanian Village A]

Growing Resistance in Response to Oppressive or Authoritarian Messages

Historically, western medicine is a foreign medical system in the DREAM-GLOBAL target communities, who practiced their own forms of traditional medicine. In Canada in particular, where there is a history of colonialism and oppression of Aboriginal people, their traditions, and medical practices by the western government, we heard in discussion that

pharmacotherapies still symbolize this hegemony for some people.

> *It is really hard for the elders to understand why they have to take pills. They have a lot of qualms about pill taking. But some just take whatever they are told.* [First Nation Community C]

Others are not just apprehensive, but suspicious that the western medications are intended to be harmful. This fear was articulated to be related to the experience people or their family members had with the Indian Residential School (IRS) system throughout the Canadian colonial history. The IRS system was operating in Canada from 1831 to 1996 and has touched most Aboriginal families [24]. To attend IRS, Aboriginal children were often forcibly removed from their parents and subjected to harsh and often abusive treatment during their stays at the IRS [25]. This history is embodied in the explanation offered by one of the First Nations participants:

> *It is really hard for older people to accept medication; they are so set in their ways. Some never do adapt. They develop ideas, so and so is giving me those pills because they (non-Aboriginal people) want to kill me. They have things on their minds, their own views, (like) "If you try to scare me I will stop taking my pills.*" [First Nation Community C]

The oppressive relationship between the Canadian government and Aboriginal people has infiltrated many aspects of their daily life and is historically deeply intertwined with the medical system [25-26]. As a consequence, active resistance may become the response to instructions that are perceived as authoritarian:

> *Ask: "Did you take your medication?" instead of saying "Take your medication!"… Or send a simple reminder…It is less intrusive. Otherwise you are telling me what to do! But you can't tell me what to do. I am taking it when I am ready to do it…you get tired of listening to this [authoritarian approach from outsiders].* [First Nation Community C]

Although oppression was less of a discussion topic in Tanzania, this concept nevertheless emerged also in conversations with Tanzanian participants. For example, when participants reviewed the message 'keep taking your medication as you have been instructed!' the authoritarian tone was also challenged:

> *When you translate the word "instructed" (in this message), use the Swahili word "endelea". It means "keep on going (with this medication)". It feels more like a reminder. It is the most polite way of saying this. The direct translation of the word "instructed" is a word that is more of a command, which we are not using (in friendly conversation)…* [Tanzanian Village A]

Feeling Empowered by Messages That Build on Healthy Cultural and Traditional Practices

Just as important as staying away from authoritarian or oppressive messaging, participants suggested building on strengths within their culture whenever possible by reinforcing healthy cultural and traditional practices.

For example considering alternative flavorings for sodium, Tanzanian participants suggested that herbs were not used in their cooking but there were alternatives that could be considered:

> *We don't have other spices we can add. The alternatives to salt include: a sauce of pepper or tomato.* [Tanzanian Village A]

Aboriginal participants cautioned against blanket statements about the reduction of meat in their diet, as many of their diets were based on wild meats which are much lower in fat than meat from domesticated animals. Therefore suggesting increasing traditional meats compared with domesticated meat consumption was perceived as the better message.

> *Lean meat - what about moose meat? Moose meat is excellent. There's two Canada Food Guides—there's the Native Canada Food Guide. Part of that is moose meat—it has less fat. That is a traditional aspect.* [First Nation Community A]

Participants also stressed that some foods were not only part of traditional life but also an important food staple acquired through hunting; therefore a change in some food items may simply not be possible for people at this time due to food preferences and the prohibitively high cost of alternatives.

> *Don't change traditional meat eating patterns.* [First Nation Community B]
>
> *Don't say to avoid smoked foods. People eat that…We use smoked, we like smoked fish—that's our traditional food.* [First Nation Community B]

Physical activity was also discussed in its traditional form, such as "walking in the bush" to pick plants or hunt and participants explained that these traditional land-based activities could also be excellent for stress reduction. Others stressed the importance of incorporating messages encouraging traditional activities over modern Western concepts of fitness such as fitness center based workouts or fitness classes.

> *(Add) snowshoeing, canoeing, cross country skiing (to your physical activity messages).* [First Nation Community B]

Ability to Adopt Specific Health Behaviors Is Shaped by Local Social Determinants of Health

Participants in both countries stressed that the messages should be centered around local realities such as income, education and cultural norms: essentially those that make up the social determinants of health (SDOH). The need to consider the generally low income, barriers to access services and foods, and cultural preferences for food and exercise were particularly emphasized.

In many Aboriginal communities in Canada, fresh fruit and vegetables were described as simply not affordable and many varieties are therefore not realistic as food choices.

> *Not everybody eats fruit every day. They are too expensive for one thing.* [First Nation Community B]
>
> *I know a lot of poor people that use (Food Banks) and can't afford to buy bananas, apples and oranges.*

> *They eat meat and potatoes and peas and that's it.* [First Nation Community A]

The experience in Tanzania was quite similar to the Aboriginal experience:

> *We eat fruits—in season—but when they are not in season it is difficult.* [Tanzanian Village A]

Further, in Tanzania, participants advised not to send messages to reduce meat consumption because meat was very expensive and meat consumption was therefore already very low:

> *Don't say: "Reduce the amount of meat you eat per sitting." We don't normally eat a lot meat because we can't afford it. (1/2 kilo for the whole family).* [Tanzanian Village A]

In other cases, participants stressed to only use geographically relevant messages. For example for people living inland in rural Tanzanian villages, fresh fish is not affordable. Only salt cured fish can be purchased:

> *Change (the messages about fish) to avoid salty fish. None of the other (messages about the health benefits of fish) apply.* [Tanzanian Village A]

In Tanzania, exercise advice was also adapted to include only those that are culturally relevant.

> *Eliminate hiking, bicycling, swimming and fitness classes. Instead say: walking quickly, digging, chopping firewood when done regularly will help to reduce your blood pressure.* [Tanzanian Village A]

In Canada, the diversity of Aboriginal communities also required further tailoring of physical activities to ensure relevance to climate, access and affordability.

Health Literacy Is Supported by Pragmatic Messages That Fit the Local Context

In terms of phrasing, participants discussed that health messages would need to be clear and practical and describe easily actionable advice like "rinse your canned beans to remove extra sodium" instead of higher level information such as "for better heart health reduce sodium in your diet." The second message assumes that the patient has the correct health knowledge about hidden sodium in their diet, which may not be accurate.

Similar discussion ensued around practical tips for relaxation and stress reduction. In Canada participants requested clear instructions on techniques that stimulate relaxation and in Tanzania participants suggested an emic term to describe relaxation, which in that cultural context requires first a calm mind before the body can be relaxed:

> *Give examples, like: "try deep breathing" or "have you gone for a walk today?"* [First Nation Community A]
>
> *Change message to "try to have peace of mind to help control your high blood pressure".* [Tanzanian Village A]

Clarity was also requested for accessing health care providers for high blood pressure and what to do in the meantime as one is waiting to access services:

> *So where do you go when (your blood pressure) is high? ...what can you do for yourself so you don't have to go to the emergency room?* [First Nation Community C]

In some cases suggestions for particular designations to describe the health care providers were made to ensure community members would be clear on who the patient is to contact. In Tanzania, participants decided that a title was best:

> *No problem with the word "daktari". People take this to mean anyone at the clinic.* [Tanzanian Village A]

Clear and practical instructions were also sought for physical activity.

> *Add the kinds of exercise (recommended to improve blood pressure)—be specific.* [First Nation Community A]

Finally there was consistent emphasis that when the Indigenous languages are used, testing with the local population is required to ensure the appropriate dialect is employed as considerable variation exists in the meaning of some words or phrasing in different geographic areas. The discussion points demonstrate the importance of pragmatic content to enable participants to follow instructions and improve health behaviors.

Summary of Themes and Subthemes

Our research uncovered six main themes or factors that influence the level of congruence between the message content that researchers perceive to pass on to message recipients versus the message content that is actually perceived by message recipients. Based on these substantive theories, Table 2 provides operationalizing strategies for the development of text messages in order to optimize the congruence of the perceived message content between sender and recipient. These strategies are based on our analysis of themes and subthemes and their relevance to message development.

We then checked for alignment of the main themes and operationalizing strategies with the BCW essential conditions of behavioral change (ie, *capability*, *opportunity*, and *motivation)* in order to determine the fit of our findings with this theoretical model of behavioral change [21].

We found that each of the 6 main themes and their related operationalizing strategies are a close fit with one or more of the BCW`s three conditions of the behavior system. For example, positively framed messages appear to be acting on message recipients' motivation for behavioral change, whereas recognizing SDOH would impact on recipients' capability and opportunity for behavioral change. The relationship of the behavioral change conditions to each of the main themes is provided in Table 2.

Table 2. Main themes and operationalizing strategies for text message development.

Main strategies based on themes	Operationalizing strategies for message development based on sub-themes	Behavioral change wheel
Use positively framed advocacies, they are more persuasive; avoid negative or non-affirming framing of advocacies	Empower and ease stress by pointing to successes	Motivation
	Inspire	Motivation
	Show respect for receivers	Motivation
	Show compatibility with positive indigenous views of health as "living a good life"	Motivation
Avoid fear- or stress-inducing messages	Do not exacerbate people's stressful lives (eg, experience of low income or racism)	Motivation
Avoid oppressive or authoritarian messages	Show respect for autonomy: Authoritarian messages are perceived as lacking in respect; invoke historic distrust issues with colonial/medical system; and may cause defiant response	Motivation
	Provide healthy life style education message along with pharmacotherapy	Motivation
Build on healthy cultural and traditional practices whenever possible; avoid incongruity with cultural and traditional practices	Empower with a strengths-based approach to local culture	Capability, opportunity, motivation
	Show respect for culture	Capability, opportunity, motivation
Recognize social determinants of health as drivers of ability to adopt behaviors; avoid disconnect with the reality of social determinants of health and the diversity of cultures within a population	Consider cultural settings and cultural norms related to lifestyle	Capability, opportunity
	Understand affordability and accessibility of foods and medications	Capability, opportunity
	Consider access to providers and/or medications in the health care system	Capability, opportunity
Ensure pragmatic content within the local setting ; avoid lack of clarity and lack practicality of content	Preference for practical tips over higher level advice	Capability
	Avoid ambiguity in wording and assumptions	Capability
	Consider and check the local dialect in translation	Capability

Discussion

Framework for the Development of Culturally Safe Messages

Inherent in the development of SMS text messages for mobile health interventions is a collection of (often tacit) assumptions about the function of the text messages and in particular the way in which they may impact on health behaviors. Our research provides a detailed examination of the underlying behavioral theories and their mechanism of interaction with our constructed grounded theory to explain how the content and meaning of text messages is abstracted by the receivers. We found that the meaning received can differ significantly from the meaning perceived by the sender and as a result mediate the receiver's health behaviors in previously unanticipated ways.

Semiotic approaches to meaning help us understand how meaning is derived in communication beyond the meaning of simple text, through more abstract, tacitly embodied signs and symbols. These symbols may not be shared between the sender and the recipient. Lotman explores text as a meaning-generating mechanism from a semiotic perspective as follows:

> *...the everyday receiver of information is concerned with the content of the message...the text is treated as something not valuable, not in itself, but merely as a kind of packaging from which the topic of interest is extracted [27]*

The function of this process of information exchange in health communication then is to transfer the message in such a way that the thought and meaning envisioned by the sender (or researcher) matches the thought of the receiver (or participants) as they decode the message as much as possible. Lotman explains that:

> *the system works well if the message received by the addressee is wholly identical to the one dispatched by the addresser and it works badly if there are differences between texts. The differences are classed as errors [27]*

We applied Lotman's concepts to SMS message development in order to deconstruct how meaning is generated in text messages for health interventions such as DREAM-GLOBAL and to identify the point where errors are most likely to occur (see Figure 1). We postulated that the decoding stage can result in differences (or errors) if the factors that mediate the perspectives of the receivers during the decoding stage are poorly understood by the message creators.

Conversely then, these errors can be significantly reduced through rigorous research of the factors that mediate decoding and applying this knowledge in the encoding process. Major factors that mediated decoding and the creation of meaning among Aboriginal populations in Canada and rural populations in Tanzania based on our constructed grounded theory are illustrated in Figure 2. We have named these factors the Mediators of Meaning. Operationalizing strategies to apply the Mediators of Meaning in the encoding process (ie, the crafting of SMS messages) are provided in Table 2.

The significance of our grounded theory of mediators of meaning is further underscored by their fit and influence on the conditions of capability, opportunity and motivation which are essential to the creation of health behavior change according to the BCW. This finding is particularly significant as all mobile health interventions are arguably always designed to change one or more components in this behavior system. Figure 3 illustrates the behavioral conditions that are most impacted by each of the mediators of meaning identified in our research.

Figure 1. Generation of meaning from SMS messages in mobile health interventions.

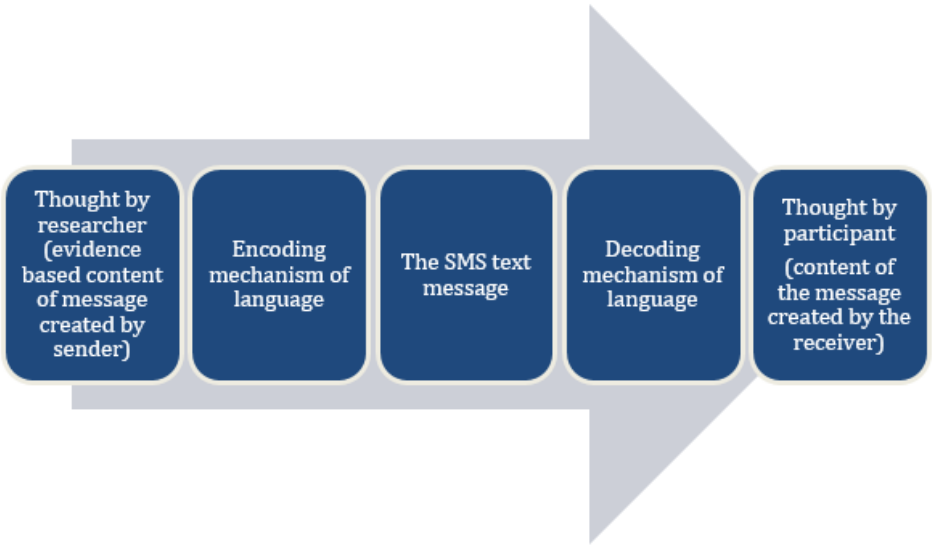


Figure 2. Grounded theory of mediators of meaning in text messages in mobile health interventions in Aboriginal communities in Canada and rural villages in Tanzania.

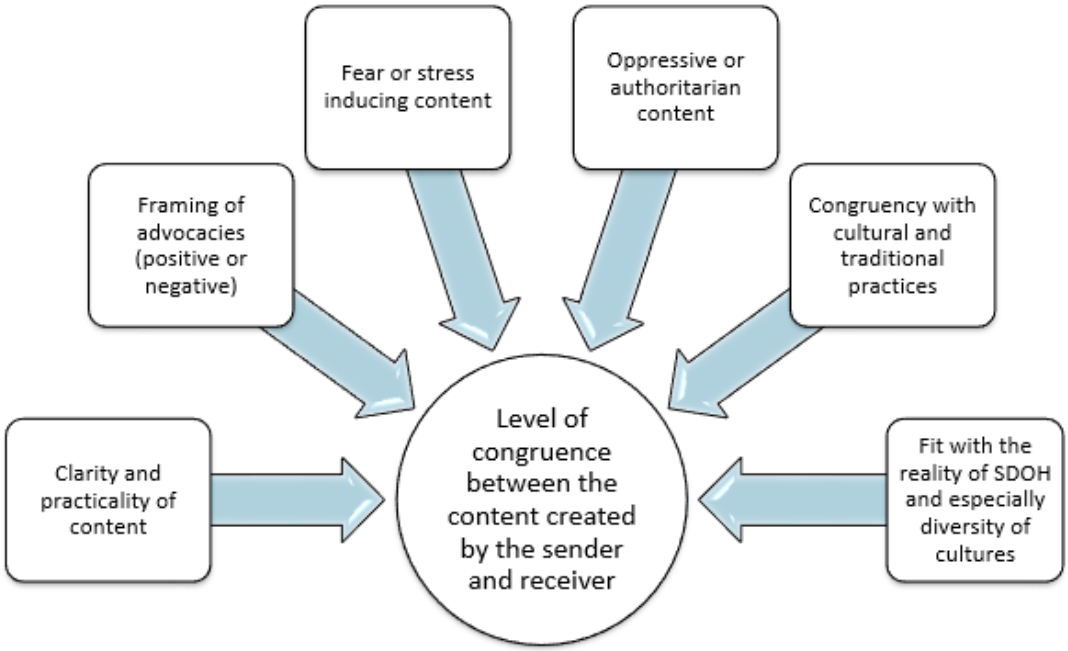
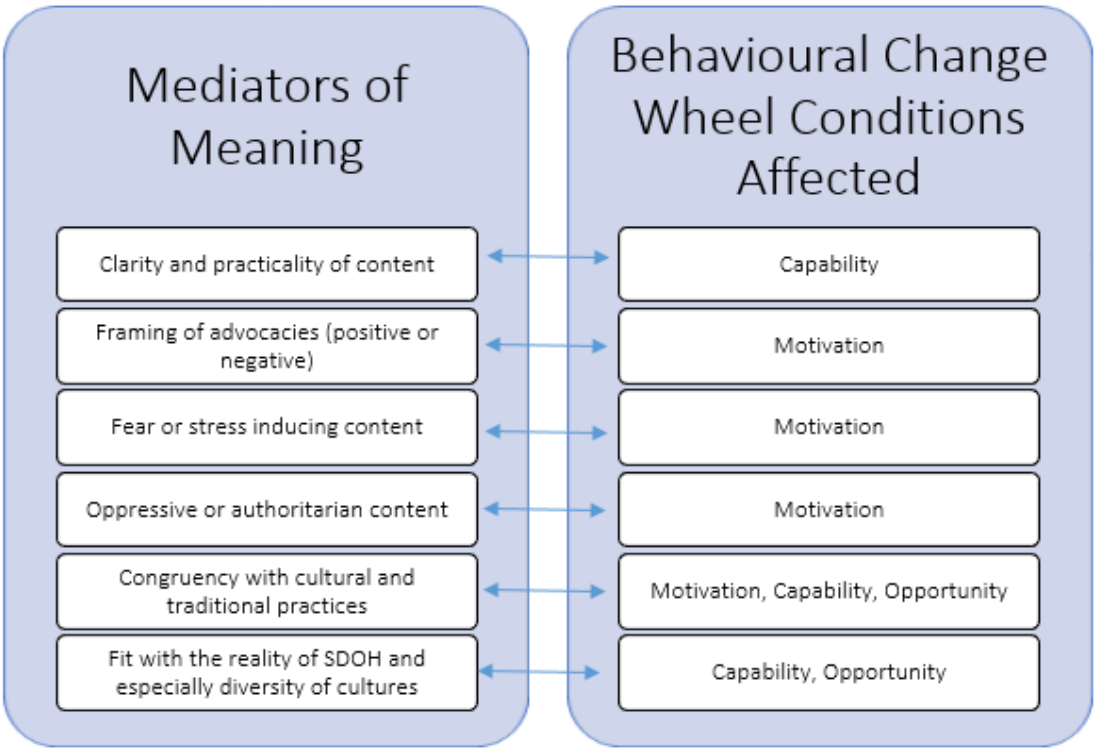


Figure 3. BCW conditions impacted by the mediators of meaning in SMS messages.



Implication of Our Research for the Development of Text Messages for Health Interventions

We created a formative research process to develop culturally-based and theory-driven text messages from a set of guidelines based SMS messages to support lifestyle and medication management for hypertension prevention and management. We employed a process that involved close collaboration and dialogue between researchers and representatives of the intended group of recipients of messages. This collaboration focused on developing congruency between the message content sent by the researchers and the message content received by the target population.

Our approach has gone beyond simplistic tailoring of messages to different cultural settings. It allowed us to unpack the hidden assumptions related to culture, health and the health system, and tacit explanatory models of hypertension with which health communication text might be laden. Instead, our methodology provided space for a dialogue between external experts with technical health knowledge and community experts with the lived experience understanding. This dialogue allowed us to draw conclusions about why and how culture and context mediate meaning and to explore the phenomenon of errors of meaning in the transmission of health messages. Our research approach was highly effective in the development of appropriate content and acceptable messages for hypertension management and prevention in diverse cultural settings. Based on our research, we are confident that our approach to the development of theory-driven, evidence-based, and culturally safe text messages in mobile health interventions could be adapted to other cultural and geographic environments and various health issues. Our approach can be used as a model to test and adapt text messages in diverse mobile health intervention projects within various cultural contexts. It can also be applied to health communication message development more generally.

Our constructed grounded theory of the six major mediators of meaning that impact directly on the conditions necessary for behavioral change have served as an effective framework for message development in four different settings where target populations face diverse economic, geographic and structural disparities. The congruence between these mediators and behavioral change theories (see Figure 3) is another indication of the potential applicability of these mediators as a guiding framework to the development of text messages in various mobile health interventions, particularly in low resource environments. The strategies outlined in Table 2 should therefore be considered and tested in the development of text messages in other mobile health interventions. To further substantiate our model, future research should also directly focus on how participants respond to text messages developed with this approach and consider further exploring gender as a mediator as part of the SDOH category.

Limitations

The SMS messages have been successfully implemented in six First Nations communities in Canada with positive informal feedback on the acceptability of the content from Aboriginal stakeholders during the currently ongoing process evaluation of the DREAM-GLOBAL pragmatic randomized controlled trial (RCT). However, the trial is still in its early implementation phase in Tanzania and conclusive data on retention or outcomes is not yet available. Additional formal evaluation research on

the effectiveness of our approach to optimize mediators of meaning in our SMS messages is required to further substantiate this model of formative research for mobile health interventions.

Conclusion

Our research shows how discrepancies develop between the message created by researchers and the message received by the recipient in mobile health interventions. In our grounded theory research involving Aboriginal people from Canada and rural villagers in Tanzania, the discrepancies between researchers and recipients were primarily generated by six mediators of meaning in SMS messages, including (1) negative or non-affirming framing of advocacies, (2) fear- or stress-inducing content, (3) oppressive or authoritarian content, (4) incongruity with cultural and traditional practices, (5) disconnect with the reality of the SDOH and especially the diversity of cultures within populations, and (6) lack clarity and/or practicality of content.

The six mediators of meaning provide the basis for sound strategies for message development because they impact directly on the necessary conditions of behavioral change of the BCW. These differences between the sent and received messages impact on behavioral changes by acting directly on capability, opportunity and motivation for behavioral change. This kind of critically-oriented formative research is necessary to develop messages that are not only evidence-based but also congruent with the target populations' capabilities, opportunities, and motivations, in order to optimize the necessary conditions for improvements in health behaviors. Outcome research after implementation of the intervention regarding the acceptability of the messages as perceived by users is needed to further substantiate our model.

Our research underscores the urgent need for mobile health interventions to incorporate and evaluate the quality of SMS messages and to examine the mediators of meaning within each cultural and demographic target group, because the quality of text messages impact significantly on the effectiveness of a text message-based health intervention. Reporting on formative research will improve the transparency in mobile health intervention research and allow researchers in the field to move away from the current black box of SMS text message development.

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Conflicts of Interest

None declared.

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Abbreviations

BCW: behavioral change wheel
CBPR: community-based participatory research
CHEP: Canadian Hypertension Education Program
DASH: dietary approaches to stop hypertension
DREAM-GLOBAL: Diagnosing hypeRtension - Engaging Action and Management in Getting LOwer Bp in Aboriginal and LMIC
IRS: Indian residential school
LMIC: low- and middle-income countries
RCT: randomized controlled trial
SDOH: social determinants of health
SMS: short message service

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Original Paper

Hypertension Health Promotion via Text Messaging at a Community Health Center in South Africa: A Mixed Methods Study

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Abstract

Background: The use of mobile phones to deliver health care (mHealth) is increasing in popularity due to the high prevalence of mobile phone penetration. This is seen in developing countries, where mHealth may be particularly useful in overcoming traditional access barriers. Non-communicable diseases may be particularly amenable to mHealth interventions, and hypertension is one with an escalating burden in the developing world.

Objective: The objective of this study was to test whether the dissemination of health information via a short message service (SMS) led to improvements in health knowledge and self-reported health-related behaviors.

Methods: A mixed methods study was carried out among a cohort of 223 hypertension clinic patients, in a resource-poor setting in Cape Town, South Africa, in 2012. Hypertensive outpatients were recruited at the clinic and administered a baseline questionnaire to establish existing knowledge of hypertension. Participants were then randomly assigned to intervention or control groups. The intervention group received 90 SMSes over a period of 17 weeks. Thereafter, the baseline questionnaire was readministered to both groups to gauge if any improvements in health knowledge had occurred. Those who received SMSes were asked additional questions about health-related behavior changes. A focus group was then conducted to obtain in-depth feedback about participants' experience with, and response to, the SMS campaign.

Results: No statistically significant changes in overall health knowledge were observed between the control and intervention groups. The intervention group had positive increases in self-reported behavior changes. These were reaffirmed by the focus groups, which also revealed a strong preference for the SMS campaign and the belief that the SMSes acted as a reminder to change, as opposed to providing new information.

Conclusions: Although the content of the SMSes was not new, and did not improve health knowledge, SMSes were effective in motivating positive self-reported behavior change among hypertensive patients.

Trial Registration: Pan African Clinical Trials Registry Number: PACTR201412000968462. Registered 18 December 2014 (Archived by WebCite at http://www.webcitation.org/6fhtyLRcO).

(JMIR mHealth uHealth 2016;4(1):e22) doi:10.2196/mhealth.4569

KEYWORDS

telemedicine; health knowledge, attitudes, practice; developing countries; hypertension

Introduction

mHealth, the use of mobile phones to support health care, is often seen to have great potential, as mobile technology has a high prevalence, with 6.8 billion subscriptions worldwide [1]. This extends to the developing world, with Africa having the fastest growing market for cell phone technology, and over 75% of the low-income South African population already owning, or having access to, a cell phone number [2]. mHealth can be implemented for a variety of health-related functions: to provide information, act as reminders of clinic visits, encourage behavior changes, and be actively used in symptom diagnoses and drug adherence checking [3][4][5]. However, there are few evaluations that thoroughly investigate the viability of the mHealth intervention, typically drawing on either quantitative or qualitative data, but not both. Furthermore, cost-effectiveness, context, and acceptability are still contentious issues, and therefore, even though strong potential exists, the viability of mHealth interventions in all situations is not clear and further investigation into such matters is still merited [6][7].

The use of mHealth interventions in the control and management of non-communicable diseases is relatively well established; however, there is a paucity of research on its viability from lower-middle-income countries [8]. Hypertension is one of the many non-communicable diseases on the rise in the developing world, including South Africa [9], where the prevalence is approximately 21% [10]. This can in part be attributed to increasing rates of rural-urban migration, as hypertension is relatively uncommon in rural South Africa [11]. It is further exacerbated by socioeconomic factors that encourage poor diet and sedentary lifestyles and contribute to low knowledge levels (both of risk factors and treatment) amongst the poorer urban population, which ultimately increases complications in hypertension [12]. Low knowledge levels in hypertensive patients are one of the key barriers to hypertensive care [13]. Furthermore, there is a particular demand for lifestyle modification information in South Africa [14], and treatment and control of non-communicable diseases are part of South Africa's National Development Plan [15].

mHealth interventions represent an opportunity to overcome the significant access barriers to health care seen in developing countries [16][17], due to the traditional socioeconomic and rural and urban divides [6], as well as an opportunity to address low knowledge levels and contribute to positive behavior change. According to social cognitive theory, short message service (SMS) interventions may be particularly good at increasing knowledge, as they allow for repeated learning, grant a high level of autonomous learning, and allow the learner to learn at their own pace and in a low-stress environment [18]. This paper therefore seeks to test whether the dissemination of health information via SMS leads to improvements in health knowledge and self-reported health-related behaviors amongst chronic hypertensive patients in a resource-poor setting.

Methods

An SMS campaign consisting of both knowledge and lifestyle information was designed. A mixed methods approach that employed a controlled clinical trial and a focus group evaluated the SMS campaign. The project was approved by the University of Cape Town's Health Sciences Faculty Human Research Ethics Committee (HREC REF 043/2011).

The details of this mixed methods approach are described below.

Recruitment and Study Setting

Participants (n=223) were recruited from a chronic hypertension outpatient clinic support club at a community health center in the Gugulethu township of Cape Town. Gugulethu is a densely populated poor urban settlement with 95.5% of dwellers speaking Xhosa as their mother tongue, 35% unemployment with an average yearly household income of US $3300 (2001), and the majority falling within an age range of 20-34 years [17]. Participants were assigned to experiment (n=109) or control groups (n=114) alternating in order of recruitment. To ensure informed consent, fieldworkers used an information sheet and consent form to brief participants about the project in their language of choice—either English or Xhosa. All participants signed consent forms both at recruitment and prior to the exit interview. The possibility of being in the control group was detailed for the participants in the consent form. The intervention group received the SMSes, and the control group received standard of care and no SMSes. All participant data were stored safely either in a locked cupboard or on a secure, password-protected cloud server.

Text Messaging

SMSes were designed in conjunction with health promoters and staff at the Gugulethu Community Health Centre, and reviewed by academics and clinicians from the Department of Family Medicine at the University of Cape Town. The SMSes were then translated from English into Xhosa (2 of the 3 official languages of the Western Cape, the provincial site of the study) and back translated to ensure that the meaning of the message was accurately preserved. A total of 90 SMSes were created and disseminated over 17 weeks (see Multimedia Appendix 1) and included 2 introductory SMSes and reminders of the option to opt out. Information in the SMSes covered knowledge of hypertension and healthy lifestyle suggestions. "Did you know" introduced the knowledge SMSes and "Health Tips," the lifestyle SMSes.

Knowledge and Self-Reported Behavior Change Assessment

Control and intervention arm participants were administered a preintervention multiple-choice questionnaire (26 questions). The questionnaire explored demographic profiles (7 questions) and baseline knowledge of symptoms, risk factors, health behavior, and how to control hypertension (19 questions) (see Multimedia Appendix 2).

After the intervention, the same questionnaire was administered to participants in both the control and intervention groups, with additional behavior-related questions administered to the intervention group (see Multimedia Appendix 3). The scoring was as follows: for the questions that had 1 correct answer, a score of 1 was assigned if the participant chose the correct answer, and a score of −1 if they chose the incorrect answer or

a score of 0 if they answered that they did not know. For the questions where participants could give more than 1 answer, the number of incorrect answers was subtracted from the number of correct answers. Further details on scoring are outlined in Multimedia Appendix 4.

Focus Group

In order to further explore the results from the questionnaire, 7 participants who received SMSes partook in a 2-hour focus group, held at the community health center. Participants were chosen at random and invited via phone call until a total of 10 had confirmed, although only 7 arrived on the day. The focus group was conducted by 1 investigator, observed by 1 research assistant, and recorded using a Dictaphone and note taking. A language translator was present at the focus group, allowing participants to communicate in the language of their choice. The topics explored knowledge change, the impact and efficacy of SMSes, and the relationship between SMS receival and behavior change, and are outlined in the focus group discussion guide (Multimedia Appendix 5). Recordings were transcribed and thematic analysis was carried out in consultation with the investigator's and researcher's notes.

Statistical Analysis

Fisher's exact tests were performed to determine statistical difference between the control and intervention groups for all questions, except for the questions that had multiple correct answers, in which case, 2 sample *t* tests were performed. Statistical significance was set at $p<.05$.

Results

Participants

In total, 224 participants were recruited (Figure 1). Of the 224 participants, 1 was a duplicate and 54 (24%) were lost to follow-up between baseline and exit interview (23 in the intervention arm and 31 in the control arm); a further 10 in the intervention arm were excluded from analysis for reporting receiving fewer than half the SMSes or being accidentally interviewed in duplicate and giving conflicting answers; while 13 were excluded in the control arm as they reported erroneously receiving SMSes at the exit interview.

The mean age of the cohort was 52.83 years, with a standard deviation of 11.62 years and a range between 26.81 and 85.73 years. Most participants (108/146, 74.0%) were female. In total, 64.4% (94/146) indicated that Xhosa was their first language; 43.8% (64/146) indicated that they were married; the majority indicated that they had some form of secondary education (84/146, 56.9%), with 2/146 (1.4%) indicating that they had a tertiary qualification; just under half (67/146, 45.9%) indicated that they were unemployed; less than a third indicated that they were employed (40/146, 27.4%); and 26.0% (38/146) indicated that they received a pension. A fifth (29/146, 19.9%) indicated that they had no monthly income; similarly, just less than a third (43/146, 29.5%) indicated that their monthly income was less than US $500.

No problematic demographic differences were observed between the control and intervention groups at baseline. In terms of baseline knowledge scores, both groups had an average total of 17 out of 31 (54.8%) (Table 1).

Figure 1. Participant diagram. 224 participants were originally recruited, but due to loss to follow up and various exclusion criteria, only 146 (76 in experimental arm, 70 in control arm) were included in the final analysis.

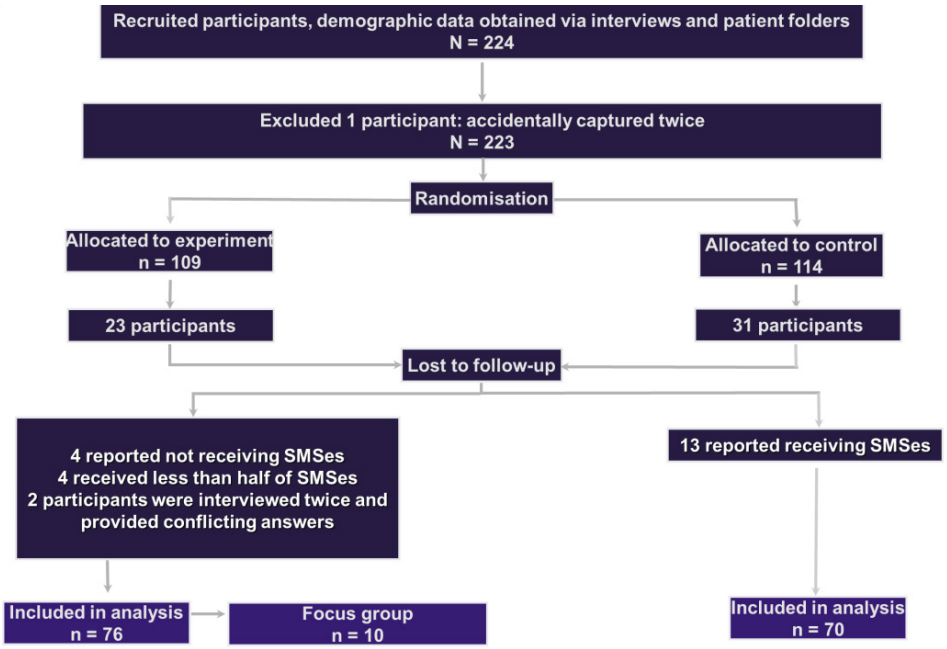

Table 1. Comparison of baseline demographics and knowledge scores between control and intervention groups.

		Intervention	Control	Overall sample
Age – Mean (range)		54.23 (27.9-86.19)	54.44 (26.81-92.15)	54.34 (26.81-92.15)
Gender – N (%)				
	Female	79 (77.45%)	85 (82.52%)	164 (80.0%)
	Male	23 (22.55%)	18 (17.48%)	41 (20.0%)
Language – N (%)				
	Xhosa	66 (60.55%)	72 (63.16%)	138 (61.88%)
	English	43 (39.45%)	40 (35.09%)	83 (37.22%)
	Afrikaans	0 (0.0%)	2 (1.75%)	2 (0.90%)
Marital status – N (%)				
	Married	48 (44.04%)	47 (41.23%)	95 (42.60%)
	Single living with partner	5 (4.59%)	3 (2.63%)	8 (3.59%)
	Single living with family	47 (43.12%)	51 (44.74%)	98 (43.95%)
	Single living with others	2 (1.83%)	2 (1.75%)	4 (1.79%)
	Divorced	3 (2.75%)	1 (0.88%)	4 (1.79%)
	Widow or widower	4 (3.67%)	10 (8.77%)	14 (6.28%)
Education – N (%)				
	Below Grade 7	20 (18.35%)	26 (22.81%)	46 (20.63%)
	Between Grade 7 and 12	63 (57.80%)	62 (54.39%)	125 (56.05%)
	Passed matric	23 (21.10%)	24 (21.05%)	47 (21.08%)
	No matric but diploma	2 (1.83%)	1 (0.88%)	3 (1.35%)
	Postmatric qualification	1 (0.92%)	1 (0.88%)	2 (0.90%)
Employment status – N (%)				
	Unemployed	55 (50.46%)	48 (42.11%)	103 (46.19%)
	Employed	26 (23.85%)	32 (28.07%)	58 (26.01%)
	Pension	27 (24.77%)	34 (29.82%)	61 (27.35%)
	Not looking for employment	1 (0.92%)	0 (0.0%)	1 (0.45%)
Monthly income – N (%)				
	None	24 (22.02%)	18 (15.79%)	42 (18.83%)
	Less than R4000	26 (23.85%)	32 (28.07%)	58 (26.01%)
	R4000-R10,000	1 (0.92%)	2 (1.75%)	3 (1.35%)
	Pension or social grant	58 (53.21%)	62 (54.39%)	120 (53.81%)
Hypertensive knowledge score – Mean (range)		8.77 (1-15)	8.54 (2-16)	8.65 (1-16)
Health-seeking behavior score – Median (range)		8 (2-10)	8 (4-11)	8 (2-11)
Overall score – Median (range)		17 (3-24)	16 (8-22)	17 (3-24)

Knowledge and Self-Reported Behavior Changes

Overall, no significant changes in knowledge were observed between the control and intervention arms at exit. However, in the individual questions, the intervention arm demonstrated a significantly higher knowledge of what to do in terms of medication adherence when they leave Cape Town, their place of residence, for an extended duration (81% vs 94%, $p<.05$ (see Table 2)). This is an important piece of knowledge, as there is a high seasonal migration of this population from Cape Town to the more rural Eastern Cape province of South Africa during holiday periods.

Table 2. Knowledge scores for control and intervention groups at exit.

Question	Control score	Intervention score	*P* value
Condition questions overall score (observed range)	9.71 (5-13)	9.6 (6-15)	.77
-What is high blood pressure? (% correctly answered)	59%	49%	.06
-What is normal blood pressure?	59%	73%	.31
-What puts you at risk for developing high blood pressure? (score)	2.897	2.744	.45
-Does everybody who has high blood pressure have symptoms?	56%	62%	.20
-What complications may you prevent by managing your high blood pressure?	1.176	1.103	.67
-Can you stop taking your medication without asking your doctor?	97%	92%	.38
-Can high blood pressure be cured?	87%	87%	.79
-When you leave Cape Town, which one of the following is right?	81%	94%	.03
-If you have high blood pressure, contact the clinic if you have which of the following symptoms?	1.25	1.19	.68
Behavior questions overall score (observed range)	7.78 (5-10)	8.05 (6-10)	.15
-Can you reduce your blood pressure?	91%	94%	.89
-Is smoking good or bad if you have high blood pressure?	99%	99%	>.99
-Is keeping a normal weight important if you have high blood pressure?	99%	96%	.62
-How much should you drink, if at all, if you have high blood pressure?	51%	56%	.64
-How much should you exercise 3 days a week?	29%	28%	.12
-What are the best ways to manage your stress?	1.221	1.372	.14
-Do eating habits affect blood pressure?	74%	85%	.07
-Is salt good or bad for a person with high blood pressure?	18%	12%	.54
-What should you cut down on if you have high blood pressure?	99%	99%	>.99
-Are vegetables and fruit good for a person with high blood pressure?	99%	100%	.22
Overall score (observed range)	17.5 (11-23)	17.7 (13-23)	.69

Positive self-reported behavior change was reported by participants in the SMS intervention for all categories questioned (see Table 3).

Table 3. Self-reported behavior changes for intervention arm.

Behavior change	Self-reported answer (%)			
	Yes	No	Don't know	N/A
Have you stopped smoking since the SMS campaign?	13	0	1	86
Have you lost weight since the SMS campaign?	58	28	5	9
Have you reduced your alcohol intake since the SMS campaign?	12	6	3	79
Have you increased your exercise since the SMS campaign?	81	12	1	6
Have you started eating healthier since the SMS campaign?	88	5	3	4
Have you reduced your consumption of red meat since the SMS campaign?	65	9	8	18
Have you increased your consumption of fruit and vegetables since the SMS campaign?	87	1	1	10
Have you reduced your salt intake since the SMS campaign?	63	3	10	24

Focus Group Results

All participants in the focus group reiterated the self-reported behavior change results. Thematic analysis found that the SMSes were generally viewed in a positive light, with 4 themes being elucidated. Firstly, the SMSes were viewed not as a source of new information, but rather as a motivation for change, which was felt to be extremely useful:

> *Ok, for me since I hear this thing time and again, wherever I go, I go to Groote Schuur [hospital], I go*

> *to Victoria hospital, even here and see dieticians, wherever I go, I am told these things, but I never took them seriously. But the SMSes made me believe in all the things that I've been told all the time, and made me took the matters on my own hands. You know, like I took them seriously, and do everything. Because sometimes I do get pamphlets to read and read them and realise that they are related to everything that the SMSes are telling you what to do, but the SMSes made me took matters into my own hands, and do things right.*

Many participants thus suggested that the SMSes functioned as a reminder to change, which emerged as the second theme:

> *I did know before, but a lot because it [the SMSes] always come and remind me so I was, always my mind was always pressured on, so it was good for me.*
>
> *As I received the SMSes, especially where they were telling me on what to eat, and what to reduce, on like salt, and then about what kind of fat, margarine or soft butter you must use, I have changed, everything according to what the SMSes were telling me. And, ever since I got on this project I have managed to lose a little bit of weight.*

Thirdly, when the participants were asked why the SMSes motivated them, they described the SMSes as "trustworthy" and "caring" and felt like they were being looked after:

> *because those people [researchers] that took our particulars were from the University of Cape Town, they were very educated people. They are like doctors to us, you know; got a lot of information on how to keep our health, keep uh, healthy.*

Lastly, they also stressed that SMSes were readily available compared with other forms of information; participants felt that having the information on their mobile phone was more useful than getting a pamphlet or getting information from health professionals:

> *I did get the information from the dietician, but I did not follow up. When you are getting the SMSes it's a reminder, it's on your phone. You can always read your messages, it always reflects. So it is easy for you to follow-up than being told full scale listening to someone.*
>
> *It's between you and your phone, there's no one next to you, so by reading you are thinking back of your mind 'I think I will try to do this one'.*

Discussion

The results demonstrated almost no differences in knowledge between the control and intervention arms at exit, with the exception of 1 question. Self-reported behavior change in the intervention group showed significant trends toward healthier lifestyles. This observation was confirmed by focus groups, which emphasized the utility of the SMSes as a reminder, and a source of motivation to change, rather than a source of new knowledge.

There are a few possible explanations for no observed difference in knowledge results between the control and intervention groups. Firstly, the survey questions may not have been suitable in assessing participants' knowledge; they were not sufficiently difficult for measuring a change. Census data on baseline education levels for our population demographic indicate the majority have not finished secondary schooling [17], and this informed the design of our survey questions. Furthermore, baseline questions were formulated in conjunction with health care professionals around what information was felt was important for the patient to know. While low levels of education were confirmed by our baseline assessment demographic data, it appears participants' specific health knowledge behavior was relatively high. Indeed, they may have been so high (participants knew on average 54.8% of the information based on their baseline questionnaires) that there may not have been enough leeway for any statistically significant gains to be observed. In many ways, this is a positive, as it suggests that the health care staff are providing good health information, among other possible sources. This may also be due to the fact that our patient population was sampled from a hypertensive club, which may not be reflective of general patients with hypertension. Subgroup analysis stratified by some of the baseline demographics, such as education level, may have accounted for such factors but could not be performed due to limited sample size. Secondly, methodological issues were encountered with the SMSes service delivery. On average, 29.7% of SMSes failed to deliver to the intervention group. This was due to the service provider and casts doubt on the validity of the results. Lastly, loss to follow-up was also a significant problem, which reduced the statistical power of the results.

The findings do nonetheless suggest that SMSes are effective in motivating behavior change. However, there is a high potential for bias, as only *self-reported* behavior changes were reported. The health behavior change results could not be confirmed objectively with blood pressure and weight changes before and after the intervention, due to poor medical record keeping in patient clinic folders. While the focus group findings supported the self-reported behavior change findings from the questionnaire, the same self-reporting biases exist, and there may also be selection bias at play in the focus group, as participants self-selected into the focus group. The focus group further suggested that the SMSes were functioning as "cues to action"—see, for example, the Health Belief Model [19]. The Health Belief Model theorizes that health seeking behavior is influenced by a range of beliefs, such as perceived severity, perceived benefits, self-efficacy (confidence in one's ability to take action), as well as reminders to action that activate the readiness of the patient to seek good health. The SMSes may act as one such reminder, as they provide information as well as remind the patient of this information on a daily basis. Furthermore, the Stages of Change theory [20] postulates that behavior change is a staged process starting at precontemplation and working through 5 stages toward maintenance or termination of the behavior. The SMS campaign appears to be particularly good at moving from the precontemplation to the contemplation or preparation stage. It is uncertain whether the campaign was long enough or particularly well suited to moving participants into the next stage of "action," although self-reported behavior

change suggests it might have been. Combined, these results suggest an expressed interest in changing behavior following the SMS intervention, even if it is uncertain whether this resulted in behavior change.

In conclusion, the results suggest that more research is required before implementing SMS interventions for chronic disease in developing countries, and that any intervention should be entered with caution, realizing some of the limitations of the developing world. Firstly, the infrastructure for their successful implementation may not be available [21], a problem experienced in this intervention by a high SMS delivery failure rate. Secondly, they may not be a necessary, or good, vehicle for knowledge dissemination. However, SMSes do appear to act as a reminder for the patient, and participants reported they felt they were being better looked after by receiving the SMSes, and that the SMSes were cueing positive health-related behavior changes. This could potentially make them a very useful tool for assisting in the management of chronic conditions. Future studies should incorporate objective measures of behavior change, such as weight and blood pressure changes. Recent trials have also suggested that personalization of the SMSes and tailoring toward the individual receiving the SMS can have a marked improvement on outcomes, a theme that could also be explored in future work [22].

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Conflicts of Interest

None declared.

Multimedia Appendix 1

List of hypertension SMS campaign SMSes.

[PDF File (Adobe PDF File), 46KB - mhealth_v4i1e22_app1.pdf]

Multimedia Appendix 2

Hypertension SMS campaign baseline questionnaire.

[PDF File (Adobe PDF File), 51KB - mhealth_v4i1e22_app2.pdf]

Multimedia Appendix 3

Hypertension SMS campaign exit questionnaire.

[PDF File (Adobe PDF File), 44KB - mhealth_v4i1e22_app3.pdf]

Multimedia Appendix 4

Questionnaire scoring calculations.

[PDF File (Adobe PDF File), 76KB - mhealth_v4i1e22_app4.pdf]

Multimedia Appendix 5

Focus group discussion guide.

[PDF File (Adobe PDF File), 47KB - mhealth_v4i1e22_app5.pdf]

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Original Paper

Guidelines and Recommendations for Developing Interactive eHealth Apps for Complex Messaging in Health Promotion

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Abstract

Background: The now ubiquitous catchphrase, “There’s an app for that,” rings true owing to the growing number of mobile phone apps. In excess of 97,000 eHealth apps are available in major app stores. Yet the effectiveness of these apps varies greatly. While a minority of apps are developed grounded in theory and in conjunction with health care experts, the vast majority are not. This is concerning given the Hippocratic notion of “do no harm.” There is currently no unified formal theory for developing interactive eHealth apps, and development is especially difficult when complex messaging is required, such as in health promotion and prevention.

Objective: This paper aims to provide insight into the creation of interactive eHealth apps for complex messaging, by leveraging the Safe-D case study, which involved complex messaging required to guide safe but sufficient UV exposure for vitamin D synthesis in users. We aim to create recommendations for developing interactive eHealth apps for complex messages based on the lessons learned during Safe-D app development.

Methods: For this case study we developed an Apple and Android app, both named Safe-D, to safely improve vitamin D status in young women through encouraging safe ultraviolet radiation exposure. The app was developed through participatory action research involving medical and human computer interaction researchers, subject matter expert clinicians, external developers, and target users. The recommendations for development were created from analysis of the development process.

Results: By working with clinicians and implementing disparate design examples from the literature, we developed the Safe-D app. From this development process, recommendations for developing interactive eHealth apps for complex messaging were created: (1) involve a multidisciplinary team in the development process, (2) manage complex messages to engage users, and (3) design for interactivity (tailor recommendations, remove barriers to use, design for simplicity).

Conclusions: This research has provided principles for developing interactive eHealth apps for complex messaging as guidelines by aggregating existing design concepts and expanding these concepts and new learnings from our development process. A set of guidelines to develop interactive eHealth apps generally, and specifically those for complex messaging, was previously missing

from the literature; this research has contributed these principles. Safe-D delivers complex messaging simply, to aid education, and explicitly, considering user safety.

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KEYWORDS

mhealth; complex messaging; vitamin D; eHealth smartphone apps; interactive

Introduction

In 2013, there were 97,000 eHealth apps in major app stores [1]. Comments in the literature support the notion that these kinds of apps may be beneficial to health [1-4]. Some eHealth experts and technology advocates have predicted that one day they will prescribe an app as they would a medication [5]. Despite the potential benefits of eHealth apps [6], especially in the case of complex messaging, most eHealth interventions are developed commercially, while health organizations have lagged behind in this field [7].

The effectiveness of these apps can vary if development does not draw on change theories [2], employ scientific foundations, or involve health care professionals [3]. To date, much has been done broadly on designing for behavioral change [2,8,9] and on app development [9,10]. However, the domain of eHealth app development is still broadly under-researched. From a health perspective, involvement from health care professionals is crucial for efficacy and rigor [4,6,11], and patient safety must be considered as these apps have the potential to cause harm [11]. The reality that health information needs are somewhat different from general interests [12] means that health-specific considerations are important for app development in this domain.

More recently, clinician involvement has occurred [13], but there is still limited research in this area to guide development of eHealth apps. The lack of published examples describing eHealth app development makes it difficult to determine an eHealth app development process that is rigorous, research-based, and involves health care professionals. This paper aims to formulate recommendations to guide development of interactive eHealth apps by drawing on the principles from the broad app development literature and the Safe-D case study. The development of the D-Safe app to prevent vitamin D deficiency was used as case study. The app is currently being evaluated in a randomized controlled trial (RCT), which is underway (ACTRN 12613000972729). While the app developed is input into a current RCT, this paper focuses on how the app was developed and recommendations learned from the development. The RCT protocol and results will be the subject of later publications. Similarly, our work on personalizing messages for young women is published elsewhere [14].

High-level exposure to ultraviolet (UV) radiation from the sun is a major risk factor for skin cancer, yet UV exposure is needed for vitamin D synthesis in the skin. In Australia, skin cancer awareness has risen considerably in recent years. At the same time, research has demonstrated low vitamin D levels in various population samples despite abundant natural UV radiation. On the whole, Australians have adopted the Cancer Council's "slip-slop-slap" campaign message [15], thereby reducing sun exposure and potentially inhibiting vitamin D synthesis. In one study, 31% of 18-24 year-olds residing in Australia were vitamin D deficient [16]. Currently, the message to the public is complex and potentially confusing: sunlight is needed for vitamin D, yet agencies, including the Cancer Council, urge individuals to limit "exposure to reduce the risk of melanoma" [17]. Difficulty stems from the need to balance adequate and safe UV exposure to stimulate sufficient vitamin D synthesis, against the harmful levels that increase risk of melanoma and other skin cancers. There are many variables to consider and conflicting recommendations. This is what we refer to as complex messaging, as the recommendations for safe sun exposure depend on an individual's personal attributes and changing environment conditions. Vitamin D deficiency is diagnosed and managed primarily through general medical practitioners (GPs). However, a recent survey [18] found that the advice patients received differed from expert recommendations.

In addition, only a few foods such as oily fish, sun-exposed mushrooms, and eggs contain appreciable amounts of vitamin D [19]. Even with margarine and some other foods in Australia being fortified with vitamin D [17], the average Australian diet alone is not enough to achieve sufficient vitamin D. Moreover, barriers exist to widespread supplementation [17], such as cost and non-compliance issues. Therefore, safe sun exposure remains a high priority, as UV radiation is the major source of vitamin D [19]. However, UV varies based on location, season and time of the day, cloud cover, and pollution. In addition to these environmental factors, vitamin D synthesis is affected by skin pigmentation. For example, darker skin requires longer exposure than fairer skin to synthesize the same amount of vitamin D [20]. Vitamin D from sunlight is dependent on exposed skin as the greater the area covered, the less there is available for synthesis. Use of sunscreen has similar impact, diminishing UV absorption, thus reducing vitamin D synthesis [20].

To address these diverse variables, we selected an app as the best medium to provide the complex messaging required to guide safe but sufficient UV exposure, as it affords the two-way information exchange required for interactive, tailored recommendations. Utilizing an interactive eHealth app enables portability to record sun exposure duration and frequency as it occurs. Hence, more reliable exposure measurements [5,21,22] can be captured than is possible from traditional diary-based interventions, potentially improving safety and accuracy. Interaction is especially important because static one-way interventions would not be able to provide recommendations based on individual and external factors at the time of exposure, as is required for user safety. Moreover, we found that many young women aged 16-25 years, the target audience for the study and Safe-D app, wanted information regarding required

sun exposure (36/47, 77%) while over half (32/47, 68%) believed an app could help improve vitamin D levels and also identified a need for better information than their GP currently provided.

The Safe-D study is limited to English-reading females aged 16-25 years residing in the State of Victoria, Australia. Therefore, the Safe-D app is in English only and designed for this target audience. Safe-D, and thus this research, does not include social media integration during its evaluation. There is a need for this limitation to restrict the opportunity for participants to share information with non-app intervention participants during its evaluation, insuring RCT integrity. Further to these limitations, the app is available only on Apple and Android devices, using existing technologies of Global Positioning System (GPS) and readily available UV data from the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) and Bureau of Meteorology (BOM). The limitation to Apple and Android devices only was based on Australian Interactive Media Industry Association (AIMIA) results that 49% of Australians own a smartphone, predominantly Apple and Android devices [23]. As AIMIA results are disaggregated from gender and age, a Web survey was conducted to understand the young female smartphone landscape. Of the respondents, 98% (56/57) owned a smartphone, 95% of those comprising Apple and Android devices, reinforcing the decision to develop for these platforms only.

Theoretical Background

Safe-D development conformed to eHealth, persuasion, and interactivity best practices. A literature review was conducted to align development with current literature, presented thematically in this section. The aim of Safe-D was to persuasively encourage UV exposure. Persuasive technologies are those to prompt behavior change and reinforce learning [9]. A variety of concepts in the literature [2-4,9,10,24-28] were considered in the development of the app, including persuasion through monitoring and tracking, simplicity, rewarding behaviors, gamification, tailored messages, and improving user experience (UX).

Monitoring and Tracking

Eysenbach [2] found that participants liked to monitor, track, and review records, and he established that "simply viewing records…could prompt healthier behavior." Along similar lines, it has been found that the interactivity of tracking physical activity led to an increase in steps through incremental changes [27]. Therefore, young women tracking other quantifiable events may do the same. Interactive eHealth apps for complex messaging should enable exposure tracking and performance indicators.

Simplicity

Dennison et al [2] also uncovered competing participant desires for accurate records without frequent data entry. Where entry is complicated and time-consuming, users discontinued tracking [10,26]. The premise behind these findings is expressed by Fogg [3] who argued that barriers that could prevent desired behavior must be removed for the behavior to occur. Therefore, as much as interaction is important, it seems that data entry by the users also has to be quick, easy, and convenient, while accurate.

Rewarding Behavior

Rewarding positive behaviors, rather than punishing non-compliance, leads to continued engagement [2,8,26,29]. Consolvo and Landay [8] found negative reinforcement does not encourage behaviors, nor does lack of credit for compliance. Therefore, it was important to consider how to reward behaviors while not punishing non-compliance.

Gamification

Gamification is the use of game elements in non-game contexts to provoke competition [30]. Calvo and Peters [31] found that provision of information alone only motivates change in 10% of individuals and suggested that interactive gamification may increase motivation and intervention compliance, a strategy also suggested by Segerstahl et al [10]. Given convergent recommendations, interactive eHealth apps for complex messaging should consider gamification to encourage use and improve compliance.

Tailored Messages

It is well published that tailored messages are most effective at motivation [2,8,26,28]. While messages are vital for an eHealth intervention to aid learning, doing so excessively dissuades users [2]. The contexts of target users must be considered to deliver relevant messages at opportune times for desired behavioral change to occur [3]. Clinicians also should be involved in complex message construction and messages tested for suitability and relevance with target users.

User Experience

UX encompasses "reactions and feelings, which arise from interactions with a system" [10]. UX elicitation can be accomplished by applying visually appealing designs [8,28]; a competent look and feel [28]; creative, fun, and humorous elements [26]; ease of use; error tolerance; and system responsiveness [9]. The literature indicates that for successful persuasion, UX must be considered [2,9,10]. Therefore, interactive eHealth app development should focus on user-centered design by involving users and leveraging researcher expertise in UX and human computer interaction.

Methods

This research had dual goals of developing Safe-D while utilizing the process to understand development principles for interactive eHealth apps for complex messaging. These dual goals contribute to the development of a tangible solution in the form of the Safe-D app, while corresponding with intended outcomes of participatory action research [32,33]. Participatory action research was employed as it enabled a team of subject matter experts to work collaboratively with target users to develop the app, while researchers in the team reflected on the experience to garner recommendations. The experts involved included subject matter expert clinicians, a biostatistician, information systems researchers, external developers, public health practitioners, and target users.

App Development

As is commonplace in qualitative research, development began relatively theory-free [34] in "round-table"-style discussions and ideation meetings with the team. Initial meetings were then used to fully appreciate and articulate the complex and confounding factors of achieving adequate vitamin D synthesis, which the app would have to cater for. These discussions were important to establish the range of variables to be considered, the diverse contexts of the target users, and, just as importantly, common understanding between the different groups of experts at the table. This was not only an important part of the app development process but was also the beginning of the participatory action research process.

A preliminary survey was conducted to further understand what young women wanted in an app, to inform design decisions. The survey was conducted online and advertised via a Melbourne Health media release, the "Netball Scoop" forum, VGen Core group, the Youth Affairs Council of Victoria monthly e-newsletter, and an email to past participants in the Young Female Health Initiative (a collaborative comprehensive health study of 16-25 year-old women in Victoria, Australia). A total of 71 respondents commenced the survey. Of these, 57 passed all eligibility criteria to participate, that is, being English-speaking females aged 18-25.

Developers were hired, and development followed stages from the software development lifecycle, selected due to its applicability to both business and health care scenarios [35]. The stages of our software development lifecycle were iterative and tailored to incorporate agile development ideologies [36]. These are described in Table 1. An existing algorithm [37] was selected to calculate recommendations for UV exposure due to applicability in New Zealand, similar in latitude to Australia.

Table 1. Development phases.

Development phase	Process and data generated to help develop the Safe-D App
Requirements analysis	Requirements were written and a literature review and focus groups were conducted.
Design	Wireframes were created to elicit non-functional and evolving requirements.
Design validation	Designs were validated in informal focus groups, an advisory private Facebook group, and informal "guerilla testing," asking young women approached in public places for opinions regarding designs. Outcomes were used to (1) determine preferences, (2) validate designs as flexible, non-offensive, and culturally sensitive, (3) validate messages conveyed the intended message, and (4) test the app concept.
Development	The contracted developers created Safe-D for Apple and Android platforms iteratively and collaboratively with the other researchers.
Beta testing	Core team members who used with Apple and Android devices were given access to Safe-D. Additional beta testers were seconded from the larger team to ensure a range of platform and operating system configurations, making a total of 24 beta testers, consisting of 6 from the target demographic while others acted as expert reviewers.
Retrospective	This is the final phase, adopted from agile methodologies. Retrospectives are specific meetings reflecting on the development and identifying improvements. Retrospective data enabled triangulation so findings did not rely solely on observations of the authors.

Throughout each stage, available recommendations from the literature (as previously outlined) were used to help create the best experience in the app.

Developing Recommendations

Researcher reflections and observational notes were used to highlight recommendations for future developments. This analysis was triangulated through data collected during retrospectives. Each member (ie, information systems and medical researchers, medical professionals, beta testers and app developers) shared what they thought went well, what did not, and what they would do differently next time based on this experience. Post-development, retrospective data were organized thematically through affinity mapping to check against initial researcher observations. This process condensed the data in a manageable format to identify any themes and relationships between themes, using an inductive approach, as per Neuman [33]. The data analysis enabled theoretical abstractions and pattern detection for identification of overarching principles for development of interactive eHealth apps for complex messaging.

Results

As this research had the dual goals of first developing the Safe-D app and then using this process to develop recommendations for future app development, the results will be presented separately: the Safe-D app and development recommendations.

Safe-D App

Safe-D aims to safely improve vitamin D status, through individualized UV exposure recommendations, messages, and learning. Safe-D will be presented by the major actions that users take within the app, which are initial setup, tracking UV exposure, monitoring progress, recording missed exposure, and viewing messages.

Initial Setup

Initial app setup is required when the user accesses the app for the first time. Safe-D prompts for (1) push notification and GPS permissions needed to provide interactive personalized recommendations based on real-time locational UV, (2) answers to the Fitzpatrick skin-type questionnaire [38] to determine skin type (avoiding self-selection error), which is input once, stored, and used in calculations, and (3) avatar skin, hair, and eye color

and hairstyle configuration. These selections are used to present an avatar that will remind the user of themselves, without tying skin tone to skin type, thus increasing attention and persuasion [3,9,10,25,26,39]. The avatar configurations enable users to comfortably represent themselves for greater persuasion through imitation. There were extensive UX considerations regarding avatar and clothing options. The avatar does not propagate unrealistic body image, and cultural awareness was considered through inclusion of the hijab and niqab options.

Tunneling, the practice of guiding users through 1 question per screen, was implemented to reduce cognitive load. All data entry is simple to encourage usage, and logon details can be remembered for automatic sign-in to remove barriers to future use. As Safe-D is intended for initial evaluation in an RCT, access must be restricted to only participants through password protection.

Tracking UV Exposure

To record UV exposure, the avatar must first be dressed. This is a seamless and fun interaction used to record exposed skin and sunscreen protection. Sunscreen and clothing are required for exposure calculations. Therefore, they are explicitly prompted. Exposed skin entry is simple: the avatar enables easy, visual, touch entry of clothing to calculate exposed skin. For usability, the avatar defaults to clothing from the last exposure, removing a step if exposed skin remains stable exposure-to-exposure.

These inputs, with locational UV levels and skin type, are used to calculate and display safe exposure recommendations. As exposure has a safe limit, the timer cannot simply count down. Exposure counts down to zero, then up in red to indicate, alert to, and dissuade overexposure. Gamification promotes usage, inspired by Fish n' Steps metaphor [30]: a fish whose health improved or deteriorated with exercise. In the study, steps did not increase in the prestudy pedometer-only phase, yet when using Fish n' Steps there was a positive impact on 74% (14/19) of participants [30]. In Safe-D, a sunflower was selected to reiterate connotations of sun exposure. As exposure reaches target, the sunflower health display grows healthier and happier. If healthy exposure is exceeded, health declines. When the user stops timing, they are provided with interactive feedback regarding whether more exposure is required or exposure has been met, or exceeded.

Monitoring Progress

There are two ways to monitor progress on the app: viewing today's exposure or overall exposure. Today's exposure is visible on the homepage by assessing the sunflower's health state. The sunflower health state can also be assessed while the timer is running. Overall progress is monitored via statistics, displaying the current consecutive days-of-use in the form of a streak, and longest consecutive use. Streak here is used in the sporting sense to refer to a running total of consecutive days when the app was accessed. To encourage reaching exposure, without exceeding the defined safe limit, Safe-D enables easy entry and viewing of exposure, making it apparent when the safe limit is exceeded. The progress display of how much exposure the user has had each day allows them to adjust behavior accordingly. This visual display takes into account that exposure can be too high, too low, or just right for the most number of users. Inspiration was garnered from discussions with other app designers [40] at the Melbourne Quantified Self group meetup, which also points to the concept of a "goldilocks" zone (the zone for just the right level of access to information for users, or an ideal level of desired behavior). In this case, the goldilocks zone refers to just the right level of exposure to sunlight for each user, which is integrated with a traffic light display system. Therefore, the "just right" level of sunlight exposure is denoted as green, "too high" is red to signal danger, and "too low" is yellow to indicate it is suboptimal without reprimanding the user. This "just right" goldilocks zone is dependent on the acceptable statistics based on the algorithm behind the app.

Recording Missed Exposure

Missed exposure can occur for two reasons: a user may be unable to get sun or may forget to record it. When unable to get sun, the "I Can't Get Sun Today" feature records the reason. If users forget to start or stop the timer, they can retrospectively enter or delete using "My Sun Exposure." Users may be unable to get sun for a number of reasons, and this function handles this sensitively without punishing a user by forcing them to lose their in-app streak.

Exposure Recommendations

Safe-D aims to safely improve long-term vitamin D status through UV exposure. Thus, to prevent indefinite app reliance, information is required for learning. The complex messaging occurs on a per scenario basis (see Table 2), and different messages are delivered in different ways. These messages are complex because, while the same scenarios trigger messages for all users, the content of these messages varies based on the user's skin type, how much skin they have exposed and whether they are using sunscreen or not, the current UV based on their current location, and the exposure they have already had for the day. Messages can be delivered in one or multiple modalities: in-app messages to deliver point-of-interaction information, push notifications requiring action and garnering attention to trigger this action as per the Fogg Behavioral Model [3], and mail messages available for later retrieval. Table 2 shows the scenarios that trigger messages to send and how these messages are delivered.

Table 2. Safe-D messages and medium per scenario.

Scenario	In app	Push	Mail
Timer stopped without reaching exposure	Yes		
Exposure reached	Yes	Yes	
Exposure exceeded	Yes	Yes	
Exposure exceeded and timer not stopped	Yes	Yes	
Exposure exceeded and "Get Vitamin D" accessed when UV is still above low	Yes		
Exposure exceeded and "Get Vitamin D" accessed when UV is now low	Yes		
Too much sun without reaching exposure, via the "Too Much Sun" function	Yes	Yes	
Safe-D not used		Yes	
UV in current location changes during exposure	Yes	Yes	
Forecast UV is extreme or very low		Yes	Yes

From our preliminary survey, 64% (7/11) of respondents provided an answer for the acceptable number of notifications per day, reporting 1-2 notifications per day as acceptable. However, beta testing revealed that 1 per day when the user was not actively using Safe-D was annoying and could potentially inhibit use. Push notifications send to a user's phone only under the following circumstances: the timer is running and/or behavior needs to occur, Safe-D was not used the previous day, the user recorded "Too Much Sun" yesterday, and an educational message sent once a week.

Viewing Messages

Messages can be viewed either as push notifications or through in-app mail. Messages can be sent to groups to improve effectiveness rather than generic messages sent to all. Other messages are interactive, based on user inputs. Mail was designed in a way that enables tailored messages to be sent to defined groups. Hardcoded events are recorded in the Safe-D dashboard that researchers can access and identify individuals who may need special messages. An example of how this could be implemented is to look at users who continually flag that they cannot get sun today because they are "too busy." A sensitively tailored message could then be sent to such a participant to encourage them to make time. In more extreme cases if a participant continuously exceeds app-defined safe exposure limits, it would be possible for the non-blinded researcher to identify and contact them directly for their safety.

Educational notifications are delivered weekly. These are designed to be fun, non-clinical, and short. Messages cannot build on previously received messages as participants can start Safe-D at different times. Clinical experts in bone health and dermatology first reviewed all written copy, and expert bodies, such as the Cancer Council, are referenced where appropriate. Messages are framed positively to avoid reprimanding users [8], and they correlate to the state of the sunflower to reinforce the metaphor and learning. Messages were created to be interesting and non-repetitive, cycling through different wording to avoid monotony due to repetition.

Discussion

Key Development Recommendations from the Safe-D Study

As previously indicated, the literature [2-4,9,10,26-29,31] suggested the following design concepts: persuasion through simple tracking, rewarding positive behaviors, not punishing non-compliance, considering message timing, including gamification, and designing UX. We extended these design concepts in the form of the following recommendations based on key learnings from the Safe-D project.

Recommendation 1: Involve a Multidisciplinary Team in the Development Process

As recommended in the literature [9,30,31], multidisciplinary teams are important in similar contexts. One of the key challenges for such a team is to ensure understanding of the complexities of the problem and the cultures within the different disciplines involved. It was important to ensure that team members were able to meet face to face as much as possible for discussions, clarifications, safety advice, and approvals. It is also crucial to get all the information systems researchers and clinicians in agreement on the scope and requirements of the app before involving the app developers.

It is important to note that despite all the preparation in our study, it was not always possible to ensure that all roles and messages were fully understood. For example, developers may want a decision quickly, not appreciating that clinician review and approval was required. Similarly, clinicians may have unrealistic technical expectations. It is important to work through these issues and also ensure that there is adequate time set aside for the complexities of working in the multidisciplinary team. This recommendation reflects Gold et al's findings [41] regarding multidisciplinary teams in their development of eHealth intervention on social networking sites.

Recommendation 2: Managing Complex Messaging is Crucial to Engage Users

Conveying the complex and potentially confounding sun exposure factors to users was challenging. The recommendations from the study for managing the complex messaging were three-fold: (1) minimize user input requirements into the app to keep it relatively simple, (2) deliver safe personalized key messages to users when appropriate, and (3) manage the push messages from a central server.

First, the principle of minimizing input while making the complexity as invisible to the user was important. Safe-D achieved this by managing external factors in the background and only asking users for information that the app could not detect. The external UV level data sources (ARPANSA and BOM) were input into an algorithm, which was essential to calculate safe, personalized recommendations. Use of an algorithm enabled clear output based on individualized inputs, as is required for complex messaging. The mechanics of this algorithm, however, should not be apparent to users. The algorithm helped to determine which messages are most relevant and appropriate to individuals. If no algorithm exists, it is recommended that teams take the time to create one that provides the required output by taking into consideration all inputs and develop automated test coverage to run algorithms for complex messaging through all possible input combinations, especially when there is no existing algorithm available.

Second, it is the messages themselves that convey the complex information simply, with the use of gamification to further simplify understanding. These messages can be delivered in one or multiple modalities: in-app messages to deliver point-of-interaction information, push notifications when action is required, garnering attention to trigger the desired behavior as per Fogg [3], and mail messages with content available for later retrieval. When employing gamification, the metaphor used should tie back to the health problem to reinforce learning by leveraging a heuristic to prompt for behavior when not using the app.

This research has built on work by Fogg [3] and Oinas-Kukkonen and Harjumaa [9]. Push notifications follow Fogg's Behavioral Model as "without an appropriate trigger, behavior will not occur" [3]. The timing of exposure-related notifications should be designed to be during use and to not occur at inopportune times [9]. Similarly, push notifications regarding the same event should occur no more than twice, as constant prompts can lead to annoyance [9].

Third, the health messages should be simplified and controlled from a central server. This is so that messages can be updated when needed and pushed to users when relevant, without requiring them to update the app. It is useful to enable the delivery of customized messages to user subsets from the central server. In addition, this allows for later retrieval of education messages to reinforce education. It is then also easier to track which user has received which messages to help avoid repetitiveness.

Recommendation 3: Design for Interactivity

By designing for interactivity, we applied concepts from the literature [2-4,9,10,24-28] to provide tailored recommendations [8-10], remove barriers to use [3,8-10], and achieve simplicity [2,9]. Through developing Safe-D, we extended these concepts to contribute specific implementations of them for eHealth apps that future developments can utilize.

Tailored Recommendations

While the literature posits that tailored messages have greater persuasion [9,28], information on how to tailor these messages in an eHealth context is lacking. Thus, we expanded this principle based on lessons learned in message construction and beta testing. To postulate, recommendations should be based on input from the individual user and relevant external information, and based on each user's interactions with the app (accounting for start of use of app, frequency of interaction, and nature of the interaction).

Removing Barriers to Use

Dennison et al [2], Fogg [3], and Segerstahl et al [10] recommended that, for persuasion to occur, barriers to use must be removed. This research provides specific mechanisms to remove barriers, based on those experienced by beta testers. Removal of these barriers was addressed in design improvements through mechanisms to avoid repeat data entry, including facilitating quick entry of login details by enabling "Next" and "Go" keyboard options to move through fields with ease; remembering login details; storing static information (information that does not change with each interaction), rather than prompting for it; defaulting inputs to last used, rather than requiring re-entry; and touch-only input.

Simplicity

While the literature states that data entry must be simple to encourage use [2,10], strategies for simplicity are lacking. This research provides specific recommendations to achieve simplicity in an eHealth intervention. Simplicity can be achieved by working with target users to determine input options; providing touch-only entry of these closed-input options/choices, rather than free-text input; providing key information on the homepage for at-a-glance assessment; and push notifications to prompt for action, reducing cognitive burden.

These strategies simplified the interface to a few simple clicks, rather than extensive data entry. The push notifications reduced the need for users to remember recommendations and exposure time. As a result, the Safe-D app is easy to use, requiring minimal time to learn, and adopts an intuitive interface.

In summary, development followed the concepts from the literature of iterative and flexible development, continuous evaluation and refinement, participatory development, a multidisciplinary team and involvement of end-users, and active participation to fully appreciate and understand the issue up front [9,30,31]. Despite this adherence, challenges were still faced owing to complex messaging and differences in focus between clinicians and developers. The recommended development principles are designed to reduce challenges faced

in the development of future interactive eHealth apps for complex messaging.

Generalizability

The principles we have presented in this paper were created through drawing inferences from Safe-D development. Safe-D takes multiple inputs and provides individualized and varying messaging to aid learning for users to optimize ongoing cutaneous vitamin D synthesis; continued exposure is required indefinitely to maintain vitamin D status. These principles can be leveraged for development of eHealth apps with similar individualized and complex messaging requirements where a one-size-fits-all message would be harmful. Examples of some potential eHealth apps that would require complex messages are described in Table 3.

Table 3. Potential future eHealth apps with complex messaging needs.

eHealth app topic	Complex messaging
Allergy	Allergy management requires ongoing monitoring and actions. An app would require personalized messages to each individual as their allergies and combination of allergies would vary.
Diabetes, hyperglycemia, hypoglycemia, and insulin resistance	Disordered blood glucose requires complex messaging based on real-time individual readings to provide correct advice for the individual's requirement at the time, be it to take insulin, glucose, or maintain current levels.
Management of chronic illness	Many chronic conditions require individualized care plans based on the severity of the condition and any comorbidities. Care plan apps need to be able to accept multiple metrics that the user needs to track and deliver the right messages based on how they are tracking against each metric.
Musculoskeletal disorders	The recommendations such an app would need to provide on the amount and type of physical activity would need to take in to account confounding factors of disorder (eg, osteoporosis), age, flexibility, and any temporary injuries.

Potentially most of these conditions will require individualized and complex messaging with the move towards personalized medicine [42,43]. While these principles will aid in development of other eHealth and interactive apps, they will not all be directly transferable to certain situations. For example, some condition characteristics or demographics may make it impractical to have patients as part of the study team. It is suggested here that these principles do not represent a set procedure, but rather recommended guidelines.

Limitations

This paper has not presented a detailed description of the Safe-D app to maintain the integrity of the RCT. This information will be included in future reports after the RCT is completed. While Safe-D has been extensively beta tested, resulting in improvements, formal evaluation was not performed as part of this research. The RCT will evaluate whether Safe-D succeeds in its purpose to safely improve vitamin D status in young women and, therefore, the applicability of these principles to complex messaging. The proposed principles may not be applicable to all complex messaging and are not currently ranked in priority. Further, as the findings are based on a reflective analysis from participatory action research, it is possible that the guidelines may have inherent bias. This was mitigated somewhat through the triangulation of data, including using beta testers who were not involved directly in the app development. These limitations can be addressed through future research directions.

Future Directions

Future research, as part of the Safe-D study, should include an evaluation of the usability and utility of the app. The greater study will confirm whether or not the app is effective in safely improving vitamin D status. For example, it is possible to reach exposure limits for the day, to stop sun damage, without synthesizing enough vitamin D when limited skin is exposed. The algorithm may be updated during the study, as well as other changes based on participant interviews during site-visits regarding experiences, to improve effectiveness. A future improvement to Safe-D may include indicating to the user whether they will likely get adequate vitamin D based on what they are wearing, enabling them to change clothing or alter sunscreen use to improve synthesis.

As this research provides recommended principles for developing interactive eHealth apps for complex messaging, the results are largely theoretical at this stage and require validation before their suitability can be entirely understood. The lack of evaluation is a limitation to these principles. While behavior change was experienced anecdotally among the core researchers and beta testers, the Safe-D study will validate the app and therefore the principles applied in its development. Furthermore, future work in the eHealth app area should leverage these principles to validate them.

Conclusion

This research has provided insights into how to develop interactive eHealth apps for complex messaging. This outcome was achieved by drawing on examples from the literature. A set of guidelines to develop interactive eHealth apps generally, and specifically those for complex messaging, was previously missing from the literature. This research has contributed these principles. Safe-D delivers complex messaging to simplify education, explicitly considering user safety. Therefore, it showed a set of recommendations that might help develop a complex eHealth app that is simple for target users to engage with.

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Conflicts of Interest

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Abbreviations

AIMIA: Australian Interactive Media Industry Association
ARPANSA: Australian Radiation Protection and Nuclear Safety Agency
BOM: Bureau of Meteorology
GP: general practitioner
GPS: Global Positioning System
RCT: randomized controlled trial
UV: ultraviolet radiation
UX: user experience

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Original Paper

Mobile Phone Apps for the Prevention of Unintended Pregnancy: A Systematic Review and Content Analysis

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Abstract

Background: Over 50% of pregnancies in the United States are unintended, meaning that the pregnancy is mistimed, unplanned, or unwanted. Unintended pregnancy increases health risks for mother and child, leads to high economic costs for society, and increases social disparities. Mobile phone ownership is rapidly increasing, providing opportunities to reach at-risk populations with reproductive health information and tailored unintended pregnancy prevention interventions through mobile phone apps. However, apps that offer support for unintended pregnancy prevention remain unevaluated.

Objective: To identify, describe, and evaluate mobile phone apps that purport to help users prevent unintended pregnancy.

Methods: We conducted an extensive search of the Apple iTunes and Android Google Play stores for apps that explicitly included or advertised pregnancy prevention or decision-making support in the context of fertility information/tracking, birth control reminders, contraceptive information, pregnancy decision-making, abortion information or counseling, sexual communication/negotiation, and pregnancy tests. We excluded apps that targeted medical professionals or that cost more than US $1.99. Eligible apps were downloaded and categorized by primary purpose. Data extraction was performed on a minimum of 143 attributes in 3 domains: (1) pregnancy prevention best practices, (2) contraceptive methods and clinical services, and (3) user interface. Apps were assigned points for their inclusion of features overall and for pregnancy prevention best practices and contraceptive information.

Results: Our search identified 6805 app descriptions in iTunes and Google Play. Of these, 218 unique apps met inclusion criteria and were included in the review. Apps were grouped into 9 categories: fertility trackers (n=72), centers and resources (n=38), birth control reminders (n=35), general sexual and reproductive health (SRH) information (n=17), SRH information targeted specifically to young adults (YA) (n=16), contraceptive information (n=15), service or condom locators (n=12), pregnancy tests (n=10), and games (n=3). Twelve apps scored at least 50 points (out of 94) for overall number of features and at least 15 points (out of 21) for contraceptive information and pregnancy prevention best practices. Overall, 41% of apps did not mention any modern contraceptive methods and 23% mentioned only 1 method. Of apps that did mention a modern contraceptive method, fewer than 50% of these apps provided information on how to use it. YA SRH apps had the highest percentage of pregnancy prevention best practices in each app. Demographic and interface evaluation found that most apps (72%) did not target any race and only 10% explicitly targeted youth. Communication interface features were present in fewer than 50% of apps.

Conclusions: This review identified several useful, evidence-based apps that support the prevention of unintended pregnancy. However, most apps miss opportunities to provide users with valuable information, interactive decision aids, and evidence-based interventions for unintended pregnancy prevention. Further, some apps in this space may increase the likelihood of unintended pregnancy due to the low effectiveness of the contraceptive methods promoted.

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KEYWORDS

mHealth; eHealth; mobile phone; app; systematic review; unintended pregnancy; family planning; pregnancy prevention; contraception

Introduction

Over 50% of pregnancies in the United States are unintended [1]. An unintended pregnancy is a pregnancy that is mistimed, unplanned, or unwanted at the time of conception, as the result of interrelated factors associated with knowledge, access, and behavior [2]. Unintended pregnancy increases the likelihood of adverse maternal and child health outcomes and results in high economic costs; US society supports US $11 billion in annual public insurance costs for pregnancy and first-year infant care [2,3]. Unintended pregnancy disproportionately affects younger women 18-24 years old, African American women, and lower-income women, contributing to cycles of poverty and inequality in the United States [2,4,5].

For these reasons, reducing unintended pregnancy is a compelling and complex public health challenge and a national public health goal. The US Department of Health and Human Services' *Healthy People 2020* campaign aims to reduce unintended pregnancy by 10% by 2020 [6]. One way that they are doing this is by supporting evidence-based family planning programs, including those that leverage smartphones to deliver reproductive health information [7-12]. However, most smartphone family planning research focuses on text-message based approaches. Because smartphones are a relatively novel mechanism of health information delivery and behavioral intervention, there is little evidence on how smartphone technology is being leveraged to prevent unintended pregnancy.

Mobile phone apps have rapidly expanded in scope, sophistication, and reach, presenting a unique opportunity to put tools for pregnancy prevention in the pockets of millions of Americans. More than 145 million people in the US (58% of the mobile market) have a smartphone and that number is projected to increase to 220 million by 2018 [13]. Additionally, smartphone ownership demographics align well with those at high risk for unintended pregnancy; 77% of low-income 18- to 29-year-olds own smartphones [14]. Although health-related apps proliferate, there is no evidence that evaluates how they are being used to prevent pregnancy. Our research team conducted a systematic review of smartphone apps to answer the following questions:

Q1. What types of apps are currently available for family planning and pregnancy prevention?

Q2. Through what mechanisms are these apps preventing unintended pregnancy and are these approaches evidence-based?

Q3. What features of mobile technology are included in the user interface of these apps?

Q4. Who are the intended users of these apps and what is their feedback on these apps?

Methods

Search and Screening Strategy

In September 2014, we developed a comprehensive set of 30 search terms by using Medical Subject Headings terms and by consulting with researchers leading 2 other ongoing reproductive health systematic reviews. We also developed the following set of inclusion and exclusion criteria:

1. App includes or advertises at least one component of pregnancy prevention or decision-making such as the following: fertility information (ie, charting, information, etc) that claims to help prevent pregnancy; birth control reminders that claim to help prevent pregnancy; contraception information that explicitly notes pregnancy prevention; pregnancy decision-making information; sexual communication or negotiation information focused on preventing pregnancy.

2. App provides abortion information or counseling.

3. App is a pregnancy test (not including practical joke pregnancy tests).

4. App is for personal use by individuals looking to make decisions about their pregnancy (ie, not for clinicians, researchers);

5. App is not specific to one event (such as a conference);

6. App is in English;

7. App does not cost more than US $1.99.

To be included in the review, the app had to either explicitly state that it could help prevent unintended pregnancy or have content that supported unintended pregnancy prevention or decision-making, such as information on how to negotiate safe sex, clarification of pregnancy intention, or information about birth control. We also included apps that provided abortion counseling or related information following the rationale that individuals seeking information about abortion may have significant need for improved reproductive health/family planning services to prevent future need for abortion. We therefore wanted to assess the information provided at this key juncture. Similarly, we included pregnancy test apps that may not have a primary purpose of preventing unintended pregnancy but may be the first point of access for individuals whose contraceptive method has failed and, regardless of whether they are pregnant, may be in need of improved family planning or contraceptive counseling.

We only included apps that cost US $1.99 or less because we wanted to evaluate apps that were at a price point that is accessible to the majority of consumers. While most apps were indeed free, we did not limit the review to free apps because we also wanted to assess whether there were significant quality differences between paid and unpaid apps. After a brief,

preliminary review of apps, US $1.99 was selected as an appropriate cutoff given the high availability of apps at the US $0.00, US $0.99, and US $1.99 levels. Additionally, paid apps that advertised the same services as their free counterparts were excluded to avoid duplication.

Each search term was put into both the iTunes store and Google Play store search engines and the resulting number of app descriptions was recorded for each search term (see Appendix I for search terms and search engine results). Search terms with high returns, such as "sex," were automatically capped at 500 app descriptions by iTunes and 250 app descriptions by Google Play. All app descriptions were screened for relevance based on the inclusion criteria; however, because of the high number of returned app descriptions and there being no way to export the app descriptions into a spreadsheet, only apps that met inclusion criteria were documented. Therefore at the app description review level, we were unable to document the individual reasons for the exclusion of 6183 apps. Among the 4 reviewers, inter-rater reliability (IRR) checks were done independently for 20% of app description results in iTunes and Google Play (40% total), with IRR ranging from 94% to 100%. An additional screening of 100 (33%) of the included app descriptions was done collaboratively by all 4 reviewers for further quality control and shared understanding.

Codebook Development

The codebook and data extraction form were finalized using examples from ongoing systematic reviews, as well as sources of pregnancy prevention best practices [15-17]. We established 3 broad domains—(1) pregnancy prevention best practices, (2) contraceptive information and clinical services, and (3) user interface—and data extraction points were created in each domain. Additional purpose-specific questions were developed once the primary purpose categories for all apps were finalized. Purpose-specific questions were developed for the young adult sexual and reproductive health information apps, birth control reminders, and fertility tracking apps in order to capture the nuances of these particular pregnancy prevention strategies. In total, the codebook included 143 data extraction points for every app, plus up to an additional 15 purpose-specific data extraction points.

Data Extraction and App Assessment

Data extraction occurred in November 2014. In this study, 2 researchers with iPhones were assigned to iTunes and 2 with Android phones to Google Play. Apps were downloaded to the respective phones and 10% of those apps were co-reviewed between same-platform reviewers, with IRR scores of 92% and 95%.

Q1. App Purpose

To answer the first research question about what types of apps are in the family planning space, apps were categorized by their perceived primary purpose (eg, birth control reminders, fertility trackers, etc). Categorization was done on an iterative basis as the app descriptions were reviewed in the stores and was finalized by the team during the data extraction phase when content was reviewed in depth. Apps were assigned only to 1 category.

Q2. Mechanism of Pregnancy Prevention and Evidence-Based Practices

We used 3 methods to evaluate the mechanisms through which the apps attempted to prevent unintended pregnancy and their use of evidence-based approaches.

After a thorough review of PubMed and the gray literature, we identified a recent evidence-based clinical practice guideline for the prevention of unintended pregnancy that incorporated interventions for pregnancy prevention and evidence from federal and non-governmental programs into a comprehensive framework for unintended pregnancy prevention [16]. These guidelines provide a full spectrum of essential primary, secondary, and tertiary prevention services, including:

1. *Primary:* Assessment of personal and family health risk factors for unintended pregnancy (including intimate partner violence and substance abuse), appropriate screening tests, and prevention services;
2. *Secondary:* Assessment of pregnancy status, options counseling, support to continue pregnancy, and early abortion care; and
3. *Tertiary:* Pregnancy diagnostics/screening, crisis counseling, options counseling, support and termination referral coordination.

We further distilled these guidelines into the 7 pregnancy prevention best practice queries below, which either directly prevent unintended pregnancy (P1, P2, P4, P5, P7) or potentially lead to support for the termination of a current pregnancy or the prevention of future unintended pregnancy (P3, P6). We assessed each app for the inclusion of these 7 items, assigning 1 point per included item for total possible score ranging between 0 and 7.

P1. Does the app screen for or provide information about substance abuse?

P2. Does the app screen for or provide information about intimate partner violence?

P3. Does the app refer the user to pregnancy testing?

P4. Does the app ask the user to consider a life plan or their pregnancy intentions?

P5. Does the app provide behavioral contraceptive counseling?

P6. Does the app provide abortion counseling or referral?

P7. Does the app provide information about emergency contraception?

Second, to summarize the overall inclusion of information about contraceptives, we assessed the presence or absence of a mention of 14 barrier, device, or drug-based/hormonal contraceptive methods (eg, male condom, female condom, diaphragm, sponge, cervical cap, oral contraceptive, injectable contraceptive, intrauterine device (IUD), implant, patch, ring, spermicide, emergency contraception, and surgical sterilization) from the World Health Organization's modern methods list and the more comprehensive Planned Parenthood birth control list, as well as less effective methods such as fertility tracking and withdrawal [18-20]. We also assessed whether the app described

how to use the contraceptive method, and whether the app provided information on the effectiveness of the contraceptive method. Finally, we evaluated whether the app provided information on where to access (any) contraceptives (eg, at a clinic, a pharmacy, a grocery store), whether the app located (any) contraceptives near the user, whether the app provided (any) information on contraceptive risks or side effects, whether the app included (any) information on side effect management or switching contraceptive methods, and whether the app discussed dual protection (ie, prevention of both pregnancy and sexually transmitted infections (STIs)).

Third, we quantitatively scored each app using 2 scores: (1) the first based on the total number of desirable features (interface and content) included out of 84 possible features and (2) the second score based on the number of contraceptive methods out of the 14 noted above and the number of 7 possible pregnancy prevention best practices included in the app (possible score of 21; see Appendix III). We qualitatively described any innovative or useful features in the top-scoring apps. If the app provided a clear overall message about how to avoid unintended pregnancy, it was weighted to receive 10 points. For example, to meet this criteria fertility trackers had to go beyond notifications like "you are fertile today" and provide actionable prevention guidance such as "use a condom during sex to prevent pregnancy this week."

Q3. User Interface

Answering the third research question about which features of smartphone technology were represented was done with consultation from an app development specialist who helped clarify and define the different components of smartphone user interface. We reviewed apps for 16 desirable interface features, 13 of which could directly support prevention of unintended pregnancy through access, knowledge, or communication, such as GPS, maps navigation, clinic/service locators, contraceptive locators, interactivity (ie, setting profiles and getting tailored information), appointment scheduling, public/forum communication, direct communication (eg, chat, text, call), push notifications, informative videos, audio, and a decision aid feature to help users actualize pregnancy intentions, clarify contraceptive preferences, and/or make decisions about sexual partners or activity. An additional 3 positive features, including customizable skins/background, main menu/navigation bar, and text/image clarity, were included in the evaluation because they contribute to user experience and the likelihood that a user will continue to use the app or recommend it to peers. We also evaluated apps for the presence of 4 undesirable components of interface, including whether the app crashed during review, whether navigational links were broken, whether there was advertising, and whether the app required purchase after being downloaded in order to use the basic features advertised in the free version.

Q4. Targeted Users and User Feedback

Demographic information about app users was not publicly available, so we devised a methodology to answer this research question based on the images in the apps. To evaluate racial inclusion, we reviewed all of the images of people in the apps and classified each image as Caucasian, Hispanic, African American, East Asian and/or Indian based on physical appearance. When there was racial or ethnic ambiguity, the image was tagged in multiple race/ethnicity categories.

We also reviewed for gender-targeting. Apps were deemed to be targeting females if it was explicitly stated or if the apps only provided services that are relevant to a female (such as tracking her own menstrual cycle). Apps were deemed to be targeting males if the app only provided male sexual or reproductive health information. Apps that were categorized as gender-inclusive were apps for shared tracking of fertility or birth control information, gender-neutral service/contraceptive locators, or gender-neutral or gender-inclusive information about contraceptives and sexual and reproductive health (SRH). In terms of age, we reviewed for general versus young adult targeted apps. Apps were categorized as young adult if the app title or description stated that it was for "teens," "young adults," "girls," "boys," "youth," "adolescents," or "students."

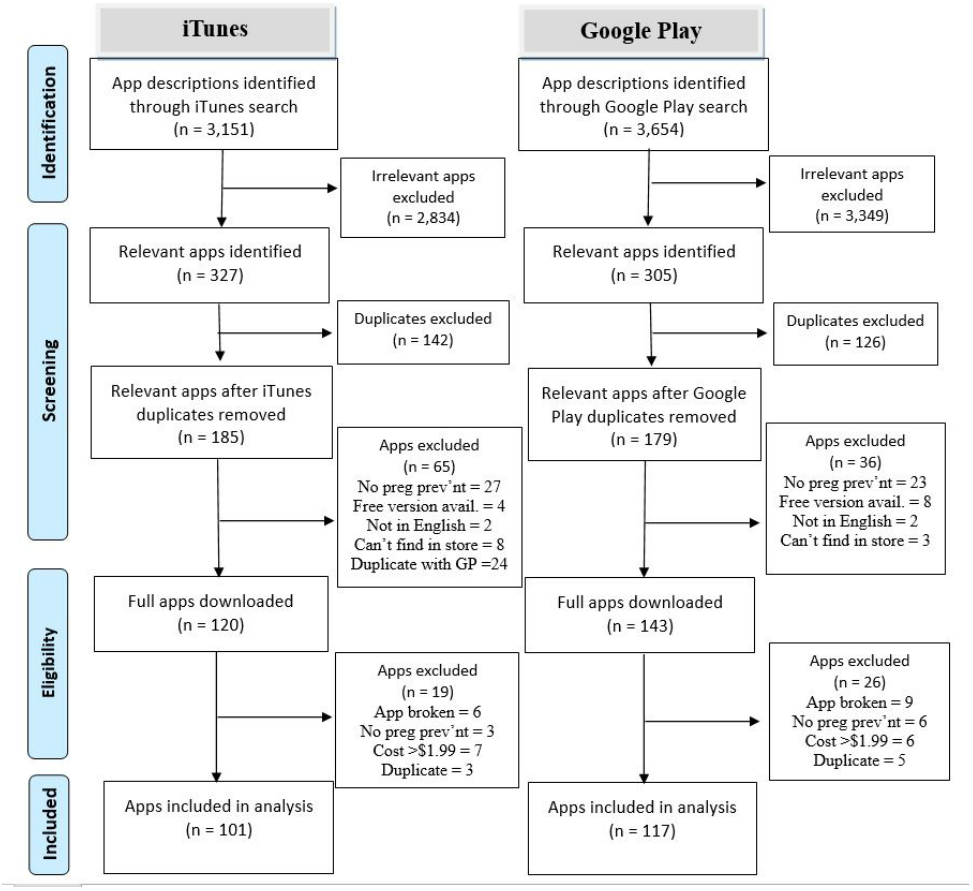
Finally, we conducted an overall analysis on user ratings and downloads. iTunes does not provide information on number of downloads (an indication of app popularity) so only Google Play apps were analyzed for use and ratings.

Results

Search Results and Categories

Our search strategy resulted in 6805 app descriptions in iTunes (3151) and Google Play (3654) (see Figure 1 for a PRISMA diagram of the search results [21]). Of these, 218 unique apps met inclusion criteria and were included in the review (101 in iTunes, 93 in Google Play, and 24 listed in both). See Appendix II for full list of included apps. Apps that were available in both iTunes and Google Play were removed from the iTunes group and only analyzed as Google Play apps to avoid duplication. Within the iTunes and Google Play stores, 105 included apps were found in the health and fitness (48%), 68 apps in medical (31%), 20 in lifestyle (9%), 12 in education (6%), and 13 in other store departments (6%).

Figure 1. PRISMA diagram for iTunes and Google Play search results.

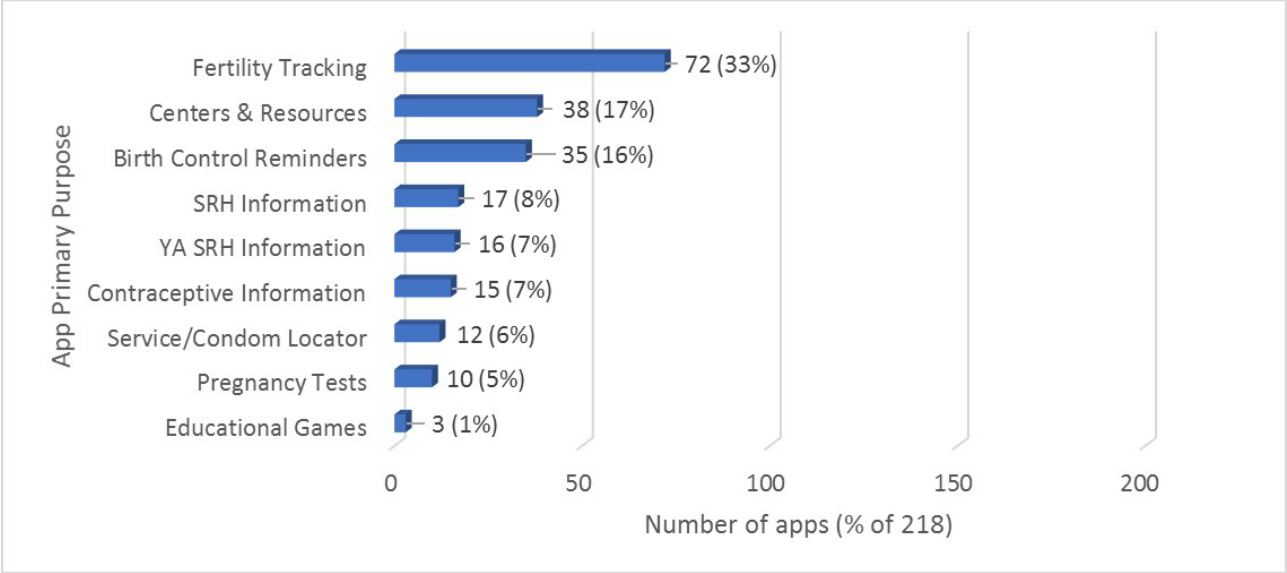


Q1. App Purpose

Nine "primary purpose" categories were generated based on the apparent purpose and content of the 218 included apps (Figure 2). These categories were fertility tracking apps (n=72), centers and resources (n=38), birth control reminders (n=35), SRH information apps (n=17), SRH apps for young adults (YA) (n=16), contraceptive information apps (n=15), contraceptives or service locator apps (n=12), pregnancy tests (n=10), and education games (n=3). The largest category, fertility trackers, included apps that explicitly advertised that they could help women prevent pregnancy by assisting the user with fertility awareness-based methods of family planning, also called natural family planning. Fertility trackers mostly utilized user-provided information about menstrual cycles and cervical biomarkers to predict when a woman would or would not be fertile. It is important to note that fertility tracking is more commonly used by those trying to become pregnant and these apps could be used for that purpose as well. No fertility tracking apps we identified were exclusively designed for the purpose of preventing pregnancy.

The next largest group of apps, centers and resources, was developed for facilities that offer clinical services, pregnancy testing, and/or abortion counseling. With a few exceptions, such as the Planned Parenthood app, these center-based apps primarily referred users to pregnancy support centers that provide pro-life or "life affirming" pregnancy options counseling. The third largest category, birth control reminders, explicitly advertised pregnancy prevention. Birth control reminder apps generally used visual cues such as blister packs or calendars, push reminders, and alarm features to remind the user to take their birth control. Birth control methods supported by these reminders were mostly daily oral contraceptives, but a few were for alternative contraception, including the ring (NuvaRing), the patch, and the shot (Depo-Provera). Other categories included apps that provided general SRH information and apps that provided SRH information in a more targeted manner to young adults. We also identified groups of apps that primarily provided contraceptive method information, typically as a descriptive list of types of contraceptives; apps that were for the purpose of locating SRH services or condoms using GPS features; pregnancy tests, which collected information about biological and behavioral user experience; and educational games.

Figure 2. Primary purposes of 218 apps that support unintended pregnancy prevention.



Q2. Methods for Pregnancy Prevention

Only 65 apps (30%) conveyed a clear message on how to prevent pregnancy. Of the 7 evidence-based best practices, screening for unintended pregnancy risk factors—such as substance abuse or intimate partner violence—were the least common practices in these apps, in 13 (6%) and 19 (9%) of apps, respectively (see Figure 3). Behavioral contraceptive counseling, defined as persuasive counseling that recommends or describes the importance of contraceptives, was also infrequently included. The most common evidence-based pregnancy prevention method in apps—referral to pregnancy testing—was offered by less than a third of all apps.

When we analyzed the presence of best-practices by app primary purpose, we found that YA SRH apps integrated the highest percentage of overall best practices into their services offered, followed by center and resource apps and general SRH information apps (Table 1). Fertility tracking apps, birth control reminder apps, and pregnancy test apps incorporated the fewest best practices for preventing unintended pregnancy.

Figure 3. Pregnancy Prevention Best Practices Found in Apps.

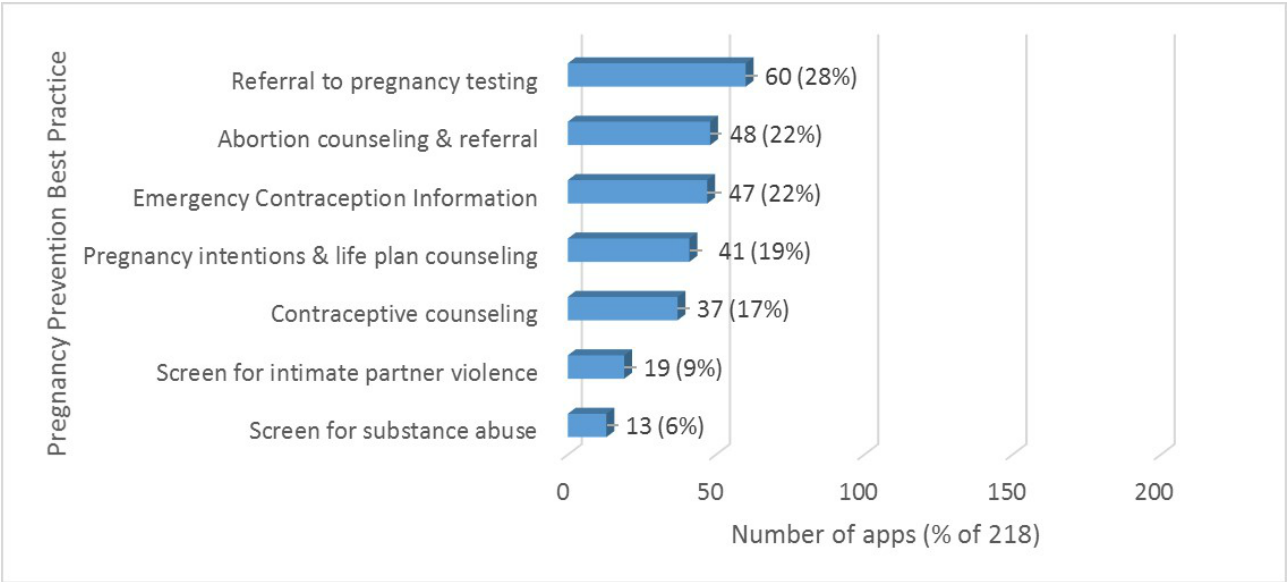


Table 1. Number and percentage of pregnancy prevention best practices in apps by app purpose.

App primary purpose (n)	Pregnancy prevention best practices, n (%)							
	P1	P2	P3	P4	P5	P6	P7	3+[a]
Fertility Tracking (72)	0 (0)	0 (0)	2 (3)	1 (1)	6 (8)	0 (0)	1 (1)	0 (0)
Centers and Resources (38)	1 (3)	3 (8)	34 (89)	29 (76)	3 (8)	32 (84)	14 (37)	29 (76)
Birth Control Reminders (35)	0 (0)	0 (0)	2 (6)	0 (0)	1 (3)	0 (0)	0 (0)	0 (0)
Contraceptive Information (17)	1 (6)	0 (0)	2 (12)	3 (18)	5 (29)	1 (6)	8 (47)	3 (18)
SRH Information (16)	4 (25)	7 (44)	4 (25)	4 (25)	7 (44)	4 (25)	8 (50)	8 (50)
YA SRH Information (15)	7 (47)	8 (53)	9 (60)	3 (20)	11 (73)	9 (60)	11 (73)	10 (67)
Service/Condom Locator (12)	0 (0)	1 (8)	2 (17)	1 (8)	3 (25)	2 (17)	4 (33)	3 (25)
Pregnancy Tests (10)	0 (0)	0 (0)	5 (50)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Educational Games (3)	0 (0)	0 (0)	0 (0)	0 (0)	1 (33)	0 (0)	1 (33)	0 (0)

[a]3+ Includes 3 or more of best practices P1-P7.

Contraceptive Information

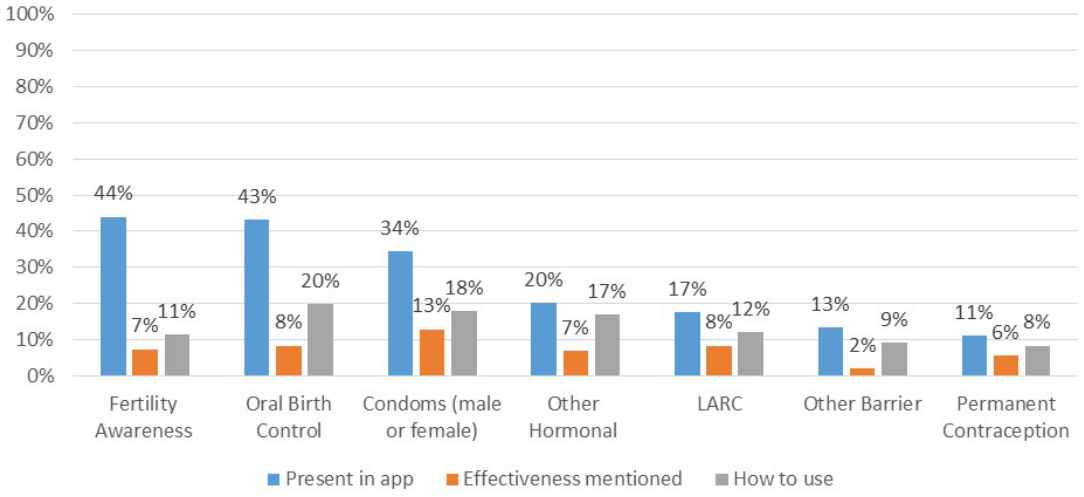
Although there was a wide range of contraceptive methods that appeared in some apps, 89 apps (41%) did not mention any of the 14 modern contraceptive methods we evaluated and 51 apps (23%) mentioned only 1 of these methods. The most commonly mentioned methods were fertility awareness (96; 44%), oral birth control pills (94; 43%), and male or female condoms (75; 34%) (Figure 4). Of the apps that did mention a contraceptive method, less than half of all apps provided further information on how to use the method or the method's effectiveness at preventing pregnancy.

SRH information, YA SRH information, and contraceptive information app categories had the greatest number of individual apps that mentioned the largest number of contraceptive methods. On average, apps in each of these 3 categories mentioned 7 contraceptive methods and were also more likely to mention the effectiveness of the contraceptive methods, compared with other app categories. Fertility tracking apps seldom mentioned any other method than fertility awareness except when discouraging the use of hormonal contraceptives because they affect the user's menstrual cycle, making it harder to track. Birth control reminders rarely mentioned the use of contraceptive methods other than the particular method that app was promoting, even if the user entered data showing poor adherence.

In terms of access to contraceptives, 36 apps (17%) provided information on where users could access contraceptives (eg, clinics, pharmacies, grocery stores, etc) and 17 apps (8%) helped users locate contraceptives near them (using GPS or a search for that city). Unsurprisingly, contraceptive locator apps had the highest percentage of apps with access information, with 92% (11/12) of contraceptive locator apps including both where to seek contraceptives and help in locating these venues. YA SRH apps followed with 75% of YA SRH apps providing information on where a user could access contraceptives and 31% helped users locate specific points of sale. A total of 41% and 40% of SRH information apps and contraceptive information apps, respectively, provided information on where users could locate contraceptives—but only 1 app in each category provided specific locator services.

Contraceptive information apps, SRH information apps, and YA SRH apps had the highest percentage of apps that discussed contraceptive side effects (53%, 47%, and 44%, respectively), as well as the highest percentage of apps that discussed side effect management or switching methods (20%, 18%, and 13%, respectively). Notably, only 1 of 35 birth control reminder apps included any information on contraceptive side effects or switching. YA SRH apps, SRH information apps, and contraceptive information apps had the highest percentage of apps that included information about dual protection (ie, protection against both pregnancy and STIs) at 75%, 71%, and 53%, respectively.

Figure 4. Percentage of mobile phone apps containing information about types of contraceptive methods, their effectiveness, and use.



Scoring and Qualitative Evaluation

There was a strong correlation (0.93) between overall scores (out of 94) and contraceptive information/best practices scores (out of 21). Fifteen apps scored at least 50 points for overall features and at least 15 points for contraceptive information and pregnancy prevention best practices, but 3 were excluded from the "high-score" list because they crashed during testing and were therefore not reviewed here (Table 2). Of the 6 top-scoring apps, 1 app was on YA SRH information, 4 were general SRH information, 1 app was from the contraceptive information category, and 1 from the centers and resources category. Most of these apps had credible public health-related developers such as Planned Parenthood, New York City (NYC) Department of Public Health, and the National Health Service (NHS) in the United Kingdom (UK). In addition to the contraceptive information and pregnancy prevention best practices features, these apps included features like GPS, push notifications, decision aids, a clear description of how to avoid unintended pregnancy, information on dual protection and STIs, and many other of the 84 attributes that contribute to user experience and support the prevention of unintended pregnancy. In this study, 5 of the 11 top-scoring apps were developed in the United States and 4 were developed in the United Kingdom.

Two of the top-scoring apps, Mayo Clinic About Birth Control and SafeSex Guide, cost money to download (US $1.99 each). However, when comparing apps that were free (n=176) to paid apps (n=42), paid apps actually scored lower on average for both best practices (3.2 vs 3.8) and overall (13.4 vs 16.4).

In addition to the quantitative scoring, reviewers also wrote brief descriptions of the apps, including notable features or problems. Among the highest-scoring apps, there were several features that are worth highlighting. The *Mayo Clinic: About Birth Control* app included a useful interactive decision aid that guided users to a contraceptive method that was a good fit for them based on a series of questions about pregnancy intentions, health conditions, personal habits, privacy requirements, and general preferences. This app also provided helpful videos, pictures, and a glossary of contraceptive information. A useful feature in the *My Sex Doctor Lite* app is a series of questions that lets young adults explore whether they are in an abusive or controlling relationship. The *My Sex Doctor Lite* app is structured in a question-and-answer format and also asks (and answers) other questions about sexual health, relationships, STIs, and unintended pregnancy. *Teens in NYC* navigates young adults through questions about where to go for sexual health services, what types of birth control are available, and what to expect at the clinic. A notable feature in the *Teens in NYC* app was its statement that "Teens in NYC have the right to sexual health services without getting permission from parents, girlfriends/boyfriends or anyone else," empowering teens and addressing concerns about parental and partner consent as barriers to access and use. Finally, there was an interesting feature in the *C&SH Summerset* app called a "c-card" that allows users to get information about condoms, set their condom preferences, and use the app to "purchase" condoms for free from select retailers. Users can get their c-card key fob and app PIN from a community-based "Issuer" who provides counseling and other assistance. The top scoring apps used varying approaches but provided evidence-based features and services for pregnancy prevention.

Q3. User Interface and App Features

Table 3 provides key statistics on different features of the apps ranging from whether they had a main navigation menu (157; 72%), were interactive (ie, user had the ability to set personal preferences and input profile information in a way that the app provided tailored feedback) (138; 63%), used GPS (60; 28%), or facilitated communication. Noted communication features included push notifications from app to user (90; 41%), direct or public forum communication (28% and 27%, respectively), and appointment scheduling (25; 11%). We also evaluated whether the app allowed the user to personalize the appearance of the app (39; 18%), whether the app included video (25; 11%) or audio (13; 6%), or whether the app functioned as a sexual decision aid (ie, provided tailored recommendations or scenarios to support sexual decision-making) (17; 8%). Finally, we noted when there was advertising (69; 32%) and when there were faulty elements such as unclear images, unresponsive navigation, or app crashes (43; 20%).

Table 2. Highest scoring apps overall and for contraceptive/best practices.

App name	Developer/sponsor (country)	App category (primary purpose)	Platform	Contraceptives + best practices score (out of 21)	Overall score (out of 94)
Planned Parenthood Care	Planned Parenthood Federation of America (US)	Centers & Resources	Google Play & iTunes	21	69
Sexual Health Guide	GIRT Mobile (Ireland)	SRH Information	Google Play & iTunes	19	65
No Worries	Wiltshire College, Terrence Higgins Trust, and Salisbury PCT (UK)	SRH Information	Google Play	18	71
Your Choice Your Voice	NHS and Bromley Healthcare (UK)	YA SRH Information	iTunes	18	69
My Sex Doctor Lite	MYSD LTD; NHS (UK)	YA SRH Information	Google Play	18	63
C&SH Somerset	NHS (UK)	YA SRH Information	iTunes	18	58
Mayo Clinic About Birth Control	Mayo Clinic (US)	Contraceptive Information	iTunes	17	59
Girls Incorporated of Lynn	MDPH Office of Adolescent Health and Youth Development (US)	YA SRH Information	Google Play	17	54
SafeSex101	Associated Students UCLA (US)	YA SRH Information	iTunes	15	58
SAFE	Amphibia (Malaysia)	SRH Information	Google Play	15	55
SafeSex Guide	Mobile Identity Danmark ApS (Unknown)	SRH Information	iTunes	15	54
Teens in NYC	NYC Department of Health and Mental Hygiene (US)	YA SRH Information	Google Play & iTunes	15	53

Table 3. Key user interface features.

User interface features	Number of apps	%
Main navigation menu	157	72
Interactive	138	63
GPS	60	28
Push notifications	90	41
Direct communication (live chat or email)	62	28
Public communication (forums)	58	27
Appointment scheduling	25	11
Customizable look (skins, etc)	39	18
Video	25	11
Audio	13	6
Sexual decision aid	17	8
Undesirable: advertising	69	32
Undesirable: faulty element or app crashes	43	20

Q4. Target User Demographics

Most apps (158; 72%) did not include pictures from which target race could be discerned. When images were included in the apps they depicted Caucasians in 59 apps (27%), African Americans in 24 apps (11%), Asians in 18 apps (8%), Hispanics in 13 apps (6%), and Indians in 5 apps (2%). As much as 12% of apps contained images of Caucasians only while 15% included images of multiple races. The majority of apps (73%) had no images of people from which to determine race. As mcuh as 22% of apps were available in at least one language other than English.

A total of 123 apps (56%) targeted females, 5 (2%) targeted males, and 90 (41%) targeted both females and males. Apps for birth control reminding, fertility tracking, and pregnancy testing mostly targeted females (94%, 93%, and 90% of apps, respectively). All other app categories were mostly gender-inclusive. Only in the contraceptive information category did the number of apps targeting males outnumber the apps

targeting females, and this was due to 3 male condom preference/male condom sizing apps.

A total of 21 apps (10%) explicitly targeted "youth," "teens," or "young adults" but (using the rating criteria in iTunes and Google Play) only 13% of apps were rated "high maturity" in Google Play or "17+" in iTunes, indicating that 87% of apps were considered appropriate for, though not necessarily tailored to, young adults.

In terms of use and feedback, fertility tracking apps were by far the most popular apps with total downloads at over 68 million and a per-app average of 1.68 million downloads (Table 4). In addition to being popular, fertility tracking apps were also relatively well-liked with an average rating of 4.06 out of 5 stars. Birth control reminders and pregnancy tests also had high numbers of total downloads and per-app downloads but less so than the fertility tracking apps. Educational games and apps for centers and resources were the least downloaded apps. Notably, while young adult sexual and reproductive health apps had relatively few downloads, they were the highest rated as a group with 4.37 stars, indicating user satisfaction with the services offered. Some purpose categories, such as centers and resources and YA SRH information, have more location-based services, which may account for the lower number of downloads and reviews.

Table 4. App use and rating information from Google Play apps[a].

App purpose (n)	Total downloads (average of range)	Average downloads/app	Average rating (out of 5 stars)	Total reviews
Fertility tracking (41)	68,844,675	1,679,138	4.06	1,579,017
Birth control reminders (22)	1,835,550	83,434	3.76	40,082
Pregnancy tests (7)	1,006,050	143,721	3.21	3886
SRH information (10)	114,960	11,496	3.63	383
Contraceptive information (9)	101,259	11,251	3.93	681
Service/condom locator (5)	64,050	12,810	3.46	100
YA SRH information (11)	19,590	1781	4.37	151
Centers and resources (11)	1140	104	5.00	5
Educational games (1)	30	30	n/a	n/a

[a]App usage information was not available in iTunes Store.

Discussion

Principal Findings

This systematic review of commercially available apps for iPhone and Android phones found a limited number of credible, evidence-based family planning and pregnancy prevention apps. Furthermore, identifying these apps using the search tools available in the iTunes and Google Play stores was challenging and time-consuming. Our team had to review thousands of app descriptions because there was not a sensitive search tool offered by either store. Another challenge was that once relevant apps were identified, it was often difficult to determine who had created the app and whether it was a credible source of family planning information. For example, the search term "abortion" resulted in the inclusion of several pregnancy testing centers that provided "abortion counseling." However, when our research team called the centers to learn more about them, we found that they were mostly "life-affirming" organizations that did not actually refer for abortion. The implications of these findings are that users may be overwhelmed with irrelevant and uninformative apps and not be able to find apps that are responsive to their health needs or personal choices regarding family planning and pregnancy prevention.

The most important takeaway from this review is that an in-depth review of app content revealed the frequent absence of evidence-based best practices for pregnancy prevention as well as substantive information about effective methods of contraception. Only 17% of apps mentioned long-acting reversible contraceptives, including the IUD and implant, which are the most effective and longest-lasting reversible methods for preventing pregnancy. Providing information about these methods, especially to high-risk adolescents and young adults, is critically important given the low levels of awareness among young adults and in the general population [22]. Also notable was that only about a third of apps mentioned condoms, which are the only method of contraception that protects against both unintended pregnancy and STIs. Oral contraceptives were the most commonly referred to method among all apps, but this was due to the high number of apps that had the specific purpose of reminding users to take birth control. Disappointingly, birth control reminders largely missed out on opportunities to provide additional information on what to do if a pill was missed, what to expect from side effects, and alternative or supplemental contraceptive methods.

We also expected much higher percentages of information about emergency contraception and abortion in pregnancy testing apps, and contraceptive counseling and emergency contraception information in apps that educate the user about contraceptive methods. Pregnancy test apps were uninformative and contraceptive information apps mostly provided lists of information rather than offer tailoring, contraceptive preference clarification, or screening services. Finally, we found an unfortunate lack of apps that helped users actualize pregnancy

intentions and to clarify sexual and reproductive health decisions and contraceptive preferences.

While there were a few apps that were innovative, interactive, and evidence-based, most apps in this space missed opportunities to provide useful information or interventions for unintended pregnancy prevention. Sexual and reproductive health information apps, centers and resources, and young adult sexual and reproductive health apps had the highest inclusion of evidence-based pregnancy prevention practices and the top-scoring apps were mostly found in these categories.

Another important finding of this study was that the largest group of apps that explicitly advertises pregnancy prevention is fertility trackers that support natural family planning or fertility awareness methods. This is concerning because according to the US Centers for Disease Control and Prevention, fertility awareness methods are the least effective method of birth control, with a failure rate of 24% per year [20]. One caveat, noted earlier, is that all of the fertility tracking apps included in this review could also be used to try to become pregnant and it is not possible to discern the app user's pregnancy intentions. However, with such a high number of downloads and high user approval rating, it is possible that users who are happy with the pregnancy promotion features of these apps may also use them for child spacing and pregnancy prevention purposes. However, if this group of users rely exclusively on fertility tracking apps for pregnancy prevention, it could lead to a high number of unintended pregnancies.

Centers and resources apps were not significantly different from center Web pages and included few features other than information about the centers (with the notable exception of the Planned Parenthood app). These apps therefore were not very useful as stand-alone pregnancy prevention interventions. Similarly, birth control reminders were narrowly focused on providing 1 service such as an alarm or push notification for reminders. Nearly 2 million women downloaded apps whose only pregnancy prevention feature was a daily reminder. These apps therefore largely missed an important opportunity to provide information about how to use the methods, the importance of staying on schedule, what to expect from side effects, and what to do if a dose was missed. These apps could have also been improved with the inclusion of information on dual protection, other contraceptive method options, and how to discuss contraceptive use with partners/parents/health providers.

It was also noteworthy to find that higher app price was not necessarily associated with higher app quality. Most of the 42 paid apps were for fertility tracking (n=19) and birth control reminding (n=13), which provided specific services. Only 2 of the top-scoring apps cost money, indicating that quality can be found—indeed may even be more likely to be found—in apps that are free to users because they are for the purpose of health promotion, rather than financial gain.

A final remarkable finding was the extremely small number of games that we were able to include in the review from the extraordinarily large number of games that appeared in the search results. What is worth noting is why the games were excluded, namely: games were almost exclusively played from the perspective of the "hero" sperm and the goal of most games was to avoid as many birth controls as possible in order to get to the egg and "win." Most games were therefore excluded because they did not include component of pregnancy prevention.

Limitations

This review is subject to several limitations. One challenge stems from the ineffective search tools available in the iTunes and Google Play stores, which limited our ability to accurately and easily identify relevant apps. Also, because iTunes and Google Play stores capped the app results at 500 and 250, respectively, we may have missed apps that would have been included if we had been able to find them.

A limitation noted earlier in this paper is that there is no way to distinguish who is using the apps or for what purpose. This is an especially important consideration for the fertility apps, which constitute the largest group of apps in this review but may be used primarily by women who are trying to become pregnant rather than those who are seeking to prevent pregnancy.

A third limitation is that because of the novelty of the app as a platform for supporting unintended pregnancy prevention, there is not an established framework or pregnancy prevention best practices specifically for mobile phone apps. We adapted an evidence-based clinical guideline for prevention interventions but acknowledge that these guidelines may not be relevant for every app evaluated. Along these lines, because our review was so large, many of our data extraction points were simplified to a simple presence or absence of a feature, rather than a review of the quality of that feature. As this field matures, the research presented here can help inform future work on establishing guidelines and quality frameworks for evidence-based approaches to using apps for the prevention of unintended pregnancy.

Conclusions

The conclusion of this review is that while there are several innovative, interactive, and evidence-based apps that have credible developers and provide useful information or interventions to prevent pregnancy, these apps are difficult to identify because the large majority of apps miss opportunities to help users prevent pregnancy by providing effective information, interventions, or referrals. Even more concerning is the possibility that the use of some of these apps may lead to additional unintended pregnancies due to the ineffective methods promoted or the lack of comprehensive information. A more concerted effort to promote or at least distinguish apps with credible sources and evidence-based best practices is needed. While it can be challenging to identify and adhere to guidelines for best practices, app developers should be cognizant that guidelines exist and should attempt to include additional evidence-based best practices for pregnancy prevention in their apps. Additional research on the impact of these apps on user experience, knowledge, attitudes, skills, behaviors, and outcomes would provide helpful insight into the value and effectiveness of these apps.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

I. Search Terms and Search Engine Results & Sensitivity II. App Names, Platforms, Developers, & Primary Purposes for 218 Included Apps III. Grading Criteria for Contraceptives and Best Practices and Overall Scores.

[PDF File (Adobe PDF File), 169KB - mhealth_v4i1e6_app1.pdf]

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Abbreviations

IRR: inter-rater reliability
IUD: intrauterine device
STI: sexually transmitted infection
SRH: sexual and reproductive health
YA: young adult

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Original Paper

Mobile Phone Apps for Inflammatory Bowel Disease Self-Management: A Systematic Assessment of Content and Tools

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Abstract

Background: The rising incidence of inflammatory bowel disease (IBD) over the past decade has resulted in increased health care utilization and longer IBD outpatient waiting lists. Self-management is recognized as an important aspect of chronic disease management but its application to IBD has been limited. The age of IBD onset in a majority of patients is in their 20s to 30s. Mobile phone apps are a technology familiar to young adults and represent an opportunity to explore self-management as a new model of health care delivery for IBD.

Objective: The aim of this study was to explore the content and tools of existing IBD apps to identify functionalities that may facilitate patient self-management.

Methods: We systematically assessed apps targeted at IBD patients via searches of Google (Android devices) and Apple (iOS devices) app stores with pre-defined inclusion and exclusion criteria. Apps were assessed for specific functionalities; presence of professional medical involvement; consistency with international IBD guidelines based on “complete,” “partial,” or “absent” coverage of consensus statements derived from the European Crohn’s and Colitis Organisation, American College of Gastroenterology, and the Gastroenterology Society of Australia; comprehensiveness of data that could be entered; and average pricing.

Results: Of the 238 apps screened, 26 apps were assessed, including 10 available on Android platforms, 8 on iOS platforms, and 8 on both. Over half (14/26, 54%) of the apps had diary functionalities; over a third (10/26, 39%) provided health information about IBD. None of the apps offered decision support to facilitate the self-initiation of medical therapy. Five of 26 (19%) had professional medical involvement in their design. Apps demonstrated “complete” coverage of only 38% of the international consensus statements explored. The average price of the apps was AUD$1.37.

Conclusions: Apps may provide a useful adjunct to the management of IBD patients. However, a majority of current apps suffer from a lack of professional medical involvement and limited coverage of international consensus guidelines. Future studies and app design for IBD should include professional medical involvement, evidence-based guidelines, and functionalities with decision support that are specifically tailored to patient self-management.

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KEYWORDS

IBD; apps; eHealth; smartphone; mhealth

Introduction

Inflammatory bowel disease (IBD) including Crohn's disease (CD) and ulcerative colitis (UC) is a group of chronic inflammatory disorders of the intestine that have a relapsing and remitting disease course. IBD is associated with an increased prevalence of physical and psychological morbidity, and it adversely affects quality of life, societal interaction, and functioning [1,2]. Electronic health (eHealth) technologies incorporating self-management strategies to manage patients remotely may offer an effective alternative to classical outpatient-based approaches. However, the application of eHealth technologies to the IBD setting has been relatively limited [3-9]. The age of disease onset in the majority of patients is in their 20s and 30s [10,11]. Therefore the advent of mobile phones, a technology familiar to young adults, represents an opportunity to explore a new avenue of disease management in the form of mobile phone apps.

Apps, computer programs designed specifically to be run on mobile phones and tablet personal computers, are widely available to the consumer for download from online stores. The smartphone market is rapidly expanding. Nearly half (8.67 million) of Australian adults were estimated to be using a smartphone in May 2012, which increased to 64% (11.19 million) in May 2013 [12]. Over half (56%) of US adults owned a smartphone in 2013; specifically, 79% of adults aged 18-24 and 81% of adults aged 25-34 own smartphones [13].

The proliferation of mobile phones has facilitated the emergence of medical apps designed for management of chronic conditions such as asthma, diabetes, and rheumatoid arthritis [14-16]. These diseases are similar to IBD in that they are all characterized by chronicity requiring long-term pharmacological treatment and frequent outpatient clinic visits, with intermittent flares of disease activity requiring adjustments in medication. Apps for patients with these conditions typically have a number of common specified functions, including provision of disease information, dietary and lifestyle advice, electronic diaries for symptom tracking, and medication diaries and reminders. Some novel apps and mobile phone-based systems further provide functions for self-management of disease exacerbations [17-19]. Self-management whereby patients can adjust their therapy based on pre-determined algorithms or seek medical assessments is an emerging and promising aspect of chronic disease management that allows patients to maintain greater control over their disease [20-22].

Commercially available apps in the IBD setting perform many of the same functions as those that have been studied in asthma, diabetes, and rheumatoid arthritis, yet several apps in the IBD setting have not been subjected to adequate clinical evaluation and have been devised without taking into consideration current evidence-based guidelines. These apps have also been devised with limited professional medical involvement [23]. While the evidence supporting the utility of telemedicine and Internet-based interventions in IBD is emerging [5,7], the evidence behind the efficacy of mobile phone apps in the IBD setting has been lacking. Apps nonetheless represent the next logical step in our information technology era.

The purpose of this paper was to systematically study the content and functions of commercially available apps for IBD patients in the context of current clinical practice guidelines and discuss the results in relation to their utility in assisting patient with self-management of IBD.

Methods

Selection of Apps

We conducted a search of the official app stores of Apple (iOS) and Google (Android) for IBD-related apps on March 3, 2015. Search times included all of "IBD," "crohn," "crohns," "colitis," "ulcerative colitis," and "inflammatory bowel disease." Apps were screened by assessing their descriptions to exclude non-English apps and apps not targeting patients with IBD. We downloaded the remaining apps to test devices for further screening, based on predefined inclusion and exclusion criteria (see Table 1). Test devices included commercially available smartphones operating iOS and Android.

Table 1. Systematic search criteria.

Criteria	Description
Inclusion	Smartphone app
	Runs on iOS or Android operating systems
	Available for download from official app stores of Apple or Google
	English language
	Targets patients with IBD (as intended by the publisher)
	Free and paid apps
Exclusion	Requires invitation from publisher to use
	Targets patients with conditions other than IBD (as intended by the publisher)
	Does not target patients
	Unable to be tested due to technical difficulties

App Assessment Criteria

Prior to the selection of apps, a preliminary search was conducted to identify the types of apps available for patients with IBD, which informed the development of assessment criteria that were used to assess the apps subsequently identified by this systematic review. Each app was independently assessed by 2 assessors. For all apps, we assessed for presence of professional medical involvement in the development of the apps, average ratings (out of 5), and number of reviews. Average ratings and number of reviews were available from both Google and Apple stores, so apps that were available on both platforms were documented twice. We also assessed the presence or absence of common functionalities for all apps, generated post hoc.

For diary apps, we assessed the comprehensiveness of four parameters that were able to be logged: abdominal pain, bowel habit, dietary intake, and medication. This was achieved by assessing the detail with which each symptom was able to be logged. For abdominal pain, these included the time and date, location, and severity. For bowel habits, these included time and date, consistency of stools, rectal urgency, presence of blood, and presence of mucus. For food diary apps, we assessed the extent to which time and date, type of food, quantity, and prior appetite were able to be logged. For medication, the time and date, medication name, and dosing were assessed. Where available, the input options for data entry were also assessed. For all parameters, we also included whether or not free-text notes were able to be entered.

For apps providing information related to IBD, we assessed the comprehensiveness and accuracy of the information provided. We formulated a set of statements extracted from and consistent with international guidelines for IBD from the European Crohn's and Colitis Organisation [24-29], the American College of Gastroenterology [30,31], and the Gastroenterological Society of Australia [32]. A total of 14 statements was derived (see Table 2). Apps providing disease information were assessed to have either "complete," "partial," or "absent" coverage of each statement.

Table 2. Statements derived from international guidelines for IBD.

Topic	Criteria (Crohn's disease)	Criteria (ulcerative colitis)
Overview	CD is a lifelong condition characterized by inflammation of the gastrointestinal tract	UC is a lifelong condition characterized by chronic inflammation of the colon
	CD has a relapsing and remitting course	UC has a relapsing and remitting course
	The causes of CD are unknown but are believed to be a mixture of genetic and environmental factors	The causes of UC are unknown but are believed to be a mixture of genetic and environmental factors
	The onset of CD is most common in the second and third decades of life	UC primarily presents in late adolescence and early adulthood
Diagnosis	CD is diagnosed by clinical evaluation and a combination of endoscopic, histological, radiological, and/or biochemical investigations	UC is diagnosed by clinical evaluation, proctosigmoidoscopy or endoscopy, biopsy, and negative stool examination for infective causes
	Chronic diarrhea is the most common presenting symptom of CD	Visible blood in the stools is the primary presenting symptom in UC
	Common symptoms of CD include chronic diarrhea, nocturnal diarrhea, abdominal pain, weight loss, fever, rectal bleeding	Common symptoms of UC include bloody diarrhea, rectal bleeding, and/or rectal urgency
Management goals	Goals of management in CD are the treatment of acute disease or induction of clinical remission, followed by maintenance of remission	Goals of treatment in UC are remission of symptoms, improved quality of life, reduction in long-term medication needs, and reduction of cancer risk
Treatment options	Initiation of therapy should be performed by a specialist gastroenterologist	
	GPs are important in monitoring long-term treatment plan	
	Therapy is divided into two categories: (1) acute therapy for flares to induce remission and (2) maintenance therapy in order to help maintain remission	
	Treatment for IBD may include pharmacological therapy and surgical therapy	
	Surgical therapy involves removal of a section of bowel, which may result in the patient living with a stoma for life	
	Use of complementary and alternative medicine is generally safe, but efficacy is not validated	

Results

Searches of the official app store of Google (Android) yielded 146 apps available for screening. Of these, 32 apps were excluded as they were in a language other than English. Of the remaining 114 apps, 83 were excluded for either being unrelated to IBD or not being specific to IBD. A further 7 apps were excluded as they did not appear to target patients. The remaining 24 apps included 2 outdated versions of existing apps, 1 repeat app, and 3 apps that required invitation from the developers, which were excluded, leaving 18 Android apps for analysis.

Searches of the official app store of Apple (iOS) yielded 92 apps available for screening; 19 apps were excluded as they

were in a language other than English and 46 of the remaining 73 apps were excluded for either not being related to IBD or not being specific to IBD. A further 9 apps were excluded for not targeting patients. Of the remaining 18 apps, 2 were excluded for requiring invitation from developers, leaving 16 iOS apps for analysis.

The remaining 34 apps were downloaded and analyzed. Eight apps were subsequently excluded; 7 of which were duplicates, and one of which encountered technical difficulties in accessing the app, leaving 26 apps for analysis. A flow diagram of assessment of apps identified in this review is shown in Figure 1.

The final results included 26 mobile phone apps, of which 10 were available exclusively for Android platforms, 8 exclusively for iOS platforms, and 8 available for both. A summary of the results is shown in Tables 3 and 4 [33-58].

Table 3. Summary of assessed apps.

	Operating system	Professional medical involvement	Average rating (iTunes Store)	Ratings (iTunes Store), n	Average rating (Google Play)	Reviews (Google Play), n	Cost
AnswersIn Crohn's Disease [33]	iOS	Yes	n/a	0	—	—	US $
AnswersIn Ulcerative Colitis [34]	iOS	Yes	4	1	—	—	US $
Colitis Diary [35]	Android, iOS		n/a	0	n/a	0	US $
Colitis Ulcerativa Manager [36]	Android, iOS	Yes	n/a	0	2	1	US $
Crohn's Diary [37]	Android, iOS		n/a	0	n/a	0	US $
Crohn's Disease [38]	Android, iOS		n/a	0	n/a	0	US $
Crohn's Disease & Symptoms [39]	Android		—	—	n/a	0	Free
Crohn's Disease by AZoMedical [40]	iOS		n/a	0	—	—	Free
Crohn's Disease Manager [41]	Android, iOS	Yes	—	—	4.1	10	US $
Crohns Disease Symptoms & Suggested Treatment [42]	iOS		n/a	0	—	—	US $
CrohnsTracker Pro [43]	Android		—	—	n/a	0	US $
GI Buddy [44]	Android		—	—	3.2	63	Free
GI Monitor [45]	Android, iOS		3.3	42	3.9	954	Free
IBD [46]	iOS		2.9	15	—	—	Free
IBD (Crohn's, Colitis) [47]	Android		—	—	3	21	Free
Lisa's Diet [48]	iOS		n/a	0	—	—	Free
Living With Crohn's Disease [49]	Android		—	—	2.1	17	US $
My Crohn's Diary (Android) [50]	Android		—	—	2.5	6	US $
My Crohn's Diary (iOS) [51]	iOS		n/a	0	—	—	US $
MyCrohnsandColitisTeam Mobile [52]	Android, iOS		—	—	4.3	29	Free
myIBD [53]	Android, iOS	Yes	1	1	3	2	Free
Pentasa Timer [54]	Android		—	—	5	5	Free
Poocount [55]	Android		—	—	5	1	Free
Toilet diary [56]	Android		—	—	2.3	3	Free
Ulcerative Colitis Information [57]	Android		—	—	3.3	3	Free
Vualoo [58]	iOS		n/a	0	—	—	Free

Table 4. Functionalities of assessed apps.

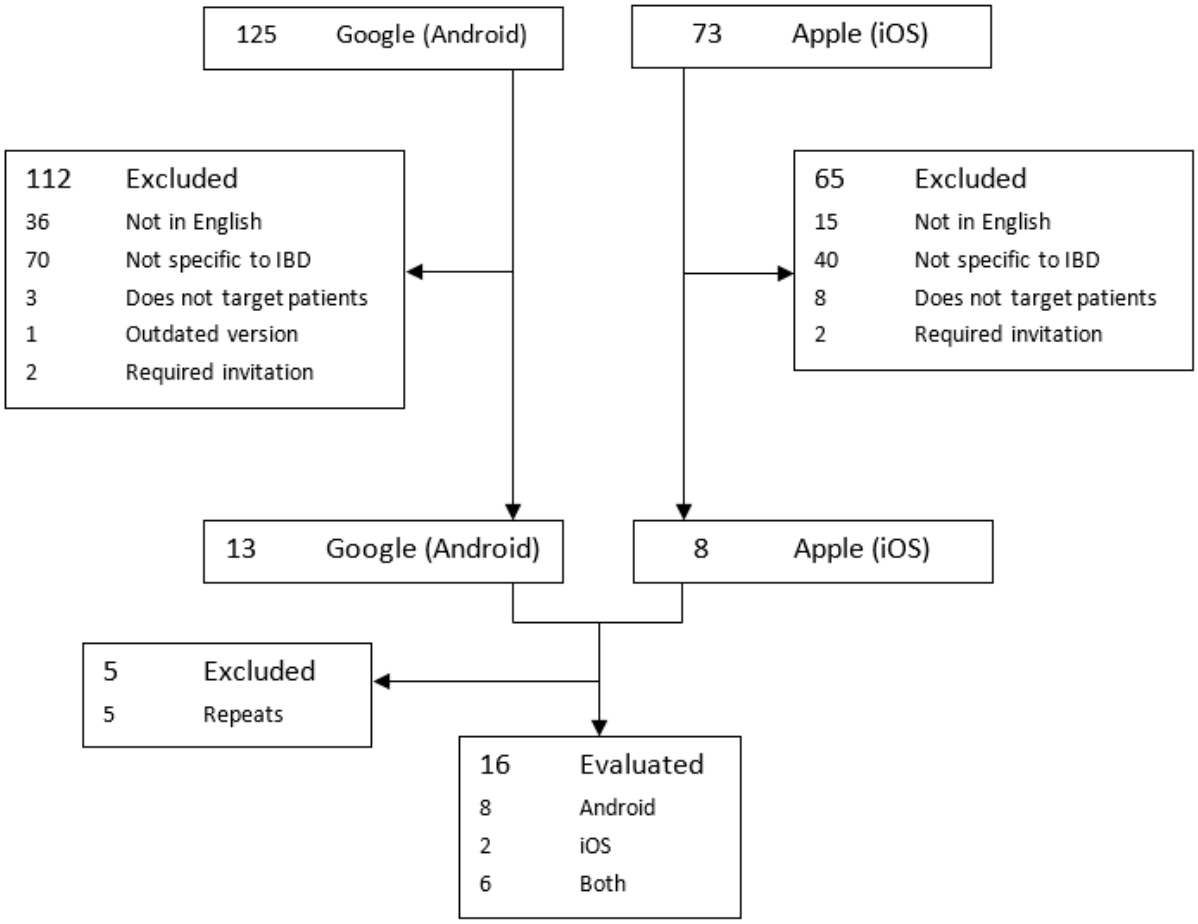
	Bowel motion tracking	Pain tracking	Mood/psychological tracking	General symptom tracking	Dietary tracking	Medication tracking	Graphing/analysis	Community/social functions	Reminder system	Disease information
AnswersIn Crohn's Disease [33]										Yes
AnswersIn Ulcerative Colitis [34]										Yes
Colitis Diary [35]	Yes	Yes	Yes	Yes	Yes	Yes	Yes			
Colitis Ulcerativa Manager [36]	Yes	Yes		Yes	Yes	Yes	Yes			
Crohn's Diary [37]	Yes	Yes	Yes	Yes	Yes	Yes	Yes			
Crohn's Disease [38]										Yes
Crohn's Disease & Symptoms [39]										Yes
Crohn's Disease by AZoMedical [40]										Yes
Crohn's Disease Manager [41]	Yes	Yes		Yes	Yes	Yes	Yes			
Crohns Disease Symptoms & Suggested Treatment [42]										Yes
Crohns Tracker Pro [43]		Yes		Yes						
GI Buddy [44]	Yes	Yes		Yes	Yes	Yes		Yes		
GI Monitor [45]	Yes	Yes		Yes	Yes	Yes	Yes	Yes	Yes	
IBD (Crohn's, Colitis) [47]					Yes				Yes	Yes
IBD [46]										Yes
Lisa's Diet [48]					Yes					
Living With Crohn's Disease [49]										Yes
My Crohn's Diary (Android) [50]				Yes	Yes	Yes				
My Crohn's Diary (iOS) [51]			Yes	Yes	Yes					
MyCrohns andColitis Team Mobile [52]								Yes		
myIBD [53]	Yes	Yes		Yes	Yes	Yes	Yes			
Pentasa Timer [54]										
Poocount [55]	Yes						Yes			
Toilet diary [56]	Yes	Yes		Yes			Yes			
Ulcerative Colitis Information [57]										Yes
Vualoo [58]										

Five apps documented professional medical involvement in the development of the apps on the summary pages of the respective Google or Apple stores [33,34,36,41,53,59]. However, 2 of these apps stated only that "doctors" were involved, without specifying a particular person or organization [36,41]. One app was developed by a hospital [53]. Two apps appear to be original work by a gastroenterologist [33,34]. Most apps lacked app-store reviews, with only 7 apps having more than 10 reviews and only 1 app having more than 100 reviews. The latter app, however, had 954 reviews from the Google Play store [45]. Fourteen apps were free of charge, while the remaining 12 ranged from AUD$1.07-$8.22. When considering all 26 apps, the average cost was AUD$1.37 per app.

Thirteen apps exclusively had diary functionalities that allowed patients to track one of more aspects of their IBD. Of these, 9 apps presented only health information about IBD, 1 app had both, and 3 apps had neither. Of the 14 diary apps, 2 apps tracked only dietary intake, 3 apps tracked only disease symptoms, while the remaining 9 tracked both. Two apps had reminder functions, and both of these also had diary functions [45,47]. Eight apps were able to create graphs and/or tables to succinctly display logged information. Two apps were able to generate possible triggers for symptomatic episodes with a percentage likelihood based on previous user input [35,37]. One app [45] allowed photo sharing and communication on a message board. One app [52] was an adaptation of an online forum, where both app users and website users could post on the same message boards. One app [54] was utilized as a basic timer with no IBD specific functionalities but targeted patients with UC according to its description. One app allowed the

tracking of calprotectin levels but was excluded from the analysis as it required an invitation from the developers.

Figure 1. Flow diagram of search and selection process of apps.



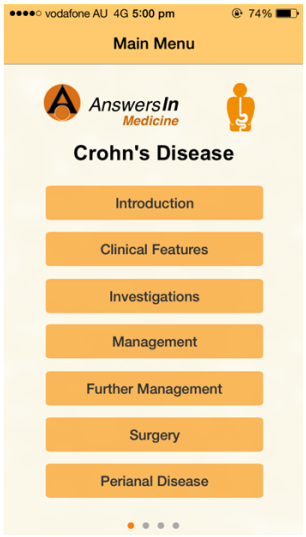
Apps Providing Disease Information

Ten apps provided information about Crohn's disease, ulcerative colitis, or both. Nine of these apps provided information as their sole function, while 1 app also had diary functions [47]. However, the scope of the information provided in this app [47] was limited to the patient's own experiences, while the diary function was limited to tracking only foods consumed without specifying time, quantity, or associated symptoms. Of the other 9 apps, 6 provided information on Crohn's disease [33,38-40,42,49], 1 provided information on UC [57], and 2 provided information on IBD collectively [46,47]. Of the 6 Crohn's disease apps, 1 displayed news and updates of latest research [40] and 1 app offered only dietary suggestions with no information about the disease itself [38]. Two apps, while comprehensive, were more suited for medical professionals [33,34]. An example of an app providing disease information is shown in Figure 2.

Only 2 apps providing disease information were created with professional medical involvement [33,34]. The information from 2 apps was discovered to have been derived from an online source, although the source location was not provided in either app [39,57]. One app was claimed to have been an original work and published as an e-book [49].

Eight information apps were evaluated for consistency with information from international IBD guidelines. Two of the 10 apps that included disease information were excluded from the analysis as one app included only news updates about IBD [40] while the other app included food suggestions for IBD without information about the disease itself [38]. We assessed the extent to which the IBD apps covered the 14 statements derived from international guidelines based on "complete," "partial," or "absent" coverage. Of the 112 potential instances where apps were assessed for one of the 14 identified statements, 42 (38%) statements demonstrated "complete coverage" and 30 (27%) statements demonstrating "partial coverage." The remaining 40 (36%) statements demonstrated "absent coverage."

Figure 2. Screenshot of the main menu of the app AnswersIn Crohn's Disease.



Diary Apps

Symptom Diary Apps

Summaries of the symptom diary apps for IBD found in this study are shown in Tables 5 and 6.

Although most of the symptom diary apps for IBD had the capacity to log multiple parameters, there was considerable heterogeneity regarding the detail with which symptoms were able to be recorded. Most of the symptom diary apps allowed the detailed recording of each bowel movement (including stool consistency and presence or absence of blood), but 2 apps [36,41] allowed only the logging of stool frequency. An example of a symptom diary app is shown in Figure 3. While most apps enabled recording of the specific times during which symptoms were experienced, 1 app instead elected to restrict the description of the timing of symptoms to a collective description of either daytime symptoms or nocturnal symptoms [53]. Four apps provided daily summary pages enabling a summary of symptoms over the course of a day, rather than the option of logging individual symptoms as separate new entries [35-37,41]. All apps except one [43] allowed users to input additional information in a "Notes" section.

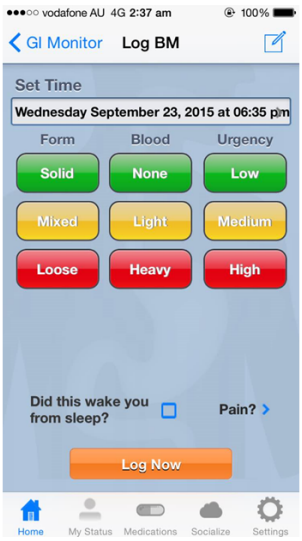
Table 5. Apps offering bowel motion tracking.

	Time	Consistency	Urgency	Blood	Mucous	
Colitis Diary	Date and time	Multiple checkboxes (7 options)	Checkbox	Checkbox ("bloody stool")	Checkbox ("mucus with stool")	Blood and mucus are under "consistency"
Colitis Ulcerativa Manager	—	5-point scale (water, liquid, soft, normal, hard)	—	Checkbox ("blood within the stool")	Checkbox ("slime within the stool")	Can log defecation frequency per day
Crohn's Diary	Date and time	Multiple checkboxes (7 options)	Checkbox	Checkbox ("bloody stool")	Checkbox ("mucus with stool")	Blood and mucus are under "consistency"
Crohn's Disease Manager	—	5-point scale (water, liquid, soft, normal, hard)	—	Checkbox ("blood within the stool")	Checkbox ("slime within the stool")	Can log defecation frequency per day
GI Buddy	Date and time	3-point scale (formed, semi, liquid)	4-point scale (none, hurry, immediate, accident)	4-point scale (trace, blood, mucus, blood + mucus)	4-point scale (trace, blood, mucus, blood + mucus)	Blood and mucus are on same scale
GI Monitor	Date and time	3-point scale (solid, mixed, loose)	3-point scale (low, medium, high)	3-point scale (none, light, heavy)	—	
myIBD	Date and 2-point scale (day, night)	10-point sliding scale	10-point sliding scale	10-point sliding scale	—	
Poocount	Date and time	—	—	3-point scale (blood 0, blood +, blood ++)	—	
Toilet diary	—	Checkbox ("diarrhea")	Checkbox ("enormous pressure")	Checkbox ("blood")	Checkbox ("mucus")	

Table 6. Apps offering pain tracking.

	Time	Severity	Location	
Colitis Diary	Date and time	10-point drop down menu	—	Includes a dropdown menu for “pain description”
Colitis Ulcerativa Manager	Date and time	10-point sliding scale	—	
Crohns Diary	Date and time	10-point drop down menu	—	Includes a dropdown menu for “pain description”
CrohnsTracker Pro	Date	—	—	
Crohn’s Disease Manager	Date and time	10-point sliding scale	—	
GI Buddy	Date and time	4-point scale (none, mild, moderate, severe)	—	
GI Monitor	Date and time	10-point sliding scale	—	
myIBD	Date	10-point sliding scale	Picture-based	User is able to tap on arbitrary location on picture of abdomen
Toilet diary	—	—	—	Only has checkbox for presence of “cramp”

Figure 3. Screenshot of the interface of GI Monitor for recording bowel movements.



Food Diary Apps

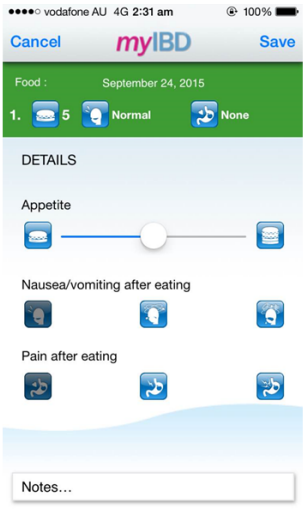
A summary of the food diary apps found is shown in Table 7.

Most diary apps were able to record both symptoms and dietary intake, except 2 apps [47,48], which were able to record only dietary intake. An example of a food diary app is shown in Figure 4. Inconsistencies were present in the ability of apps to log the date and time of meals. One app [47] offered only the ability to list “good foods” and “foods to be avoided” without the capacity to log food intake throughout the day. Five apps enabled logging of daily food intake but did not include the timing of food intake. Most apps offered only free-text input for the names of food; however, 2 apps [44,48] had a search function to select predefined foods. Although some apps in this study provided a search function or dropdown menu [35,37,43,44,50], the list of food items was often not comprehensive. One app used the smartphone camera to take pictures of meals as they were logged [48]. Two apps only logged meals in the form of a free-text input section titled “influence of food” as part of a broader diary entry [36,41]. Two apps recorded the serving size of each food item [44,50]. One app recorded the appetite of the user prior to consuming the food [53]. Eight apps allowed users to type free-text notes to record additional information regarding each meal.

Table 7. Apps offering dietary tracking.

	Time	Food item	Serving size	Appetite	Note function	Additional features
Colitis Diary	—	List menu OR free input	—	—	Yes	Can log other triggers such as "skipped a meal"
Colitis Ulcerativa Manager	—	—	—	—	Yes	
Crohns Diary	—	List menu OR free input	—	—	Yes	Can log other triggers such as "skipped a meal"
Crohn's Disease Manager	—	—	—	—	Yes	
CrohnsTracker Pro	Date	List menu OR free input OR saved items	—	—	—	
GI Monitor	Date and time	Free input	—	—	—	Can log perceived difficulty of digesting food
GI Buddy	Date and option of breakfast, lunch, dinner, snack	Search function OR free input OR saved items	Yes	—	—	Can set custom meals
IBD (Crohn's, Colitis)	—	Free input	—	—	—	Allows logging of "good foods" and "foods to avoid"
Lisa's Diet	Date and time	Drop down menu OR free input OR saved items	—	—	Yes	Can search for foods flagged by other users
My Crohn's Diary (Android)	Date and time	Drop down menu OR free input	Yes	—	Yes	Can log fluid intake separately
My Crohn's Diary (iOS)	Date	Free input	—	—	Yes	Can log fluid intake separately
myIBD	Date	—	—	Yes	Yes	Can log associated nausea and pain levels

Figure 4. Screenshot of the interface of myIBD for the recording of dietary intake.



Management Apps

Decision Support Apps

At present, no apps offering decision support specific to self-initiation of therapy were identified by this study. However, the app, GI Monitor, was able to automatically generate a quality-of-life score based on patient-reported outcomes collected via the diary function [45].

Reminder Apps

While none of the apps found used a reminder system as their primary functionality, 2 apps had medication reminder functions [45,47]. Both of these apps also had diary functions. However, one of these lacked any useful ability to track symptoms or dietary intake [47].

Discussion

Principal Findings

Mobile phones represent a promising tool to facilitate self-management in chronic disease. Self-management aims to give a degree of disease control back to the patient by improving self-efficacy, knowledge, and understanding of their disease. Despite their appeal, the evidence regarding the role of apps in self-management of IBD is limited and their optimal use to facilitate self-management is yet to be determined.

This systematic review utilized a systematic approach to explore the content and tools of commercially available mobile phone apps for patients with IBD. However, a lack of standardized assessment criteria for eHealth modalities such as apps precluded a specific rating and/or ranking of the utility of the apps by the reviewers. Although the user ratings of the apps were included in this review, they are a somewhat subjective representation of the apps' quality of content and functionalities. Ratings and total number of ratings are likely to demonstrate the popularity or perceived value by patients, which can be influenced by advertising or referral (such as a health service "prescribing" a particular app). We acknowledge that a mobile app rating scale has been proposed as a potential method of assessing apps, but such a scale is yet to be validated [60]. This review highlights the need for consensus regarding regulation and evaluation of eHealth technologies if mobile phone apps and other eHealth modalities are to be integrated into mainstream medical practice.

In our assessment, apps providing disease information demonstrated extensive coverage of various topics in IBD, including disease overview, causes, symptoms, diagnosis, and treatment. Although some of these topics were explored in depth, the apps failed overall to provide complete coverage of many of the evidence-based statements derived from international guidelines. This indicates that the majority of apps were not sufficiently accurate or comprehensive as patient education tools, which is most likely explained by the lack of professional medical involvement in their development. In this study, although we anticipated that a proportion of the apps would lack professional medical involvement in their design, we did not expect that this would exceed three quarters of the apps identified. Medical professionals should be consulted in the development process of apps to help ensure that relevant, evidence-based information is included within patient education tools. A lack of evidence undermines the safety and quality of mobile phone apps and thus may pose risks to patients [61]. Peer-reviewing medical apps represents another potential solution to quality assurance, but its feasibility is unknown [62]. Ultimately it is important to ensure that patient safety is not compromised, especially if the app is to be recommended or "prescribed" by a doctor.

Despite the theoretical importance of professional medical involvement, adherence to evidence and app regulation, mobile phone apps that are not used are ultimately ineffective. The challenge is to balance the safety and quality requirements of medical mobile phone apps with the design features required to promote adherence to therapy. Uptake and usage of mobile and Internet technology are influenced by an array of factors, such as perceived risk of use, perceived usefulness, and degree of user-centric focus, which have been described in behavioral change models in emerging eHealth literature [63-65]. Addressing adherence to management is a necessary prerequisite alongside the quality and safety requirements of apps as potential medical devices. Therefore, future app developments should have strong grounding in behavioral change theory and place considerations in predictions of usage and user-centric approaches. A development framework devised for Internet interventions may be applied to the mobile phone app setting to integrate the magnitude of complex design features [66].

App content is also important in improving adherence and plays the most significant role in effecting behavioral change. This review identifies a number of tools and functionalities in existing apps that may be beneficial. Patient education in IBD is important to enable everyday behaviors that promote well-being and prevent deterioration [67]. Volitional non-adherence, which is prevalent in IBD and contributes to greater disease activity, reduced quality of life, and greater health care costs [68-75], may be addressed by adequate provision of disease information. Patients who are better informed about their condition and medications are more likely to adhere to their prescribed treatment regimens [76,77]. An ideal patient education app provides appropriate evidence-based information that effectively meets the educational needs of patients.

Prior to the advent of the smartphone, SMS (short message service) text messaging provided a method for medication reminders using traditional mobile phones. In controlled environments, reminder text messages have been shown to decrease the incidence of missed medication doses and improve adherence to treatment [74,78] and there is some research to suggest that reminders have a dose-response effect [79]. Apps that provide a reminder functionality may be useful in enhancing compliance in poorly adherent patients [80,81]. Compared with SMS, apps may offer additional interactivity, customizability, and functionality. However, the usefulness of smartphone reminder apps in practice remains to be seen and studies exploring reminder text messages have been limited to controlled environments with small sample sizes. Future studies should explore the efficacy and dose-response relationship of reminder apps in large populations consisting of patients who

are non-adherent due to involuntary factors such as forgetfulness.

Mobile phone apps with diary functionalities are emerging as a potential successor to traditional paper-based diaries due to their improved accessibility and convenience. Despite their feasibility being demonstrated in several other chronic disease settings [14,16,23,82,83], there have been no completed studies that have investigated commercially available IBD diary apps. However, the self-management app, "Health PROMISE", as of May 2015 is being investigated for its effects on various outcome measures including quality of life, number of emergency visits, and number of hospitalizations in an IBD cohort as part of a multicenter study [21]. Furthermore, while not a smartphone app, a recent study found that Web-based diaries (using the Harvey-Bradshaw index) were effective in the monitoring of clinical disease activity in patients with Crohn's disease with good correlation demonstrated with the more widely accepted Crohn's disease activity index [84]. The benefit of symptom diaries is that they allow patients to maintain a degree of control over their condition in the setting of alterations in disease activity and medications, and in doing so, may help increase engagement of patients in their management and facilitate adherence. However, while previous studies have shown electronic diaries to be feasible in controlled environments, there has been little evidence supporting the usage and efficacy of commercially available electronic diaries. Studies to evaluate the optimal use of diary apps in the assessment and monitoring of IBD patients are therefore required.

Symptom diaries may have further utility when combined with food diaries as a means of identifying potential dietary triggers for gastrointestinal symptoms in IBD [85-88]. Self-initiated food avoidance is highly prevalent in patients with IBD [89]. The use of food diaries has consequently been recommended by the Crohn's & Colitis Foundation of America [90,91]. Symptom diaries can therefore be correlated with particular meals to help identify food precipitants and can be reviewed by dieticians to help guide food selection and avoid unnecessary caloric restriction. Moreover food diaries may help identify patients at risk of malnutrition and nutritional deficiencies, which are more prevalent in IBD patients [89,92].

Programs that provide decision support to the patient are emerging as promising management options in IBD [20,22]. Decision support apps use patient-reported outcomes collected via diary functionalities to generate individualized management plans for the patient. However, none of the apps studied in this review contained specific information regarding alarm symptoms and none of the apps provided specific feedback to patients in the event of an escalation of symptoms, thereby potentially limiting their utility in self-management. Although the efficacy and feasibility of apps in facilitating self-initiation of therapy is yet to be proven [93], apps that provide decision support for patients are currently in development and are likely to be regulated in the United States and United Kingdom as medical devices, rather than commercial programs [21,94,95]. The implications are unclear, but regulatory guidelines for the development and evaluation of such apps are required.

Although apps that have been specifically developed for self-management of IBD are lacking, evidence from other chronic diseases suggests that they may have a role in improving self-efficacy, knowledge, and understanding and enhance adherence to prescribed therapy. Developing a comprehensive self-management app may mark the important first steps in propagating self-management in IBD in a similar vein to the creation of asthma management plans for asthma self-management. Apps may potentiate the self-initiation of therapy in acute IBD flares by first measuring disease activity using a symptom diary and providing appropriate subsequent management advice. A novel asthma self-management program with natural language recognition capabilities was recently found to promote medication adherence and patient confidence over the course of its trial [18]. The program allowed adolescents to communicate with the system via text messaging, emulating conversation with a clinician. It was able to interpret patient descriptions of asthma exacerbations and generate management plans using a predefined algorithm. A diabetes self-management app similarly incorporated an algorithm to calculate the required insulin bolus amount depending on blood glucose levels before meals, carbohydrate counts, and planned physical activity that were manually entered into the program [17]. These apps not only provide treatment advice in critical times where professional consultation is not readily available but also increase the control that patients have over their own illnesses. While these eHealth solutions have demonstrated some efficacy in controlled environments, larger population-based studies are required to supply more reliable evidence for their use in clinical practice.

Although a Web-based approach to IBD management has been demonstrated to improve patient engagement, quality of life, and reduce the duration of relapse, there are currently no data supporting the efficacy of IBD apps in self-management [22]. Gastroenterologists have also suggested that digital tools should focus on promoting patient compliance with treatment, with reduced emphasis on patient-physician concordance [96]. Reaching a compromise between empowering patients with shared decision making and encouraging patients to follow instructions to improve compliance will require discussions between patients and their clinicians. However, it remains to be established as to whether self-management apps that improve patient autonomy will have a positive or negative impact on treatment compliance.

Limitations

The main limitation of this systematic review was that the assessment method for the apps was developed by the authors and has not been validated. This was necessary due to a lack of published studies on IBD apps, as well as a lack of end-user data to allow a quantitative assessment of the efficacy of the apps. Furthermore, the formal assessment of the identified apps did not take design or usability into account. This systematic review was also limited to English-language apps for the two most popular operating systems, Android and iOS. Despite the limitations of this review, we believe that it has provided a real-world exploration of the IBD apps that are currently available and their strengths and limitations respectively.

Conclusion

Apps may provide a useful adjunct to the monitoring and management of patients with IBD. Current apps available for IBD offer varying degrees of content, functions, and levels of care but do not offer patients decision support for their IBD self-management. IBD apps currently suffer from a lack of professional medical involvement, adherence to international clinical guidelines, and validation from clinical studies. These limitations jeopardize the safety and quality of apps as potential medical tools from the clinician's perspective. The design process is complex and needs to reconcile the needs of clinicians with design features that are desired by patients. Despite their current limitations, apps have the potential to become useful tools to implement clinical pathways and algorithms to support decision making for patients and engage patients in taking an active role in their care. Future mobile phone apps should use behavioral change models in their development to improve uptake and adherence. Future studies should explore the perceived needs of patients and clinicians in relation to apps in the IBD setting. Such information would inform the development of quality apps that meet the needs of both patients with IBD and their treating clinicians. Further clinical testing is required before the routine recommendation of mobile phone apps to support the management of IBD becomes feasible. Ultimately, it is unlikely that a single app will fulfill the needs of all patients with IBD, but more likely that clinicians will prescribe a range of apps each with a specific purpose tailored to the relevant needs of each individual IBD patient.

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Authors' Contributions

DC was responsible for data collection, drafting of manuscript, and critical appraisal of article for important intellectual content. PDC was responsible for study concept and design, drafting of manuscript, and critical appraisal of article for important intellectual content.

Conflicts of Interest

None declared.

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Abbreviations

CD: Crohn’s disease
GESA: Gastroenterological Society of Australia
IBD: inflammatory bowel disease
SMS: short message service
UC: ulcerative colitis

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Original Paper

Interrater Reliability of mHealth App Rating Measures: Analysis of Top Depression and Smoking Cessation Apps

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Abstract

Background: There are over 165,000 mHealth apps currently available to patients, but few have undergone an external quality review. Furthermore, no standardized review method exists, and little has been done to examine the consistency of the evaluation systems themselves.

Objective: We sought to determine which measures for evaluating the quality of mHealth apps have the greatest interrater reliability.

Methods: We identified 22 measures for evaluating the quality of apps from the literature. A panel of 6 reviewers reviewed the top 10 depression apps and 10 smoking cessation apps from the Apple iTunes App Store on these measures. Krippendorff's alpha was calculated for each of the measures and reported by app category and in aggregate.

Results: The measure for interactiveness and feedback was found to have the greatest overall interrater reliability (alpha=.69). Presence of password protection (alpha=.65), whether the app was uploaded by a health care agency (alpha=.63), the number of consumer ratings (alpha=.59), and several other measures had moderate interrater reliability (alphas>.5). There was the least agreement over whether apps had errors or performance issues (alpha=.15), stated advertising policies (alpha=.16), and were easy to use (alpha=.18). There were substantial differences in the interrater reliabilities of a number of measures when they were applied to depression versus smoking apps.

Conclusions: We found wide variation in the interrater reliability of measures used to evaluate apps, and some measures are more robust across categories of apps than others. The measures with the highest degree of interrater reliability tended to be those that involved the least rater discretion. Clinical quality measures such as effectiveness, ease of use, and performance had relatively poor interrater reliability. Subsequent research is needed to determine consistent means for evaluating the performance of apps. Patients and clinicians should consider conducting their own assessments of apps, in conjunction with evaluating information from reviews.

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KEYWORDS

mobile applications; mental health; evaluation studies; health apps; ratings

Introduction

Although there are over 165,000 mHealth apps currently available, few have undergone an external quality review [1,2]. Currently patients and doctors may find themselves turning to the Apple iTunes or Android Google Play app stores to identify which apps may be helpful and avoid those that may be ineffective or even harmful. The user ratings in these marketplaces are not designed to be a metric of medical appropriateness, safety, or efficacy of apps. Quality reviews conducted by trusted third-parties are important, as it is typically infeasible for clinicians and patients to evaluate the security, validity, and efficacy of apps. Third-party reviews have played an important role in highlighting the quality of enterprise software (eg, KLAS), consumer electronics (eg, Underwriters' Laboratories), and even food (eg, Zagat) [3]. Health care providers and patients have a similar need for quality reviews of mHealth apps.

There are numerous challenges in rating apps. The availability of clinical data to guide app recommendations is poor. Medical research on apps is far behind. For example, while over 20 million American's suffer from depression each year and there are over 1000 depression apps in consumer marketplaces [4], a recent review found only 10 published studies on depression apps [5]. The United States Food and Drug Administration does not offer guidance either, noting it does not plan to regulate many apps that are of low risk [6]. The efforts of professional and regulatory bodies to curate apps have also been disappointing, with the recent news of the shutdown of the British National Health Service's Health App Library [7] after a study revealed that many apps accredited actually transmitted medical data in an unsecure manner and that several lacked privacy policies [8], among other concerns. Finally, any app rating system would have to be continually updated, as apps themselves are often upgrading and changing.

Despite the substantial challenges in rating apps, there have been important efforts to begin to understand how to best approach the problem. Several methodologies have been proposed for evaluating the quality of apps [9-11], although no standardized method exists, and little has been done to examine the consistency of the evaluation systems themselves.

One methodology of note that was introduced after the design of this study is the Mobile App Rating Scale (MARS), a 23-item scale that demonstrates strong internal consistency and interrater reliability in a research study involving 2 expert raters [12]. However, like many scales, its validity is still uncertain and it has not been widely adopted yet. Furthermore, there have been both generalized frameworks [11] and specialty-specific efforts [13-15] that use inconsistent measures to evaluate quality. However, it is unclear how any of these methodologies and scales hold up in real-world clinical practice and when used by non-expert raters. Given the rapid growth in the number of mHealth apps and the constant updating of existing apps, it makes sense that clinicians will need to utilize and apply app ratings [2].

The need for quality measures of mHealth apps will become increasingly important as more patients ask physicians for app recommendations. The lack of standardized quality measures is concerning, as app use carries risk and can lead to adverse outcomes for both patients and clinicians. Poorly designed apps may offer ineffective care or even cause harm [16]. Clinicians may place themselves at legal, professional, and ethical risk if digital technologies are recommended inappropriately [17]. Furthermore, if apps are eventually to be prescribed by providers and reimbursed by payers, there must be a robust way to evaluate the safety and effectiveness of apps [18]. Standardized measures with high interrater reliability are needed to evaluate mHealth apps. Nonetheless, without standardized measures for evaluating app outcomes, clinicians have difficulty comparing the quality of apps when making recommendations. When measures are available, quality measures with low interrater reliability are problematic, as ratings produced are not necessarily reflective of what would be experienced by other raters or users.

In order to foster the development of standardized app quality measures, we seek to evaluate the interrater reliability of existing measures [19] and provide direction on which should be incorporated in standardized app evaluation systems. In addition, we seek to determine whether the interrater reliability of the measures is consistent across multiple types of apps, and which of these measures may be the best to incorporate into app evaluation systems and tools. As mHealth apps are used for a wide range of purposes, it is important to understand which quality measures consistently perform with high interrater reliability, regardless of the nature of the apps being evaluated.

Methods

Selection of Apps

To evaluate whether the interrater reliability of quality measures is consistent across multiple types of apps, we evaluated the top 10 search results displayed by the US Apple iTunes App Store for iOS (iPhone, iPod Touch, and iPad) returned by queries for "depression" and "smoking" in March 2015 (see Multimedia Appendix 1). While rankings are in constant flux as apps are updated and rated by app store users, the apps selected reflect those most visible to users seeking assistance at the time of selection. This was done to increase the realism of the sample, as users without pre-existing knowledge of which apps to seek are likely to pick those they see first.

Depression and smoking cessation (hereafter referred to as "smoking") categories were selected because they are common issues, cause significant comorbidity, and have been the targets of many early mobile phone interventions that are directly marketed to patients [20-22]. In 2013, over 15 million US adults suffered from depression (6.7% of the population) [23], and over 42 million Americans smoked cigarettes (nearly 18% of the population) [24]. Also, a recent study suggested that when considering apps by treatment type, mental health and behavioral disorders are the largest sector—more numerous than both cardiac and cancer-focused apps [25]. The clinical evidence supporting apps in these categories has the potential to be more robust than supporting apps managing other indications [26].

Selection of App Quality Measures

We reviewed existing mHealth app ratings sites and the literature to identify app evaluation measures. At this time, there is no gold standard for rating apps and no central repository of app ratings. While the list of measures evaluated may not be definitive, it is varied and reflective of the practice of a number of organizations. The Anxiety and Depression Association of America (ADAA) and PsyberGuide were two websites that were used as sources of measures. The ADAA rates apps on ease of use, perceived effectiveness, personalization, interactiveness/feedback, and research evidence on a 5-point scale [27]. PsyberGuide evaluates the basis of the research behind the app, the source of the funding for the research, the specificity of the proposed intervention, the number of consumer ratings, whether a product advisory board with clinical thought leadership exists, and whether the app has been revised within the past 12 months [28].

Although the ADAA and PsyberGuide measures were the best characterized, we also used measures cited in the literature, including whether an app has password protection and import/export capabilities [29], whether an app is uploaded by a health care agency versus a non-health care agency [30], whether the developer is contactable and the advertising policy is clearly stated [31], whether there is a lack of errors or hang-ups and continuous access to the data [32], whether an app discloses potential risks, and whether it offers technical support or help [33].

mHealth apps must be safe, accurate, effective, secure, and protect privacy to be used by patients, recommended by health care professionals, and eventually reimbursed [2]. While it is difficult to assess the safety or accuracy of an app without an in-depth review, it is possible to rapidly determine whether an app has security measures such as password protection and encryption, and privacy measures such as an explicit privacy policy. Likewise, it can be difficult to assess the effectiveness of an app. We included three measures of effectiveness: perceived effectiveness, research evidence base for an app, and whether or not the app claimed that the effectiveness was tested. Evaluating perceived effectiveness required the reviewers to subjectively evaluate the app against its stated objective, whereas the evidence base and statement of effectiveness made by the app were evaluated based on discrete findings. Table 1 summarizes all of the app quality measures included in this study and presents the terms of each measure exactly as defined for reviewers.

App Review Process

Each app was rated by up to 6 reviewers. Reviewers were an interdisciplinary group including clinicians, technology experts, and researchers; all are study co-authors. Reviewers were instructed to rate all 20 apps (Multimedia Appendix 1) on all 22 measures (see Table 1). Each reviewer reviewed a minimum of 17 of the 20 apps on each of the 22 measures.

Reviews were conducted between March and May 2015. All apps were reviewed running on iPhones. Reviewers did not discuss their reviews with each other to ensure that each rating was independent. For each of the apps, the reviewers were provided a copy of Table 1, with space for their ratings. Reviewers were not provided with any additional training in the review methodology in order to best approximate what would occur if the reviewers read about the metrics independently. No human subjects were used in this study. Results are reported in aggregate only, not at the app level.

Reviewers were asked to download the apps to their personal iPhones and then to assign values to each of the measures using only information provided within the app itself and in the iTunes App Store for iOS. As reviewers used their personal iPhones, it is likely that multiple hardware and operating system configurations were used during the review process. Although reviewers were asked to spend several minutes examining each app, they were not asked to use the apps in a realistic manner. Realistic use would not have been feasible, as the reviewers were selected for their expertise in mHealth, rather than for their history of depression or smoking. This short duration of use simulates what is likely to occur when apps are evaluated by experts without a personal need for the apps in question.

After reviews were completed, the reviewers were sent screenshots from each of the apps and asked to verify that the apps they reviewed were the same as the ones shown. One reviewer was unable to review one smoking app and misidentified a second smoking app and one depression app. In the cases where apps were misidentified, they were treated as missing. Each measure was applied up to 120 times (20 apps rated by 6 reviewers). However, due to app identification issues and occasional cases of reviewer uncertainty about the proper rating to apply, each measure was only applied between 109 and 112 times, yielding data completeness between 91% and 93%, depending on the measure (see Table 2).

Table 1. mHealth app quality measures evaluated.

Measure	Source	Range	Definitions
Ease of use	ADAA	1-5	5=very easy; 1=very difficult
Effectiveness (Perceived)	ADAA	1-5	5=highly likely; 1=highly unlikely
Personalization	ADAA	1-5	5=complete ability; 1=no ability
Interactiveness/Feedback	ADAA	1-5	5=very interactive, helpful feedback; 1=not interactive, no feedback
Basis of research	PsyberGuide (& ADAA[a])	0-3 (and 1-5[a])	3=data from at least one randomized controlled trial; 2=data from at least one non-randomized non-controlled trial; 1=data from an open study; 0=no data provided
Source of funding for research	PsyberGuide	0-2	2=research supported exclusively by government agency or non-profit organizations; 1=research supported in full or part by for-profit organizations; 0=no data provided
Specificity of intervention	PsyberGuide	1-3	3=the application is designed to improve a specific condition or symptom; 2=the application is designed to help with non-specific items such as "mood" or "brain fitness"; 1=the application is designed to track and monitor items such as symptom severity or medication; 0= no data provided
Number of consumer ratings	PsyberGuide	1-3	3=ratings exist from >50 users; 2=ratings exist from 25-50 users; 1=fewer than 25 user ratings
Product advisory support	PsyberGuide	0-1	1=yes; 0=no
Software support	PsyberGuide	0-1	1=yes; 0=no
Password protection	Kharrazi et al (2012)	0-1	1=yes; 0=no
Import/export capabilities	Kharrazi et al (2012)	0-1	1=yes; 0=no
Uploaded by health care agency	Pandey et al (2012)	0-1	1=yes; 0=no
Encryption	Powell et al (2014)	0-1	1=yes; 0=no
Explicit privacy policy	Powell et al (2014)	0-1	1=yes; 0=no
Effectiveness tested (claimed by app)	Powell et al (2014)	0-1	1=yes; 0=no
Developer contactable	Lewis	0-1	1=yes; 0=no
Advertising policy stated	Lewis	0-1	1=yes; 0=no
Errors and performance issues	Martinez-Perez et al (2013)	0-1	1=yes; 0=no
Continuous availability of data	Martinez-Perez et al (2013)	0-1	1=yes; 0=no
Discloses potential risks	Ferrero-Álvarez-Rementería et al (2013)	0-1	1=yes; 0=no
Offers technical support or help	Ferrero-Álvarez-Rementería et al (2013)	0-1	1=yes; 0=no

[a]1=no research evidence; 5=ample research evidence; ADAA scale not used.

Data Analysis

Interrater reliability for each app quality measure was evaluated for both the depression and smoking categories separately, as well as for the two categories combined. Krippendorff's alpha was used to assess interrater reliability, as it allows for ordinal ratings to be assigned, can be used with an unlimited number of reviewers, is robust to missing data, and is superior to Cohen's kappa [34-37]. An alpha .667 was used to indicate agreement [35]. A negative alpha indicates less agreement than would be expected by chance and indicates that there may have been inconsistencies in how measures were applied. Krippendorff's alpha was calculated using the krippalpha module for Stata [38].

Results

Table 2 summarizes the interrater reliability of app quality measures overall and by application type, that is, depression or smoking. The level of data completeness for each measure is additionally reported. When considered in aggregate, only the measure for interactiveness and feedback reached our threshold for agreement. However, a number of other measures came close, with alphas .5: presence of password protection, whether the app was uploaded by a health care agency, number of

consumer ratings, whether the app had an explicit privacy policy, whether the app had encryption, whether the app was based on research, and whether the app had product advisory support. There was the least agreement over whether apps had errors or performance issues, stated advertising policies, were easy to use, made claims about effectiveness being tested, and made data continuously available.

When ratings for depression apps were evaluated independently, both interactiveness and feedback measure and the password protection measure reached our threshold for agreement. Meanwhile, when ratings for smoking apps were evaluated independently, there was perfect agreement (alpha=1) on whether the apps were uploaded by health care agencies and whether the apps were encrypted. There were also differences in app quality measure reliability between the depression and smoking apps. The difference in alpha when applied to depression versus smoking apps was greater than .4 for the following measures: encryption, import/export capabilities, and specificity of intervention.

Table 2. Interrater reliability of depression and smoking apps by measure.

Measure	Interrater reliability (Krippendorff's alpha)			Completeness, %
	Aggregate	Depression	Smoking	
Interactiveness/Feedback	0.69	0.69	0.67	93
Password protection	0.65	0.75	0.37	93
Uploaded by health care agency	0.63	0.60	1.00	93
Number of consumer ratings	0.59	0.74	0.42	93
Explicit privacy policy	0.55	0.73	0.38	93
Encryption	0.54	0.51	1.00	92
Basis of research	0.53	0.55	0.44	93
Product advisory support	0.52	0.55	0.44	93
Offers technical support or help	0.45	0.50	0.35	93
Software support	0.44	0.42	0.44	93
Import/export capabilities	0.42	0.47	0.04	93
Developer contactable	0.42	0.38	0.36	93
Personalization	0.42	0.38	0.49	93
Specificity of intervention	0.36	0.33	-0.14	91
Source of funding for research	0.36	0.22	0.59	92
Discloses potential risks	0.31	0.23	0.00	93
Effectiveness (Perceived)	0.30	0.43	0.12	93
Continuous availability of data	0.27	0.22	0.09	93
Effectiveness tested (claimed by app)	0.21	0.11	0.34	93
Ease of use	0.18	0.09	0.23	93
Advertising policy stated	0.16	-0.04	0.20	93
Errors and performance issues	0.15	0.28	0.03	93

Discussion

Principal Findings

Overall, we found only a few measures with high interrater reliability; most of the app measures had poor interrater reliability. The measures with the highest degree of interrater reliability tended to involve the least rater discretion. For instance, the presence of encryption and whether or not the app was uploaded by a health care agency can be assessed largely on a factual basis, while the ease of use measure is subject to interpretation. Surprisingly, the presence of interactiveness/feedback, the measure with the greatest degree of interrater reliability overall, was a subjective measure. This suggests that raters were able to come to directional agreement about interactiveness/feedback. While the measure was subjective, it may have led to more consistent ratings than many of the objective measures, as it could be assessed by examining an app holistically rather than by correctly identifying a single feature. While the presence or absence of a feature can be objectively determined, it can also more easily be missed by a reviewer performing a rapid review.

For mHealth apps to be successfully used in clinical practice, they need to be safe and effective. Reviewers had moderate agreement on security/privacy measures, including the presence of password protection, explicit privacy policy, and encryption. Perceived effectiveness had low interrater reliability suggesting that even finding agreement on which apps may actually offer

effectiveness is challenging. Effectiveness tested as claimed by the app also had low interrater reliability. The basis of research behind an app had better interrater reliability and may be a more reliable indicator of effectiveness than perceived effectiveness. Due to the current limited data on the efficacy of most apps, relying on the research base alone is difficult at this time. Given the increasing shift to value-based care with rewards for delivering high-quality care based on evidence-based principles, subsequent research may examine ways of more consistently evaluating the performance of apps on these useful dimensions. Automated outcomes reporting may be a means of gauging effectiveness, and automated crash reporting may be a means of gauging performance [3].

Beyond effectiveness, other clinically important measures, such as ease of use and performance issues, also had relatively poor interrater reliability. Reviewers rated perceived effectiveness and ease of use with 5-point Likert scales in this study. More robust measures are needed for these important measures. The validated System Usability Scale [39] could be considered to measure ease of use.

We also found differences in the performance of measures between the smoking and depression apps. Depression apps had much higher interrater reliability on the presence of password protection than did smoking apps. Several of the smoking apps had passwords associated with the social network functionality, but not the rest of the app, which may have been a source of ambiguity for reviewers. The measures on whether an app was uploaded by a health care agency and contained encryption had perfect agreement for smoking apps, but not for depression apps. Therefore, there may be fundamental differences between categories of apps that impact the interrater reliability of measures. As a result of this heterogeneity, it may be necessary to validate the interrater reliability of measures separately for each category of apps.

While the challenge of rating mHealth apps may be new, issues related to rating scales are not new to health care. Measuring quality of care of hospitals and health care systems is challenging, and there is also at times little consensus between various metrics [40]. Perhaps organizations seeking to rate apps can learn from the quality improvement and safety literature to understand how to best implement effective rating scales.

Overall, the results suggest a need for great caution when assigning and interpreting app ratings (see Table 3). Organizations rating apps should create robust measures with clearly defined criteria to ensure consistency. They should then test the interrater reliability and validity of their measures and utilize only ones with high levels of agreement. The reliability of reviews can further be improved by carefully training reviewers on how to consistently apply the measures. Consumers of reviews—both patients and clinicians—should interpret reviews cautiously, especially if they rely on measures that have not been shown to be reliable and valid. Clinicians may wish to use reviews as a mechanism for selecting potentially beneficial apps and then carefully test apps before recommending them to patients to ensure that the reviewers' definitions of quality are consistent with their own. There may likewise be value in discussing apps with colleagues before recommending them, as it appears that clinicians may not identify quality issues consistently. Even in this era of digital health, clinician judgment may still be the best available tool for evaluating apps. Table 3 summarizes lessons learned from our app review.

Table 3. Key lessons learned for clinicians, patients, and app reviewers.

For clinicians	For patients	For app reviewers
Interpret mHealth app reviews cautiously, especially if measures have not been validated	Interpret mHealth app reviews cautiously	Use previously validated measures with high interrater reliability, if available
Consider reviewing apps personally before recommending apps to patients	Consult with your health care provider or another trusted source	Train reviewers on the measures using standardized specifications
Consider discussing apps with colleagues		Involve patients or reviewers with the condition of interest in the reviews
Use clinical judgment as a tool for evaluating apps		Record the name and version of the app being reviewed, as well as the date of the review

Limitations

While this study provides some initial conclusions about interrater reliability, it may have limited generalizability and does not address measure validity. Only 20 apps in two categories were evaluated, and some differences were found in the interrater reliability of the measures across categories. We included only Apple iOS apps for iPhone devices; Android-only apps were not considered. Furthermore, the apps selected may not be representative of their respective categories.

The app review methods used may have contributed to low measure interrater reliability. The measures of review completeness suggest that reviewers sometimes had issues determining the appropriate ratings for measures or finding the right apps. Future researchers and physicians prescribing apps should consider providing direct links to apps to ensure that there is no confusion. It is easy to imagine situations where physicians recommend apps to patients by name, and then patients are unable to properly identify apps as other available apps have similar titles. Likewise, detailed measure definitions and additional reviewer training may help future reviewers provide more complete ratings with confidence. Nonetheless, each measure was applied 109 or more times, out of a potential total of 120 applications, indicating that in the majority of cases, reviewers were able to properly identify the app and apply a rating for the measure. Further, there may be idiosyncrasies in the rating behavior of the 6 reviewers who participated.

Of note, we did not include any patient ratings in our review process. In the future, it would be interesting to compare the ratings of patients versus expert reviewers. It is possible that patients with depression or tobacco use disorder may have been able to identify salient app features that our reviewers missed. Further research is needed in this important area.

Last, reviews were performed over a 3-month period between March and May 2015, and it is possible that the apps themselves evolved through updates during the period in a way that impacted the reviews. While this issue impacts interrater reliability, it also impacts the usefulness of reviews, as patients and clinicians may sometimes have to rely on reviews that were conducted on prior versions of apps.

Conclusions

Our study suggests that some measures have greater interrater reliability than others and that the relative interrater reliability of measures is not robust across categories of mHealth apps. Unfortunately, the research also suggests that some of the most clinically useful measures—effectiveness and ease of use—have relatively poor interrater reliability. Organizations seeking to rate apps should consider the interrater reliability of the metrics they are utilizing and select metrics with lower levels of ambiguity. Clinician judgment thus remains critical in evaluating and understanding the clinical role of mobile phone apps.

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Conflicts of Interest

ACP has an ownership stake in ArxViva, Inc. and Payer+Provider Syndicate and is on the scientific advisory board of PsyberGuide. SC is an Associate Editor of iMedicalApps. ABL has support from the Commonwealth Fund and is an advisor to the Hacking Medicine Institute.

Multimedia Appendix 1

mHealth apps.

[PDF File (Adobe PDF File), 279KB - mhealth_v4i1e15_app1.pdf]

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Abbreviations

ADAA: Anxiety and Depression Association of America

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Short Paper

Health Behavior Theory in Popular Calorie Counting Apps: A Content Analysis

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Abstract

Background: Although the Health & Fitness category of the Apple App Store features hundreds of calorie counting apps, the extent to which popular calorie counting apps include health behavior theory is unknown.

Objective: This study evaluates the presence of health behavior theory in calorie counting apps.

Methods: Data for this study came from an extensive content analysis of the 10 most popular calorie counting apps in the Health & Fitness category of the Apple App Store.

Results: Each app was given a theory score to reflect the extent to which health behavior theory was integrated into the app. The highest possible score was 60. Out of the 10 apps evaluated, My Diet Coach obtained the highest theory score of 15. MapMyFitness and Yumget received the lowest scores of 0. The average theory score among the apps was 5.6.

Conclusions: Most of the calorie counting apps in the sample contained minimal health behavior theory.

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KEYWORDS

cell phones; mobile applications; telemedicine; weight loss; caloric restriction

Introduction

The Health & Fitness category of the Apple App Store features hundreds of calorie counting apps [1]. According to a survey by the Pew Research Center, 31% of health app users track their diet using apps [2]. Integrating health behavior theory into apps has been identified as a way to increase the likelihood for long-term dietary changes in behavior [3]; however, diet-related health apps are generally void of health behavior theory [3,4].

To date, no research has analyzed the extent to which popular calorie counting apps include health behavior theory. One important limitation of previous research on general health and fitness apps is the short amount of time and engagement with apps during content analysis. Methodologies used in previous studies are useful for providing a general overview of content, but their limited scope makes it challenging to identify all of the instances of health behavior theory integration. The purpose of this study was to conduct an extensive content analysis of the 10 most popular calorie counting apps from the Health & Fitness category of the App Store. Specifically, the purpose of this analysis was to evaluate the presence of health behavior theory in the selected calorie counting apps when used extensively over the course of one week.

Methods

Study Design

This study design featured a content analysis of calorie counting apps available through the App Store. Two Master of Public Health graduate students trained in health behavior theory coded the apps to determine the extent to which health behavior theory constructs were present in the apps.

Sample

iOS apps were selected because they have been identified as scoring slightly higher than Android apps on measures of user reviews and rankings [5]. Since more than half of cell phone users only download apps that are free, the sample was limited to free apps [6]. An approach similar to what has been done in previous studies was used to identify the most relevant and popular apps [4,7]. Keywords *calorie counter* and *diet tracker* were used to identify apps. The initial search returned 319 unique apps. The study sample comprised the 10 most popular apps as determined by the number of stars and reviews. The sample was limited to 10 apps to allow the graduate student coders a minimum of one week to engage with and code each app.

Procedure

Coders each downloaded 5 different study apps to iPhones. They used a single app exclusively to track calories for all meals over the course of at least 7 days and repeated this process until all 10 apps had been used. The interface of each app was thoroughly explored and coded based on a rubric adapted from West et al and Doshi et al [3,8].

To determine the level of interrater reliability between the two graduate student coders, they each coded two preliminary apps, which entailed coding 60 theoretical items each for a total of 120 items. The researchers then calculated the kappa for interrater agreement as .809. This coefficient shows substantial agreement based on the range .61 to .80 recommended by Landis and Koch [9].

Measurement

The measurement, including instrument selection and methodology, was adapted from a study conducted by West et al to evaluate health theory in dieting apps, which are distinct from calorie counting apps [3]. Constructs from the health belief model, transtheoretical model, theory of planned behavior, and social cognitive theory were addressed in the rubric. The coding instrument included 12 constructs relative to calorie counting (Table 1). Each of the 12 constructs was assessed on 5 levels of user interaction, leading to 60 theory-based items. The 5 levels of user interaction as described by West et al were general information or guidelines, assessment, feedback, general assistance, and individually tailored assistance [3,8].

Table 1. Theory integration in selected calorie counting apps (n=10).

Behavior constructs	General information[a]	Assessment[b]	Feedback[c]	General assistance[d]	Individually-tailored assistance[e]
Knowledge[f,g,h,i]	3	0	0	0	0
Perceived benefits[f,g,h,i]	1	0	0	1	0
Perceived barrier[f,g,i]	0	0	0	0	0
Perceived risks[f,h]	1	0	0	0	1
Self-efficacy[g,h,i]	1	0	0	2	1
Social norms[g,h]	0	0	0	1	1
Self-monitoring[g,i]	4	1	1	4	2
Goal setting[i]	2	3	3	2	3
Stimulus control[g,i]	2	0	0	1	4
Self-reward[g,i]	1	0	0	0	1
Social support[g,i]	2	0	0	2	5
Vicarious learning[g,i]	0	0	0	0	0

[a]App provided primarily general information or data that were not individualized.

[b]Assessment: app asked the user for current behavioral practices or strategies.

[c]Feedback: app offered comments on the user's current behavioral practices or strategies.

[d]General assistance: app offered nonindividualized suggestions about how to change or apply a strategy (not based on assessment or feedback).

[e]Individually tailored assistance: app provided suggestions on how to change or apply a strategy specifically tailored to the user.

[f]Health belief model.

[g]Transtheoretical model.

[h]Theory of planned behavior.

[i]Social cognitive theory.

Analysis

STATA version 13 statistical software (StataCorp) was used for analysis. Each app was coded according to the 5 levels of each of the 12 constructs. A subscale was created for each construct by summing the values of the user interaction levels. The possible range was 0-5. Next, a total theory score was assigned to each app by summing the construct subscale values. The total theory scores ranged from 0 to 60.

Results

The number of reviews for apps ranged from 24 to 2435. The number of stars for apps ranged from 4 to 5. Across all levels of interaction, the constructs that were most commonly coded for included knowledge, self-monitoring, goal setting, social support, and stimulus control. A score was assigned to each app to reflect the extent to which theory is integrated. In general, apps lack health behavior theory. My Diet Coach obtained the highest theory score of 15. MapMyFitness and Yumget received the lowest rankings with scores of 0. The average theory score was 5.6 (Table 2).

Table 2. Theory scores of selected calorie counting apps.

Name of application	Theory score (0-60)
My Diet Coach	15
My Diet Diary	14
MyFitnessPal	8
MyNetDiary	7
Calorie Counter, Dining Out, Food, and Exercise Tracker	6
PhotoCalorie	4
Lose It!	1
MapMyRun	1
MapMyFitness	0
Yumget	0

Discussion

Principal Findings

The majority of the apps in this study only minimally integrated health behavior theory. The lack of health behavior theory integration may be an early indication of the low potential for the study apps to influence behavior long term. These apps are popular among users, as noted by number of stars and reviews, but the apps may or may not be successful in changing user behavior. App developers likely have a skillset focused on the technical aspects of development with a goal to create a popular app, not to integrate health behavior theory [4]. This gap in information highlights the need for cooperation between certified health education specialists and app developers [4].

Knowledge was only dealt with on a superficial level; the apps provided general information but did not assess the user's knowledge in an effort to change it. In some respects, this mirrors attempts to change behavior using traditional mediums characterized by one-way transfers of information. Evidence of self-monitoring was identified in study apps, but this would be expected because the purpose of calorie counting apps is to track diet.

Including theoretical health constructs such as goal setting and social support in the creation of apps is a progressive step for developers, but future research is needed to determine the effectiveness of these constructs to change health behavior. Additional studies should measure how effective these goals are—for example, whether goals are considered SMART goals (specific, measurable, achievable, realistic, timely). Social support received the single highest score; many apps provided options to share successes in calorie counting and weight loss on different social networking sites.

There were encouraging examples of health behavior theory integration into study apps, but there were also some constructs that were missing and these could be easily integrated into future versions. Self-efficacy is defined as one's belief in his or her ability to produce a desired result. For the purposes of this study, self-efficacy could be measured by users' confidence in their ability to eat fewer calories. A high self-efficacy enhances human accomplishment by promoting a strong assurance in the ability to master difficult tasks [10]. Weight loss can be a daunting feat to accomplish, and low self-efficacy is a barrier to improving diet and achieving a healthy weight. Future apps can address increasing self-efficacy by incorporating a confidence rating scale for users to more easily conceptualize improvements in self-confidence. In addition, future apps can implement individually tailored messages of support and encouragement to boost user confidence.

According to McAlister et al, vicarious learning is "learning to perform new behaviors by exposure to interpersonal or media displays of them, particularly through peer modeling" [11]. Examples of successful dieting behavior can influence the behavior of people who are trying to diet. Future apps could include videos of people successfully counting calories in public settings or links to social media to foster peer support activities.

These interactions could help the person dieting learn from positive behaviors and make healthier decisions.

Self-reward has been defined as "short-term and frequent rewards that people give themselves" [11]. Individuals are able to feel satisfaction in their progress as they provide themselves with these rewards [11]. Self-reward can motivate the individual to press forward in dieting and calorie counting when results are not immediate. Many times, individuals are capable of enduring short-term negative effects acknowledging that they can lead to positive long-term outcomes [11]. An example of self-reward in an app would be to encourage the user to set aside money every day they count calories in order to buy things that bring fulfillment. Another example of how an app could integrate this construct would be sending an individualized email to remind users to reward themselves for counting calories. This reward may be set by the individual in compliance with their desires and needs.

Limitations

Several limitations should be considered when interpreting the results of this study. First, the researchers limited their sample to 10 calorie counting apps. It is possible that an evaluation including a larger sample size would have produced different results. However, previous studies using larger sample sizes have also found that health apps lack health behavior theory [3,4]. A small sample size was selected for this study to enable coders to use each app for an entire week to evaluate the presence of health behavior theory. Second, apps that included physical activity components were included in the sample. It is possible that some of the theories observed in the apps were intended for physical activity and not calorie counting. Consequently, the results may overestimate the presence of health behavior theory. Apps that contained a physical activity component were included in the sample because the majority of calorie counting apps measure both calorie intake and calorie expenditure, and calorie expenditure is measured using physical activity.

Conclusion

The majority of apps available today allow users to acquire knowledge and track behavior. While this is a step in the right direction, it is not sufficient for behavior change. Future apps should incorporate constructs such as self-efficacy, vicarious learning, and self-reward to increase positive outcomes and behavior change in users.

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Conflicts of Interest

None declared.

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