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Contents

Original Papers

Original Paper

Efficacy of Mobile Apps to Support the Care of Patients With Diabetes Mellitus: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Abstract

Background: Diabetes Mellitus (DM) is a chronic disease that is considered a global public health problem. Education and self-monitoring by diabetic patients help to optimize and make possible a satisfactory metabolic control enabling improved management and reduced morbidity and mortality. The global growth in the use of mobile phones makes them a powerful platform to help provide tailored health, delivered conveniently to patients through health apps.

Objective: The aim of our study was to evaluate the efficacy of mobile apps through a systematic review and meta-analysis to assist DM patients in treatment.

Methods: We conducted searches in the electronic databases MEDLINE (Pubmed), Cochrane Register of Controlled Trials (CENTRAL), and LILACS (Latin American and Caribbean Health Sciences Literature), including manual search in references of publications that included systematic reviews, specialized journals, and gray literature. We considered eligible randomized controlled trials (RCTs) conducted after 2008 with participants of all ages, patients with DM, and users of apps to help manage the disease. The meta-analysis of glycated hemoglobin (HbA1c) was performed in Review Manager software version 5.3.

Results: The literature search identified 1236 publications. Of these, 13 studies were included that evaluated 1263 patients. In 6 RCTs, there were a statistical significant reduction (P<.05) of HbA1c at the end of studies in the intervention group. The HbA1c data were evaluated by meta-analysis with the following results (mean difference, MD −0.44; CI: −0.59 to −0.29; P<.001; I^2=32%).The evaluation favored the treatment in patients who used apps without significant heterogeneity.

Conclusions: The use of apps by diabetic patients could help improve the control of HbA1c. In addition, the apps seem to strengthen the perception of self-care by contributing better information and health education to patients. Patients also become

more self-confident to deal with their diabetes, mainly by reducing their fear of not knowing how to deal with potential hypoglycemic episodes that may occur.

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KEYWORDS

diabetes mellitus; self-care; mobile applications; telemedicine

Introduction

Diabetes Mellitus (DM) is a chronic disease that is considered a global public health problem which results in clinical, social, economic, and quality of life impacts for patients, leading to increased morbidity and mortality [1]. Complications of diabetes including cardiovascular diseases are the leading causes of death globally and are responsible for 50-80% of diabetes deaths [2]. In 2014, the global prevalence of diabetes was estimated at 9% among adults aged 18 years and older [3]. This is increasing with incidence data demonstrating an overall growth in diabetes, particularly among developing countries [4]. There are several factors associated with the rising incidence including lifestyle and diet changes. There is evidence that a large proportion of cases and complications of diabetes may be prevented by changes in lifestyle [5]. Additionally, treatment compliance by patients including control of blood pressure, a leading cause of death in patients with diabetes, is a major concern across countries [6-10].

Education and self-monitoring by diabetes patients helps to optimize and make possible satisfactory metabolic control enabling improved management and reduced morbidity and mortality [11-12]. Self-monitoring of glucose levels is also recommended for patients at risk of developing type 2 diabetes, characterizing it as an important tool for the promotion of health. In the process of encouraging patients to improve metabolic control, the importance of self-monitoring of blood glucose is one of the main strategies to assist themselves, especially those with type 1 diabetes. This highlights the importance of developing technologies to facilitate and optimize self-care, especially in the achievement of therapeutic goals for diabetic patients [11-12]. Published studies have already begun to discuss the potential of mobile apps and tablets with improving symptom management in patients with chronic diseases [13-16].

Global growth in the use of mobile phones makes them a powerful platform to help provide tailored health, delivered conveniently to patients. Several studies have documented the efficacy, challenges, and potential of mobile phones to improve health indicators in diabetes [17-24]. Mobile phones are developing rapidly mainly with regard to information processing, design, and features. These devices, called smartphones, have evolved from the ability to just make phone calls to multiple functions by combining resources on personal computers through software (apps) run by operating systems. Nowadays, the number of smartphone users is higher than traditional mobile phone users. Mobile phones allow users to install, configure, and access specialized apps on their devices [25].

Many types of apps have been developed and are available to users on the Internet such as games, entertainment, productivity, and aspects of health. Apps that contribute to health stand out in this context. In 2015, there were an estimated 500 million smartphone users in the world using apps that contributed to health care [26]. It is projected that there will continue to be a significant growth in the use of health apps, for example, by 2018 it is estimated that half of 1.7 billion “smartphone” and “tablet” users worldwide will download and use health and well-being apps [24,25].

In 2014, the Flurry platform studied app users of the health and well-being category from Apple Store [4]. An increase of 62% in the use of these apps was seen after 6 months of follow-up, with the health and well-being category growing 87% faster than the apps industry in general. This accelerated growth in apps suggests the need to conduct studies of efficacy, safety, and effectiveness to assess their benefits on patient care [27].

Consequently, given the importance and growth of mobile health apps and the potential advantages of this type of technology in addressing major concerns in the management of diabetic patients, it is important that the effectiveness of these technologies to support patient care need be evaluated.

Methods

This principally involved a systematic review and meta-analysis of published studies using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) [28].

Eligibility Criteria

The search period considered studies from 2008 to 2016. The rationale for adopting this criterion is based on the fact that in 2008, the main app stores (iOS, Android), that is those that dominate the market, were launched allowing users the autonomy to download and use apps in general. Prior to this time, the software was only distributed directly by suppliers and manufacturers, and the number of smartphone users was small. Consequently, the inclusion of studies prior to 2008 may introduce bias, characterized by other distribution format and use of apps [29].

We included RCTs and used the PICOS (participants, interventions, comparison, outcomes, study design) to define inclusion criteria (Textbox 1).

Textbox 1. Inclusion criteria.

Population: adults or children were included that were diagnosed with DM type 1 or 2 (with or without comorbidities).

Intervention: mobile health apps that users input data, receive feedbacks, connect with health professionals or learn about diabetes.

- Control or comparator: any comparator was acceptable (traditional control group, an alternative intervention, or a within subject pre-post design).
- Outcome measures: the outcomes considered to evaluate the effectiveness of the apps were: biochemical parameters (HbA1c, blood glucose, total cholesterol, weight, high density lipoprotein cholesterol (HDL), low density lipoprotein cholesterol (LDL), triglycerides, blood pressure) and quality of life.

The exclusion criteria of the study are as follows:

Studies that just looked solely at the main function of mobile phones for transmitting health data by short message service (SMS) or by Internet as well as studies in which health apps had targeted health professionals were excluded. Nonrandomized studies, not controlled, quasi-experimental, and partial results were also excluded.

Databases and Search Strategy

The research was performed in the electronic databases MEDLINE (Pubmed), Cochrane Register of Controlled Trials (CENTRAL), and LILACS (Latin American and Caribbean Health Sciences Literature) for published studies from 2008-2016. A combination of the following MESH terms (Medical Subject Headings), "diabetes mellitus type 2," "diabetes mellitus type 1," "mobile applications," "telemedicine," and their respective entry terms were used in the strategy. In addition, a manual search was undertaken of references from identified publications and systematic reviews from 2008 for the following journals: Online Journal of Public Health Informatics; Journal of Medical Internet Research; BMC Public Health; Journal of Telemedicine and Telecare; Journal of Diabetes Science and Technology; and Journal of Telemedicine and eHealth, health and technology. With the purpose of expanding, the coverage of publications which included a search of the following gray literature sources was conducted: Digital Library of Theses and Dissertations of the University of São Paulo (USP), Digital Library of Theses and Dissertations of the Federal University of Minas Gerais general (UFMG), and electronic database ProQuest Dissertation & Theses. No language restriction was applied.

Study Selection and Data Collection

To select studies, references were read in 2 phases (title or abstract and the full article) by 2 independent reviewers. Disagreements were resolved by a third reviewer.

After full reading of pertinent studies, a standardized form was designed to collect data from the selected studies by 2 independent researchers. The form was used to compile information about the duration and period of studies, participants at the beginning and end of each study, the age groups, health problems, and comorbidities. Interventions in both groups of participants, name and features of apps, countries where studies were conducted, clinical data, and other information were also collected.

Assessment of Risk of Bias

The evaluation of risk of bias followed recommendations of Cochrane Collaboration. Each domain was classified as having a low risk of bias, high or unclear. This assessment was performed by 2 independent researchers and disagreements were resolved by consensus [30-31].

Summary of Data and Statistical Analysis

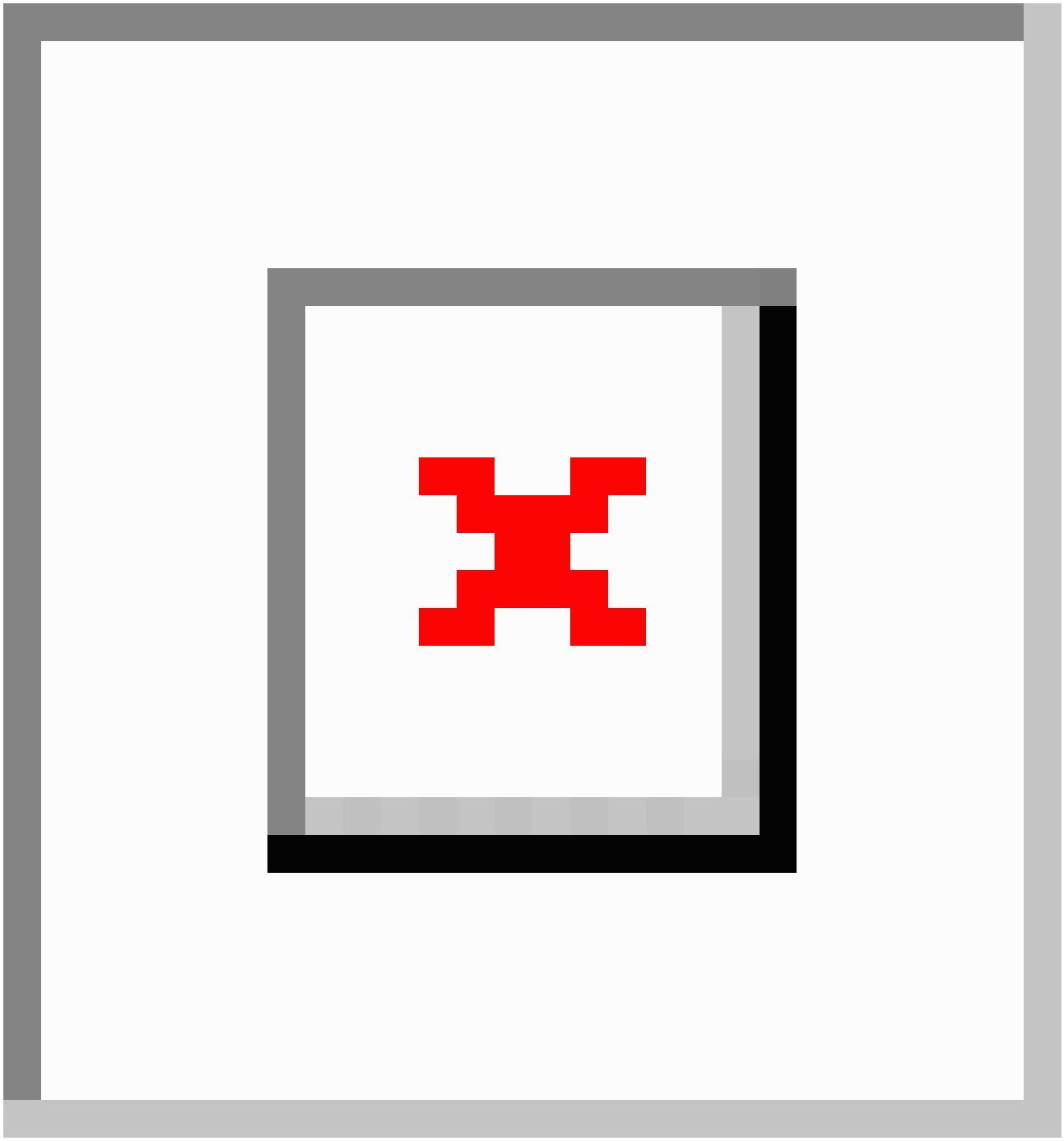
Data collected from HbA1c could be combined in a meta-analysis using random effects model from *Review Manager (RevMan, computer program) version 5.3*. Results were presented as mean difference (MD) with 95% CI. Heterogeneity analysis with an I^2> 40% and *P* value (chi-square test) <.10 were considered as significant heterogeneity. Sensitivity analysis was conducted to investigate the causes of heterogeneity, excluding 1 study each time and checking the changes in values of I^2 and *P*. Other outcomes were assessed as joint analysis because a few studies had provided enough data to be included in a meta-analysis. A subgroup analysis was also performed to check influence of exposure type that participants were submitted to, that is, conventional or remote access to health professionals and the number of features available in the app.

Results

Study Inclusion

The literature search identified 1236 publications, of which 92 were considered potentially eligible. Thirteen studies were finally included in the meta analysis [32-41]. The main reasons for the exclusions were: (1) the interventions were not apps, (2) studies were not RCT, and (3) participants were not diabetes patients (Figure 1).

Figure 1. Flowchart of selection of references to systematic review.



Characteristics of Studies and Participants

The included studies were performed in the United States [32,33,34], Italy [35,36], England [37], Norway [38], Germany [39], Finland [40], Australia [41], Netherlands [42], France [43] and 1 study was conducted in 3 different countries (Italy, England, and Spain) [44]. The duration of studies varied from 1 to 12 months. Of the included studies, 8 were performed in more than 1 center [32,33,35,37,38,41,43,44], whereas the remainder were performed at a single center [34,36,39,40,42]. Only 4 studies reported conflicts of interest (Table 1) [35,36,43,44].

Table 1.

Study	Name (app)	Features	Country	Duration (months)
Hsu (2015) [34]	CollaboRhythm	Storage and feedback of glucose data. Graphical display of data. Storage of eating habits and physical activity. Feedback on insulin dose and calculating carbohydrate consumption. Alarms to take medicine. Telemedicine via SMS text messaging (short message service, SMS) and videoconferencing	United States	3
Drion (2015) [42]	Dbees	Storage and feedback of glucose data, carbohydrate intake, physical exercise, and medication	Netherland	3
Quinn (2014) [33]	MDMA	Storage and educational feedback of biochemical and physiological data about carbohydrate intake and medication	United States	12
Holmen (2014) [38]	Few Touch Application (FTA)	Storage and feedback of glucose data, graphical display of data, storage of eating habits and physical activity, and planning of individual goals	Norway	12
Berndt (2014) [39]	Mobil Diab (mDiab)	Storage and feedback of glucose data. Generates alerts for professionals who perform monitoring when risk is monitored	Germany	1
Nagrebetsk (2013) [37]	t+ Diabetes	Storage and graphical feedback about glucose level. Orientation aid in self-titration of oral hypoglycemic medication under the supervision of a nursing team	England	6
Kirwan (2013) [41]	Glucose Buddy	Storage and feedback of glucose data, insulin, and medication. Graphical display of data. Function to assist in diet, exercise, and planning of individual goals	Australia	9
Rossi (2013) [35]	Diabetes Interactive Diary (DID)	Storage and feedback of glucose data. Feedback on insulin dose and calculating carbohydrate consumption, telemedicine via SMS text messaging	Italy	6
Orsama (2013) [40]	Monica	Feedback on inserted biochemical parameters, graphical display of data, planning individual goals, motivational messages, and change of habits	Finland	10
Quinn (2011) [32]	MDMA	Data storage of biochemical, physiological, carbohydrate intake, and medication with educational feedback	United States	12
Castelnuovo (2011) [36]	METADIETA	Present questionnaires about weight and HbA1c, data on carbohydrate intake, connect via SMS with a nutritionist	Italy	12
Charpentier (2011) [43]	Diabeo System	Storage and feedback of glucose data. Feedback on insulin dose and calculating carbohydrate consumption. Store physical activity	France	6
Rossi (2010) [44]	Diabetes Interactive Diary (DID)	Storage and feedback of glucose data. Feedback on insulin dosage and calculating carbohydrate intake, telemedicine via SMS	Italy, England, and Spain	6

The main intervention evaluated in the studies was the use of mobile apps to assist in the monitoring of diabetes patients. In all studies, the intervention group had remote or conventional access to health professionals. Eleven different mobile apps were identified as the intervention product. The features of apps included health data storage, feedback on physiological parameters, motivational messages, function to assist with a healthy diet and exercise, functions for insulin dosage adjustment, chat and videoconferencing with health professionals, alarm for drug therapy compliance, health goals, and calculating carbohydrate intake. All participants in the

control groups were subjected to standardized health treatment (Table 1).

Four studies included the percentage of participants that smoked (16% to 17%) [32,33,38,40]. Two studies also measured percentage of participants who exercised regularly [38,40]. Additionally, 34.4% [38] and 77% [40] of participants participated in physical activities. The average age of participants of these 2 studies was more than 57 years old.

The total number of participants who began studies included in this review was 1263, wherein 1068 participants took part until the end. It was found there was no association between sample loss and use of mobile apps or smartphones that would compromise outcomes. Regarding ethnicity, only 3 studies reported data. Overall, 50% or more of participants were white [32,33,37]. Education was reported in 8 studies. In 6 studies, 75% or more of the participants had, at least, completed high school [32,33,35,42-44] and 60% of sample in the intervention group were men [37-40,42]. In one study, less than 50% of the participants had completed high school [38]. Another study reported the average years of study among participants to be 11.7 years [40].

One study evaluated if the use of mobile app when compared with standard treatment, could present differences in their effectiveness based on the age of patients (≥ 55 or <55 years old). However, there were no significant differences in the outcomes measured between the 2 age groups [33]. The baseline characteristics of participants are presented in Table 2.

Table 2.

Study		Sample (n)	Age in years (SD)	Gender (% men)	Participant's disease	Disease's duration (SD)
Hsu (2015) [34]					DM[a] type 2	
	App	20	53.3 (0)	-		9.6 (0)
	Control	20	53.8 (0)	-		9.0 (0)
Drion (2015) [42]					DM type 1	
	App	31	33 (23)	64.5		18 (17)
	Control	32	35 (18)	62.5		15 (14)
Quinn (2014) [33]					DM type 2	
	App (< 55 years)	37	47.3 (6.8)	37.8		6.8 (4.5)
	App (≥ 55 years)	25	59.0 (2.9)	68.0		10.3 (5.8)
	Control (< 55 years)	29	47.4 (7.5)	62.1		8.9 (7.5)
	Control (≥ 55 years)	27	59.5 (2.8)	37.0		9.2 (6.0)
Holmen (2014) [38]					DM type 2	
	App	51	58.6 (11.8)	67.0		11.2 (7.3)
	App[b]	50	57.4 (12.1)	50.0		9.6 (8.4)
	Control	50	55.9 (12.2)	40.0		9.4 (5.5)
Berndt (2014) [39]					DM type 1	
	App	34	12.9 (2.0)	62.0		5.0 (3.7)
	Control	34	13.2 (2.9)	56.0		5.3 (4.0)
Nagrebetsk (2013) [37]					DM type 2	
	App	8	56 (8.0)	71.0		3.0 (2.0)
	Control	9	60 (13.0)	71.0		2.3 (7.4)
Kirwan (2013) [41]					DM type 1	
	App	36	35.97 (10.67)	52.7		19.69 (9.64)
	Control	36	34.42 (10.26)	25.0		18.19 (9.77)
Rossi (2013) [35]					DM type 1	
	App	63	38.4 (10.3)	46.0		16.2 (10.0)
	Control	64	34.3 (10.0)	49.1		15 (8.4)
Orsama (2013) [40]					DM type 1	
	App	24	62.3 (6.5)	54.0		-
	Control	24	61.5 (9.1)	54.0		-
Quinn (2011) [32]					DM type 2	
	App	23	52.8 (8.0)	52.2		7.7 (5.6)
	App[c]	22	53.7 (8.2)	45.5		6.8 (4.9)
	App[d]	62	52.0 (8.0)	50.0		8.2 (5.3)
	Control	56	53.2 (8.4)	50.0		9.0 (7.0)
Castelnuovo (2011) [36]					DM type 2 or obesity	

Study		Sample (n)	Age in years (SD)	Gender (% men)	Participant's disease	Disease's duration (SD)
	App	17	49 (16.5)	68.7		-
	Control	17	54 (11.7)	35.3		-
Charpentier (2011) [43]					DM type 1	
	App[e]	59	31.6 (12.5)	37.3		14.7 (9.1)
	App[f]	60	32.9 (11.7)	38.3		17.6 (8.9)
	Control	61	36.8 (14.1)	34.4		16.9 (10.5)
Rossi (2010) [44]					DM type 1	
	App	67	35.4 (9.5)	44.8		17.1 (10.3)
	Control	63	36.1 (9.4)	41.0		15.8 (10.7)

[a]DM: diabetes mellitus.

[b]Intervention is the use of the app associated with health counseling of nurses specialists in diabetes.

[c]Intervention is the use of the app and data shared with medical researchers of the study.

[d]Intervention is the use of the app and data shared with medical researchers of the study associated with quarterly reports delivered to participants from data entered.

[e]Intervention is the use of the app and access health professionals as control group.

[f]Intervention is the use of the app and access health professionals remotely.

Risk of Bias

When evaluating risk of bias, 11 out of the 13 studies presented low risk of selection bias [32,35-44] and 1 showed unclear data [34]. However, in the performance and detection categories, all studies presented high risk of bias. Only 1 study showed unclear data on incomplete outcomes [36]. All studies had low risk on selective reporting (Figure 2).

Figure 2. Analysis of the risk of bias.

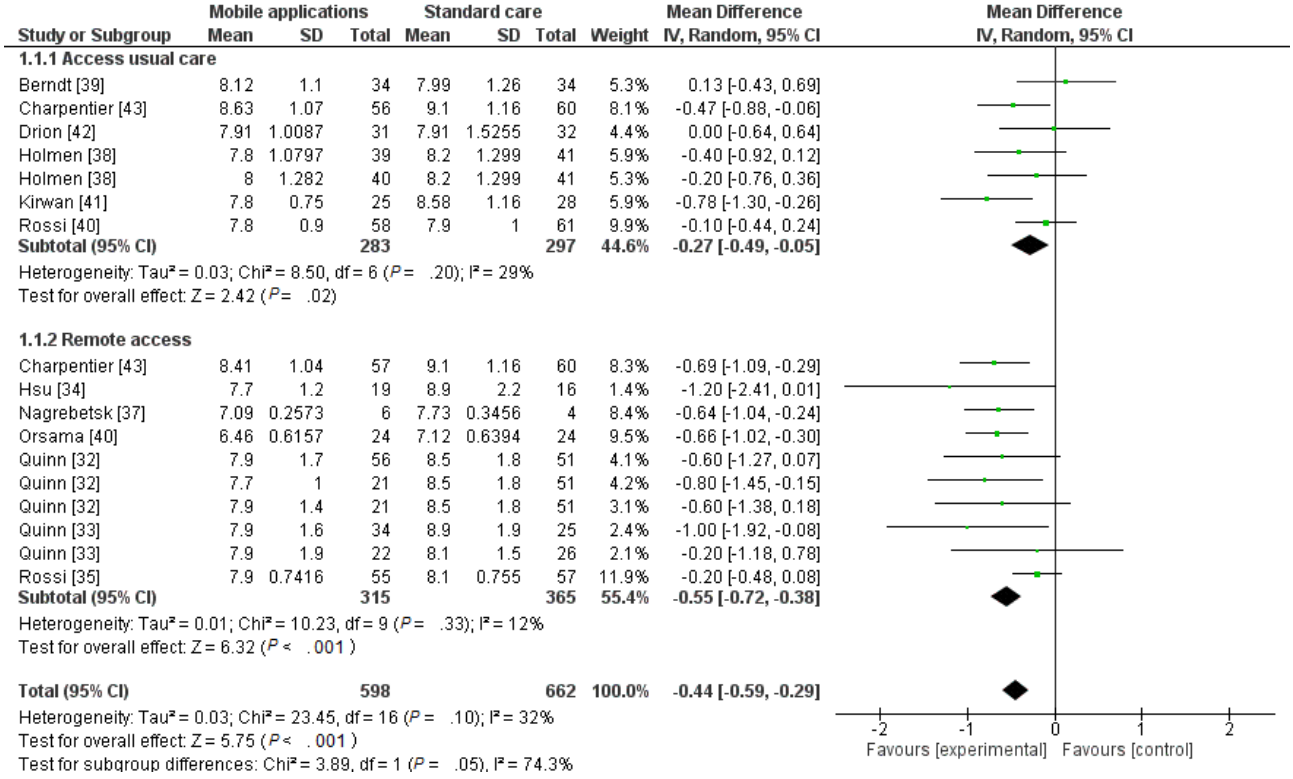
Glycated Hemoglobin and Hypoglycemic Episodes

HbA1c was measured in 12 studies [32-35,37-44]. In 6 studies, there were statistical significance difference in the reduction of this parameter favoring the intervention within 12 months of follow-up (P<.03) [32-34,40,41,43].

Overall, the meta-analysis showed the effectiveness of the use of apps to control diabetes (P<.001), with lower heterogeneity (MD −.44; CI −0.59 to −0.29; P<.10; I^2= 32%). The sensitivity analysis showed that excluding the study [41] in the subgroup "Access to usual care" and [35] in the subgroup "Remote Access," there was a reduction of heterogeneity in both subgroups to zero without changing the direction of outcome (Figure 3).

Hypoglycemic episodes were reported in 5 studies [34,35,39,43,44]. In 1 study, 30 and 33 mild episodes were recorded in the intervention and control groups respectively and a serious episode in the control group [39]. In 3 studies, episodes were recorded in each group without significant difference [34,43,44]. In a third study, the intervention group had a lower relative risk (0:14; CI 0.07-0.029) of severe hypoglycemic episodes. [35]

Figure 3. Forest-plot of glycated hemoglobin of diabetes patients who used a health app and have access physically or remotelly to health professionals.



Subgroup Analysis

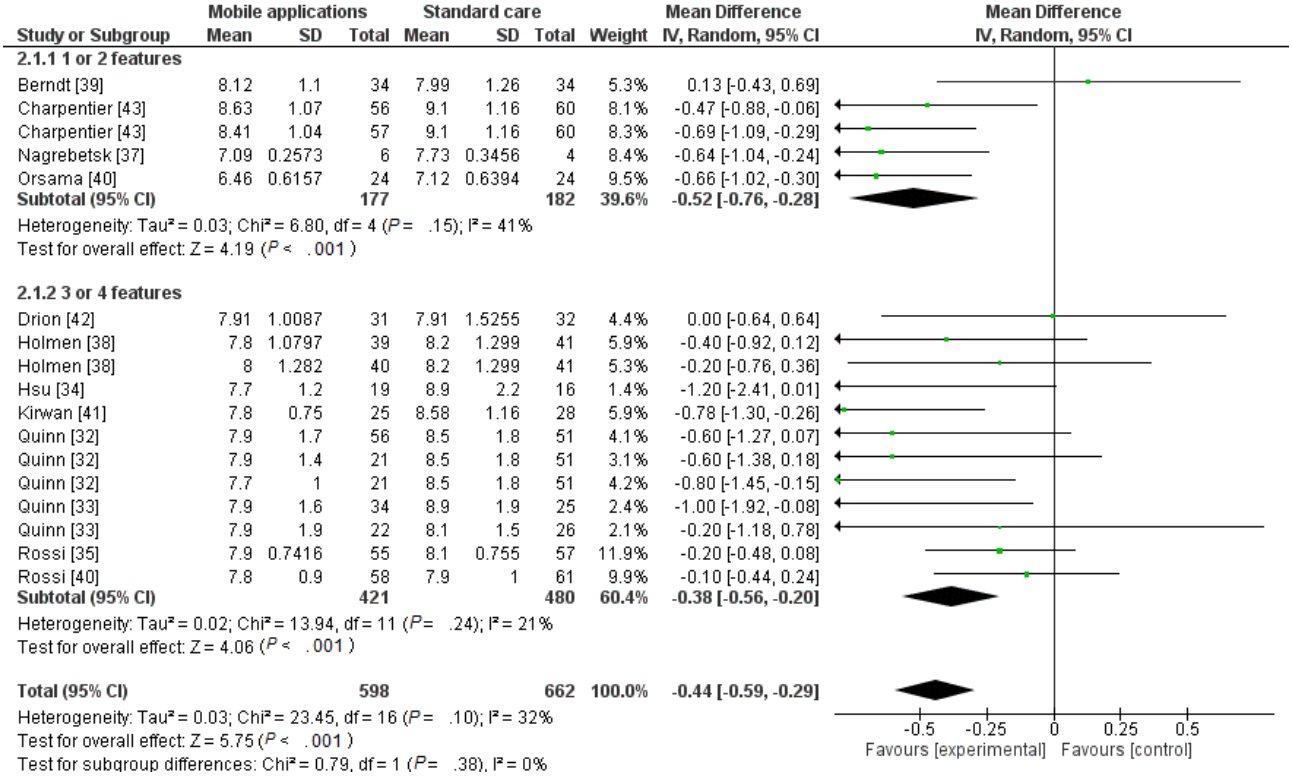
Subgroup analysis was performed to evaluate if the route of access to health professionals for monitoring diabetes, in addition to the app, affected outcomes in terms of HbA1c. In 7 studies, participants in the intervention group had access to health professionals remotely [32-35,37,40], in 5 studies, participants had access to usual care [38,39,41,42,44,] and in 1 study intervention participants had access to health professionals remotely or physically [43]. Both subgroups showed favorable results in HbA1c control (Figure 3).

The number of features available in the app of each study was also evaluated to check their impact on HbA1c. Four main features were identified in apps that contributed to achieving glycemic control. These were “storage and feedback of blood glucose data,” “function to assist in diets,” “function to aid at physical exercises practice,” and “control over dosage and adherence to drug therapy” [45].

Subgroups were separated in order to evaluate studies where the apps provide 1 or 2 features of the 4 identified for glycemic control (P=.05) [37,39,40]. It was demonstrated that the subgroup with fewer features in an app had outcomes with borderline significant difference. The subgroup where apps had more than 2 functionalities generated the following results (P<.001) [32-35,38,41-44] (See Figure 4).

A subgroup analysis was performed to evaluate if there was a difference among different types of diabetes mellitus. Both subgroups showed favorable results of HbA1c control to intervention group compared with control group.

Figure 4. Forest plot of glycated hemoglobin of diabetes patients who used a health app according to the number of selected app features.



Secondary Outcomes

Different secondary outcomes were evaluated in some studies. Four studies were conducted using an assessment of fasting blood glucose assessment. However, there was no significant reduction in any study [35,39,41,44]. Six studies assessed weight changes [35,36,38-40,44]. Four studies assessed changes in blood pressure [32,35,40,44] and 3 studies measured total cholesterol, high-density lipoprotein, low-density lipoprotein, and triglycerides [32,35,44]. The results were presented by a joint analysis (Table 3).

Table 3. Joint analysis of secondary outcomes.

Outcome	Intervention (n)	Control (n)	Mean difference (95% CI)	*P* value	I² (%)
Fasting blood glucose [35,39,41,44]	172	180	0.05 (−1.39 to 1.49)	.95	79%
Body weight [35,38,39,44]	226	193	−0.39 (−1.43 to .66)	.47	0%
Systolic blood pressure [32,35,40,44]	221	179	0.10 (−2.36 to 2.55)	.94	0%
Diastolic blood pressure [32,35,40,44]	221	179	0.37 (−1.10 to 1.85)	.62	0%
Total cholesterol [32,35,44]	211	169	−3.44 (−12.87 to 6.00)	.48	44%
High-density lipoprotein [32,35,44]	211	169	−2.15 (−5.40 to 1.10)	.19	58%
Low-density lipoprotein [32,35,44]	211	169	1.69 (−5.67 to 9.06)	.65	26%
Triglicerides [32,35,44]	211	169	−14.67 (−33.40 to 4.06)	.12	58%

Quality of life was assessed in 6 studies using different measuring instruments: Disease-Specific Quality-of-Life (DSQOL) [35], Diabetes Quality of Life (DQOL) [41], Diabetes Quality of Life for Youths (DQOLY) [39], and 36-Item Short-Form (SF-36) [38,42,44]. Three studies found positive and statistical significant changes in quality of life and satisfaction with treatment in the intervention group [35,39,44]. Health improvements reported by participants with the app were the perception of hyperglycemia episodes, social relationships, decreased fear of hypoglycemia, perception that the apps aid treatment, and healthier dietary habits.

Discussion

Principal Findings

The meta-analysis found a significant difference throughout 12 months among the intervention group in terms of better HbA1c control. However, overall there were no significant differences with respect to secondary outcomes between the groups. These results indicate relevant questions about the potential of tools for self-monitoring and self-care by patients and the role of remote access to health care professionals where there appears to be similar effectiveness with conventional access to diabetes patients.

We believe it is worth mentioning that while these results have shown significant differences compared with the control group for control of HbA1c, only 2 studies [37,40] reached values considered suitable for glycemic control, which is 7%, according to the global consensus [46,47]. This demonstrates the major challenge in achieving satisfactory results in the treatment of diabetes, despite all groups of participants having shown better average results at the end of the studies.

In other studies that averaged more than 7%, the maximum average value found was 8.63% in the intervention group [43]. The United Kingdom Prospective Diabetes Study shows that every percentage point decrease in HbA1c reduces by 35% the risk of vascular complications [48]. Another study showed that HbA1c values between 7.4(1.4) and 7.7(1.4) do not increase the risk for retinopathy and nephropathy, respectively, while values above 9.3(1.1) and 9.6(1.2) show increased risk of development and progression of retinopathy and nephropathy, respectively [49].

Association between use of apps and remote access to health professionals demonstrated great effectiveness in controlling HbA1c. Studies in which intervention groups accessed health professionals similar to the control groups also showed significance difference in outcomes. This suggests that the use of apps by themselves may not be more effective than standard treatment. Apps have better results when they include tools of remote communication with health professionals or access them face to face.

The number of features that apps offer also appears to influence HbA1c levels. Studies in which apps had even 2 features showed borderline results between the 2 groups. Results were favorable when more than 2 features of control were available in the app, ie, more than 2 of “storage and feedback of blood glucose data,” “function to assist in diets,” “function to aid at physical exercises practice,” or “control over dosage and adherence to drug therapy.”

Studies evaluating quality of life reported that use of apps have increased the perception of knowledge by participants about their health problems. This may represent a contribution to perceived need for self-care by users [35,39,44]. These results corroborate the proposed measures of health promotion by the International Diabetes Federation [12].

The high risk of bias for blinding participants and masking interventions is followed by almost the impossibility of health professionals and patients unaware of the use of apps and smartphones in care process. However, some studies reported there is no empirical evidence to support the conclusion that problems in masking the interventions may compromise the results [50,51].

An important characteristic measured in these studies was participants’ education. It is expected that individuals with higher education have greater ability in adopting new technologies. This may be a limitation of the studies because results favoring app users might not have had the same outcomes if participants had less education. In a study conducted in Norway [38], most of the participants had education below high school, and any measured outcomes showed results with significant difference for 1 of the groups. However, the Norwegian study may not be a good reference because Nordic countries are highly digitalized societies, which is not yet a reality in a number of countries including Brazil [52].

All studies included in this systematic review were undertaken in developed countries and therefore it is necessary to measure the ability to generalize with developing countries. Access to apps requires the presence of a smartphone or tablet and Internet access for satisfactory performance. In Brazil, statistics from the Web-based statistics portal Statista suggests that by 2017, 42.5% of mobile users will be smartphone users [53]. In absolute numbers, Brazil will have nearly 170 million mobile phone users by 2018 [54], suggesting that more than one third of Brazilians will have access to a smartphone by 2018. According to the World Bank, Internet access in Brazil in 2014 reached 57.6% of the population [55], allowing the potential use of apps in health care processes.

Age may also be an influencing factor to the adoption of new technologies [56-60]. In 5 of the studies, participants had an average age under 40 years [35,41-44]. In other studies, participants had a mean age of 50 years, except 1 study with teenagers. Studies with participants with an average age of 40 years showed improvements in outcomes including HbA1c [41,43], triglycerides [44], and a relative risk reduction shield for hypoglycemic episodes [35]. However, 1 study showed no significant difference in outcomes among people under and over 55 years old in the 2 groups [34].

A last important analysis was related to a higher proportion of men (60% of sample) in the intervention group of some studies [37-40,42]. Reference showed that men were more interested in adopting new technologies, while women preferred to take opinions before use [61]. However, the included studies in this review showed men and women had comparable results.

After performing the analysis, it can be concluded that use of apps for diabetes control as an aid to treatment can be considered an effective measure, especially when patients have access to health professionals. Sustainable health systems need to invest in disease prevention and health promotion actions. Self-monitoring actions aim to raise awareness and education about the role of patients and family in managing their health problems. At the same time, smartphones with Internet access have the potential to provide data from clinical parameters measured at home that can relieve pressures on health systems directly due to improved access for those who really need to

use clinics and hospitals and, indirectly, by reducing costs and increasing therapeutic effectiveness.

The results from this meta-analysis suggest that self-monitoring can be delivered by smartphones, with increasing use of smartphones by people from different socioeconomic conditions. The use of such devices can still be considered complex and potentially a barrier to access among elderly patients. However, in the medium term, population aging will include almost all in a highly connected and digitalized society.

Conclusions

This systematic review suggests that use of apps in patients with diabetes could help improve the control of HbA1c. In addition, the apps seem to strengthen the perception of self-care by contributing better information and health education to diabetes patients. App features including "storage and feedback of blood glucose data,' 'assist in diet," "help practice in physical exercise," and "assist in control of dosage and adherence to drug therapy" as well as access to health care professionals contributes to a better glycemic control. Patients also become more self-confident to deal with their diabetes, mainly by reducing fear of not knowing how to deal with potential hypoglycemic episodes that may occur and improving their quality of life.

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Conflicts of Interest

None declared.

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Abbreviations

DM: diabetes mellitus
HbA1c: glycated hemoglobin
MD: mean difference.
RCTs: randomized controlled trials
SMS: short message service

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Original Paper

Resting and Postexercise Heart Rate Detection From Fingertip and Facial Photoplethysmography Using a Smartphone Camera: A Validation Study

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Related Article:

This is a corrected version. See correction statement: http://mhealth.jmir.org/2019/1/e11616/

Abstract

Background: Modern smartphones allow measurement of heart rate (HR) by detecting pulsatile photoplethysmographic (PPG) signals with built-in cameras from the fingertips or the face, without physical contact, by extracting subtle beat-to-beat variations of skin color.

Objective: The objective of our study was to evaluate the accuracy of HR measurements at rest and after exercise using a smartphone-based PPG detection app.

Methods: A total of 40 healthy participants (20 men; mean age 24.7, SD 5.2 years; von Luschan skin color range 14-27) underwent treadmill exercise using the Bruce protocol. We recorded simultaneous PPG signals for each participant by having them (1) facing the front camera and (2) placing their index fingertip over an iPhone's back camera. We analyzed the PPG signals from the Cardiio-Heart Rate Monitor + 7 Minute Workout (Cardiio) smartphone app for HR measurements compared with a continuous 12-lead electrocardiogram (ECG) as the reference. Recordings of 20 seconds' duration each were acquired at rest, and immediately after moderate- (50%-70% maximum HR) and vigorous- (70%-85% maximum HR) intensity exercise, and repeated successively until return to resting HR. We used Bland-Altman plots to examine agreement between ECG and PPG-estimated HR. The accuracy criterion was root mean square error (RMSE) ≤5 beats/min or ≤10%, whichever was greater, according to the American National Standards Institute/Association for the Advancement of Medical Instrumentation EC-13 standard.

Results: We analyzed a total of 631 fingertip and 626 facial PPG measurements. Fingertip PPG-estimated HRs were strongly correlated with resting ECG HR (r=.997, RMSE=1.03 beats/min or 1.40%), postmoderate-intensity exercise (r=.994, RMSE=2.15 beats/min or 2.53%), and postvigorous-intensity exercise HR (r=.995, RMSE=2.01 beats/min or 1.93%). The correlation of facial PPG-estimated HR was stronger with resting ECG HR (r=.997, RMSE=1.02 beats/min or 1.44%) than with postmoderate-intensity

exercise (r=.982, RMSE=3.68 beats/min or 4.11%) or with postvigorous-intensity exercise (r=.980, RMSE=3.84 beats/min or 3.73%). Bland-Altman plots showed better agreement between ECG and fingertip PPG-estimated HR than between ECG and facial PPG-estimated HR.

Conclusions: We found that HR detection by the Cardiio smartphone app was accurate at rest and after moderate- and vigorous-intensity exercise in a healthy young adult sample. Contact-free facial PPG detection is more convenient but is less accurate than finger PPG due to body motion after exercise.

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KEYWORDS

heart rate; mobile apps; photoplethysmography; smartphone; mobile phone

Introduction

There are over 100,000 health-related apps in the health and fitness category in the Google Play Store and the iTunes App Store designed for mobile devices (ie, smartphones or tablets) [1,2]. The number of health-related apps is increasing by 25% each year [3]. Mobile device usage has constantly been on the rise over the last few years [4], with an estimated 6.9 billion subscriptions globally [5]. In the United States, 64% of adults own at least one smartphone [6], and 62% of smartphone owners have used their phone to obtain health information. In Europe, 50% of citizens own a smartphone [7]. In the Asia Pacific region [8], the number of smartphone users is estimated to reach 1.2 billion in 2017. With technological advances and the increasing trend of mobile device usage, mHealth is becoming popular and is seen as an opportunity to promote health and fitness, provide health maintenance, or enhance lifestyle management [9-11]. Compared with home health devices and computers, personal mobile devices with health-related apps installed are more convenient, portable, and accepted [12,13]. Older adults are more likely to own a smartphone than a computer [11]. An estimated 19 million people use mobile health devices worldwide [14].

Over the last few years, multiple smartphone devices and apps were developed to facilitate heart rate (HR) monitoring. Monitoring of HR during exercise can be used to assess fitness level and intensity of exercise. It is also useful for patients who are taking medications that affect HR to guide disease management. Recently, several smartphone apps capable of measuring HR and detecting arrhythmia have also been reported [15,16]. Modern smartphones allow measurement of HR by detecting pulsatile photoplethysmographic (PPG) signals with built-in cameras from the fingertips or the face without physical contact by extracting subtle beat-to-beat variations of skin color that is similar to HR fluctuations [17,18]. The PPG signal is typically recorded by placing a finger over the camera lens, which measures color changes due to fingertip blood volume changes [19]. Facial PPG recording using the smartphone camera is a novel method of detecting pulsatile PPG signal without physical contact [20,21].

HR estimation using the built-in smartphone cameras may provide readily accessible, inexpensive, and user-friendly means to measure HR without additional hardware such as wrist bands or watches. However, validation of HR measurements detected from smartphone-based PPG apps is limited [22-24]. This study aimed to evaluate the accuracy of HR measurements at rest and after exercise using the Cardiio-Heart Rate Monitor + 7 Minute Workout (Cardiio) smartphone-based PPG detection app compared with a continuous electrocardiogram (ECG) as the reference.

Methods

Participants and Recruitment

We recruited 40 healthy participants between 18 and 40 years old with no current medical conditions and who were not taking regular medications. Demographics characteristics were collected. Body height and weight were measured under standard anthropometry procedures, and body mass index was calculated as weight in kilograms divided by height in square meters. Blood pressure was measured using an automatic blood pressure monitor (Tango M2, SunTech Medical, Inc., NC, USA) before and after testing procedures. The participants were evaluated for facial skin color by using the von Luschan skin color chart (range 1-36) [25]. This study was approved by the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (CREC Ref. No. 2016.550).

Study Setup

We set up 2 iPhones (iPhone 6S; Apple, Inc, Cupertino, CA, USA) and a 12-lead ECG treadmill (GE Series 2000, GE Medical Systems Information Technologies Inc, Milwaukee, WI, USA) for HR measurements. Backdrop and background light intensity was standardized during signal acquisition and was captured in the unit of lux. The Cardiio (Cardiio Inc, Cambridge, MA, USA) smartphone app was installed in the 2 iPhones for facial and fingertip PPG detection. HR measurements were taken by continuous 12-lead ECG, and facial and fingertip PPG detection simultaneously. Each participant was given at least a 5-minute rest interval before testing began. We took 3 measurements of resting HR and averaged them for analysis before exercise. Participants were then tested on a motorized treadmill using the Bruce test protocol from stage 1 to stage 4 (2.7, 4.0, 5.5, and 6.8 km/h) [26]. Each participant underwent 2 sequential tests on the treadmill to achieve (1) moderate-intensity exercise, defined as 50% to 70% maximum HR, and (2) vigorous-intensity exercise, defined as 70% to 85% maximum HR. Maximum HR was calculated as 220 beats/min minus the participant's age [27]. HR recordings were acquired immediately when moderate- and vigorous-intensity exercise was achieved based on HR from the continuous ECG and repeated successively until return to resting HR.

Heart Rate Measurements

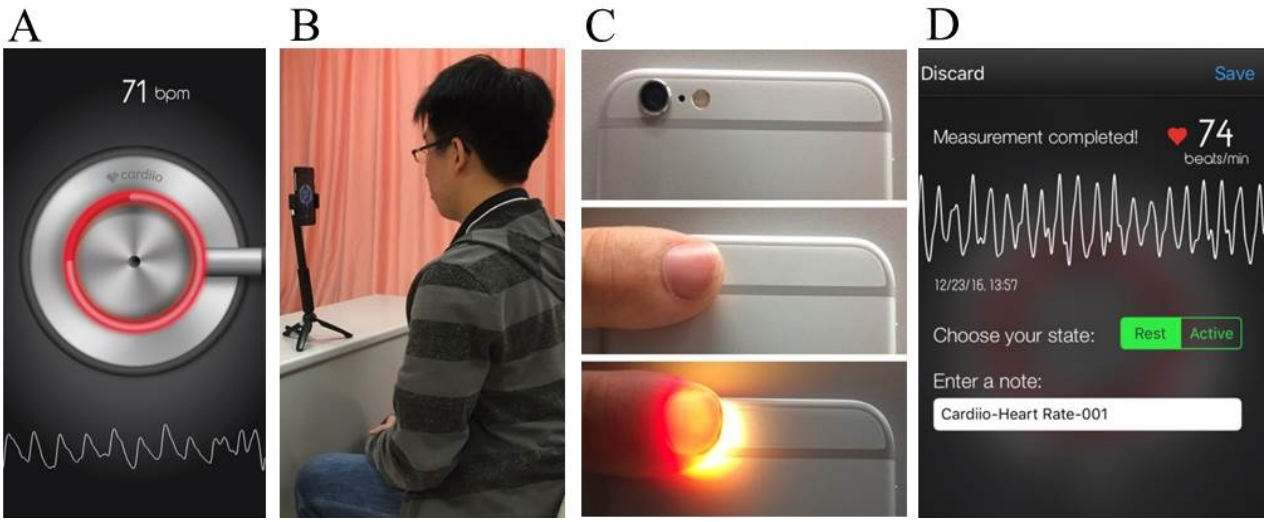
12-Lead Electrocardiogram

Continuous 12-lead ECG was our reference standard of HR measurement. We compared HRs detected by the Cardiio smartphone app with simultaneous 12-lead ECG recordings.

Facial PPG Detection

We asked participants to sit in front of an iPhone placed upright on a desk approximately 30 cm away. Once the Cardiio smartphone app was activated, a large circle appeared on the screen, and each participant needed to position the image of his or her entire face within the circle so that it was captured by the front camera (Figure 1). Participants were instructed to hold still for 20 seconds during each measurement. The continuous pulsatile PPG signal from the face detected by the camera was displayed on the bottom of the iPhone screen. An estimated HR measurement analyzed by the Cardiio smartphone app was displayed as a result. Participants were asked to keep their movements to a minimum and not to speak during measurement.

Figure 1. (A) Cardiio smartphone app. (B) Setup to acquire photoplethysmographic (PPG) signals from the participant's face. (C) Obtaining PPG signals from the fingertip. (D) Example of a report produced by the Cardiio smartphone app.



Fingertip PPG Detection

Fingertip PPG signals were recorded for each participant by placing their index fingertip over the iPhone's back camera for 20 seconds. Once the finger was placed in contact and illuminated by the adjacent LED flash, a continuous pulsatile PPG signal from the fingertip was detected by the camera and displayed on the bottom of the iPhone screen (Figure 1). It was analyzed by the Cardiio smartphone app for an estimated HR measurement and displayed as a result. Participants were asked to keep their movements to a minimum and not to speak during measurement.

Statistical Analysis

We present numerical results as mean (SD) or median (interquartile range, IQR). Pearson correlation (r) and coefficient of determination were applied to determine the nature of the relationship between the HR measurements made by the Cardiio smartphone app (face and fingertip PPG detection) and by the standard 12-lead ECG. We performed the paired Student t test and Wilcoxon signed rank test to determine the difference between the means and medians measured by both devices. Root mean square error (RMSE) was performed to evaluate the spread of errors between predicted and observed values. Bland-Altman plots were used to examine agreement between ECG and PPG-estimated HR. All statistical analyses were performed using IBM SPSS statistical software (IBM SPSS Statistics for Windows, version 22.0; IBM Corporation). All analyses were 2-tailed, and P values of <.05 were considered statistically significant.

We recorded a total of 665 fingertip and 665 facial PPG measurements. Boxplots were used to determine extreme outliers for any observation outside the upper and lower fences that were 3 times the IQR. Potential outliers were checked for accuracy before exclusion. Failed measurements (n=4 facial measures) and extreme outliers were possibly caused by the monitor losing fingertip skin contact or misalignment of the face. We excluded 69 outliers for PPG measurements representing unrealistic HR values (n=34 fingertip measures and n=35 facial measures), resulting in 631 fingertip and 626 facial PPG measurements for analysis.

Results

Characteristics of Participants

Table 1 summarizes participants' characteristics. Of the 40 healthy participants, 50% (n=20) were men, and the mean (SD) age was 24.7 (5.2) years. The median von Luschan skin color among participants was 23 (IQR 19-25); the lightest skin color was 14 and the darkest was 27. Male participants had a higher body mass index, resting systolic blood pressure (SBP), and resting diastolic blood pressure (DBP) than the female participants. There were no significant differences in postexercise SBP and DBP between the sexes. The median backdrop and background light intensity during signal acquisition was 199 lux (IQR 127-249).

Table 1. Baseline characteristics of the study participants.

Variables	Male (n=20)	Female (n=20)	All participants (N=40)	*P* value
Age in years, mean (SD)	23.9 (4.6)	25.5 (5.8)	24.7 (5.2)	.34
von Luschan skin color, median (IQR[a])	23.5 (22-24)	19 (18-25.75)	23 (19-25)	.19
Height in cm, mean (SD)	172.5 (5.8)	160.1 (5.9)	166.3 (8.5)	<.001
Weight in kg, mean (SD)	69.0 (10.2)	51.8 (5.4)	60.4 (11.9)	<.001
Body mass index in kg/m^2, mean (SD)	23.1 (2.4)	20.2 (1.7)	21.6 (2.5)	<.001
Resting SBP[b] in mmHg, mean (SD)	132.6 (15.0)	117.0 (17.2)	124.8 (17.8)	<.001
Resting DBP[c] in mmHg, mean (SD)	78.7 (11.1)	72.8 (9.0)	75.7 (10.5)	.01
Postexercise SBP in mmHg, mean (SD)	146.3 (20)	135.1 (29.1)	140.7 (25.4)	.05
Postexercise DBP in mmHg, mean (SD)	73.4 (12.1)	74.9 (19.9)	74.2 (16.3)	.68

[a]IQR: interquartile range.

[b]SPB: systolic blood pressure.

[c]DBP: diastolic blood pressure.

Fingertip PPG-Estimated Heart Rate

We analyzed 80 averaged resting HR values from 234 PPG measurements, and overall 397 postmoderate- and postvigorous-intensity exercise HR values.

For resting HR, the Cardiio app captured 6% (5/80) of HR values ≥100 beats/min, and the mean (SD) HR was 73.41 (12.60) beats/min (range 52.67-112 beats/min) (Table 2). The mean (SD) difference in HR between fingertip PPG measurements and the reference ECG was –0.05 (1.03) beats/min (*P*=.69, paired *t* test; Table 3).

Table 2. Comparison of heart rates (HRs) measured by electrocardiogram (ECG), and fingertip and facial photoplethysmography (PPG).

Activity	Device	n	HR≥100 beats/min, n (%)	HR (beats/min)		
				Mean (SD)	Minimum	Maximum
Fingertip PPG detection						
Resting						
	ECG	80	5 (6)	73.46 (12.74)	52.67	114.00
	Cardiio	80	5 (6)	73.41 (12.60)	52.67	112.00
Postmoderate-intensity exercise						
	ECG	177	51 (28.8)	90.33 (19.85)	51	142
	Cardiio	177	50 (28.2)	89.97 (19.95)	50	145
Postvigorous-intensity exercise						
	ECG	220	132 (60.0)	105.30 (20.07)	58	157
	Cardiio	220	133 (60.5)	105.12 (19.91)	57	157
Facial PPG detection						
Resting						
	ECG	80	5 (6)	73.46 (12.74)	52.67	114.00
	Cardiio	80	5 (6)	73.17 (12.64)	51.50	112.67
Postmoderate-intensity exercise						
	ECG	188	55 (29.3)	90.44 (19.33)	51	142
	Cardiio	188	56 (29.8)	89.35 (19.47)	52	138
Postvigorous-intensity exercise						
	ECG	201	114 (56.7)	103.46 (19.14)	58	157
	Cardiio	201	110 (54.7)	102.53 (19.16)	59	158

Table 3. Accuracy of measuring heart rate (HR) using Cardiio smartphone app compared with reference electrocardiogram.

Statistic	Resting HR	Postmoderate-intensity exercise HR	Postvigorous intensity-exercise HR
Fingertip PPG[a] detection			
Coefficient of determination	.993	.988	.990
RMSE[b] (beats/min)	1.03	2.15	2.01
RMSE (%)	1.40	2.53	1.93
Wilcoxon signed rank test, *P* value	.53	.09	.60
Paired Student *t* test, *P* value	.69	.03	.19
Mean (SD) difference (beats/min)	–0.05 (1.03)	–0.36 (2.14)	–0.18 (2.02)
Median difference (beats/min)	0.500	0	0
Facial PPG detection			
Coefficient of determination	.994	.965	.960
RMSE (beats/min)	1.02	3.68	3.84
RMSE (%)	1.44	4.11	3.73
Wilcoxon signed rank test, *P* value	.02	<.001	.08
Paired Student *t* test, *P* value	.01	<.001	.001
Mean (SD) difference (beats/min)	–0.29 (1.03)	–1.09 (3.67)	–0.93 (3.84)
Median difference (beats/min)	–1.166	–2.000	–1.000

[a]PPG: photoplethysmography.

[b]RMSE: root mean square error.

The mean (SD) HR of postmoderate-intensity exercise was 89.97 (19.95) beats/min (range 50-145 beats/min) with 28.2% (50/177) of HR values ≥100 beats/min captured by the Cardiio app. For postvigorous-intensity exercise, the mean (SD) HR was 105.12 (19.91) beats/min (range 57-157 beats/min) with 60.5% (133/220) of HR values ≥100 beats/min captured (Table 2). The mean (SD) differences in HR between fingertip PPG measurements and the reference ECG were –0.36 (2.14) beats/min (*P*<.05) for postmoderate-intensity exercise and –0.18 (2.02) beats/min (*P*=.19) for postvigorous-intensity exercise (Table 3).

Table 4 shows correlation coefficients of HR between the Cardiio smartphone app and the reference ECG. Fingertip PPG-estimated HRs were strongly correlated with ECG HR at rest (*r*=.997, *P*<.001; RMSE=1.03 beats/min or 1.40%), postmoderate-intensity exercise (*r*=.994, *P*<.001; RMSE=2.15 beats/min or 2.53%), and postvigorous-intensity exercise (*r*=.995, *P*<.001; RMSE=2.01 beats/min or 1.93%), as Figure 2 illustrates.

Table 4. Correlation test (*r*)[a] of heart rate between reference electrocardiogram (ECG) and Cardiio smartphone app.

Activity	ECG	Fingertip PPG[b] detection	Facial PPG detection
Resting	1	.997	.997
Postmoderate-intensity exercise	1	.994	.982
Postvigorous-intensity exercise	1	.995	.980
Postexercise overall	1	.995	.983

[a]*P*<.001 for all correlations (correlation is significant at the .01 level, 2-tailed).

[b]PPG: photoplethysmography.

Figure 3 presents the Bland-Altman plots with 95% limits of agreement. The Cardiio smartphone app had 95% of resting HR measurements fall within –1.98 and +2.07 beats/min, while postexercise HR measurements were within –3.81 and +4.32 beats/min.

Figure 2. Scatter plots comparing measurements of heart rate (HR) estimated from the Cardiio smartphone phone app photoplethysmographic (PPG) signals and from a reference electrocardiogram (ECG). *P*<.001 for all correlations. (A) Resting estimated HR from fingertip PPG signals. (B) Resting estimated HR from facial PPG signals. (C) Postexercise HR from fingertip PPG signals. (D) Postexercise HR from facial PPG signals.

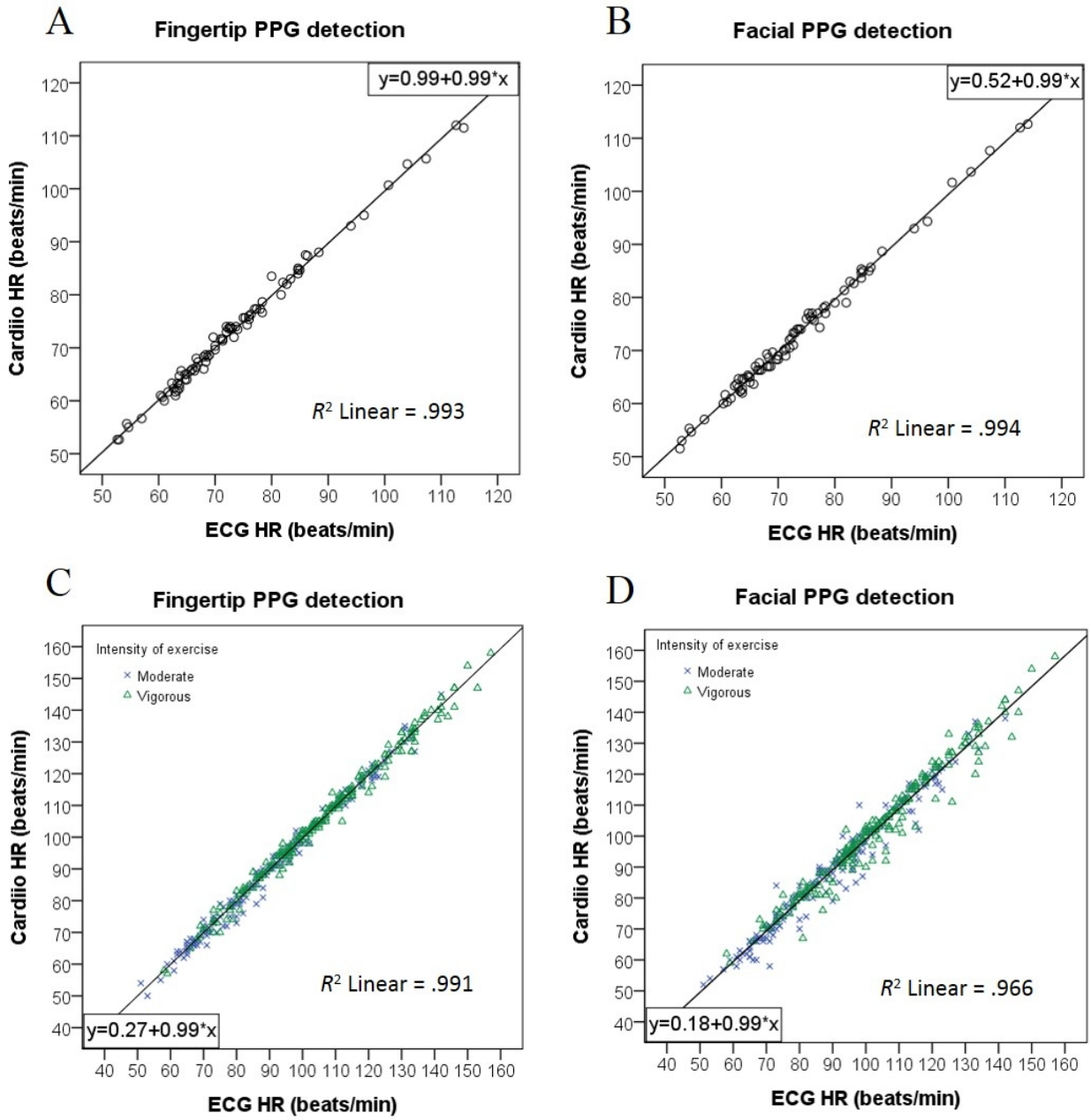
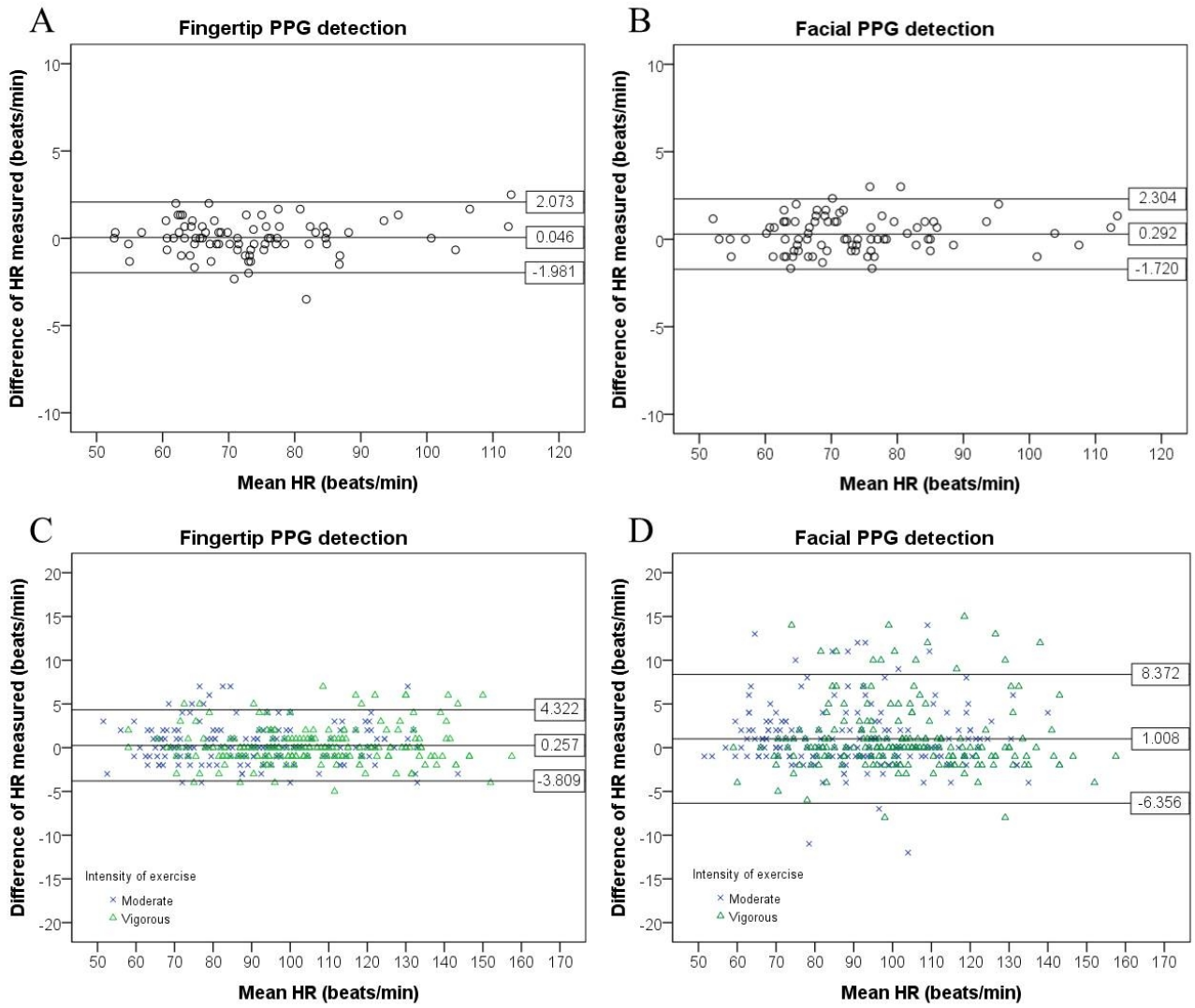


Figure 3. Bland-Altman plots of limits of agreement in resting heart rate (HR) estimated from the Cardiio smartphone app and a reference electrocardiogram (ECG). (A) Resting estimated HR from fingertip PPG signals. (B) Resting estimated HR from facial PPG signals. (C) Postexercise HR from fingertip PPG signals. (D) Postexercise HR from facial PPG signals.



Facial PPG-Estimated Heart Rate

We analyzed 80 averaged resting HR values from 237 facial PPG measurements and a total of 389 postexercise HR values.

The mean (SD) HRs were 73.17 (12.64) beats/min (range 51.50-112.67 beats/min) at rest, 89.35 (19.47) beats/min (range 52-138 beats/min) postmoderate-intensity exercise, and 102.53 (19.16) beats/min (range 59-158 beats/min) postvigorous-intensity exercise (Table 2). Facial PPG detection determined 6% (5/80) of resting, 29.8% (56/188) of postmoderate-intensity exercise, and 54.7% (110/201) of vigorous-intensity exercise HR values ≥100 beats/min (Table 2).

The mean (SD) difference in HR between facial PPG detection and the reference ECG at rest was –0.29 (1.03) beats/min (P<.05), while postmoderate- and postvigorous-intensity exercise HR differences were –1.09 (3.67) beats/min (P<.05) and –0.93 (3.84) beats/min (P<.05), respectively (paired t test comparing fingertip PPG detection with reference ECG, Table 3).

The HR values from facial PPG measurements and the reference ECG were positively correlated (Table 4). The correlation of facial PPG-estimated HR with ECG HR (r=.997, P<.001; RMSE=1.02 beats/min or 1.44%) was strong at rest. Facial PPG-estimated HR was also strongly correlated with ECG HR after exercise under moderate intensity (r=.982, P<.001; RMSE=3.68 beats/min or 4.11%) and vigorous intensity (r=.980, P<.001; RMSE=3.84 beats/min or 3.73%) (Figure 2).

The Cardiio smartphone app had 95% of resting HR measurements fall within –1.72 and +2.30 beats/min, while postexercise HR measurements were wider and within –6.36 and +8.37 beats/min, as illustrated in the Bland-Altman plots (Figure 3).

Discussion

Principal Findings

According to the literature, HR monitors are considered accurate and regarded as excellent when r ≥.93 and RMSE<6.8% [28,29]. The American National Standards Institute/Association for the

Advancement of Medical Instrumentation EC-13 standard states that the accuracy requirements for HR monitors are RMSE≤5 beats/min or ≤10%, whichever is greater [30]. Our results showed that the Cardiio smartphone app using both fingertip and facial PPG detection can be regarded as excellent and considered accurate in measuring HR at rest, and after moderate- to vigorous-intensity exercise.

PPG estimation of resting HR from both the fingertip and the face demonstrated very high accuracy. The RMSE were less than 1.5% (RMSE=1.40% from fingertip and RMSE=1.44% from facial PPG measurements). The errors between PPG-estimated resting HR and ECG HR were <1%, as illustrated by the coefficients of determination (Figure 2).

In particular, the results of fingertip PPG measurements were consistent and accurate in the different physical activity levels tested in this study. Fingertip PPG-estimated HRs were strongly correlated with both resting and postexercise ECG HR (all r ≥.99; Table 4). HR was underestimated with mean differences of <0.5 beats/min or median differences of 0 beats/min at rest and after exercise compared with the reference ECG (Table 3).

For facial PPG measurements, the accuracy of HR estimation was better at rest and diminished with exercise. The coefficient of determination of facial PPG-estimated HR was stronger with resting ECG HR (R^2>.99) than postexercise ECG HR (R^2≥.96) (Table 3). For postexercise HR detection, facial PPG underestimated HR values with mean differences of approximately 1 beat/min or median differences of 1-2 beats/min when compared with ECG HR (Table 3). Possible explanations are blushing and excessive facial motion due to heavy breathing after exercise leading to misalignment of the face with the camera.

Overall, the Bland-Altman plots showed better agreement between ECG and fingertip-estimated HR than between ECG and facial PPG-estimated HR, and that 95% limits of agreement were wider for facial than for fingertip PPG estimation (Figure 3). The results demonstrated the ability of a PPG-based smartphone app to provide meaningful and accurate readings at rest and after exercise.

Limitations

Limitations of our study include that (1) this was a convenience sample of healthy young adults, which may limit generalizability; and (2) the method of HR detection from fingertip and facial PPG using iPhone's front and back cameras, which may not apply to other smartphone cameras. We recommend further evaluation of the accuracy of taking HR measurements in a real-world environment under nonstandardized background lighting and in expanded exercise settings. We suggest conducting further studies including a larger number of participants with an extended age range and more skin tone colors to increase generalizability. This study did not include patients with arrhythmia or other heart-related problems, which is an area for future investigation. Future work could also study user feedback relating to health-sensing mobile apps.

Conclusions

Smartphone use is becoming ubiquitous. People are increasingly relying on smartphones and health-related apps for health care purposes. Smartphone apps must be validated for their accuracy, reliability, and effectiveness in providing health care benefits. Capturing a PPG signal with the built-in smartphone cameras may provide a readily accessible and inexpensive means to measure HR. Our results have demonstrated that HR detection by the Cardiio smartphone app is accurate at rest and after moderate- and vigorous-intensity exercise in a healthy young adult sample. Both fingertip and facial PPG have shown high accuracy in measuring resting HR with reference to an ECG. Although touchless facial PPG detection is more convenient, fingertip PPG is more accurate for HR detection after exercise.

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Conflicts of Interest

YCP and MZP are cofounders and employees of Cardiio Inc and have an ownership stake in the company. There are no other potential conflicts of interest relevant to this study.

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Abbreviations

DBP: diastolic blood pressure
ECG: electrocardiogram
HR: heart rate
IQR: interquartile range
PPG: photoplethysmography
RMSE: root mean square error
SBP: systolic blood pressure

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Cloudy with a Chance of Pain: Engagement and Subsequent Attrition of Daily Data Entry in a Smartphone Pilot Study Tracking Weather, Disease Severity, and Physical Activity in Patients With Rheumatoid Arthritis

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Abstract

Background: The increasing ownership of smartphones provides major opportunities for epidemiological research through self-reported and passively collected data.

Objective: This pilot study aimed to codesign a smartphone app to assess associations between weather and joint pain in patients with rheumatoid arthritis (RA) and to study the success of daily self-reported data entry over a 60-day period and the enablers of and barriers to data collection.

Methods: A patient and public involvement group (n=5) and 2 focus groups of patients with RA (n=9) supported the codesign of the app collecting self-reported symptoms. A separate “capture app” was designed to collect global positioning system (GPS) and continuous raw accelerometer data, with the GPS-linking providing local weather data. A total of 20 patients with RA were then recruited to collect daily data for 60 days, with entry and exit interviews. Of these, 17 were loaned an Android smartphone, whereas 3 used their own Android smartphones.

Results: Of the 20 patients, 6 (30%) withdrew from the study: 4 because of technical challenges and 2 for health reasons. The mean completion of daily entries was 68% over 2 months. Patients entered data at least five times per week 65% of the time. Reasons for successful engagement included a simple graphical user interface, automated reminders, visualization of data, and eagerness to contribute to this easily understood research question. The main barrier to continuing engagement was impaired

battery life due to the accelerometer data capture app. For some, successful engagement required ongoing support in using the smartphones.

Conclusions: This successful pilot study has demonstrated that daily data collection using smartphones for health research is feasible and achievable with high levels of ongoing engagement over 2 months. This result opens important opportunities for large-scale longitudinal epidemiological research.

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KEYWORDS

smartphone; mHealth; attrition; weather; arthritis

Introduction

Smartphone health apps are increasingly recognized as potentially powerful tools for epidemiological research, allowing researchers to recruit large numbers of participants, monitor them in real time, and collect novel types of data [1]. Apps can support self-reported data collection—a digital version of a patient questionnaire. Apps can also collect and transmit data derived from within the phone or link to other wearable devices and sensors, generating datasets previously unachievable. However, engaging and retaining participants can be challenging in longitudinal studies. The average app (not limited to health) loses 77% of its users within 3 days, with more than 95% lost within 90 days [2].

One research question answerable using smartphone data collection is the association between weather and pain. Previous studies have suggested that more than two-thirds of patients with musculoskeletal pain believe in this association [3,4], with more than half believing they can predict the weather based on their joint symptoms [5]. Although patients commonly report associations with temperature and humidity [6], the scientific evidence to support a causal association remains uncertain [7-11]. Limitations of previous studies have included small sample sizes, low geographical and meteorological variability, and the lack of longitudinal clinical data alongside high-quality weather data. For example, in one of the larger studies (>500 patients with chronic pain), pain-related data were collected from participants on a single occasion and compared with the average weather for a single year across 4 cities [3]. The potential benefits of understanding the relationship are twofold. First, it would be possible to generate pain forecasts, allowing patients to plan their forthcoming activities. Second, an understanding of what within the weather influences pain may feed back into further research to identify pain mechanisms and novel interventions to manage pain.

All the necessary ingredients to study the association between weather, disease severity, and physical activity in patients with arthritis could become available using app-based self-reported disease severity, global positioning system (GPS) coordinates to pull local weather data, and GPS and accelerometer data to monitor physical activity. However, is such a study both technically feasible and acceptable to patients, with sustained engagement over long periods of time?

A feasibility study was conducted in patients with rheumatoid arthritis to demonstrate proof of concept that they will use smartphones to provide regular self-reported data, with linked data from the device's hardware. Specific objectives were to (1) codesign the smartphone app with patients for daily self-reported data entry, (2) elicit enablers of and barriers to regular data collection, (3) quantify the completeness of daily self-reported data entry and attrition over 60 days, and (4) assess the completeness of weather data and position and movement data.

Methods

Overview

The study design included establishment of a patient and public involvement (PPI) group, qualitative research including focus groups and interviews informing codesign of the app, daily prospective data collection for 60 days with entry and exit interviews, and descriptive statistics to measure data completeness and attrition. The study received ethical approval from the National Research Ethics Service Committee East Midlands – Northampton (REC reference 14/EM/1209).

Establishment of a Patient and Public Involvement Group

A PPI group (n=5) of people living with arthritis was established, meeting every three months throughout the project. Their remit was to provide views based on personal experience of musculoskeletal conditions to shape the research questions and methods, help design the app, and assist in interpreting emerging results. Members of the PPI group were derived from a local network for involving people in research and were reimbursed for their time, in line with national recommendations.

Focus Groups

A total of 2 focus groups of adult patients with rheumatoid arthritis (9 total participants) were held to understand motivators of and possible barriers to frequent data entry. Focus groups were facilitated by KS with CS. Participants were recruited via the rheumatology clinic of a large teaching hospital. A set of PowerPoint (Microsoft) slides were used to prompt and guide discussions in conjunction with a predeveloped topic guide. Participants discussed multiple topics including beliefs about associations between weather and joint pain, existing views and experiences on the use of smartphones and other digital technologies, and views about recording symptoms for use in research. A preexisting health-monitoring smartphone app, designed by uMotif (a digital health company) and known to have high patient engagement [12], was then introduced using a brief film to prompt discussion and feedback [13]. Patients'

views were sought on the design, usability, and variables to be recorded. The focus groups were audio recorded with consent and transcribed. Immediately following the focus groups, a rapid summary of key bullet points was produced in order to feed back to the wider team for any issues with implications for technical development and changes before the feasibility study. These issues were mainly structured around key topics covered in the discussion including beliefs about the weather, the significance of key symptoms and wording of the questions and scoring within the motif, motivation to capture data, anticipated barriers, and facilitators for regular use. Data were then analyzed fully by KS with discussion and input from CS and WGD using a framework approach [14]. Initial coding was used to create a framework of key themes and summaries within tables created in Word (Microsoft). Extracts from each transcript were pasted into the tables to build up a summary of cases and create tables summarizing data for each theme. All participants in the 2 codesign focus groups also went on to participate in the pilot study (see details below).

App Design

The existing core design of the app was a "motif" data input interface comprising 10 variables on a single screen, each of which the participant could slide to generate a self-reported score (Figure 1). Data items were configured to include study-specific questions and possible responses. Longitudinal results were graphed within the app. Participants were requested to enter values for the 10 data items daily with an automated alert at 6:24 pm each evening. Codesign of the app was thus limited to configuration of the existing platform.

In addition to the core self-reported data entry app, uMotif built a separate prototype "capture app" for Android devices that would collect GPS data hourly and continuous raw accelerometer data. The hourly geolocation enabled all available weather variables (including temperature, pressure, dew point pressure, relative humidity, and wind speed and direction) to be pulled via the Met Office DataPoint application program interface [15]. Accelerometer data were sampled at 100 Hz, capturing the *x*, *y*, and *z* coordinates at each sample point. The app was designed to run constantly with the resultant data batch uploaded to the uMotif server when the app had Wi-Fi connectivity. The capture app was only available for Android, restricting the pilot study to Android smartphones. Participants were invited to download the self-report and capture apps to their own phones or were loaned a smartphone. The data flow is shown in Figure 2.

Figure 1. Screenshot of uMotif app and list of data items. Each segment of the motif represents 1 of the 10 questions listed in the box. Participants slide the segment to score their response to the question stem with each question having 5 possible ordinal responses. In the example shown, the participant is responding to the question "How severe was your fatigue today?" with a response of "Moderate fatigue," selected from options of no fatigue, mild fatigue, moderate fatigue, severe fatigue, and very severe fatigue. RA: rheumatoid arthritis.

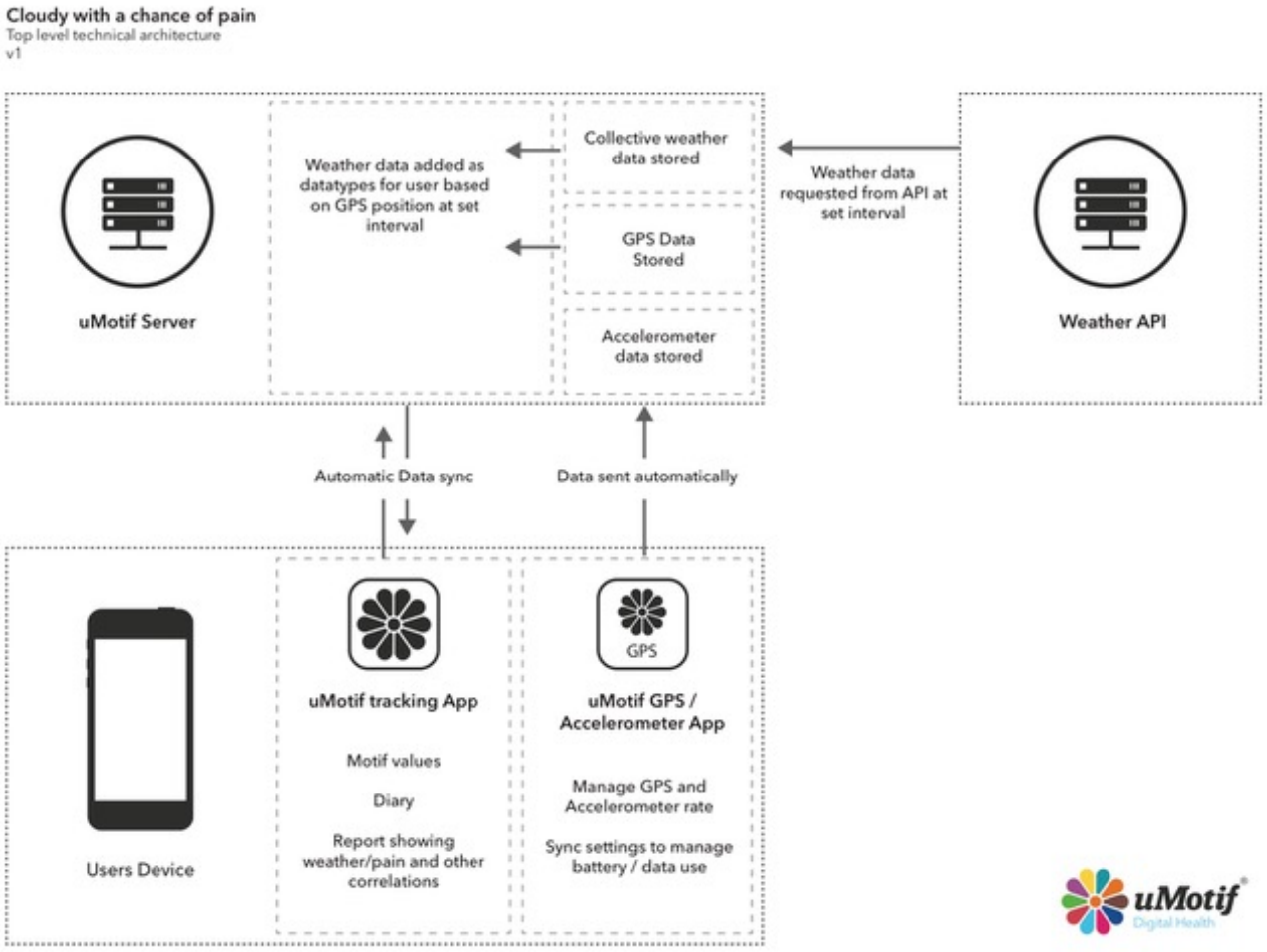
RA-specific items

1. Pain severity
   "How severe was your pain today?"
2. Fatigue
   "How severe was your fatigue today?"
3. Tiredness on waking
   "How tired did you feel when you woke this morning?"
4. Morning stiffness
   "How stiff did you feel on waking this morning?"
5. Wellbeing
   "How well did you feel today?"
6. Overall disease severity
   "How severe has your R.A been today?"

Non RA-specific items

7. Mood
   "How has your mood been today? "
8. Physical activity
   "How long have you exercised today?"
9. Time spent outside
   "How much time have you spent outside today?"
10. Perceived influence of weather
    "How much has the weather influenced your pain today?"

Figure 2. Data flow. API: application program interface; GPS: global positioning system.



Feasibility Study Including Entry and Exit Interviews

Following app codesign, 11 additional patients were recruited from the same clinic for pilot data collection over a 60-day period. Coupling with the 9 participants from the focus groups resulted in 20 patients for the feasibility study. Inclusion criteria were adults with a physician diagnosis of rheumatoid arthritis and Wi-Fi access at home (necessary because of the large raw accelerometer file sizes). Sampling for the study was both purposive and pragmatic. We aimed to purposively sample for maximum variation to ensure we included a mix of both men and women, older and younger people with the condition, people with different social circumstances (such as employment vs retirement, and living alone or with others), and people with various levels of familiarity with using technologies such as smartphone and computers. These were all factors that we considered as potentially important in relation to feasibility, interest, and engagement with using an app for this study. We also aimed to sample between 20 and 30 participants based on the time and resources available and our experience in conducting similar studies. Initial analysis demonstrated that we had been successful in recruiting a diverse sample and no new themes were emerging, indicating that we achieved sufficient saturation in collection of the data.

Recruitment began March 2015 and the study concluded in July 2015. Among the participants, 2 patients were recruited in June and thus could not be followed up for the full 60 days; they were followed up for only 30 days. Semistructured, 45- to 60-minute interviews were conducted by KS with participants at study entry and exit. Topics discussed included those covered in the focus groups, but we also considered personal views and experiences in more depth including beliefs about the impact of the weather on symptoms, any previous experiences of using health apps, and prior use and perceived skills for using a smartphone, as well as views about the usability of the app and motivators for and barriers to regular use. The follow-up interview focused mainly on the participants' experiences using the app throughout the pilot period, as well as support needed and attitudes toward sustaining prolonged use. Recording and data analyses were conducted as for the focus groups.

Descriptive Statistics

Demographic information was summarized for the 20 patients. Each patient was considered under active follow-up for 60 days (30 days for the 2 late recruits) or until he or she withdrew. For each patient, the *participant completion rate* was defined as the number of days with at least one data item entry divided by the total number of days under active follow-up. The *overall completion rate* was calculated across all participants as the proportion of all eligible days where at least one entry was completed. Results are additionally reported as the *overall completion rate for full motifs*, requiring all 10 segments to be reported on a given day. Weekly data entry was also considered, where completion was defined as good if data were inputted

5-7 days, moderate if 2-4 days, and poor if 0-1 days. Patients were only considered in weekly figures if they had not withdrawn midweek and thus were eligible to enter data on all 7 days. The completeness of weather data was reported as the proportion of days any weather data were collected and the proportion of days that weather data could be matched to that day's symptom data.

Results

Configuration of Core Smartphone App for Self-Reported Data

Focus group members were aged 54-69 years; of the 9 members, 6 were female. Members of the focus groups and the PPI group gave positive feedback about the initial app design and thought the flower-like motif was visually appealing, quick, and easy to use. All were enthusiastic about the project and reported that they would be highly motivated to collect and contribute their data for this research. This enthusiasm was linked to their interest in the study hypothesis.

A key focus of discussions related to the wording of questions, additional data that could be useful, and ways to improve usability of the app. Changes made in response to the focus groups and PPI group discussions were rewording of terms used to describe symptoms and changes to the scoring framework. For example, the word "depression" was changed to "mood" because negative connotations with depression meant potential reluctance to indicate their experience of this. Also, in previous versions of the uMotif core app, a score of 5 (out of 5) was associated with a symptom being the best. This was counterintuitive to participants because they were often asked to rate pain in clinical settings, where the highest score would equate to most severe pain. Consequently, changes were made to align with participants' expectations.

Demographics of Participants in the Prospective Study

A total of 20 patients were recruited for the prospective data collection (5 male and 15 female). The median age was 57 years (range 30-74 years). All participants were White British, reflecting the local population demographic. Among the participants, 3 used their own Android smartphone, whereas 17 were loaned a smartphone (13 had an Apple iPhone, 4 had no smartphone).

Patient Motivation for Data Entry at Baseline

As in the focus groups, patients discussed how their interest in participating was related to a desire to contribute to answering the underlying, understandable hypothesis. The majority of participants (17/20, 85%) believed in a strong association between aspects of the weather and their symptoms. The remaining 3 had either given little thought to this association or felt strongly that it did not exist, but they remained interested in participating.

Individuals were content to record data using a smartphone app, even though some were unfamiliar with the technology. Most participants believed that sharing daily self-reported electronic data with clinicians and other health professionals could potentially improve their clinical care and self-management over time and may motivate future research data collection using smartphones.

Patient Attrition

A total of 6 patients dropped out of the study on days 0, 2, 23, 34, 40, and 53 (Table 1). The first patient to withdraw entered no data and cited problems with Wi-Fi. Of the remaining 5 patients, 1 patient withdrew because of poor health and 1 patient because of family illness; 2 patients withdrew because of an unacceptably rapid loss of battery life, attributable to the capture app. The final withdrawal was because of difficulty managing data entry.

Completeness of Study Data

The overall completion rate was 68%, with completion rate per participant listed in Table 1. Participants 5, 8, 11, and 13 remained highly engaged (≥90% completion) across the full study period. Patients entered data at least 5 times per week 65% of the time and at least twice per week 85% of the time (Table 2 and Figure 3). Of the 12 participants who remained in the study for 60 days, 6 entered data at least 5 times per week every week. Of the 932 participant-days under study, 586 (63%) had a complete motif, that is, where all 10 variables were recorded. This means that 93% of the 631 participant-days with data had a complete motif. The completion rate per variable was almost identical, ranging from 610/932 days (65%) for perceived influence of weather (item 10, Figure 1) to 617/932 days (66%) for "tiredness on waking" (item 3, Figure 1).

Table 1. Completeness of self-reported data entry.

Participant number	Time in study (days)	Number of days with entries	Participant completion rate, %	Reason for withdrawal
1	60	46	77	
2	60	48	80	
3	60	40	67	
4	60	38	63	
5	60	55	92	
6[a]	40	11	28	Battery life
7	60	49	82	
8	60	59	98	
9[a]	34	18	53	Battery life
10	60	9	15	
11	60	56	93	
12	60	33	55	
13	60	60	100	
14	60	52	87	
15[a]	23	11	48	Difficulty using smartphone
16[a]	53	7	13	Family illness
17[b]	30	18	60	
18[a]	2	2	100	Ill health
19[b]	30	19	63	
20[a]	0	0		Wi-Fi problems
Total	932	631	68	
Mean	46.6	31.55	68	

[a]Indicates patient requested to be withdrawn from study.

[b]Indicates follow-up censored at 30 days because of late recruitment.

Table 2. Completeness of data entry by week.

Week in study	Number of patients in study	Number of participants entering data, n (%)		
		0-1 Times per week	2-4 Times per week	5-7 Times per week
Baseline	20	N/A[a]	N/A	N/A
Week 1	18	0 (0)	3 (17)	15 (83)
Week 2	18	1 (6)	3 (17)	14 (78)
Week 3	18	3 (17)	4 (22)	11 (61)
Week 4	17	4 (24)	2 (12)	11 (65)
Week 5	14[b]	2 (14)	3 (21)	9 (64)
Week 6	13	3 (23)	4 (31)	6 (46)
Week 7	13	3 (23)	3 (23)	7 (54)
Week 8	12	2 (17)	2 (17)	8 (67)

[a]N/A: not applicable.

[b]Two patients censored after week 4 because of late recruitment.

Weather data were available for 64% of person-days of active follow-up, with 70% of symptom scores having weather data available for the same day. Weather data were pulled from 28 different Met Office stations, 7 of which were unable to provide atmospheric pressure or visibility. The first 5 days of self-reported pain and air temperature data from the first participant are shown in Figure 4.

Movement data from the accelerometers within the smartphones were not formally analyzed. Because of high power usage by the accelerometer, patients needed to regularly charge their phone, resulting in a lack of continuous monitoring.

Figure 3. Number of days providing data, by week, for eligible participants.

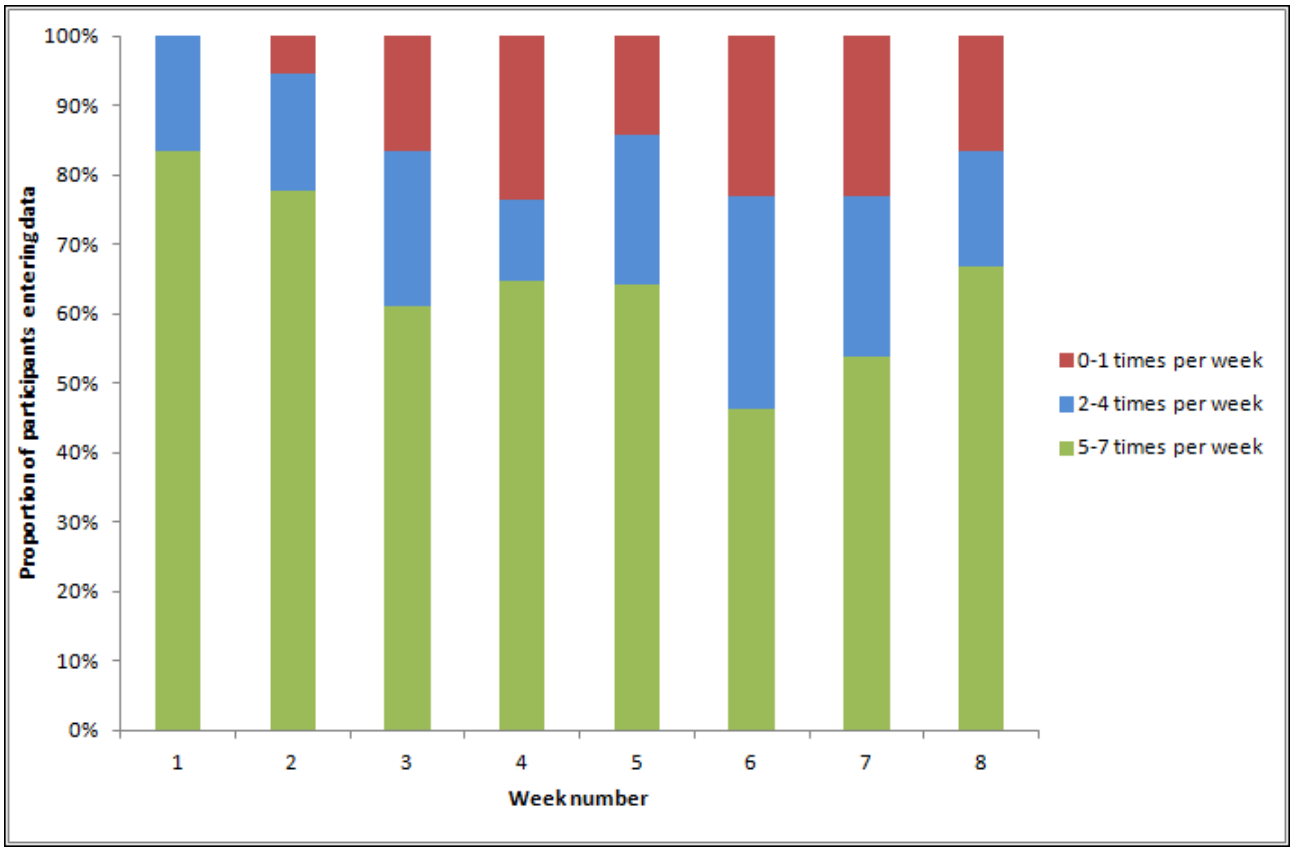


Figure 4. Example of self-reported symptom data and weather data from Global Positioning System–derived Met Office data (pain and temperature).

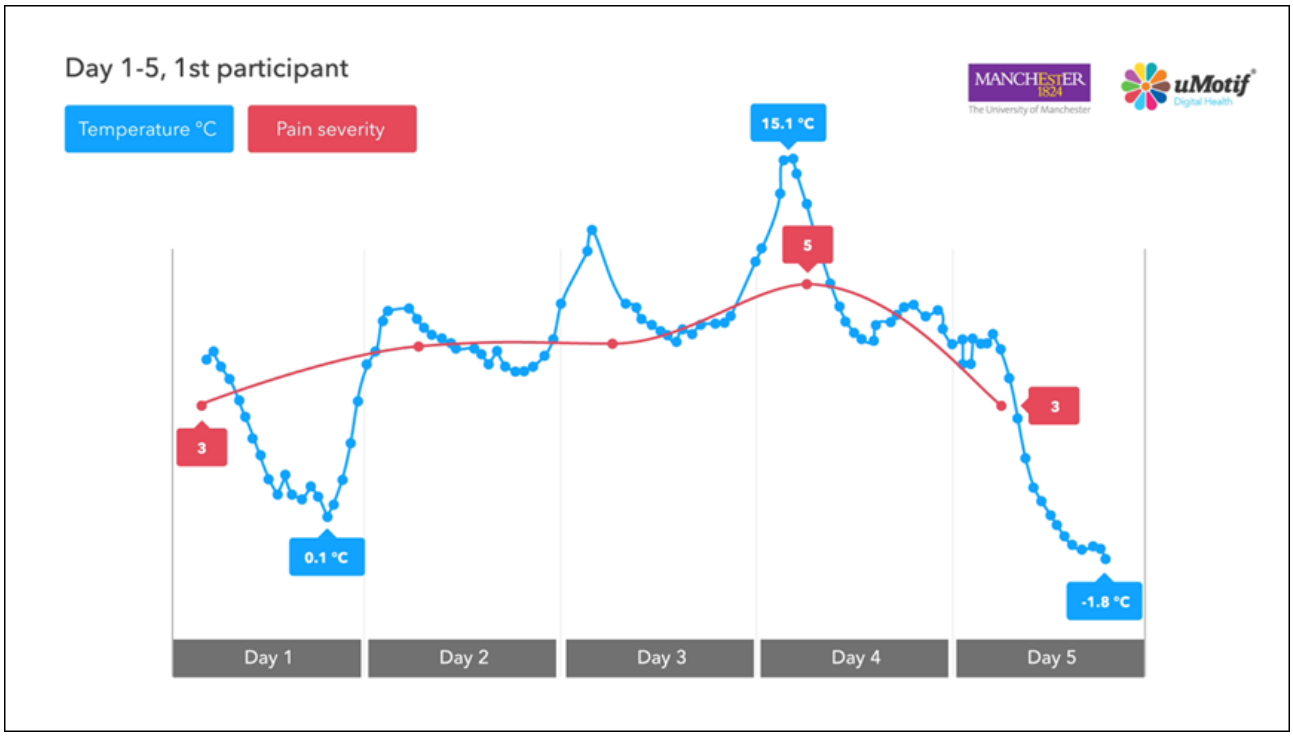


Table 3. Key themes and quotes arising from participant feedback after data collection.

Themes and summary of main views	Example extracts
Positive usability and engagement:	
Easy to use and visually pleasing Interest and perceived value of research topic Potential to inform and influence clinical care Enjoyed using the diary entry, or found useful Feedback graphs helpful Acceptable daily scoring entry Training and technical support helpful Passive monitoring acceptable	"I know myself the weather is a massive factor...Everybody I know has got a smartphone, so if it can improve people's health and their condition and how they're managed then brilliant." [P13] "The way I look at it is it probably will help me in the future. But it'll help a lot more people with their symptoms and especially if it's going to go through to GPs and consultants." [P4] "I'm really impressed with it...I think anybody could use it...even people that are not technically minded." [P3] "Using the slider to score my symptoms was very easy and simple...I thought the motif was very well designed and very simple to use." [P5] "I'm a bit of a nerd, so I will probably have a good look at those [graphs] to see how I have been scoring during the pilot." [P11]
Barriers to ongoing engagement:	
Perceived lack in technical skills Training and support needs Battery life Problems with graphs and slider Phone not carried at all times Passive monitoring not accurate or too intrusive	"Accessing the app was difficult for me, because I'm not used to smartphones." [P15] "It's a hindrance in one sense, because the phone is totally alien, to me so when trying to update the app, I found myself struggling. As with everything, you would learn if you had it for any length of time." [P19] "I ended up deleting the apps as they just drained my battery and I didn't what to get caught out and not be contactable as my son is in and out of hospital." [P6] "I tried to access the feedback graph area, and it just wouldn't load it just keep saying, loading so I didn't try again." [P19] "I had a stroke then a fall and broke my hip I've been in and out of hospital and a care home so it was hard for me to carry on with it for the whole sixty days." [P12]

Participant Feedback at End of Data Collection

Feedback was structured around the two core themes of positive usability and engagement and barriers to ongoing engagement (see Table 3).

Positive Usability and Engagement

As reported earlier, participants were highly motivated to engage with the study as almost all believed that the weather had an impact on their symptoms and that the research might have clinical value in addition to providing scientific evidence. All patients acknowledged that the app was straightforward and easy to use, even for individuals with poor manual dexterity. Widespread satisfaction was expressed with the visual aspects of the 10-segment motif (Figure 1), which patients considered a positive alternative to a list of questions. Others commented on how interactive and intuitive they found the user interface. The daily alert was a helpful reminder. Scoring once a day was seen as an appropriate frequency. Some patients expressed interest in scoring more often, whereas others considered scoring more frequently too intrusive. All individuals wanted to access graphs of their own data.

Barriers to Ongoing Engagement

Participants described a variety of technical and contextual barriers. Participants encountered memory problems on their phone due to large files and experienced poor battery life, both related to the accelerometer data. Lack of constant access to Wi-Fi affected a few patients' continuous engagement because failure to upload accelerometer files via Wi-Fi led to increasing file storage, affecting the phone's performance. Problems with battery life led to participants leaving their phones connected to power at home, leading to 2 withdrawals.

A minority of participants speculated that some users may find the smartphone technology and app confusing. In contrast, most other patients believed that people unfamiliar with smartphones would be able to use the app with minimal training and support. This view was supported by the low levels of missing data despite 85% (17/20) of participants using loaned phones, 4 of whom had never used a smartphone. Those without prior experience using an Android phone often felt they would have benefited from a user guide to help navigate around the phone.

Lack of knowledge, experience, and confidence in smartphone use required 7/20 participants to need phone support or visits from a researcher (range 1-5, average 2.5). Such difficulties eventually led participant 15 to withdraw from the study despite stating that the app itself was quite simple.

Contextual barriers to ongoing engagement included difficulties in integrating a new smartphone into participants' daily lives, as well as factors associated with living circumstances (eg, caring responsibilities). Individuals strongly felt that the app should be compatible with their own smartphones.

Participants had several ideas for encouraging prolonged use beyond the 60 days. Some suggested incentives to future participants (eg, gift vouchers). Others wanted researchers to encourage ongoing participation through regular contact. One patient suggested participants should be given the opportunity to join an online study forum to allow patients to communicate and share experiences.

Discussion

Principal Findings

Increasing smartphone ownership offers new opportunities for research through self-administered questionnaires and other novel longitudinal data in large populations [16-18]. In the United Kingdom, smartphone ownership is high and continues to increase: currently estimated at 66%, ranging from 88% in those aged 25-34 years to 49% in those aged 55-64 years and 17% in those older than 65 years [19]. Longitudinal observational research requires participants to continue to provide data through time. To date, limited evidence exists in mHealth studies about attrition: an attribute describing the decline in the numbers of users and decline in the intensity of use. This study, examining daily symptom entry over 60 days, has demonstrated good levels of engagement and discovered some of the motivating factors for participants.

Levels of Engagement Compared With Existing Literature

Maintaining ongoing participation and self-reported data is important for research studies because of missing data and possible resultant selection bias. Few studies have reported completeness of longitudinal health data collection using smartphones for research. In a 90-day study of sleep disturbance in 30 patients with breast cancer, the overall compliance rate for daily data entry following a push notification was 45% [20]. A 2-month study using smartphones to examine compliance in patients with cardiac disease following hospital discharge recruited 11 patients, only 4 of whom completed data entry beyond 31 days [21]. Thus, our results show better ongoing engagement than other studies in the limited literature on smartphone collection of longitudinal self-reported data.

Factors Influencing Engagement

Factors that influence attrition in longitudinal eHealth studies include participant characteristics (eg, demographics, early adopters vs laggards), level of information provided before the study, ease of enrollment, ease of dropout, usability of the technology, burden of data entry, ability to integrate into daily life, external events, “push” factors (eg, remote or personal contact), positive feedback or encouragement, tangible and intangible advantages in completing the study, networking effects (eg, peer pressure, community building), and user experience [22]. The 6 patients who dropped out of this study exemplify three of these domains: external factors, ability to integrate into daily life, and usability of the technology. Personal and family health issues led to 2 withdrawals, a finding expected in any longitudinal study. Three withdrew because the study was incompatible with their daily life. Increasing reliance on smartphones in daily life meant that the loss of battery life, caused by the “capture app,” was unacceptable to 2 users.

Participants who remained in the study demonstrated a sustained intensity of use. Our experience involving end users during the design phase (via focus groups) and throughout the project (via the PPI group) has demonstrated the importance of having users inform key changes and ongoing engagement. As others have highlighted [23-25], the design features of an interface and embedded symptom questions need to make sense to people in their lives. Participants were keen to participate and help answer the question about the association between weather and pain, irrespective of their own beliefs. In addition, they were engaged by contributing to new research and app design for collecting data that could additionally prove useful for self-management and clinical management. The age profile of participants may have influenced ongoing engagement. Older participants may have more time available but needed more support. The high ongoing engagement could be explained in part by support from the research associate (KS), which was required for 7/20 participants. This provided technical support and encouraged continued interest in the study. Without such support, there may have been further withdrawals. In a larger study, such support may not be possible and indicates the importance of planning creative ways to sustain interest and ongoing communication with the research team.

Limitations

Participants in the 8-week study reflected the demographic of the population from which they were selected: rheumatoid arthritis is more common in women with a typical median age of around 56 years and a wide age distribution. Age may influence levels of attrition in either direction. Younger participants may be more engaged and be retained through the study, for example, because of greater confidence with the technology. Conversely, an older population may be more dedicated to the study, perhaps with more time to spare. The latter may in some cases also be less familiar or routinely engaged in using smartphones. By actively including these individuals in this study, we intended to gain realistic insights into the challenges of including and supporting such individuals. Our participants elected to participate and may thus be more inclined to remain engaged through the study compared with unselected individuals. That said, participants would always consent to join mHealth research studies making these results generalizable to future research projects. Other possible limitations of the study include the provision of Android smartphones to a high proportion of participants, thereby not truly testing engagement using a participant’s own smartphone. We did not compare responses within the app to paper-based questionnaires, although other studies in rheumatology have found no differences in patient responses comparing digital with paper collection [26].

Next Steps

This successful feasibility study has led to a larger study, Cloudy with a Chance of Pain, examining the association between weather, arthritis, and other chronic pain. Important learning from the feasibility study includes the decision to exclude the “capture app” to collect raw smartphone accelerometer data because of battery life problems and the importance of the quick, low-burden visual app with its automated prompt. In the first month, more than 8000 participants were recruited. As data will be collected over a longer period of time, we intend to draw on methods of positive feedback and encouragement not used within this feasibility study, including a citizen-science component (as in [27]).

Conclusions

In conclusion, we have demonstrated that daily data collection using smartphones for health research is feasible and achievable with high levels of ongoing engagement over 2 months. This result opens important opportunities for large-scale longitudinal epidemiological research, although further research is required in this evolving area to understand the best approaches to minimize attrition and ensure robust study results.

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Authors' Contributions

WGD wrote the draft manuscript. SR and KS performed the quantitative and qualitative analysis, respectively. All authors discussed the draft and provided comments and suggestions for change. All authors have approved the final report.

Conflicts of Interest

RL, BH, and BJ work for uMotif, the company that provided the software application. All analyses were performed at the University of Manchester, independent from these 3 authors. The remaining authors have no conflicts of interest to declare.

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Abbreviations

GPS: global positioning system
PPI: patient and public involvement

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Original Paper

Investigating the Perceptions of Care Coordinators on Using Behavior Theory-Based Mobile Health Technology With Medicaid Populations: A Grounded Theory Study

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Abstract

Background: Medicaid populations are less engaged in their health care than the rest of the population, translating to worse health outcomes and increased health care costs. Since theory-based mobile health (mHealth) interventions have been shown to increase patient engagement, mobile phones may be an optimal strategy to reach this population. With increased development of theory-based mHealth technology, these interventions must now be evaluated with these medically underserved populations in a real-world setting.

Objective: The aim of our study was to investigate care coordinators' perceived value of using a health behavior theory-based mHealth platform with Medicaid clients. In particular, attention was paid to the perceived impact on patient engagement. This research was conducted using the patient-provider text messaging (short message service, SMS) platform, Sense Health (now Wellpass), which integrates the transtheoretical model (TTM), also called the stages of change model; social cognitive theory (SCT); supportive accountability; and motivational interviewing (MI).

Methods: Interviews based in grounded theory methodology were conducted with 10 care managers to understand perceptions of the relationship between mHealth and patient engagement.

Results: The interviews with care managers yielded a foundation for a grounded theory model, presenting themes that suggested 4 intertwined correlative relationships revolving around patient engagement: (1) A text messaging (short message service, SMS) platform supplements the client-care manager dynamic, which is grounded in high quality, reciprocal-communication to increase patient engagement; (2) Texting enhances the relationship between literacy and access to care for Medicaid patients, increasing low-literacy patients' agency to access services; (3) Texting enhances communication, providing care managers with a new means to support their clients; and (4) Reminders augment client accountability, leading to both increased motivation and readiness to change behaviors, as well as an improved client-care manager relationship.

Conclusions: Messaging platform features tied to health behavior theory appear to be effective in improving patient engagement. Two-way communication (supportive accountability), trusted relationships (supportive accountability, SCT), personalized messages (TTM), and patient input (TTM, SCT, MI) appeared as the most relevant components in achieving desired outcomes. Additionally, reminder messages were noted as especially useful in making Medicaid patients accountable and in turn engaging them in their health and health care. These findings convey suggested elements for inclusion in other mHealth interventions aiming to improve patient engagement in Medicaid populations.

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KEYWORDS

communication; health behavior; Medicaid; mHealth; patient engagement; safety-net providers; text messaging

Introduction

Untapped Potential of Medicaid Patients and Mobile Phones

Medicaid populations, that is those that qualify for the US government health insurance program for low-income individuals and families, are less engaged in their health care than the rest of the population, which translates to worse health outcomes and increased health care costs [1-2]. In this report, patient engagement will "denote a broader concept that includes activation; the (use of and participation in) interventions designed to increase activation; and patients' resulting behavior, such as obtaining preventive care or engaging in regular physical exercise" [1]. Activation, in turn, is defined as "understanding one's role in the care process and having the knowledge, skill, and confidence to manage one's health and health care" [1]. This lower engagement is due to a complex number of structural and behavioral factors, including the lower access to care, and lower education levels and lower income levels, characteristic of Medicaid recipients [2]. Still, research indicates that Medicaid recipients use their cell phones as frequently as their non-Medicaid counterparts [3], suggesting that this may be an optimal strategy for reaching this medically underserved population. Since mobile health (mHealth) technology has shown potential to increase patient engagement in care delivery and chronic disease management across safety-net populations [4,5], cell phones may be able to be leveraged to reduce health disparities in this group.

Collaboration With Minimal Evaluation

There is a paucity of data showing how mHealth interventions elicit patient engagement [6-9]. Whereas theory is being integrated in many digital health interventions after an initial disconnect between mHealth developers and researchers [10-14], there is a lack of real-world testing of these mHealth initiatives [15,16]. Determining how to best disseminate and implement evidence-based interventions among the intended audience (implementation science) can help "speed translation from discovery to application and public health benefits" [17]. Using data from the theory-based patient-provider texting (short message service, SMS) platform, Sense Health (Wellpass as of January 31, 2017) (Multimedia Appendix 1), there is a unique and timely opportunity to investigate how a theory-based mHealth intervention leads to engagement among a medically underserved population in a 'real-world' setting. The purpose of this research was to investigate whether and how integrating behavioral health theory into mHealth interventions leads to improved patient engagement in Medicaid populations, using a live texting platform.

Communication in a High-Cost, High-Needs Population

The United States spent US $492.3 billion on Medicaid in the federal fiscal year of 2014 [18], which represents an annual growth of 5.2% since 2010 [19]. Patient engagement has become a crucial part of the discussion on how to reduce these costs [1], with the question becoming not whether to increase patient engagement, but rather to determine the most effective strategies to do so [20]. Low health literacy is one significant factor explaining the characteristic low engagement of Medicaid populations, which has implications for unequal access to care [21,22]. Health literacy is defined as "the degree to which an individual has the capacity to obtain, communicate, process, and understand basic health information and services to make appropriate health decisions" [23]. When health care providers ensure that communication is occurring at patients' literacy level, they are able to increase their patients' understanding of their own health [1,24], which may motivate patients to take a vested role in their own care [2,25]. In other words, patient-provider communication has the potential to trigger greater patient engagement. As a result, this increases access to care, which by definition, in addition to the ability to utilize care, entails: "Finding providers who meet the needs of individual patients and with whom patients can develop a relationship based on mutual communication and trust" [26].

The ubiquity of cell phones [3] and the rapid influx of mHealth initiatives into the public market [27] indicate that it is possible to make this type of communication a consistent part of the Medicaid population's daily routine. Indeed, mHealth interventions have been propagated as the ultimate medium for the dissemination of behavioral health programs [4,9]. If research and practice in the mHealth field can be well integrated, this can facilitate important gains in public health impact. That is, mHealth technology might be able to mediate the thus far intractable relationship between health literacy and access to care, particularly in terms of care utilization and the development of meaningful patient-provider relationships among Medicaid populations by making patients more confident and capable managers of their own health.

Using Sense Health to Fill a Research Void

Presently, the mHealth field is at a crossroads: the cell phone medium is at risk of losing its utility for public health delivery due to the dearth of research evaluating the effectiveness of the over 100,000 available, predominantly consumer-facing mobile apps [27,28]. Sense Health has integrated health behavior theory into the development of its mobile communication platform from the outset, thus presenting an opportunity to assess the implications of using a theory-based approach. The platform offers evidence-based coaching programs for chronic disease management and postdischarge compliance, appointment and medication reminders, and customized support, through 2-way mobile messaging. Specifically, the content of the platform is based on the transtheoretical model (TTM, also called the stages of change model) [29] and motivational interviewing (MI) [30], by tailoring semiautomated messages based on patients' motivation and readiness to change. In practice, this means patients set their own goals [30] and messages are tweaked to encourage either cognitive exercises, such as simulation activities for less eager patients, or conscious action such as verbal commitments from the people who are keen to make positive changes to their behavior. The structure of the platform itself is also grounded in theory, including supportive accountability, which recognizes the importance of human support to amplify the effectiveness of mobile behavior change interventions [31]. To keep patients accountable to someone they trust, the platform connects them to their coach, that health

expert who the patient already views as a steadfast source of support. This way, the platform acts to supplement existing communication. The 2-way conversation the coach has with the patient lets them jointly set the expectations of the program, which increases patient buy-in. In addition, by grounding the platform in trusting relationships and patient input, two constructs central to social cognitive theory, this texting platform inherently supports behavior change [29].

The findings on whether and how this theory-driven platform drives engagement can be used in the development and improvement of other mHealth interventions.

Research Aims

The two primary goals in this research report were to determine the relationship between a theory-based texting platform and patient engagement through the perception of health care providers, specifically care managers, and whether these findings can be translated to other mHealth interventions. As high-need patients' access to care is maximized with the assistance of care managers [21], their perspectives on using health technology are crucial to maximizing adoption of such interventions. This report aimed to:

(1) Examine the association between a theory-based texting platform and patient engagement

- Determine care managers' perception of technology in the patient-provider relationship
- Determine care managers' evaluation of patients' opinions on technology use in a care-delivery setting
- Determine which technology components are related to patient engagement

(2) Make recommendations for how mHealth interventions can be refined to enhance engagement, and ultimately health outcomes, among Medicaid populations

(3) Outline recommended components of an evidence-based and theory-informed mHealth intervention

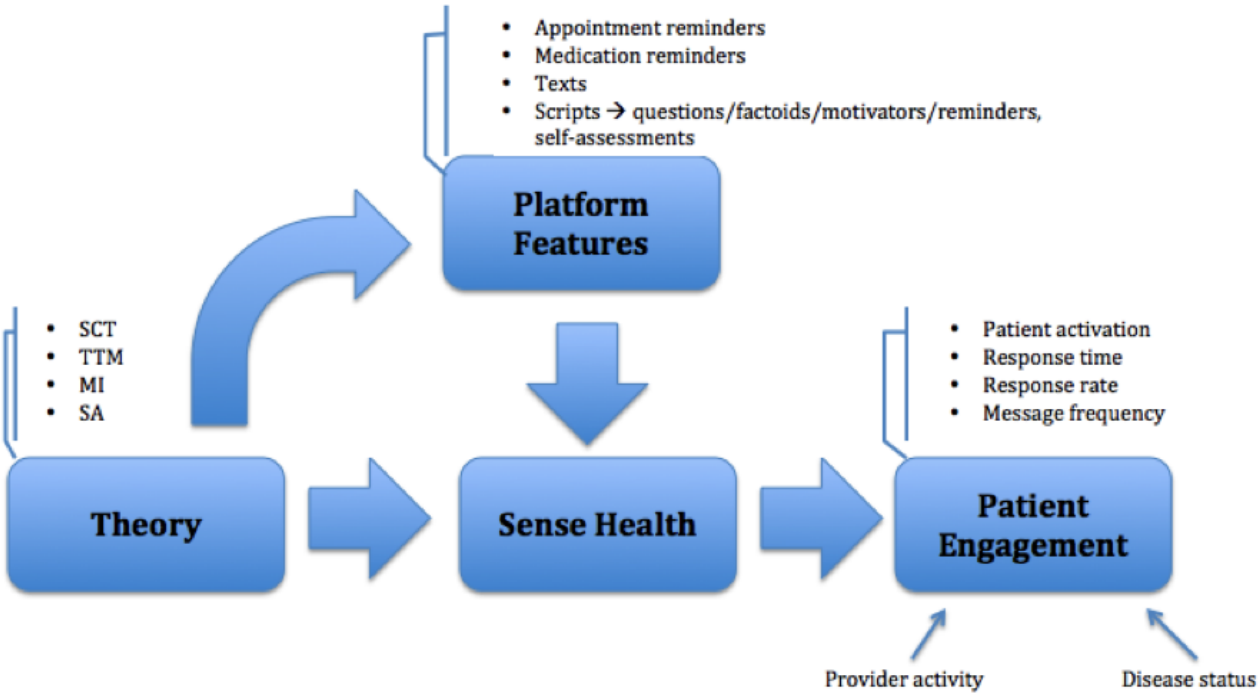
Methods

Overview of Research Design

This study presents qualitative research conducted through grounded theory-based interviews with care managers, which focused on their perceptions of integrating mobile technology with Medicaid clients. Grounded theory enables researchers to develop a theory to explain the phenomenon of interest [32]. Phrased differently, grounded theory is most appropriate for research that seeks to discover something new. The new theory is "grounded" in qualitative data garnered from those who actually experience the process: as the study progresses, the researcher's initial exploratory question becomes refined until an understanding is reached regarding the topic of investigation [33]. That is, grounded theory involves "systematically discovering a theory from data" [34]. This is also when the information harnessed from interviews in the field will have reached the point of "thematic saturation" (also referred to as theoretical saturation) [32-34]. Saturation occurs when the information obtained becomes redundant, contributing nothing new or pertinent to the study's findings [32,34]. Results can then explain existing practice and provide recommendations for future use surrounding the subject matter [32]. In this case, the phenomenon of interest is the perception of care managers on using mHealth technology with Medicaid patients. This approach is most appropriate for addressing this study's aims, as mHealth stands to benefit from theories specific to its nuances, instead of trying to understand how mHealth is experienced through an amalgamation of existing theories created for less technological health intervention programs. As this phenomenon is not well documented, a grounded theory approach was used to structure the interview guides to help identify important factors and issues to guide future studies (Multimedia Appendix 2). The interviews focus on barriers to clients accessing care and care coordinators providing care. This would entail discussions of engagement; patient-provider communication; patient management of health, health literacy, patient motivation and readiness to change; integration of technology; and support and accountability of both the patient and provider. If this exercise indeed revealed that care coordinators perceived that aspects of technology improved patient engagement, additional inquiries on how they improve engagement would be added to the interviews. These relationships would be further probed in the context of the texting platform's feature set to determine, as per the second aim, recommended components of an evidence-based and theory-informed mHealth intervention. The relationships that were explored in this study, as per the aforementioned aims and this study design, are visualized in a conceptual model (Figure 1).

Note that theoretical concepts and processes embedded in Sense Health were not discussed during user trainings, nor were they explained in the course of the interviews (Multimedia Appendix 2). The platform is typically framed during one-time trainings as a means to facilitate the user's workflow. Prospective interviewees' interactions with Sense Health employees are otherwise restricted to technical support. This study was approved under the IRB protocol IRB-AAAQ5254 by the Columbia University Medical Center Institutional Review Board.

Figure 1. Conceptual model reflecting aims and study design.



Recruitment

The data for this study came from interviews structured using a grounded theory approach with care managers who use the Sense Health platform. These care managers were recruited through email via a message crafted by the study author and sent by the provider experience manager at Sense Health. Recruited care managers were interviewed either in-person or over the phone, depending on their location and which method was chosen as most convenient for the interviewee. The approximately 30-60 minute interviews were audiorecorded either with a mobile phone or laptop computer depending on the setting of the interview. Respondents were required to provide verbal consent for study participation, including the recording. At the outset, participants were informed about the purpose of the study, the main research questions, and what information the author was planning to cover during the interview. Participants were then told they could skip a question or stop the interview at any time if they felt uncomfortable. After the recordings were professionally transcribed, the files were deleted.

All providers enrolled with Sense Health were eligible to be interviewed (Table 1). All providers were emailed the same day and the first 10 to respond were included in the qualitative component of the study. Respondents had three different job titles and were from six different organizations (Table 2). It was anticipated that 10 respondents would allow for theoretical saturation, and therefore to achieve the aims of this project, as dictated by Ward [33] who similarly used grounded theory to explore perceptions of a health care delivery setting with 13 interviewees, and Moola, Fusco, and Kirsh [35] who investigated perceptions of caregivers with a sample of 7. Guest, Bunce, and Johnson [36] systematically investigated the degree of data saturation over the course of thematic analysis in qualitative studies and found that saturation occurs within the first 12 interviews, with basic elements of themes present as early as the sixth interview, furthermore supporting the use of a small sample to sufficiently build a grounded theory. The same study purported that saturation may be the gold standard to determine sample sizes in qualitative studies. Time restrictions also influenced this aspect of the study design, as this research was originally conducted as one section of the author's master's thesis. If theoretical saturation were not achieved following the tenth interview, more would be conducted. Due to these time constraints, the author did not want to commit to an extraneous amount of interviews, beyond where theoretical saturation likely would be achieved, as per the aforementioned citations.

Table 1. Organizational characteristics of Sense Health users.

Organization type	Organizations	Individual users
Clinical trial[a]	4	5
Community-based organizations[b]	11	261
Homecare agency	1	8
Hospital	4	30
Nutritionist practice	1	2
Total	21	306

[a] Clinical trial organizations are research studies using Sense Health.

[b]Community-based organizations encompass health homes, federally qualified health centers (FQHCs), and community mental health centers.

Table 2. Profile of respondents.

Job title (n)	Organization type (n)
Care coordinator (8)	Accountable care organization (1)
Patient health navigator (1)	Health home (3)
Care manager (1)	Community-based organization (2)

For context, all patients of the providers interviewed were Medicaid-eligible and enrolled from New York State. Hypothetical sociodemographic characteristics of the sample were drawn from Kaiser Family Foundation estimates based on the Census Bureau's March 2015 current population survey (CPS: Annual social and economic supplements; Multimedia Appendix 3) [37]. New York Medicaid beneficiaries were predominately white or Hispanic, female, over 18 years, working full time, and up to 200% of the federal poverty level.

Analysis

Dedoose version 7.0.23 (SocioCultural Research Consultants, LLC) was used to analyze the qualitative interviews. The author coded the provider interviews using grounded theory. For validation, the Sense Health provider experience manager reviewed the interview questions, coding methodology, and coding results, then provided feedback based on her daily interactions and familiarity with provider behavior. Analysis in grounded theory studies follows a rigid framework. As per the guiding literature on grounded theory, interview questions focus on understanding how individuals experience the process and identifying the steps in the process [32]. This emphasis facilitates axial coding later on, which revolves around identifying the core phenomenon, causal conditions, resultant strategies (ie, related actions and interactions), context, and consequences. Prior to axial coding, open coding takes place to allow for the formation of categories related to the phenomenon, here being care manager engagement with technology, by segmenting information. Properties of these categories are then identified. Development and refinement of these categories and the axial codes occurred in an external memo during the initial reading of the interview transcriptions (Multimedia Appendix 4). These codes were then inputted into Dedoose software to segment the actual interview transcriptions into these categories. This process is more tangibly illustrated in the Results section with interview excerpts. Next, selective coding entails connecting the categories, which also involves developing hypotheses that predict relationships related to the phenomenon, culminating in a "substantive-level theory" [32]. These connections are elucidated in the Results section of this paper.

Results

Grounded Theory Process and Interview Evolution

The Sense Health users who responded to the recruitment email varied in their activity levels on the platform, and also in their experience with the technology. However, their responses were surprisingly consistent. Sense Health was coded most frequently, as the interviewees zeroed in on texting through the platform without prompt, instead of discussing technology more macroscopically. This may be because Sense Health was the most tangible technology to the respondents and its role in engaging their Medicaid clients most visceral. None reported using other programs aside from electronic health records, which were purely used for documentation. As a result, these consistent patterns led to interview probes honing in on the Sense Health platform specifically, and engagement generally—independent of particular technology. The questions also evolved in an effort to better understand how engagement efforts were intricately tied to care coordinator bandwidth and the ability to integrate the Sense Health platform into the regular workflow. When regular patterns emerged concerning the role of care coordinators and their limited time to engage with their clients, that section of the interview guide was eliminated from proceeding interviews. The same was true for the questions concerning the typical demographics of the interviewee's client population, their strengths and weakness in health care navigation, and the degree of communication. The final two sections of the interview guide lay the grounds for the majority of subject matter in the last 4 interviews: care coordinators' perceptions of health technology, and views on their clients' perception of technology. Indeed, only during the tenth interview, no new ideas were presented on these topics.

Facilitating the Patient-Provider Dynamic

A very clear connection emerged between communication and engagement, whereby reliable, reciprocal communication between clients and care managers was indicative of the clients' desire to engage in their health and with health care—whether the opportunity existed to do so at all. The importance of communication was much more prevalent than anticipated, which is largely due to the unexpected emphasis on the patient-care manager relationship:

> *It's all about relationship-building. (...) You have to build a good relationship, and you have to build it from the get-go. That's so important, because that contact, whether they respond well to you or not, that all depends on your relationship with them. (...) Because you're working together with the client, you're working together on their goals.* [Care coordinator, Health Home]

Texting acts to facilitate this contact, functioning as a supplement to regular communication and complementing the responsibilities of care managers. Whereas goal-setting and relationship-building will occur in-person or on the phone, text messages are an additional avenue of communication, and thus support (both for supporting the clients and for clients feeling supported), and are suggested as particularly useful for check-ins, reminders, follow-ups, and the exchange of small details:

> *Ya, like I'm like 'oh, did you get the medical records from your doctor for the access-a-ride,' that's a transportation service, 'do you need help with that?'—so we do have lengthy conversations via text, we can. But things like that, following up with stuff that they're working on, or me filling them in, 'I tried contacting that intake worker at that housing place, and they said you're still on the waiting list.' So a brief update like that I'll text, it's great.* [Care coordinator, Health Home]

In addition, care managers could save time by having multiple conversations at the same time through text. Text messages thus enable continuity of communication, making provider services more accessible:

> *One of the great things I do through Sense Health is I'm able to enter their questions rather than having them come in or call me. It's easier for me to send them reminders, that for them to be like, 'Hey, are you going to be there today?' Or, 'Hey, I have a quick question. I need this,' or, 'Can you remind me of the name of this or the number,' so that I could just give it to them right away rather than to have them come in or have them call me. Especially because I'm always in and out of my desk, so if I see a message, then I can respond to them once I'm back.* [Care coordinator, Health Home]

Respondents emphasized that texting was a helpful means, but not the end goal. By maintaining a connection, the ease of communication also improved the relationship: care managers were able to remind their clients that they are there whether or not they have pressing needs. All respondents expressed that consistent communication and support were crucial to the care manager-client relationship and achieving care plan goals: "whether it's jailhouse or chronic illnesses, medical illnesses, the biggest thing is support" (Care coordinator, accountable care organization [ACO]). Notably, whereas clients who are already engaged will take to using texting as a supplement to existing communication methods with their care manager, all interviewees pointed out that adopting texting allowed them to reach clients who were not partial to phone calls or in-person meetings:

> *...it's definitely made getting in touch with some people easier. I think a lot of the care coordinators realized that over time. Where, at first, you kind of forgot that we had the service, so you're still on the phone, you're still calling and calling. Then, you know, two months go by and you hadn't been able to reach someone, you're like, 'Wait. Why don't I just text them?' There you go, they respond.* [Care coordinator, Health Home]

But all care managers repeated throughout the interviews that all clients are different:

> *It all comes down to them, personally, again, are they willing to do something? Are they willing to make that change? The ones who will, you'll see that change in them. Then the others, it's been the same story for a year or two.* [Care coordinator, Health Home]

By establishing consistent reciprocal communication, a positive cycle of engagement would then be triggered for that patient—from managing their own care, to engaging with the health care system.

A New Mode of Communication for Increased Support

Opening a new avenue for communication appeared to expand the boundaries of the existing provider-patient relationship, increasing the willingness of clients to engage. This connection was not predicated on replacing human interaction—which would be impossible in this high-need population—but instead on adding a new form of support grounded in existing trust:

> *They know that there is that trust because already they've given me, they're allowing me to text them. It builds more trust and it builds more...Like, they'll know that they can rely on me and so that's a part of it that's also good. They also, sometimes they like, 'Oh, hey, thank you so much.' It's very receptive. Overall, it's positive. I haven't had any negative encounters.* [Care coordinator, Health Home]

The type of communication that occurs through texting is different, suggesting why adopting a texting protocol could newly engage patients. All care managers noted that clients will respond to, and engage with, different communication methods differently based on their varying needs. The dialogue was agreed to be less formal and more direct, opening a rapport with a more natural conversation tone and flow:

> *It's maybe opened up more of a rapport with them. It seems like some people are more ready to share or to be texting these days than over the phone. You'll get a smiley face. It's just the texting generation we're in today that people...You can get more of a feel of someone's engagement sometimes through how they respond or just a little emotive. Yeah, I enjoy it. I don't know if I'd rather...I mean I wouldn't say (crosstalk) than speaking with them, but from an ongoing thing. If it's just something simple, if I'm just trying to make a contact with them for the month to see how they're doing, yeah, I'd rather use Sense Health, but if I really do have to speak with them or schedule something, obviously the phone platform would be great. Maybe a follow-up with them through Sense Health. Like, hey, what's going on for tomorrow?* [Patient health navigator, Health Home]

With control over the pace and content, clients could also communicate at their own speed, mitigating literacy barriers that would occur through other means (particularly in in-person interactions with health care providers). One care coordinator from a health home explained issues associated with health literacy and the resultant need for quick communication between them and their client at 2 different points in their interview:

> *They're literally sitting in the waiting area for hours, they're hungry, it's for a follow-up they don't understand...*
>
> *...some clients, they won't communicate another symptom they're having that they felt comfortable telling me. Maybe they don't like the side effects of one of their psych meds and they won't talk to their doctor about it.*

Clients were perceived, as a result, to be more open, share more details, and contact their provider more often through texts, leading to increased engagement.

Most care coordinators were selective in introducing the platform to those who they thought would most benefit. These clients were either perceived to be more adept at texting, they were not receptive to phone calls, and younger. As per a patient health navigator at a health home:

> *The younger generation, and by younger, I'm going to say like 40 and under. They're more inclined to wanting to use it, or more open-minded to using it.*

All care coordinators shared that among the clients presented with the option to communicate through texts, acceptance was nearly unanimous:

> *I think it's (texting) just so commonplace now that they just accepted. 'Oh, okay.' (...) If they do decline it's just because some of them don't even have a cell. The older people, some of them don't even have a cell. (...) I don't think I've ever really had the pushback of no I don't want that because it's they're meeting with us and they've agreed to this program this is free as long as they're cooperating and using it. Most of them have at least the intention of wanting to do something differently.* [Care coordinator, ACO]
>
> *Nine and a half times out of ten, they say, 'Yeah, that's great. Yeah, I can text. That's fine.'* [Patient health navigator, Health Home]

As with the care coordinator quoted above, those who did not have positive perceptions of texting were often older clients with vision issues and lack of technology skills, or those with poor literacy (often due to language barriers), and security concerns. From the provider perspective, they similarly experience more control over text communication, with the liberty to respond to clients when they are able—both in terms of availability of time and requested information:

> *When they're trying to get a hold of you, or if they just have something quick to say or ask, it can just be easier because I can see that. I can get that message while I'm on the road. I can respond when I stop somewhere. Instead of having to call back to get a full explanation of what their needs are, what the issue could be, I can just read it right then and there. Then actually start working on that, and then get back to them with an answer rather than call back to find out. Then I go and work on it. Then I call back and tell them what I've done.* [Patient health navigator, Health Home]

This newfound control facilitates the regular workflow, and as a bonus prevents unwanted drop-in appointments. The ease of use and utility for engaging patients prompted care managers to express that they wished more clients would use the texting platform, despite the time-consuming consent process. Other nominal concerns regarding the platform included the length of texts (a character limit could impede the clarity of messages), and hesitancy with clients' plan (do not want to take up limited texts available) and phone (phones with T9 keyboards are more difficult to text with).

The ubiquity of cell phones was routinely acknowledged, as well as the need to embrace that reality and work it to the providers' and clients' advantage through "positive," productive use of a familiar tool. As shared by one care manager:

> *Since we are in a world of technology, the majority of them with the exception of a couple clients of mine who are quite a bit older, they all prefer. This is the day and age where technology is what we know.* [Care coordinator, ACO]

Medicaid clients were also noted for their constant mobility, with a lack of consistent housing and employment. In the words of a health home care coordinator, communicating through text messages is a beneficial "organizational tool" for these clients given these circumstances: "text messages with medication and appointment reminders act as a pseudo-calendar." Moreover, the conversation itself acts as documentation that could be used as a reference point by both parties, and which can visually demonstrate client progress through their messages. Almost all interviewees believed that this functionality increased patient accountability, "especially given the ability to automatically follow up" (Care coordinator, Health Home). Despite this advantage, benefits could not be actualized until social and financial needs, especially housing needs, were addressed: "if you're homeless, that's going to affect your health. I know your

priority is to get a roof over your head" (Care coordinator, Health Home). Only at that point, providers explained, would clients become engaged in their health and interested in interacting with the health care system. Furthermore, they elaborated that clients would be less interested in the "whys" of their health, and more in the "hows": as in, they would be more concerned about how to deal with their illness, rather than why they have it.

Increasing Patient Accountability and Positive Behavior Change Through Reminders

If clients are willing to change their behavior, then reminders can increase engagement with their health and the health care system, and health management, especially in terms of medication adherence. This is because all respondents perceived an increase in client accountability and motivation after assigning appointment and medication reminders:

> *It does give them a little bit more of, like, 'Okay, I have to do this because she's going to know if I don't.* [Care coordinator, Health Home]

> *...because if they tell you they have an appointment coming up and you remind them to go, they're on top of things, so they're able to manage their health better. Again, that's something that I would only know if they inform me.* [Care coordinator, Health Home]

Care managers attributed these desirable outcomes to their ability to tailor the frequency of the reminders based on individual client needs, preferences, and readiness to change. With the ability to automate allowing for perfect consistency, the reminder features allow care managers to move the burden of reminding, and following up with, clients about appointments to the platform:

> *(One) client is very forgetful about his appointments and he's like, 'I need you to set the reminders.' Then he follows up, it's like, "Okay, I'm going to go.' Or he follows up with me, 'This is what's done.' It's really good because I can just send a text message, they'll send it automatically. I don't even have to do it. Then they'll know, 'Okay, I have to take care of this.*' [Care coordinator, Health Home]

Texting was found to trigger positive health behavior change, increasing patients' management of their health condition by increasing appointment attendance via reminders. Specifically, the reminders were the catalyst acting to increase clients' ability and readiness to change their behavior. Once at their appointments, clients are prompted to have follow-up conversations and questions with their care manager—and learn things they would not have taken the time to understand, or recognize, otherwise:

> *...a lot of them (...) went from not going to any appointments (for) their health, their mental health, everything was pretty bad, to going to (these) appointments consistently and having some of the problems that they were having prior help or fixed. Or at least decreased. It shows them the benefit of going to their appointments. The appointments aren't made just because. I've seen it where the medications weren't working. If they didn't go to the appointment, then they wouldn't be able to have their medication switched. Whether increased or decreased or just changed the medication altogether without that being there. It definitely helps a lot.* [Care coordinator, ACO]

Indeed, there was a positive feedback loop between access to services and engagement with both health and providers, whereby going to the doctor encouraged further engagement, and engagement in health and with a care manager encouraged clients to access services. Similar trends were apparent with medication compliance. When clients would respond that they took their medication after receiving their reminder, it would increase their motivation to keep making positive changes, as they would see the positive effects:

> *I have a client who I, basically, set up reminders all the time to take his medication. He texts me when he's done taking the medication. He answers, 'This is great, I love that I actually can let you know. I know that I have to take it, and then sometimes I oversleep or forget, and it'll send me another message just to make sure, just to remind because I haven't text 'done'. It means that I haven't taken the medication.* [Care coordinator, Health Home]

> *Sometimes being prompted, 'now is the time to take your meds,' that helps the people that really want to try to make themselves better.* [Care coordinator, ACO]

> *The ones who I have their medication reminders for, like seeing that change in themselves, they're happy about. I guess it kind of helps them just be happier about what's going on in their life.* [Care coordinator, Health Home]

Indeed, all care managers perceived motivation as the key to patient engagement. The "yes" response also would reinforce trust in the care manager-client relationship: the 2-way communication acts to keep both the care manager and client accountable, expanding the accessibility of the care manager, and ensuring that clients are doing what they are asked or supposed to. Whereas there was a split among providers on who is made more accountable, all say there is an effect, whether one party, the other, or both.

Perceptions were inconsistent on the value of tailoring responses. Some believed that personalizing messages was helpful in engaging patients, enhancing customization, triggering client memory, and proving that the messages were not automated:

> *It makes a difference, it does. Some of them will actually ask you, 'Is this really you Ashley? Are you talking to me or is this automated?' Or they'll call and ask and I'll say no I'm standing right in front of the computer and I'm the one that's texting you.* [Care coordinator, community-based organization]

Others believed that the content was helpful regardless of how it was presented:

> *I think most of them are happy that they get a reminder or they get a text. It's not so much of what*

> *the context of it is that the fact they were reminded or...A lot of them think that it comes from us personally, so the fact that they were reminded, having taken the time and trouble to remind them of something, is what helps us support them.* [Care manager, Health Home]

Interestingly, all respondents seemed to believe that it was more important for a text to come from someone trusted, than that the text is personalized, given that a supportive relationship yields improved engagement.

Emergent Grounded Theory Model

Foundation for a theory to explain patient engagement emerges from axial coding, suggesting correlative relationships among four different components of the patient-provider experience. This is illustrated in the model using different colored ovals (Figure 2). These relationships were based on themes that arose in the interviews. Using a texting platform acts to amplify two existing relationships, whereas introducing a new means to provide support and encourage accountability. The most prevalent component seems to be that technology can strengthen the relationship between the client-care manager dynamic and engagement, by facilitating the provider's ability to engage their patients, and that this relationship is founded on the quality, quantity, and reciprocity of communication. Integrating a messaging platform into the care coordinator workflow also interferes with the relationship between literacy and access to care among Medicaid patients, whereby texting, as a feature, gives patients with low literacy increased agency to access services. Finally, the messaging platform introduces new tools to care managers, providing them with both a new means to support their clients, making communication more accessible, and a tool, namely the ability to automate reminders, to motivate clients by increasing their accountability to their health.

Care managers were consistent in explaining that their client response rates to contact attempts varied based on need for assistance. Specifically, they said that most clients require several contact requests before completing a touchpoint. The interviewed care managers were explicit that, beyond maintaining engagement in previously engaged clients, implementing texting through a robust platform also triggered increased engagement in previously unmotivated clients. TTM could help to explain this new engagement, given that everyone responds to different methods for changing their health behaviors.

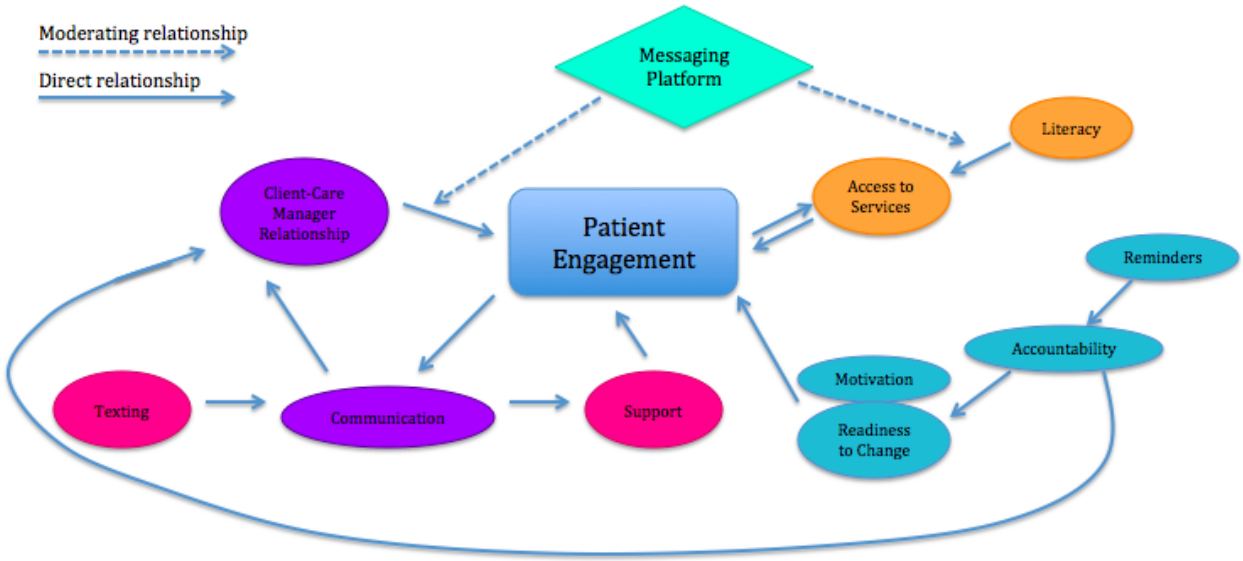
There was indication that a texting platform may improve health literacy in care managers' clients, leading to better access to care. Inherent in their job description, care managers mediate poor health literacy in clients by helping clients navigate their health and health care, and texting facilitates their ability to do so. The platform helps care coordinators' clients better understand how to manage their health (in terms of medication adherence), increasing client knowledge, and making clients more accountable to their own health and more independent in their interactions with the health care system—all aspects of high health literacy. This encourages clients to utilize care and to develop fruitful relationships with their care providers.

Providers mentioned minor differences in ease of use of the texting platform based on client background. Whereas demographic information particular to Sense Health users was not available, as it is not collected, care managers were unanimous in their interviews that they found no difference in engagement based on race, gender, or ethnicity. They did, however, note that older clients (defined differently by different respondents, ranging from 50+ to 70+ years), and those inexperienced with texting, had the most difficulty engaging in their health through text messages.

Clients would respond favorably to motivational messages but care managers perceived reminders to have greater utility in engaging their patients. The care managers shared that reminder messages were the most effective feature of the texting platform for engaging their patients. That is, appointment and medication reminders would encourage compliance, triggering a cycle of positive behavior, interest in self-care, and follow-up conversations requesting more information. In other words, reminders would act as a trigger moving clients forward to the next "stage of change," as per TTM. Providers perceived that texts amplify their ability to support their patients, whereas reminders make clients more accountable. This suggests that integrating the theory of supportive accountability was useful in attaining desirable platform outcomes. These outcomes were only possible, though, due to previously established trusted relationships between the care managers and their clients, and their focus on goals crafted with the patient—highlighting the effectiveness of two constructs of SCT.

Scripts were perceived as being ideal for improving knowledge of clients' health conditions, although no respondents had used that feature at the time of the interview. As the interviewed care coordinators did not use this feature, further research is needed to support the integration of motivational interviewing, which is tied to the goal-setting aspects of the platform. This inclination, though, aligns with the benefit of integrating motivational interviewing and TTM, as scripts incorporate these theories' constructs more than other features. Some care managers also expressed benefits to personalizing texts, and tweaking reminder messages' content and repetition frequency based on client needs, as suggested by TTM, in order to maximize engagement.

Figure 2. Grounded theory model resulting from interviews.



Discussion

Recommendations for Practice and Research

The results of this paper suggest several factors for consideration when designing mHealth interventions to enhance engagement and ultimately health outcomes in Medicaid patients. These suggestions, however, are based on a small sample and for a specific use case and thus should be interpreted accordingly. Evidence-based, theory-informed mHealth initiatives may consider incorporating 2-way communication to maximize patient accountability to their health management, as suggested by the theory of supportive accountability, and supported by the aforementioned findings. Similarly, dynamic mHealth interventions that aim to change health behavior could further investigate the benefit of using trusted health coaches to cement a relationship between the "provider" and "patient" before working on health goals. This component is tied to SCT, as well as supportive accountability, and was also emphasized in this study's results. Finally, the ability for even minor customization to health message content based on individual patient needs, preferences, and readiness to change, recommended by TTM, and the facilitation of patient agency, recommended by SCT, were demonstrated to be beneficial and are components encouraged for future interventions.

Future research can further develop the model that has emerged from this study, and help better understand the use of technology in this particular environment. The next steps for this research project, ideally, would be to interview care managers at each provider practice or health system that implements Sense Health, or any text-based technology. It would also be useful to conduct focus groups within one specific location, and with participants from various locations, to facilitate a comparison of viewpoints whereas also eliciting a more substantiated perspective of overarching themes. Provider discussions could also include a component focusing on the return on investment of implementing mHealth interventions. Finally, a much larger project would also involve patients, most likely with questionnaires since they are a vulnerable population, investigating their perspectives on using technology to manage their care, to elucidate more than just the care managers' perception of client perspectives. This study could also be scaled up even further across numerous theory-informed mHealth interventions which would yield more representative findings of what components and which theories are most effective in improving patient engagement outcomes.

Limitations

The validity of the interpretation of the findings presented here is subject to multiple threats. The interviews regarding patient engagement were from the care managers' perspective, instead of the patients themselves, which by nature makes those findings subjective. Moreover, given that interviews were conducted with the first 10 respondents to the recruitment email, their participation might be biased. They might have volunteered to be interviewed due to unusually strong opinions concerning the platform, a desire to cultivate a positive relationship with Sense Health, or an inclination to verbalize their experiences with their patients on the platform. Such volunteer bias could have influenced the results through responses that were either more positive or more negative than average. With the possibility for the respondents' user experiences deviating from the average in both directions, overall findings were likely representative of the general provider population enrolled in the texting platform.

There was also risk of researcher bias: as a former company intern, the author had expectations of how the care managers would respond according to their knowledge of user activity data on the platform. Given that Sense Health recruited the care managers interviewed, this gave the care managers certain assumptions about the purpose of the study. The author had never interacted with the interviewees prior to this research, and was not privy to their personal usage of the platform. Interviewees were ensured that their responses would remain anonymous and that their answers could not be traced back to them. The purpose of the study and the interviews was reiterated

in both the recruitment email and at the outset of the interview sessions.

Comparisons With Prior Work

The results of this study are consistent with others [1,9,12,38-42], which suggest that incorporating theory will maximize the effectiveness of mHealth behavior change interventions. The results also support findings [5,43] that cell phones can be leveraged to improve patient engagement in Medicaid populations through patient-centered care models [1,24], improved health [25], and management of chronic disease [4,44,45]. Finally, the findings presented here also fulfill the call to action to the scientific community to conduct implementation studies examining the effectiveness of theory-informed mHealth interventions in real-life, uncontrolled settings [5,9,11,15,16,39,42,46,47], as well as identifying recommended mHealth intervention characteristics [8].

Conclusions

Overall, the findings support the intended aims, helping build an assertion where integrating health behavior theory in this mHealth intervention increases patient engagement in the interviewed care managers' Medicaid clients. This adds to the existing body of literature on integrating health behavior in digital interventions, using mHealth to engage patients, and on methods of engaging patients in Medicaid populations. By addressing numerous topics in mHealth and health behavior research simultaneously, this study supports further development of theory-based mHealth interventions targeting patient engagement, while also substantiating their adoption and use in Medicaid populations. The limitations of this study also provide guidance for future studies and mHealth initiatives, helping to avoid the flaws revealed in this project's methodology and results. This is significant as this area of implementation research is in need of greater attention. Without initial forays in behavior-theory guided mHealth implementation studies, there will be no foundation for increasingly rigorous efforts. With further rigorous implementation research, eventually systematic reviews may also be conducted, which would greatly benefit the field. The implications of this projected trajectory are important: with increasing evidence for the benefit of incorporating academic knowledge in mHealth platforms, funding will become more accessible, and the impact of these programs at a population level will increase, furthermore reinforcing expanded opportunities for investigation.

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Conflicts of Interest

Brittany Sigler was provided access to Sense Health data after completing her practicum at the company, as part of her degree requirements for her Master of Public Health at Columbia University. During the period of study design, Sense Health did not employ Ms Sigler. During the course of data collection, she was hired as an employee. Sense Health had no control over the study design, or presentation of the published findings. Dr Rachel Shelton at Columbia University acted as thesis supervisor, providing feedback on design, content, and analysis. Dr Shelton had access to all data but did not have any ties to Sense Health.

Multimedia Appendix 1

Video walkthrough of Sense Health platform.

[MP4 File (MP4 Video), 11MB - mhealth_v5i3e36_app1.mp4]

Multimedia Appendix 2

Original grounded theory-structured interview guide.

[PDF File (Adobe PDF File), 60KB - mhealth_v5i3e36_app2.pdf]

Multimedia Appendix 3

Demographic characteristics of New York State Medicaid population in 2014 (N=4,534,400).

[PDF File (Adobe PDF File), 26KB - mhealth_v5i3e36_app3.pdf]

Multimedia Appendix 4

Complete codebook developed through grounded-theory methodology for analysis of care manager interviews.

[PDF File (Adobe PDF File), 65KB - mhealth_v5i3e36_app4.pdf]

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Abbreviations

mHealth: mobile health
MI: motivational interviewing
SCT: social cognitive theory
TTM: transtheoretical model

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Original Paper

mHealth for Clinical Decision-Making in Sub-Saharan Africa: A Scoping Review

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Abstract

Background: In a bid to deliver quality health services in resource-poor settings, mobile health (mHealth) is increasingly being adopted. The role of mHealth in facilitating evidence-based clinical decision-making through data collection, decision algorithms, and evidence-based guidelines, for example, is established in resource-rich settings. However, the extent to which mobile clinical decision support systems (mCDSS) have been adopted specifically in resource-poor settings such as Africa and the lessons learned about their use in such settings are yet to be established.

Objective: The aim of this study was to synthesize evidence on the use of mHealth for point-of-care decision support and improved quality of care by health care workers in Africa.

Methods: A scoping review of 4 peer-reviewed and 1 grey literature databases was conducted. No date limits were applied, but only articles in English language were selected. Using pre-established criteria, 2 reviewers screened articles and extracted data. Articles were analyzed using Microsoft Excel and MAXQDA.

Results: We retained 22 articles representing 11 different studies in 7 sub-Saharan African countries. Interventions were mainly in the domain of maternal health and ranged from simple text messaging (short message service, SMS) to complex multicomponent interventions. Although health workers are generally supportive of mCDSS and perceive them as useful, concerns about increased workload and altered workflow hinder sustainability. Facilitators and barriers to use of mCDSS include technical and infrastructural support, ownership, health system challenges, and training.

Conclusions: The use of mCDSS in sub-Saharan Africa is an indication of progress in mHealth, although their effect on quality of service delivery is yet to be fully explored. Lessons learned are useful for informing future research, policy, and practice for technologically supported health care delivery, especially in resource-poor settings.

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KEYWORDS

mHealth; decision support systems, clinical; sub-Saharan Africa; clinical decision-making

Introduction

Significance of mHealth

Mobile health (mHealth), defined as "the provision of health services and information via mobile technologies" (p.8; [1]), has gained widespread recognition as an innovative way of improving health care access especially in low-resource settings [2]. It is increasingly incorporated in behavioral change interventions for patients and health workers, patient monitoring, data collection, and health information systems [3-5]. With mobile subscription penetration estimated at 80% in sub-Saharan Africa [6], mHealth can potentially reduce gaps and inefficiencies in health service delivery in low-income countries [7].

In poor-resource settings such as Africa, the weak capacity of health systems is further stretched by health worker shortages, leading to the devolution of some service delivery tasks to lower cadre workers such as auxiliary nurses and community health workers. Although task shifting has been recognized for improving efficiency and access to health services, concerns exist whether lower cadre health workers are competent and equipped to effectively handle additional responsibilities [8]. The potential role of mHealth in enabling task shifting and service delivery in line with evidence-based practice is therefore important.

In high-income countries, where the health system landscape is more adapted for technological innovation than in low- and middle-income countries, knowledge on the use of technology for clinical decision-making is advanced [9-12]. A substantial body of literature presents evidence on the broad use and benefits of mHealth in low- and middle-income countries [13-18]. The extent to which mHealth has been specifically adopted in Africa to mitigate workforce shortages and maintain quality standards of care by serving as a clinical decision support system, is yet to be established. A preliminary search conducted by the first author identified only one review with a limited focus on the use of medical decision support systems in three sub-Saharan African countries [19]. As new mHealth innovations are increasingly being tested and adopted in resource-poor settings, it is necessary to comprehensively assess what has been achieved in order to inform implementers and policy makers on the effectiveness of technology in evidence-based practice.

Objective

The aim of this study therefore was to synthesize available evidence on the use of mobile technology as an interface for improving point-of-care clinical decision-making and the quality of care in Africa.

Methods

The 5-step framework for conducting scoping reviews as proposed by Arksey and O'Malley [20] and further developed by Levac and colleagues [21] was used as a guide in conducting this review.

Conceptualization of Key Terms

mHealth is differentiated from the broader domain of eHealth, which includes supportive factors for the use of information and communications technology (ICT) in health such as legislation, policies, and standards. This review did not include the use of technology in health beyond mobile devices such as mobile phones, tablet computers including laptops, and personal digital assistants.

Health workers are all people engaged in the promotion, protection, or improvement of population health. The World Health Organization's international classification of health workers [22] was used to specify health providers of interest. We were interested in health workers who are involved in making decisions on diagnosis, treatment, or other processes directly related to patient care, therefore excluding categories such as social workers that mainly provide supportive care. In more general terms, the review included doctors, nurses, midwives, associate clinicians, and lay health workers. Doctors were included in this review because the extent of decision support systems use by different health worker cadres in Africa was unknown.

Clinical decision-making involves making judgments about care provided in health service settings using information or knowledge, and can be defined as "...a contextual, continuous, and evolving process, where data are gathered, interpreted, and evaluated in order to select an evidence-based choice of action" (p.401 [23]).

We adopt the Institute of Medicines' definition of quality of care as service delivery that increases the likelihood of desired health outcomes, is aligned to current professional knowledge and is safe, effective, patient-centered, timely, efficient, and equitable [24]. On the basis of this, we consider that quality care is the expected outcome of improved decision-making in health settings, although it may not be explicitly reported in articles.

A mobile clinical decision support system (mCDSS) in the context of this review therefore refers to any mobile electronic or computerized system that provides evidence-based information, which enhances the ability of health care providers to deliver quality care through the prevention, diagnosis, and management of health conditions. There is sufficient literature on the use of health information from electronic medical records and surveillance data to facilitate administrative decision-making or improve clinical workflow. In this review, we included interventions in which data mining or electronic medical records were not the sole component of clinical decision support.

Building the Search Strategy

The search syntax (see Multimedia Appendix 1) was developed on PubMed using combinations and word variations of key terms for the review: mHealth, decision-making, quality of care, health care workers, and Africa, against their appropriate MeSH terms and supported by free text formats. Additional terms were included using keywords from articles of interest retrieved by a preliminary limited search on PubMed. The formula for the final search syntax was (mobile health) AND (decision-making OR quality of care) AND (health care workers) AND (Africa)

Running the Search

In December 2015, we searched the following peer-reviewed databases: PubMed, CINAHL, Web of Science Core Collection, and Cochrane. And, the grey literature electronic database K4Health (see Multimedia Appendix 2).

Without applying date limiters, the search targeted English language articles reporting use of mHealth for clinical decision-making in African countries.Relevant articles had to be manually retrieved from the grey literature database (ie, K4Health) under the thematic heading "decision support."

Weekly email alerts were set for all databases (except Cochrane and K4Health) to allow for additional articles that could emerge between the date of initial search and when the final decision was made on study selection for full reading. Additional articles were therefore assessed for inclusion until March 5, 2016. References were managed using EndNote X7.7 (Clarivate Analytics), a software program for managing bibliographies and citations.

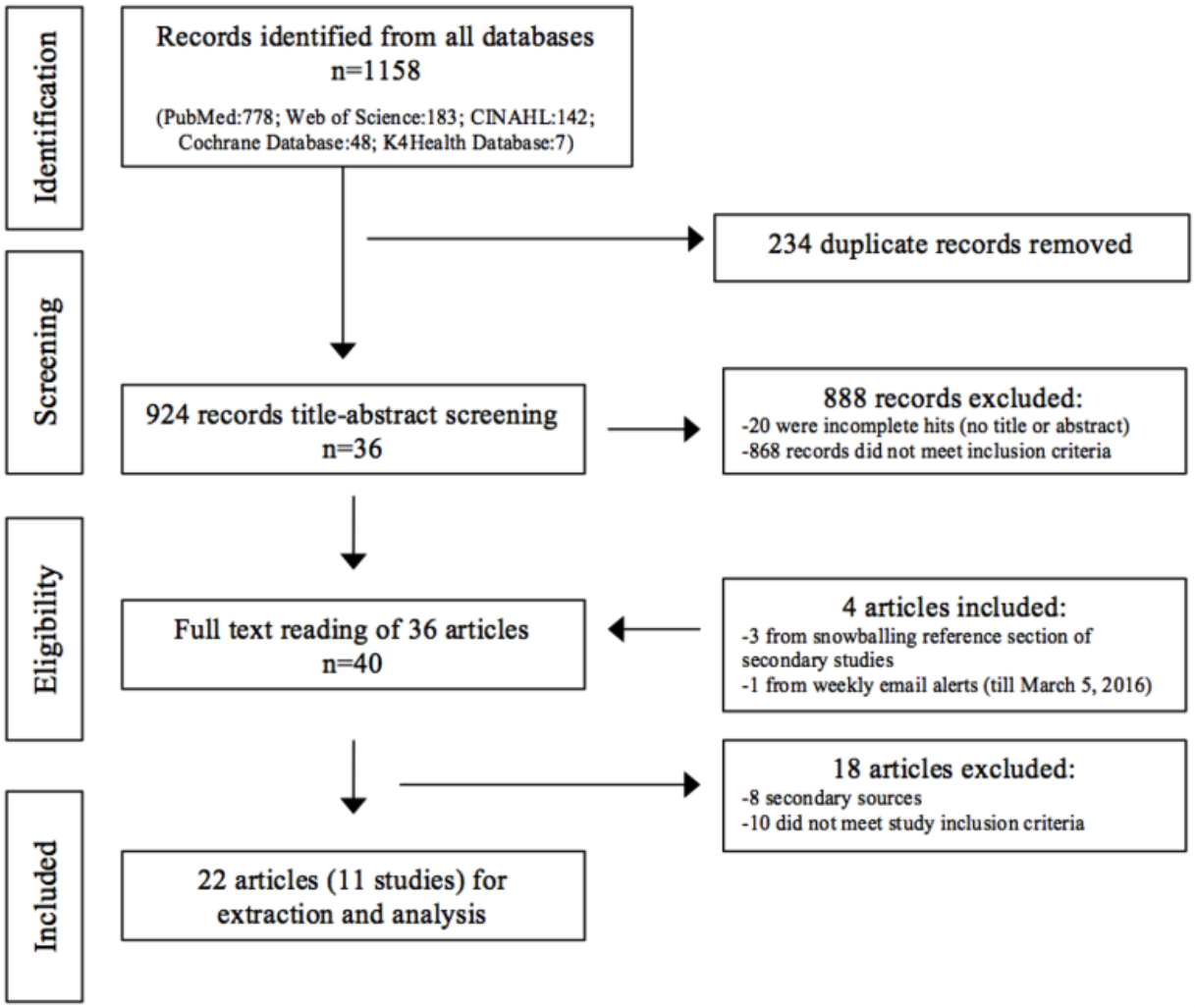
Study Selection

A total of 1158 articles were identified from running the search. After excluding duplicates, 924 articles were retained, which were screened against predetermined inclusion or exclusion criteria. Both primary and secondary (ie, literature reviews) studies were initially assessed. The reference section of secondary studies was used to identify additional primary studies, such that only relevant primary studies irrespective of study design were represented in the final list of retained studies. Mobile devices were taken to refer to mobile phones, laptops, personal digital assistants, iPads, and wearable devices, excluding ambulatory health units or desktop computers. Decision tools not integrated into a mobile device, for example, use of paper-based guidelines for decision support were also excluded. All cadres of health workers except social workers, support staff, dentists, pharmacists, and psychiatrists were included. Use of mHealth for patient shared decision-making, self-management, treatment adherence, or patient reminders was an exclusion criterion. In addition, selected interventions had to be used at the point of care, therefore excluding store and forward or remote monitoring techniques such as teleconsultation, teledermatology, and computerized provider order entry systems. We excluded nonclinical forms of decision support such as ethical or policy decision-making and managerial or administrative decision-making. Additional exclusion criteria included articles on the sole use of mHealth as a geographic information or surveillance system, or for managing patient records and data capture without an additional clinical decision support component. Finally, articles that generally discussed mHealth use or training on ICT in health with no focus on a specific intervention, were excluded.

Supported by multiple discussion meetings, two authors (IOOA and BJAA) applied the inclusion-exclusion criteria on the title and abstract sections of each article, after which 36 articles were selected for full text reading. Where primary reviewers disagreed on inclusion, a third reviewer (MZ) arbitrated. Alongside 3 articles identified from snowballing the reference section of secondary studies and 1 article identified from the weekly alerts, the 36 articles were further assessed for inclusion through full-text reading. Only 22 articles were eventually retained for synthesis and analysis. The stepwise flow is presented in Figure 1.

The subsequent stages of the review (data charting, collating, summarizing, and reporting results) are presented in the following subsections.

Figure 1. Stepwise flow of study selection.



Data Charting

Guided by the review questions, an Excel (version 14.6.6), data charting form was developed and subsequently refined as the papers were read by 2 reviewers. The following information was extracted: general study information including authors, study year, study location, and name of intervention; cadres of health workers targeted; study design and aim; characteristics of the mCDSS; contextual factors of the intervention; expected and reported outcomes of the intervention; descriptive narrative of intervention process and reported facilitators; and barriers to implementation and use of the intervention.

After a clear view of the nature of information in the selected articles was obtained, all articles were exported to MAXQDA version 12.2.0 for coding and data management.

Results

Characteristics of Studies

The 22 articles retained in the review represented 11 different studies: m4Change [25], Decision Support and Integrated Record-Keeping (DESIRE) [26], CommCare [27], mPneumonia [28], Basic Antenatal Care Information System (Bacis) [29], TBTech [30], txt2MEDLINE [31], New Algorithm for Managing Childhood Illness Using Mobile Technology (ALMANACH) [32,33], electronic Integrated Management of Childhood Illness (eIMCI) [34-36], Text Messaging of Malaria Guidelines [37-39], and Quality of Maternal and Prenatal Care (QUALMAT) [40-46]). These studies were conducted in 7 sub-Saharan African countries: Kenya, Nigeria, Ghana, Tanzania, Burkina Faso, Botswana, and South Africa. To aid ease of understanding, we took the studies as the unit of analysis and not the different articles in which they are reported. Results are presented in a narrative format.

An overview of each study is presented in Table 1. A detailed profile including study design and outcomes is presented in Multimedia Appendix 3. Key findings are outlined in Textbox 1 at the end.

Table 1. Overview of included studies.

Name of intervention	Authors (Year)	Number of articles	Study design	Country	Health domain	Target group	Type of mCDSS[a]
m4Change[b]	McNabb et al (2015) [25]	1	Quantitative pre-post study	Nigeria	Maternal health	Community health (extension) workers	Decision algorithms for antenatal care incorporating clients' data. Includes audio clips for counseling.
DESIRE (Decision Support and Integrated Record-Keeping)	Vedanthan et al (2015) [26]	1	Qualitative usability and feasibility study	Kenya	Hypertension	Nurses and clinical officers	Electronic records system coupled with algorithm-based decision support with alerts and reminders.
CommCare	Svoronos et al (2010) [27]	1	Qualitative and descriptive	Tanzania	Maternal health	Community health workers	Decision support protocols with reminders and checklists. Incorporates clients' data for pregnancy monitoring and supervisory oversight.
mPneumonia	Ginsburg et al (2015) [28]	1	Mixed methods usability and feasibility testing	Ghana	Childhood illnesses	Lesser trained health care professionals	Algorithms for managing childhood illnesses integrated with "intelligent" breath counter and pulse oximeter.
Bacis (Basic Antenatal Care Information System)	Horner et al (2013) [29]	1	Before and after cohort study	South Africa	Maternal health	Nurses	Electronic patient information system with protocols to support providers' action. Includes reminders, alerts, and checklists.
TB Tech	Catalani et al (2014) [30]	1	Mixed methods human-centered design	Kenya	Tuberculosis and HIV	Clinicians	Electronic patient records used to generate individualized reminders and decision support for provider action, education, and behavior change.
txt2MEDLINE	Armstrong et al (2012) [31]	1	Pre-post utility evaluation	Botswana	Different domains	Clinicians of varying cadres	Two-way short messaging service (SMS) of clinical guidelines with MEDLINE query function.
ALMANACH (New Algorithm for Managing Childhood Illness Using Mobile Technology)	Shao et al (2015a, 2015b) [32,33]	2	Controlled noninferiority trial and qualitative study	Tanzania	Childhood illnesses	Clinicians	Diagnostic and treatment algorithm supported by point-of-care tests and simple clinical assessments.
eIMCI (electronic Integrated Management of Childhood Illness)	Mitchell et al (2012, 2013); DeRenzi et al (2008) [34-36]	3	Mixed methods before-after cluster trial	Tanzania	Childhood illnesses	Health care professionals	Electronic protocols for the Integrated Management of Childhood Illnesses (IMCI) for stepwise examination, diagnosis, and management.
Text Messaging of Malaria Guidelines	Jones et al (2012); Zurovac et al (2011, 2012) [37-39]	3	Cluster randomized controlled trial	Kenya	Malaria	Health workers	One-way text messaging on malaria management, supported by unique motivational quotes.

Name of intervention	Authors (Year)	Number of articles	Study design	Country	Health domain	Target group	Type of mCDSS[a]
QUALMAT (Quality of Maternal and Prenatal Care)	Blank et al (2013); Dalaba et al (2014, 2015); Mensah et al (2015); Saronga et al (2015); Zakane et al (2014); Duysburgh et al (2016) [40-46]	7	Mixed methods quasi-experimental study	Tanzania; Ghana; Burkina Faso	Maternal and prenatal health	Health professionals (nonphysicians)	Electronic decision support algorithm with data integration. Includes training materials and an electronic partograph.

[a]mCDSS: mobile clinical decision support system.

[b]Although the m4Change study also used the CommCare app, we decided to treat them as independent studies because the interventions were only similar on a technical level and not part of an integrated multicountry study.

Mobile Clinical Decision Support Systems (mCDSS): Contexts, Purpose, and Features

Alone or as part of a multicountry study, Tanzania had the most number of studies (n=4) on the use of mHealth for clinical decision support, followed by Ghana and Kenya with two studies each. Interventions focused on different domains of health care but were predominantly used in maternal health (n=4), childhood illnesses such as malaria, pneumonia, and diarrhea (n=3), and chronic conditions such as human immunodeficiency virus, tuberculosis, and hypertension (n=2). Lower cadres of health workers (ie, nurses, midwives) or nonclinicians (community health workers) were specifically reported as the target group in the majority of studies. Some studies used broader descriptive terms such as “clinicians” (txt2MEDLINE; TBTech; ALMANACH; DESIRE), “health care professionals” (QUALMAT; mPneumonia), or “health workers” (Text Messaging of Malaria Guidelines), which could also include community health workers and associate clinicians.

Not all studies reported the years of education or clinical experience of the target group. QUALMAT involved associate clinicians having 1-4 years of training, mPneumonia considered users who had up to 2 years of training, and users in the eIMCI had up to 3 years postsecondary school training. Computer literary varied across studies, but most users had no or limited training before the interventions, some of which included training on technology use. Interventions were conducted in either rural (QUALMAT, DESIRE) or mixed (both rural and urban) settings as in the case of TBTech, ALMANACH, and eIMCI. Where reported, most studies were implemented in primary health care facilities (QUALMAT, Bacis, m4Change, eIMCI, mPneumonia).

Studies varied in the type of decision-support; ranging from simple guideline-based two-way (txt2MEDLINE) or one-way (Text Messaging of Malaria Guidelines) text messaging systems to more complex multifunctional systems, which incorporate patients’ data or decision algorithms (m4Change, DESIRE, QUALMAT).

Devices included mobile phones (Text Messaging of Malaria Guidelines, txt2MEDLINE, m4Change, ALMANACH, CommCare), laptops (QUALMAT) and tablets (m4Change, ALMANACH, DESIRE, mPneumonia), or personal digital assistants (eIMCI). With the exception of short messaging service (SMS)–based studies in Kenya (Text Messaging of Malaria Guidelines) and Botswana (txt2MEDLINE) in which users’ personal phones were used, other interventions provided mobile tools and included features for collection and retrieval of patient data.

Three studies incorporated additional components such as tailored motivational quotes (Text Messaging of Malaria Guidelines), performance-based financial and nonfinancial incentives (QUALMAT study), supervisory feedback (CommCare), and diagnostic tools such as pulse oximeters (mPneumonia). Considering infrastructural challenges, some studies also provided batteries, generators, and solar packs (eg, QUALMAT, eIMCI). Local language support was provided in some interventions (QUALMAT, m4Change, eIMCI).

Mobile Clinical Decision Support Systems (mCDSS): Reported Outcomes

Clinical Outcomes

Although the overall aim of a mCDSS should be to improve service delivery, health outcomes, and quality of care, not all papers assessed these. A few studies reported effects of mCDSS on quality of care and showed significant improvement in only a few quality indicators (m4Change, Bacis, QUALMAT). The m4Change project reported statistically significant improvement (P<.001) by about four points (from 13.3 to 17.2) in the quality of antenatal care (ANC) services delivered, although not all components of the 25-item quality score were significantly improved. For example, whereas six indicators including client satisfaction improved significantly at endline, a significant decline was recorded for tetanus toxoid coverage, with five other indicators showing no significant improvement. The Bacis study reported an overall increased compliance with using ANC guidelines (from 85.1% to 89.3%), but this was not statistically

significant. However, three of nine specific ANC categories (booking patients after week 20, compliance at booking, and use of protocol in patients below 18 years) significantly improved. Similar findings were noted in the larger multicountry QUALMAT study where quality indicators before and after the intervention were mostly not significantly different between intervention and control facilities. Indicators such as history taking, patient monitoring, and total technical performance improved with statistical significance (P<.01) postintervention, but remained below maximum satisfactory scores. Unexpectedly, including performance-based incentives (PBI) to enhance health worker motivation in the QUALMAT study did not improve the quality of care.

Overprescription of antibiotics was reduced by about 80% in the ALMANACH study. Although authors suggest this could be the result of improved adherence to evidence-based practice, it was not possible to identify specific factors responsible for this change.

In the SMS intervention of malaria guidelines coupled with motivational messages in Kenya, management of pediatric outpatients improved with statistical significance by 23.7% immediately after the 6-month intervention and was sustained (24.5%) up to 6 months later [39]. Guidelines were found to be most effective for activities that workers previously perceived as unimportant, such as patient counseling, complete physical examination, and follow-up. The authors ascribe this outcome to the perception that guidelines are from an authoritative source, as well as the effectiveness of reminders. Unfortunately, the study did not evaluate the effect of motivational quotes on guidelines adherence.

Perceptions of Health Workers

Health workers were generally reported to have positive attitudes toward use of mCDSS, expecting it to make their work easier or simpler, improve efficiency and accuracy, and be more reliable (QUALMAT, TBTech, Text Messaging of Malaria Guidelines). Although not all interventions had this feature, positive attitudes of workers toward mCDSS was linked to their expectation of automatically generated monthly reports, therefore relieving them of this administrative task (CommCare and Basics). mCDSS were additionally perceived to play a supervisory or monitoring role for health workers by ensuring that they followed standard practice. In the one-way SMS guidelines for malaria, the feeling of having an authority figure "looking over ones shoulders" reinforced adherence behavior. The effect of the supervisory feedback component of the CommCare app was not reported.

Studies that included a training module such as QUALMAT were also positively judged. Health workers believed that it met their needs for continuous professional development, therefore increasing competence and self-confidence and resulting in a decreased reliance on peers or referral facilities. Although it did not have a training component, similar perceptions were echoed in the DESIRE study where nurses found the app empowering and perceived it as being able to improve quality of care. The mPneumonia study inferred that in addition to the level of experience of target users, availability of resources such as medical supplies and context of use also influenced disposition of health workers to the mCDSS.

Against the background of long waiting times and understaffed facilities, SMS interventions were appreciated for being easy and concise. The frequency, length, and timing of messages in the Kenyan study on Text Messaging of Malaria Guidelines were important considerations for health workers. Although three out of every four respondents found the frequency of messages (one in the morning and another in the evening, five days a week) adequate, a few considered it excessive and noted the risk of it becoming boring or repetitive.

Health workers raised concerns about increased time periods needed for navigating decision support systems (ALMANACH, QUALMAT). Contrary to initial concerns, workflow assessments in QUALMAT showed that use of the mCDSS did not significantly increase overall time taken to deliver ANC compared with nonintervention sites, although certain tasks such as patient registration and physical examination were found to need twice as much time. This was expected since the standard preintervention paper formats had to be maintained during the intervention. It could also mean that adherence behavior had improved due to the intervention. Studies that measured effects of mCDSS compared with paper systems, such as eIMCI, report that the former was faster and easier to use and improved adherence behavior. The usability assessment of the DESIRE study found that whereas initial use of the system was challenging, given time and frequent use, users found it easier and faster (about 5-20 min) compared with standard paper practice (about 3-30 min) and eventually streamlined it into their workflow. Similar findings were reported in piloting the CommCare app. TBTech was interestingly designed such that both paper and electronic systems were integrated and aligned to existing workflow and organizational processes. This meant that the intervention was not perceived as a big deviation from routine processes of health workers, and therefore easily accepted.

There were reported experiences of conflict and uncertainty when health workers disagreed with recommendations provided by the tool or felt it limited their ability to think for themselves (DESIRE, mPneumonia, TBTech, eIMCI). This unease was especially prominent for workers with insufficient training, in which case their mind-lines (ie, knowledge base) were not reliable. In such situations, health workers were found to rely on patient reports (client-lines). In other studies, the supportive role of mCDSS was emphasized such that health workers realized that they had the authority to override recommendations of algorithms if they believed a different course of action was more appropriate (QUALMAT, Bacis, ALMANACH).

Effect of Mobile Clinical Decision Support Systems (mCDSS) on Patient-Provider Relationships

mCDSS was reported to play a role in stimulating or improving trust between patients and providers (ALMANACH, DESIRE, Text Messaging of Malaria Guidelines, eIMCI). For example, patients believed that the mobile tablet was communicating instructions to health workers from more specialized clinicians or from tertiary facilities, which boosted their confidence and trust (eIMCI, DESIRE, ALMANACH).

Compared with paper formats, which patients interpret to indicate lack of knowledge on the part of health workers, mCDSS improved patients' trust in provider skills, further motivating both parties. An improvement in the technical aspects of care such as physical examination—parts of which may be otherwise skipped—made clients feel attended to and more involved in the care process. Two studies report that use of guidelines or decision algorithms created positive feedback loops whereby more clients were willing to see health workers whose confidence was in turn enhanced (DESIRE, Text Messaging of Malaria Guidelines). A less positive effect was however reported by some nurses who felt that the tablet decreased effectiveness of patient consultation, such as missing nonverbal cues when concentrating on the tablet (DESIRE).

Sustainability, Costs, and Cost-Effectiveness of Mobile Clinical Decision Support Systems (mCDSS)

The disposition of health care workers to use mCDSS was not consistent with perceived benefits (ALMANACH, CommCare, txt2MEDLINE). For example, although majority of health workers (79-86%) reported that they would use the txt2MEDLINE system daily or weekly, the initial surge in using the system dropped after a few days. Similar but yet unexplained low levels of use were reported in some study sites under the ALMANACH intervention despite high positive attitudes and enthusiasm for the support system. CommCare suspects that drop in reporting rates after the pilot period was due to technical issues or lack of effective monitoring and supervision. Use of unique motivational messages suggests that such strategies could extend the novelty effect and increase chances of long-term adoption (Text Messaging of Malaria Guidelines).

According to eIMCI study, time efficiency of using the device was an indicator of its sustainability for routine use. Users' level of literacy and familiarity with technological gadgets were also reported to influence sustained use. For example, the Bacis study found that younger computer literate nurses were more enthusiastic and responsive to the intervention than older nurses.

Only two interventions presented a cost analysis (Text Messaging of Malaria Guidelines, QUALMAT), whereas the Bacis study reported only total cost of study implementation (US $160,000). Over a 6-month period during which 33,361 text messages were sent to 150 phone numbers, US $19,342 was spent in the Text Messaging of Malaria Guidelines study. Most (45%) of this was used to develop and pretest the service with only 13% of costs going toward actual sending of text messages and monitoring of the system. Under study conditions, cost per additional child correctly managed was US $0.5. In the QUALMAT intervention, installation costs varied widely per country—US $186,000 in Tanzania and US $23,000 in Ghana, 77% and 48% of which was spent on the preoperational phases, respectively. These differences were explained by differing contexts, resources, and expenditures needed in each country. Of note is the conclusion that up to US $1060 was required to train a nurse to use the system for a year and about US $21,000 will be required to install and operate mCDSS for 1 year in a similar rural setting.

Facilitators and Barriers to Mobile Clinical Decision Support Systems (mCDSS) Use

Technical and Infrastructural

Poor cellular network coverage and nonfunctional hardware were technical barriers to implementation and use of mCDSS (DESIRE, QUALMAT). Programs such as TBTech built on the work process of existing systems such that decision support functions could be maintained even in situations where electricity or the Internet was unavailable. Some designs allow users input and retrieve data even when offline (m4Change, DESIRE, CommCare, and mPneumonia). One study found that by creating informal communities of practice involving peers with prior experience of mHealth, technical challenges were better managed by program managers (DESIRE).

Dual Workload

In the context of low staffing and high caseloads, the concern that mCDSS would further increase workload was a frequently reported barrier to usage (QUALMAT, ALMANACH, DESIRE, mPneumonia). Most ALMANACH users reported that lack of financial incentives demotivated their use of the system although use of financial incentives in the QUALMAT intervention had no additional effect. Equally important is the role that perceived benefit of mCDSS use plays in facilitating its use. Where it was seen as better than current practice (DESIRE), useful for reporting (CommCare), accessing information (txt2MEDLINE), innovative and relevant to their work (Text Messaging of Malaria Guidelines, QUALMAT), health workers were more favorably disposed to its use.

Training

Multiple studies found that investing in initial and refresher training was a key facilitator and motivator for effective use of mCDSS (QUALMAT, DESIRE, mPneumonia, Text Messaging of Malaria Guidelines). The need for technical training was higher in older workers (Bacis) with low computer literacy, compared with younger health workers or those who used the system on their personal mobile phones (txt2MEDLINE). Contrarily, another study reported that initial technical difficulties encountered by health workers existed irrespective of sociodemographic and computer literacy levels (ALMANACH).

Supervisory Support

The role of technical and supervisory support from both the project team and formal supervisors was thought to be important in keeping users motivated (QUALMAT, CommCare, DESIRE). Delays between training and program implementation could lead to decreased skill, motivation, and general disposition to the intervention. The perception that decision support algorithms are based on updated best practices from a trusted source (national or international body) was also reported as a facilitator of use (Text Messaging of Malaria Guidelines).

Ownership

Multistakeholder engagement and ownership needed to be addressed as early as the design phase and before implementation (QUALMAT, Bacis, TBTech). Experiences of the QUALMAT team showed that poor ownership by local

stakeholders could lead to suboptimal program outcomes despite including incentives.

Health System and Resource Barriers

Health system issues such as unavailability of medicines (m4Change, ALMANACH), health commodities, understaffing (ALMANACH), and the ability to trigger the referral chain when needed, served as facilitating or inhibiting factors to evidence-based practice. Taking these into account, implementation of TBTech included supply chain management, provider training on clinical knowledge, hardware purchase, and maintenance and provision of mobile radiology units. Resource barriers included the need for airtime and financial support to maintain the system (DESIRE, Text2MEDLINE).

Textbox 1. Key findings.

- mCDSS have been used in a range of 11 interventions in sub-Saharan Africa, with a predominant focus on lower cadre workers, maternal health, and at primary health care level in rural settings.
- With a few exceptions, most interventions were usability or feasibility pilot studies using small sample sizes.
- Although individual service delivery components show improvement, existing evidence does not support the ability of mCDSS to improve quality of care or clinical outcomes in sub-Saharan Africa.
- Use of mCDSS can improve patient-provider relationships through increased trust and confidence in health service delivery.
- mCDSS may create conflicts in clinical decision-making when expert knowledge of health workers conflicts with recommendations of the expert system.
- Although health workers are generally enthusiastic about mCDSS use, there are concerns about its effects on increased workload, altered workflow, and technical challenges, which hinder adoption and sustainability in routine care.
- Facilitators and barriers to use of mCDSS include technical, infrastructural and supervisory support, ownership, and health system constraints.

Discussion

Principal Findings

This review synthesized evidence on the use of mobile technology as a clinical decision support system in Africa. Evidence indicates significant support for using mCDSS to improve health worker performance and service delivery specifically within sub-Saharan Africa. However, evidence is insufficient regarding their effects on the quality of care. Key findings are highlighted in Textbox 1.

Weak study designs, short intervention periods, and small sample sizes may explain this gap, although, even from more robust studies, the link to clinical outcomes is largely lacking [47]. Two studies, however, reported statistically significant (m4Change) and even sustained effects (SMS for Malaria Guidelines) on quality of care and provider behavior respectively, which is similar to reports on the ability of mCDSS to improve adherence to guidelines, evidence-based practice, and patient outcomes [48,49]. Other reviews have reported studies showing effects on guideline adherence or patient outcomes, which were either not statistically significant or suboptimal [47]. Specific features of computerized decision aids could enhance (eg, content control) or constrain (eg, patient narratives) the quality of decision-making [11], but we could not establish direct links between study outcomes and features of the mCDSS used. Significant improvement in clinical practice has been shown in decision support systems focused on clinicians and associate clinicians (physician assistants and nurses) [48]; however, none of the interventions compared perceptions and outcomes across different health worker cadres.

Unsustained enthusiasm regarding mCDSS use reflects the novelty effect, which in addition to perceived risk or reward can influence technological adoption [50]. High expectations or inaccurate perceptions of the capability of mobile devices may explain why some workers used the system more than others, as was the case in the ALMANACH study. It could also be due to short training or intervention periods, limiting ability of users to become familiar with the system, and to modify their expectations. According to Rogers' theory on the diffusion of innovations [51], individual, systemic, and innovation-related factors influence the adoption of innovations and their potential to effectively influence systemic change. Perceived usefulness of mCDSS in light of users' perception on its effect on their workload, alongside other institutional and resource barriers, could have hindered the transition from early to sustained adoption by health care workers. Although the relatively short duration characterizing many mHealth pilots hinder the ability to evaluate rate and effect of adoption over time, a human-centered, multistakeholder approach to design and implement these technologies has been suggested as a way to mitigate resistance and encourage efficient integration into complex environments such as health systems [27,30,40-46]. Although some of the studies in this review used strategies such as training, supervision, and financial incentives to motivate the adoption and utilization of mCDSS, there were mixed reports about their effectiveness. Direct or indirect supervisory support may additionally trigger the Hawthorne effect, influencing mCDSS adoption. Despite health worker concerns, evidence showed that consultation time was not significantly increased due to these innovations. Future studies need to understand how mCDSS influences workflow patterns—the goal of which is to improve time efficiency while retaining quality services, and they should aim to identify how mHealth innovations can be designed and implemented to effectively become an integral part of the systems in which they are introduced.

In a study on factors that influence decision-making of frontline health workers in Ghana, health workers' tacit knowledge (mind-lines) was the default mode for clinical decision-making, with guidelines used only when they were easily accessible and

simple to use [52]. The risk of overreliance on the recommendations of mCDSS (e-lines) above provider knowledge and experience, and the conflict that could result has been established in the discussions on limitations of decision support systems [49]. However, there is equal need to consider that mind-lines of health workers may be inaccurate and shaped by flawed perceptions, insufficient clinical training, and sociocultural norms [53]. The flexibility to override decision support recommendations may therefore need to be balanced with system accuracy and training or experience of users.

Findings that providers were more engaged in the care process during mCDSS use contradict anecdotal perceptions that interpersonal relationships are decreased with the use of electronic devices. Although inconclusive, whereas these effects on improved patient-provider relationships could be due to improved adherence to standard evidence-based practice, they could also be purely psychological and inflated. Future before-after studies that assess attitudinal and interpersonal changes are therefore needed.

There were no additional studies reporting the use of PBI on implementation and use of mCDSS in sub-Saharan Africa. A US study which included financial incentives (US $500-800) to nurses and clinicians over a 6-month period reported that use of the intervention was moderately sustained even after the incentives were stopped [54]. Other studies in high-resource contexts have highlighted the beneficial role of incentives at a facility level [55]. In one country site of the QUALMAT study, financial (€4297) and nonfinancial (trophies, a camera, a cell phone, and acknowledgment letters) incentives were provided at facility and individual levels respectively (p.34) [56]. Although these may have stimulated use of mCDSS, quality of care did not improve. Further investigation is needed regarding the benefits of financial or nonfinancial incentives in implementing and sustaining mCDSS use, and at what level PBI are most effective. This also highlights the multiplicity of factors that need to be taken into account to achieve effective clinical decision-making support interventions.

Recommendations for Policy, Practice and Research

A major concern of policy makers regarding added benefits of adopting mHealth is related to its cost and cost-effectiveness. Although only 2 of the 11 studies reported cost implications, willingness of stakeholders to share costs is important for continuity and sustainability. Studies that made use of personal phones of health workers (Text Messaging of Malaria Guidelines, txt2MEDLINE) utilized an indirect form of cost sharing. Assessment of stakeholders' willingness-to-pay or cost-sharing models could prompt consideration for scaling-up successful pilot interventions. Evidence points to low-cost implications and higher acceptability with SMS-based mCDSS. A Chinese study found that compared with standard paper formats, text messages were about 280 times cheaper for stimulating guideline use [57]. Although there was agreement on the ease of its use, most respondents found that the messages, which were received once daily three times a week, were too short and infrequent. It is crucial to conduct additional studies that show how and when timing, frequency, and length of text message mCDSS interventions are most suitable. Regular updates of decision support software could also minimize the risk of information being perceived as redundant.

Clinical decision-making is only one aspect of the continuum of care. Success of using electronic support as a "magic" tool is hampered by other deficiencies in the health system such as not being able to act on recommendations [33]. This may possibly explain suboptimal effects on quality of service delivery. The extent to which mCDSS increases competencies of lower cadre health workers needs to be investigated so that task-shifting strategies can better leverage technological innovation. Rigorous evaluation methodology could shed more light on outcome and impact of the use of mHealth for clinical decision support especially taking into consideration different contexts, various cadres of health workers, and their levels of experience and training. As health care systems are increasingly incorporating technological and ICT-based interventions into routine practice, training of all health professionals should be adapted to include this competence.

Limitations

Although the evidence in this review spans interventions executed within the last ten years, resources did not allow us to engage in translations of articles in other languages, which implies that we may have excluded some relevant articles from French-speaking countries. Additionally, although we recognized that we may have gained more insight into the different interventions if we had included a consultation stage in the review process [20], due to time constraints, we did not contact study authors for additional information or further ongoing research. In contrast to systematic reviews, the absence of quality assessment of papers included in scoping reviews makes findings hard to generalize and the effectiveness of studies difficult to weigh [20]. Despite these limitations, we believe that the breadth and depth of evidence presented here is sufficiently relevant for the aims of this review.

Conclusions

The volume of evidence presented on the use of mobile technology as a clinical decision support system in sub-Saharan Africa is an indication of growth in the domain and its potential for improving health service delivery in low-resource settings. Several evidence gaps need to be addressed, including specific mechanisms underlying use, sustainability, and effects of mCDSS on quality of care and their ability to be fully integrated into routine practice. In light of the effect that differences in health worker cadre, training, and intervention context could have on utilization and outcomes of mCDSS, future research should adopt comparative analyses in order to identify for whom these programs work best. It is also needful to understand in what contexts, why, how, and at what costs, mCDSS lead to changes in health worker performance. Although quality of service delivered by these interventions on a clinical and individual level is yet to be fully explored, the evidence gathered is useful for informing future policy, practice, and research.

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Authors' Contributions

IOOA conceived, designed, and performed the review with support from MZ and BJAA. IOOA drafted the manuscript and MZ, BJAA, VDB, and JvR contributed to its revision. All authors have approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Search strategy.

[PDF File (Adobe PDF File), 20KB - mhealth_v5i3e38_app1.pdf]

Multimedia Appendix 2

Search strategy for different databases.

[PDF File (Adobe PDF File), 59KB - mhealth_v5i3e38_app2.pdf]

Multimedia Appendix 3

Detailed profile of included studies.

[PDF File (Adobe PDF File), 120KB - mhealth_v5i3e38_app3.pdf]

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Abbreviations

ANC: antenatal care
Bacis: Basic Antenatal Care Information System
DESIRE: Decision Support and Integrated Record-Keeping
eIMCI: electronic Integrated Management of Childhood Illness
ICT: information and communications technology
mCDSS: mobile clinical decision support system
mHealth: mobile health
PBI: performance-based incentives
SMS: short messaging service
QUALMAT: Quality of Maternal and Prenatal Care

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Original Paper

A Mobile Clinical Decision Support Tool for Pediatric Cardiovascular Risk-Reduction Clinical Practice Guidelines: Development and Description

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Abstract

Background: Widespread application of research findings to improve patient outcomes remains inadequate, and failure to routinely translate research findings into daily clinical practice is a major barrier for the implementation of any evidence-based guideline. Strategies to increase guideline uptake in primary care pediatric practices and to facilitate adherence to recommendations are required.

Objective: Our objective was to operationalize the US National Heart, Lung, and Blood Institute's *Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents* into a mobile clinical decision support (CDS) system for healthcare providers, and to describe the process development and outcomes.

Methods: To overcome the difficulty of translating clinical practice guidelines into a computable form that can be used by a CDS system, we used a multilayer framework to convert the evidence synthesis into executable knowledge. We used an iterative process of design, testing, and revision through each step in the translation of the guidelines for use in a CDS tool to support the development of 4 validated modules: an integrated risk assessment; a blood pressure calculator; a body mass index calculator; and a lipid management instrument.

Results: The iterative revision process identified several opportunities to improve the CDS tool. Operationalizing the integrated guideline identified numerous areas in which the guideline was vague or incorrect and required more explicit operationalization. Iterative revisions led to workable solutions to problems and understanding of the limitations of the tool.

Conclusions: The process and experiences described provide a model for other mobile CDS systems that translate written clinical practice guidelines into actionable, real-time clinical recommendations.

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KEYWORDS

pediatrics; cardiovascular risk reduction; mHealth; clinical decision support; clinical practice guidelines

Introduction

Cardiovascular disease (CVD) is the leading cause of death in the United States [1] and accounts for over US $108 billion in health care expenditures annually [2]. While appreciable heart disease in children and adolescents is rare, health behaviors, risk factors, and exposures beginning in childhood can accelerate the development of atherosclerosis. Evidence that most CVD

is preventable led to the development of primary prevention guidelines for adults [3], and there has since been increasing evidence that risk-reduction strategies may also delay progression toward clinical disease among younger populations [4].

In 2006, the US National Heart, Lung, and Blood Institute (NHLBI) established an Expert Panel to develop comprehensive evidence-based guidelines addressing the known risk factors for CVD among the pediatric population, including family history, age, sex, nutrition and diet, physical inactivity, tobacco exposure, blood pressure (BP), lipids, overweight and obesity, diabetes mellitus, predisposing conditions, metabolic syndrome, inflammatory markers, and perinatal factors. The guidelines are intended for use by a broad audience of pediatric care providers—such as pediatricians, family practitioners, nurses, nurse practitioners, physician assistants, and registered dietitians—to assist in the promotion of cardiovascular health and the identification and management of specific risk factors from infancy into young adult life, with an integrated format to address the 14 major risk factors simultaneously.

In practice, pediatric care providers are credible messengers of health information, and the guideline recommendations are intended to accommodate the delivery of health messages to patients and their families by all members of the care team. The Expert Panel identified childhood health maintenance visits as an ideal context for engaging patients to increase awareness, initiate risk-reduction strategies, and promote cardiovascular health. The NHLBI guidelines provide recommendations that are specific to the age and developmental stage of the patient, considering not only the relation of age to disease expression, but also the ability of the patient and family to understand and implement medical advice. Management algorithms provide staged care recommendations for risk reduction within the pediatric care setting and identify risk factor levels that require referral from the primary care setting to a specialist. The guidelines also identify specific medical conditions, including diabetes and chronic kidney disease, associated with increased risk for accelerated atherosclerosis and provide recommendations for ongoing management of children and adolescents with these diagnoses. The report, entitled the *Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents*, is more than 400 pages and it is available as a searchable online version or can be downloaded as a PDF from NHLBI's public website [5]. A guideline summary report was published in a special issue of the journal *Pediatrics* in 2011 [6].

Failure to routinely translate research findings into daily clinical practice is a major barrier for the implementation of any evidence-based guideline and is related to barriers of knowledge, attitudes, and clinical systems [7]. In a seminal review on guideline uptake, Balas [8] suggested that it takes an average of 17 years for 14% of the original research to be integrated into clinical practice. Although methods used to develop evidence-based guidelines have improved [9,10], the widespread application of research findings to improve patient outcomes remains inadequate [7,11,12]. Strategies to improve uptake will need to enhance clinician knowledge and support confidence that guidelines can be implemented (self-efficacy) and integrated into clinical workflow.

The adoption of electronic health records in primary care, as enabled by the Health Information Technology for Economic and Clinical Health (HITECH) Act and the pursuit of satisfying meaningful use objectives, has not inhibited the use of clinical decision support (CDS) tools in practice. Defined by Osheroff et al [13] as "providing clinicians or patients with computer-generated clinical knowledge and patient-related information, intelligently filtered or presented at appropriate times to enhance patient care," these resources may hold the potential to achieve gains in clinical performance, narrow gaps between knowledge and practice, and improve safety [14]. Systematic reviews of CDS systems have demonstrated effectiveness in improving clinician practice and guideline adherence [15]. A comprehensive evaluation of systematic reviews by Jaspers et al [16] found strong evidence that CDS systems improved practitioner performance in this regard.

From the outset, implementation of the *Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents* was expected to pose a variety of challenges that were unique to the composition of the content. These issues include (1) the complexity and integrated nature of risk assessment and management, (2) the volume of information provided in the final report, (3) the establishment of prevention as a clinical priority among a nondiseased target audience, and (4) the delivery of multifaceted recommendations within the time-constrained context of the pediatric primary care setting.

Evidence-based clinical practice guidelines represent substantial effort on the part of their authors and considerable financial support to sustain years-long review and synthesis of scientific evidence. Despite the investment to rigorously develop guidelines, implementation efforts have often been less well supported and often unsuccessful in improving care, and other efforts have reported outright implementation failures [17-20]. This suggests the need for a more rigorous approach to the development of CDS systems for guideline implementation.

Consequently, in this paper we describe the process and outcomes of a project to operationalize the NHLBI guidelines into a mobile CDS system and provide multimedia artifacts associated with each step in the conversion process. The CDS was made available to pediatric primary care providers through an intervention called *Young Hearts, Strong Starts*; the methods and results from a cluster randomized trial of guideline adoption using quality improvement techniques to integrate the CDS into clinical workflows are described elsewhere by LaBresh et al [21,22]. At the time of publication, the CDS app remains publicly available from NHLBI at no cost in iTunes [23].

Methods

Evidence-based clinical practice guidelines are defined by the Institute of Medicine as "systematically developed statements intended to assist practitioner and patient decision-making about appropriate healthcare for specific clinical circumstances" [24]. However, clinical practice guidelines are not routinely written in a format suitable for conversion into a computable form that

can be used by a CDS system, necessitating use of a multilayer framework [20] for incrementally structuring guideline recommendations and converting the evidence synthesis into executable knowledge for implementation. Other layered knowledge representations that have been used in the development of CDS resources include the digital electronic guidelines library framework [25] and the guideline elements model [26]; however, such approaches require the organization of information in an explicit flow of events. Given the asynchronous nature of the ongoing assessment of pediatric cardiovascular health, we selected an alternative framework that emphasized modeling of unsequenced clinical decisions. This approach enabled development of a CDS tool appropriate for a greater variety of point-in-time assessments, rather than forcing a complete physical assessment and data entry in each session. The multilayered framework provides a reproducible approach to the progressive conversion from scientific material to technical artifacts and code base. Each layer (ie, unstructured, semistructured, structured, and executable) serves a different purpose and leverages the expertise of different roles required to implement the CDS. Different roles are involved at each step, including business stakeholders, analysts, architects, and programmers.

We used an iterative approach to the design, testing, and revision of material through each step in the translation to support the development of 4 validated modules: an integrated screener for risk assessment, a body mass index (BMI) calculator, a BP calculator, and a lipid assessment and management instrument. This information architecture was informed initially by the structure of the guideline content and reinforced by stakeholder input on clinical decision making during an initial well-child visit and subsequent follow-up to address specific findings. Our approach is described below in more detail. Multimedia Appendix 1 illustrates the progressive conversion of the evidence-based recommendations for management of overweight and obesity. Semistructured guideline content is included as Multimedia Appendix 2; structured guideline content is included as Multimedia Appendix 3; and executable guideline content for the calculator modules is included as Multimedia Appendix 4.

Unstructured Layer

This layer consists of the narrative and figures of the comprehensive evidence-based guidelines documents published by NHLBI to address the known risk factors for CVD, including family history, age, sex, nutrition and diet, physical inactivity, tobacco exposure, BP, lipids, overweight and obesity, diabetes mellitus, predisposing conditions, metabolic syndrome, inflammatory markers, and perinatal factors. Our initial effort focused on deconstructing the guidelines into a tabular framework of triggers (eg, age, elevated BMI), recommendations, and supportive actions, as organized by known risk factor. We then used the deconstructed guidelines as a roadmap to articulate the business logic to document how a patient's presentation to a clinician would qualify the patient into each known risk factor category. This approach to structuring the guideline content also enabled authoring a series of use cases for potential clinical encounters, beginning with an integrated risk assessment, then progressing to follow-up encounters based on the recommended treatment and follow-up for the mitigation of specific risk factors.

Semistructured Layer

In this layer, we added structure to the guidelines. The core organizing concept for the knowledge is a recommendation that has been triggered by the presence of a specific risk factor. From this layer onward, the emphasis is on processing within the CDS, and the recommendations excluded any statements that were not patient specific. Because domain experts are expected to be the primary authors of knowledge presented in this layer, we engaged the NHLBI Expert Panel Chair responsible for authoring the guidelines to support ongoing review of the conversion. This stage yielded a complete guideline framework in a tabular format, a matrix to illustrate how each variable triggers each recommendation, and a summary narrative of use cases.

Structured Layer

In this layer, the knowledge is specified with sufficient structure so as to make it computable and precise. This knowledge is independent of the implementation in a particular type of CDS tool or of the workflow in a particular clinical setting; however, it serves to formally define all the data elements and logic required to do so. The objective of this layer is to communicate the knowledge in the guidelines to CDS implementers to inform development of executable code. We relied heavily on a collaborative team of clinical informaticists and developers to support the translation of clinical domain requirements for computer implementation.

Executable Layer

In this layer, the knowledge is structured for use within a specific type of CDS system. This knowledge is less likely to be sharable because often it includes elements that apply only to that setting; for example, local codes for data items, details of local clinical services, and idiosyncrasies of how the end user interacts with the system. Our implementation was centered on the Personal Health Intervention Toolkit mobile technical framework that has been described elsewhere [27].

Data Model

Based on the multilayer framework, we created narrative use cases based on models of the clinical decision-making process, in addition to class diagrams in the unified modeling language and equivalent XML schemas, for representing guideline recommendations in the semistructured and the structured recommendation layers. We did not create a knowledge representation model for the unstructured layer because that comprises the free-form published guideline document. Further modeling of the executable layer is of limited utility given the specific implementation context that was used for this project.

Validation

We subjected the CDS tool to rigorous expert review throughout all stages of the conversion process. Once compiled, the app was unit tested and subjected to formal software quality assurance testing of the fully integrated tool. We developed over 400 single-expression test cases to test individual CDS rules. These cases tested the output of a specific

recommendation based on data element inputs defined in the rules. For these tests, values at, below, and above the rule boundary were tested.

We developed over 70 scenarios to exercise the system under realistic conditions and to test data element inputs across multiple domains and thresholds. In addition to tests that verified the correct recommendation, code was generated from each rule and each rule was tested to ensure it resulted in only its specified recommendation output. We tested each numeric value boundary by cases that included the thresholds and one or more values of the unit in whole numbers above or below the threshold. Values were tested in each tool and the integrated assessment regardless of duplication (ie, weight boundary tests were completed for each tool and component).

Results

We used an iterative process of design, testing, and revision through each layer of conversion, resulting in the development of a management instrument and 4 validated modules: an integrated assessment, a BMI calculator, a BP calculator, and a lipid assessment. Formatting content in each successive layer enabled expert review of the variables, triggers, and recommendation copy. On the basis of the layered representations and conversion process, we refined detailed recommendations for ease of presentation on a mobile device and developed logic to eliminate display of duplicative recommendations or supportive actions. In addition, we identified a misalignment of categories used for age-based recommendations and overlap in the NHLBI guidelines for individuals in the infant to 3-year-old and 3- to 11-year-old groups. The results of the formative user-centered design and user experience testing [28], and implementation protocol and results are described elsewhere [21,22].

When the user first enters the app on its home screen, there is the option of entering 1 of the 4 modules noted above (see Figure 1). Along the bottom of the screen, the user also has the option to toggle between 4 screens: the home screen; a recommendations screen (based on the data entered from each of the modules); a guidelines screen (with data entry instructions; a link to the guidelines website; copyright, disclaimer, and terms of use; and contact information to provide feedback on the app); and a “trashcan” screen that offers the option to clear the current patient’s data. Below we describe the features of each of the 4 modules.

Figure 1. Pediatric cardiovascular (CV) risk-reduction clinical decision support app home screen and modules. BP: blood pressure; CVD: cardiovascular disease; FHx: family history; HDL: high-density lipoprotein; LDL: low-density lipoprotein; NIH: National Institutes of Health.

Integrated Risk Assessment Screener

This module incorporates assessments of BMI, BP, and other risk factors, and then provides users with a patient summary and US National Institutes of Health (NIH) recommendations based on the patient’s risk factor information.

Body Mass Index

First, the user is asked to enter the patient’s date of birth, and the app automatically calculates the age. Then the user enters the patient’s sex, height, and weight, and the app automatically computes the BMI and the corresponding BMI-for-age percentile based on the US Centers for Disease Control and Prevention’s BMI-for-age growth chart [29] and indicates if the patient is overweight or obese. Finally, the user is asked to categorize the change in BMI as stable, improvement, increase, excessive increase, no improvement, or unknown.

Blood Pressure

The user is asked to enter the patient’s systolic and diastolic BP, and if the user hits a designated button, the app calculates the BP percentile based on the NHLBI’s BP tables for children and adolescents [30].

Other Risk Factors

The user is then asked to indicate whether the patient has any of the following conditions: hypertension, dyslipidemia, type 1 diabetes mellitus, type 2 diabetes mellitus, none of these, or unknown. If so, the user is asked to categorize the change in each of the condition as improving, not improving, or unknown. Then the user is asked whether the patient has any other high

or moderate risk conditions, with response options of yes, no, or unknown. “Risk conditions” is underlined and shown in a different color, a technique commonly used on the Internet to indicate that the user can click on a link to get the definition. The user is then asked to categorize the patient’s physical activity level as sedentary, moderate to vigorous, vigorous, or unknown, and whether this is a decrease in physical activity level (response options: no, yes, or unknown). The user is then asked whether the patient currently smokes (yes, no, or unknown) and whether the patient has a smoke-free home (yes, no, or unknown). Then the user is asked about parental risk factors; namely, whether either parent is obese (yes, no, or unknown), whether either parent has dyslipidemia (yes, no, or unknown), the mother’s total cholesterol (or unknown), and the father’s total cholesterol (or unknown). Finally, the user is asked whether the patient has a positive family history of CVD (yes, no, or unknown). “Positive family history of CVD” is underlined and displayed in a different color indicating that the user can click on this link to get the definition.

When a user indicates that data entry is complete, the app automatically moves to the recommendations screen showing a patient summary of the data entered. Then, based on the patient’s risk factors, the user is shown the relevant NIH recommendations, including the evidence grade (A-F), related to family history, nutrition and diet, physical activity, tobacco exposure, lipids, and overweight and obesity, as well as supportive actions to take or more information, in some instances.

Body Mass Index Calculator

If the user has already entered information in the integrated assessment screener, then the app displays the relevant previously entered data in this module. The user simply needs to click on the Calculate BMI button to see the BMI, BMI-for-age percentile, and indication of whether the patient is overweight or obese. When a user indicates that data entry is complete, as with the integrated assessment screener, the app automatically presents the recommendations screen showing a patient summary of the data entered and the relevant NIH recommendations.

In some instances, the user may only be interested in using the BMI calculator. If so, the user is asked to enter the same information described above under the BMI portion of the integrated assessment screener (ie, patient’s date of birth, sex, height, and weight) to obtain the BMI information, a patient summary of the data entered, and the recommendations.

Blood Pressure Calculator

As with the BMI calculator, if the user has already entered BP information in the integrated assessment screener, then the app will display the previously entered data in this module. In instances where the user is only interested in using the BP calculator, they are asked to enter the same information described above under the BP portion of the integrated assessment screener (ie, patient’s systolic and diastolic BP). All users are then asked to enter additional BP data in this module: how the BP was measured at this visit (with response options of auscultation, oscillometry, or unknown) and up to 3 BP readings. Then the user clicks on a designated button and the app calculates the average systolic and diastolic BP values, as well as the systolic and diastolic BP percentiles. As with the other modules, when a user indicates that data entry is complete, the app automatically moves to the recommendations screen showing a patient summary of the data entered and the relevant recommendations.

Lipid Assessment

As with the BMI and BP calculators, if the user has already entered information in other modules, then the app will display the relevant previously entered data in this module (ie, patient’s date of birth, sex, height, and weight). In instances where the user is only interested in using the lipid assessment, they are asked to enter this information. Then the user simply needs to click on the Calculate BMI button to see the BMI, BMI-for-age percentile, and indication of whether the patient is overweight or obese. All users are then asked to enter the type of sample that was drawn (with response options of fasting, nonfasting, or unknown). As with the other modules, when a user indicates that data entry is complete, the app automatically moves to the recommendations screen showing a patient summary of the data entered and the recommendations.

Discussion

Principal Findings

The NHLBI integrated guideline is long and extremely complex as a result of the desire to put all relevant cardiovascular risk-reduction recommendations in a single document. Because we know that guideline complexity is a barrier to guideline use [7], the CDS tool provided a means to integrate a large amount of information and recommended processes into a single handheld app. Our app was built for mobile devices to allow for greater uptake and ease of use. Much has been written about the complexity of electronic medical records that in some cases detract from clinician-patient interactions [31]. This CDS tool was not designed to support documentation of the patient encounter, but rather to enable precise, contextualized information retrieval from the NHLBI integrated guideline to the clinician during a well-child or follow-up visit. During the clinical implementation phase, the mobile version was considered far less obtrusive and was available for use by any clinician or staff member with a mobile phone or tablet, thus enhancing clinician uptake [21,22].

Cabana et al [7] noted that guideline uptake is primarily limited by 3 factors: knowledge, attitudes, and behavior (systems). The CDS tool addresses knowledge by providing brief, relevant information based on the risk factors present in the patient being seen and consequently provides only the relevant knowledge needed at the point in the care process when risk is being assessed and recommendations are being made. In the cluster randomized trial [21,22], risk such as elevated BP could be assessed by the medical assistant using the tool without the need to consult multiple tables to determine BP percentiles, which would speed up the process and allow physicians and nurse practitioners to delegate the responsibility to staff early in the process. This allows the clinician to focus on counseling the patient and their family to adopt healthy lifestyle changes. The

result was an increase in the percentage of patients for whom BP percentile was determined from 0.2% at baseline to 61.3% at 1 year after implementation, with no change in the control group, who did not have the CDS tool. Consequently, the CDS resulted in increased practice efficiency, with medical assistants performing important clinical assessments with the CDS, and allowing more time for clinicians to help patients and their families address needed lifestyle changes or, in some patients, the use of medications.

Conclusion

To overcome the challenges of translating clinical practice guidelines into a computable form for use in a CDS clinical system, we used a multilayer framework to convert the evidence synthesis into executable knowledge. We used an iterative process of design, testing, and revision through each step in the translation of the guidelines for use in a CDS tool to support the development of 4 validated modules: an integrated risk assessment; a BMI calculator; a BP calculator; and a lipid management instrument. The process and experiences described here provide a model for other mobile CDS systems that translate written clinical practice guidelines into actionable, real-time clinical recommendations.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Progressive conversion of the evidence-based recommendations for management of overweight and obesity.

[PPTX File, 388KB - mhealth_v5i3e29_app1.pptx]

Multimedia Appendix 2

Semistructured guideline content.

[PDF File (Adobe PDF File), 121KB - mhealth_v5i3e29_app2.pdf]

Multimedia Appendix 3

Structured guideline content.

[XLS File (Microsoft Excel File), 172KB - mhealth_v5i3e29_app3.xls]

Multimedia Appendix 4

Executable guideline content.

[XML File, 28KB - mhealth_v5i3e29_app4.xml]

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Abbreviations

BMI: body mass index
BP: blood pressure
CDS: clinical decision support
CVD: cardiovascular disease
HITECH: Health Information Technology for Economic and Clinical Health
NHLBI: National Heart, Lung, and Blood Institute
NIH: National Institutes of Health

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Original Paper

Feasibility and Acceptability of a Wearable Technology Physical Activity Intervention With Telephone Counseling for Mid-Aged and Older Adults: A Randomized Controlled Pilot Trial

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Abstract

Background: As adults age, their physical activity decreases and sedentary behavior increases, leading to increased risk of negative health outcomes. Wearable electronic activity monitors have shown promise for delivering effective behavior change techniques. However, little is known about the feasibility and acceptability of non-Fitbit wearables (Fitbit, Inc, San Francisco, California) combined with telephone counseling among adults aged more than 55 years.

Objective: The purpose of our study was to determine the feasibility, acceptability, and effect on physical activity of an intervention combining a wearable physical activity monitor, tablet device, and telephone counseling among adults aged 55-79 years.

Methods: Adults (N=40, aged 55-79 years, body mass index=25-35, <60 min of activity per week) were randomized to receive a 12-week intervention or to a wait list control. Intervention participants received a Jawbone Up24 monitor, a tablet with the Jawbone Up app installed, and brief weekly telephone counseling. Participants set daily and weekly step goals and used the monitor's idle alert to notify them when they were sedentary for more than 1 h. Interventionists provided brief counseling once per week by telephone. Feasibility was measured using observation and study records, and acceptability was measured by self-report using validated items. Physical activity and sedentary time were measured using ActivPAL monitors following standard protocols. Body composition was measured using dual-energy x-ray absorptiometry scans, and fitness was measured using a 6-min walk test.

Results: Participants were 61.48 years old (SD 5.60), 85% (34/40) female, 65% (26/40) white. Average activity monitor wear time was 81.85 (SD 3.73) of 90 days. Of the 20 Up24 monitors, 5 were reported broken and 1 lost. No related adverse events were reported. Acceptability items were rated at least 4 on a scale of 1-5. Effect sizes for most outcomes were small, including stepping time per day (d=0.35), steps per day (d=0.26), sitting time per day (d=0.21), body fat (d=0.17), and weight (d=0.33).

Conclusions: The intervention was feasible and acceptable in this population. Effect sizes were similar to the sizes found using other wearable electronic activity monitors, indicating that when combined with telephone counseling, wearable activity monitors are a potentially effective tool for increasing physical activity and decreasing sedentary behavior.

Trial registration: Clinicaltrials.gov NCT01869348; https://clinicaltrials.gov/ct2/show/NCT01869348 (Archived by WebCite at http://www.webcitation.org/6odlIolqy)

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KEYWORDS

physical activity; technology; mobile health; health behavior; self-control

Introduction

Background

Increasing physical activity and decreasing sedentary behavior can reduce the risk of many negative health outcomes among older adults, including cardiovascular diseases, Type II diabetes, cancer, and all-cause mortality [1-4]. The effects of moderate-vigorous intensity physical activity and sedentary behavior on these outcomes appear to be independent [5,6]; thus, older adults could benefit from interventions targeting both behaviors simultaneously. Unfortunately, rates of physical activity are low in this population. Recent estimates from objective monitoring suggest that most American adults spend less than 2% of their time in moderate-vigorous intensity physical activity [7]. Moderate-vigorous intensity activity decreases with age [8]; improving activity habits among mid-aged and older adults could prevent later functional decline and even mortality [9,10]. In addition, sedentary behavior is highly prevalent, amounting to most of adults' waking hours [11]. Although interventions have demonstrated positive effects on both behaviors, these methods suffer from limitations related to poor sustainability and poor scalability [12]. There is a clear need for interventions that are effective in the long term as well as the ones that are easy to disseminate.

Wearable electronic activity monitors are advanced versions of pedometers that are able to offer more behavior change techniques and implement them in different ways as compared with standard displays on the device itself [13]. Because these devices send information to a mobile app, they are able to offer feedback that better conforms to theoretical recommendations (eg, specific, clear, and comparing with similar others; past accomplishments; and specific goals) [14,15]. They also deliver many additional behavior change techniques that are not possible with standard pedometers, such as goal setting, social support, and cues to action. Cues to action are likely particularly important for replacing sedentary behavior with physical activity, as they alert participants to their sedentary behavior in real time. Traditionally, delivery of these behavior change techniques would require either in-person counseling or frequent (and thus expensive) tailored print materials. Delivery via mobile app offers an opportunity for interventions both effective and with broad reach.

These improvements on pedometers show promise, but wearable electronic monitors and their companion mobile apps still lack several important behavior change techniques. In particular, empirically proven techniques such as action planning and problem solving are typically absent from these apps [15]. Adding brief counseling to provision of these devices could allow interventionists to deliver the full range of behavior change techniques standard in behavior physical activity interventions. The counseling should provide any techniques missing from the apps, while the apps allow for improved implementation of other fundamental techniques.

Studies of wearable electronic devices and mobile apps published thus far have found equivocal physical activity outcomes, though their use of Fitbit and Bodymedia products may not generalize to other self-monitoring systems [13,16,17]. It is also possible that these devices may not be feasible or acceptable to older adult populations [18], who are in unique need of more effective activity interventions. Feasibility and acceptability of mobile phone–based intervention among adults aged more than 55 years is not yet clear. Some studies have found low acceptability and preference for other media [18] as well as increased barriers to mobile phone use with increasing age [19]. Older adults have also reported the feeling that iPads were designed for younger audiences than for their age group [20]. However, some studies have found positive feasibility and acceptability results for smart device health interventions in this age group [21,22]. Short-term tests indicate that activity monitors may be acceptable to mid-aged and older adults [23], but the feasibility and acceptability of longer-term usage is unclear. Of the few published studies of wearable electronic activity monitors, even fewer have described in detail feasibility and acceptability results [24].

Objective

The purpose of this study was to investigate the feasibility and acceptability of an intervention including the Jawbone Up system and telephone counseling. To our knowledge, this system is yet to be tested in intervention trials. In a content analysis of available wearables and their apps, the Up system included the most behavior change techniques and implemented them very closely to theoretical recommendations [15]. In addition to providing a wearable device and mobile app, we also provided brief weekly telephone counseling that was adapted to include behavior change techniques known to be important in physical activity research that were absent from the Up system [15,25-27]. We hypothesized that the intervention would be feasible and acceptable for this population. To operationalize these outcomes, we specifically measured days the monitor was worn and self-reported acceptability items taken from similar eHealth studies.

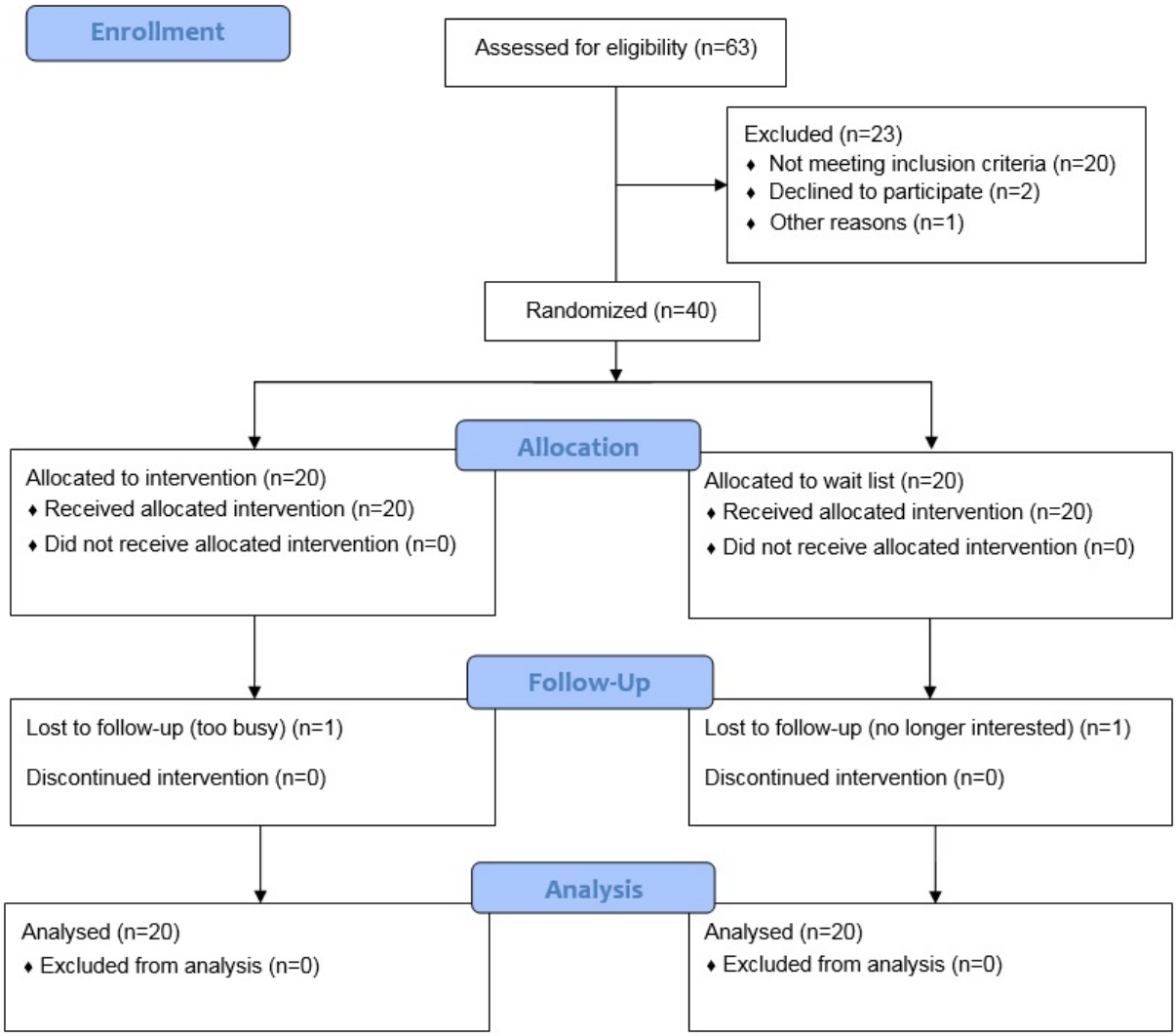
Methods

Recruitment

Figure 1 shows the CONSORT diagram for the study. This trial was a parallel randomized controlled pilot trial with 1:1 group allocation. Participants (N=40) were recruited in 2 cohorts of 20 between 2014 and 2015 via advertisements in local newspapers, online mailing lists, and university announcements. Cohort 1 was recruited over 6 months in 2014, and cohort 2 was recruited over 8 months in 2015. Major inclusion criteria were ages between 55 and 79 years, body mass index (BMI) between 25 and 35, the ability to read and understand English, and the ability to read words on a tablet-sized device. Major exclusion criteria included self-reported habitual physical

activity more than 60 min per week, health issues that might preclude safe walking, psychological issues that might interfere with full participation, current use of a wearable electronic activity monitoring system, and endorsing cardiovascular risk questions on the Physical Activity Readiness Questionnaire [28]. If the only questions endorsed had to do with taking medication, individuals could participate if they provided a doctor's consent. Randomization was conducted using standard opaque envelopes with foil (to prevent seeing the group assignment inside the envelope) and carbon paper (to provide an audit trail). The envelopes were randomly sorted by an individual not involved with the randomization visit process, then numbered sequentially. As interventionists opened each envelope, they signed and dated each envelope and saved the inner paper with original printed allocation and carbon-copied sequence number, ID number of the participant, signature of interventionist, and date of opening. Randomization was carried out using sequentially numbered opaque sealed envelopes according to standard protocols [29], with randomization stratified by the 2 cohorts to promote adequate numbers of participants able to talk to one another through the app.

Figure 1. CONSORT diagram.



Procedure

Participants attended 4 scheduled visits. The first consisted of informed consent procedures and provision of a research-grade activity monitor. Participants were provided information on the intervention procedures and nature of the wearable and app prior to providing informed consent. Approximately a week later, participants returned for a full baseline assessment and orientation to the study. A midpoint assessment occurred at 6 weeks (questionnaire and physical activity assessment only), and a full final assessment occurred at 12 weeks. Participants could not be blinded to their group. Unfortunately, resource limitations precluded using blinded assessors for all participants. All procedures were approved by the University of Texas Medical Branch Institutional Review Board and registered at clinicaltrials.gov prior to beginning data collection. Figure 1 shows the flow of participants through the trial using a CONSORT diagram.

Intervention

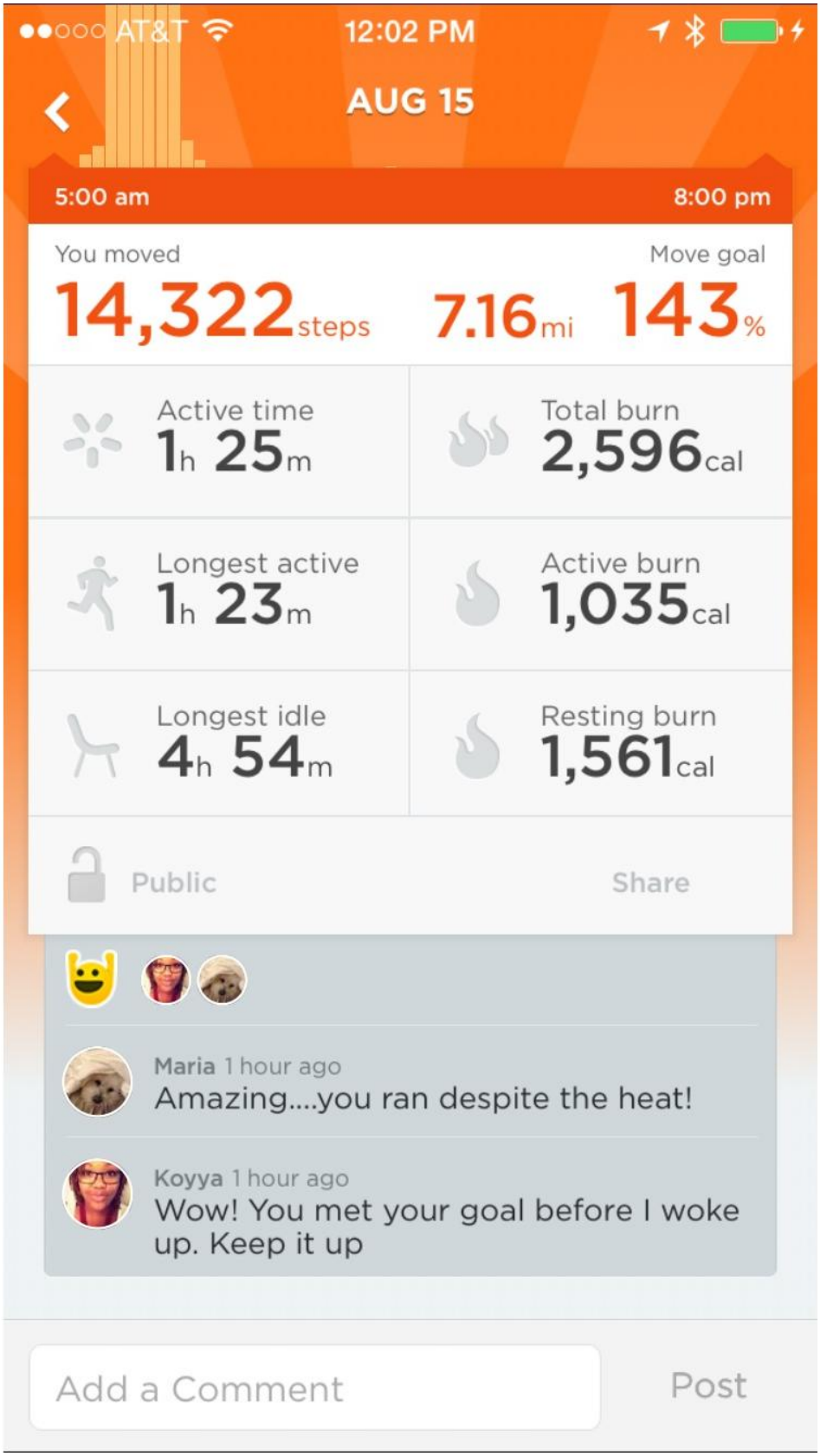
The participants randomized to the intervention group were lent a mini tablet mobile device (Apple iPad Mini, Apple Inc, Cupertino, CA) and a wearable electronic activity monitor (Up24, Jawbone Inc, San Francisco, CA) for home use during the study. The tablet was preloaded with the Jawbone Up app and synced to an Up24 for each participant. Figure 2 shows an example of activity feedback and social support in the Up app. Please note that this example used data and social interaction from researchers in the study, not from the study participants. Detailed information on the contents of the app, including behavior change techniques and adherence to theory-based recommendations, are available in a previous publication [15]. All the participants were provided with premade accounts that existed on a "team" with all other participants as well as an account for interventionist surveillance. The orientation visit included guidance on the use of the wearable and app, encouragement to comment and like others' activity, and an initial goal-setting session. Interventionists encouraged participants to view their data at least twice per day, in the morning and late afternoon or evening. Participants set goals for physical activity (short- and long-term) and sedentary behavior (longest bout length). Interventionists provided training for self-monitoring, viewing feedback, and using sedentary behavior prompts in the app. Although some changes in the appearance of the app and tools provided in the app occurred during the overall study period, no substantive changes to the physical activity feedback content occurred. We were unable to determine whether individual participants updated their apps during their intervention periods, but updates should not have affected the overall experience.

Weekly telephone counseling was provided by a team led by the principal investigator and a postdoctoral fellow with extensive training in behavioral counseling. The team included a predoctoral fellow and a clinical research coordinator who were trained by the principal investigator and the postdoctoral fellow. Initial calls by team members were observed by the principal investigator and postdoctoral fellow and feedback was provided to maintain quality. In addition, team members followed a scripted counseling guide. Counseling calls were designed to last approximately 15-20 min each. Each counseling call included a check-in for any adverse events or technical problems, reevaluation of weekly step goals, and action planning for the next week. Goals were negotiated between the counselors and individuals, with counselors suggesting at least 7000 steps per day (based on step counts found to be appropriate for very deconditioned older adults, as we determined with baseline fitness tests) [30] on 2 days per week, increasing over time to at least five days per week. Sedentary bout goals were also negotiated, with 1 h being the number suggested and typically agreed to by participants. These goals were entered into the app so that progress bars would measure progress toward the specific goals. Idle alerts used the sedentary bout goals to determine when to vibrate to alert participants that they had been sedentary too long.

Weekly special topics delivered additional behavior change techniques from the CALO-RE framework [31] that are as follows: planning social support, problem-solving, self-rewards, when and where to perform the behavior, relapse prevention, stress management, and time management. The app provided other behavior change techniques, listed in the Multimedia Appendix 1 (see Lyons et al [15] for more complete descriptions; only behavior change techniques related to physical activity are listed here). Because the SmartCoach portion of the app adjusted the content based on the user behavior, we cannot state with certainty which behavior change techniques were delivered to each participant by the app. Some participants may not have triggered delivery of every possible behavior change technique. Interventionists based their counseling on the data taken from the app over the last week to negotiate changing goals.

The wait-list control group did not receive any intervention until after their final assessment, when they were provided the intervention in full.

Figure 2. Screenshot of the Jawbone Up app.



Measures

Physical activity was measured using an ActivPAL device (PAL Technologies Ltd, Glasgow, Scotland). This small, thin device was attached to the front of each participant's thigh, midway between the knee and the trunk, using an adhesive strip. The ActivPAL is well-validated for use in measuring physical activity as well as sedentary behavior [32,33]. Participants wore the devices for a period of 7 days at each assessment period (baseline, 6 weeks, 12 weeks). No specific criteria have been

published for determining wear time and usable data for these monitors. Following the procedures of Bickmore et al [34], we removed daily activity values less than the 5th percentile (0.00 stepping minutes), as we considered it possibly representative of non-wear time (eg, time spent being mailed back and forth to participants, time being carried rather than worn). Physical activity was operationalized as mean minutes of physical activity per day, mean minutes spent sitting per day, and mean steps per day across all valid days per assessment.

Feasibility was measured in several ways. Use of the monitor was measured first by abstracting information weekly from the app. Because the interventionist account was a friend of each participant account, their daily data were posted to our news feed. We confirmed these data at the conclusion of the study using downloadable comma separated value files from the Jawbone website. These files provided extensive information as to different parts of the app that were used each day. Days in which activity, food, and sleep were logged were taken from these files. Attrition, adverse events, completed counseling calls, and reports of technical problems or loss of equipment were taken from the study records kept by interventionists (phone counseling logs) and the clinical research coordinator (records from emails and phone calls from participants). Acceptability of the monitor, app, and tablet were measured using items adapted from Vandelanotte et al [35,36]. Several additional items specific to the monitor and apps were included (eg, "I would continue using the idle alert"). These items used the same stems and responses as the ones adapted from previous research. All responses were made on a Likert-type scale from 1 (strongly disagree) to 5 (strongly agree). We also used a measure of perceived competence from the Intrinsic Motivation Inventory, with its items adapted to discuss competence using the tablet [37].

Fitness was estimated using a 6-min walk test [38]. Participants were asked to walk for 6 min in a rectangular route marked with cones, with a trained assessor tracking the time and laps completed. Once the activity was performed, participants waited where they stopped, while the assessor measured their distance from the closest cone. Distance walked in 6 min was measured in terms of feet.

Percent body fat was estimated using Dual x-ray Absorptiometry (GE Lunar iDXA, GE Medical Systems Lunar, Madison, WI) at baseline and 12 weeks. Height and weight were measured using a stadiometer and calibrated scale. Sociodemographics were recorded at the baseline and included age, gender, race, and ethnicity.

Weekly telephone counseling logs were completed by counselors to indicate whether counseling calls were completed or missed. Counselors attempted to contact participants a maximum of 5 times, if a counseling call was missed at the scheduled time.

All self-report measures were taken in-person using paper questionnaires. Several indicators of feasibility were measured using data from the mobile app, but all other assessments occurred face-to-face.

Data Analysis

Data were analyzed using the R system version 3.3.1 (R Foundation for Statistical Computing, Vienna, Austria) [39]. Differences at baseline were investigated using Student's *t* tests and chi-square tests. Differences between groups were estimated using analyses of covariance (ANCOVA), controlling for baseline values of the dependent variable. Box-Cox transformations were used to improve the validity of the inference. All the analyses used the intent-to-treat principle, bringing the last observation forward for the ones who dropped out. Multiple imputations were not used due to findings that data were not missing at random. An analysis of only study completers was also conducted for comparison purposes. In an attempt to account for potential clustering of effects due to social networking, we also ran models that included a random effect of cohort. Effect sizes presented are in the form of Cohen d.

As this was a pilot test intended to investigate feasibility, this study was not powered to detect a statistically significant difference in the primary outcome. Rather, the purpose of statistical tests was to provide estimated effect sizes that could inform decision making regarding development of a follow-up, fully powered intervention trial.

Results

As shown in Table 1, Participants (N=40) were 61.5 (SD 5.6) years old with a BMI of 30.3 (SD 3.5). They were mostly female (34/40, 85%) and white (26/40, 65%). No related adverse events were reported. In the intervention group, 1 participant dropped out as compared with 1 in the wait list control. Participants in the intervention group completed a mean of 10.2 (SD 2.4) of 12 counseling calls. Participants wore their Up24 monitors on average 81.85 (SD 3.73) of 90 days, with a minimum of 69 days. Although the intervention did not instruct usage of nonactivity portions of the app, participants also spontaneously tracked their sleep (Mean 11.70, SD 11.97 days) and food intake (Mean 2.65, SD 7.83 days). Figure 3 shows changes to wear of the monitor from week to week as mean and standard deviation (lower bar).

Table 1. Participant characteristics.

Characteristics	Intervention (n=20)	Wait list (n=20)	Total (N=40)
Age, Mean (SD)	61.25 (5.00)	61.70 (6.26)	61.48 (5.60)
Weight, Mean (SD)	82.58 (11.96)	82.14 (9.82)	82.36 (10.81)
BMI[a], Mean (SD)	30.00 (2.86)	30.68 (4.01)	30.34 (3.45)
Female, n (%)	17 (85)	17 (85)	34 (85)
White, n (%)	13 (65)	13 (65)	26 (65)
Black, n (%)	3 (15)	2 (10)	5 (13)
Other race, n (%)	2 (10)	4 (20)	6 (15)
Hispanic ethnicity, n (%)	6 (30)	5 (25)	11 (28)
College degree, n (%)	13 (65)	14 (70)	27 (68)

[a]BMI: body mass index.

During the study period, 5 Jawbone Up24 monitors were reported broken by participants and were replaced. One additional monitor was lost and replaced. No tablets were lost, and all technical problems with them were resolved without the need for replacement. Responses to acceptability questions are shown in Table 2**,** broken down to show responses by participants under the age of 60 years as compared with the participants 60 years or older. All but one of the questions (including reverse-coding the negatively worded question) received a mean rating over 4 of 5 across both age groups, with only one receiving a 3.9 for the participants ages 60 or above ("would you continue to wear the monitor?"). Usage and step data were successfully retrieved weekly from the Up app by research assistants. Because the interventionist account was a "friend" of each participant, participants' information and discussions were displayed on the interventionist account news feed.

Table 2. Acceptability of monitor, tablet, and app.

Item	Mean scores of the participants <60, n=9, mean (SD)	Mean scores of the participants >60, n=10, mean (SD)	Mean scores of all the participants, n=19, mean (SD)
Comfort using the monitor	4.78 (0.67)	4.60 (0.52)	4.68 (0.58)
Would continue to wear the monitor	4.56 (1.33)	3.90 (1.29)	4.21 (1.32)
Comfort using the tablet	5.00 (0.00)	4.30 (1.34)	4.63 (1.01)
Tablet was user-friendly	5.00 (0.00)	4.70 (0.68)	4.84 (0.50)
Felt confident using tablet	4.44 (0.73)	4.00 (1.70)	4.21 (1.32)
Convenient to use app	4.89 (0.33)	4.60 (0.70)	4.74 (0.56)
Would like to continue to use the app	4.67(1.00)	4.40 (0.70)	4.53 (0.84)
App was user-friendly	4.89 (0.33)	4.50 (0.71)	4.68 (0.58)
Would rather use a pedometer	1.00 (0.00)	1.10 (0.32)	1.05 (0.23)
Idle alert was useful	4.56 (0.73)	4.10 (1.45)	4.32 (1.16)
Would continue using idle alert	4.33 (1.12)	4.60 (0.84)	4.47 (0.96)
Step goal was useful	5.00 (0.00)	4.90 (0.32)	4.95 (0.23)
Would continue using step goal	4.89 (0.33)	4.80 (0.63)	4.84 (0.50)
Information was credible	4.78 (0.44)	4.50 (1.08)	4.63 (0.83)
Information was relevant	4.67 (0.71)	4.60 (0.52)	4.63 (0.60)
Tips and advice were specific to me	4.33 (1.00)	4.40 (1.08)	4.37 (1.01)
Perceived competence using tablet	6.80 (0.31)	6.07 (1.53)	6.41 (1.16)

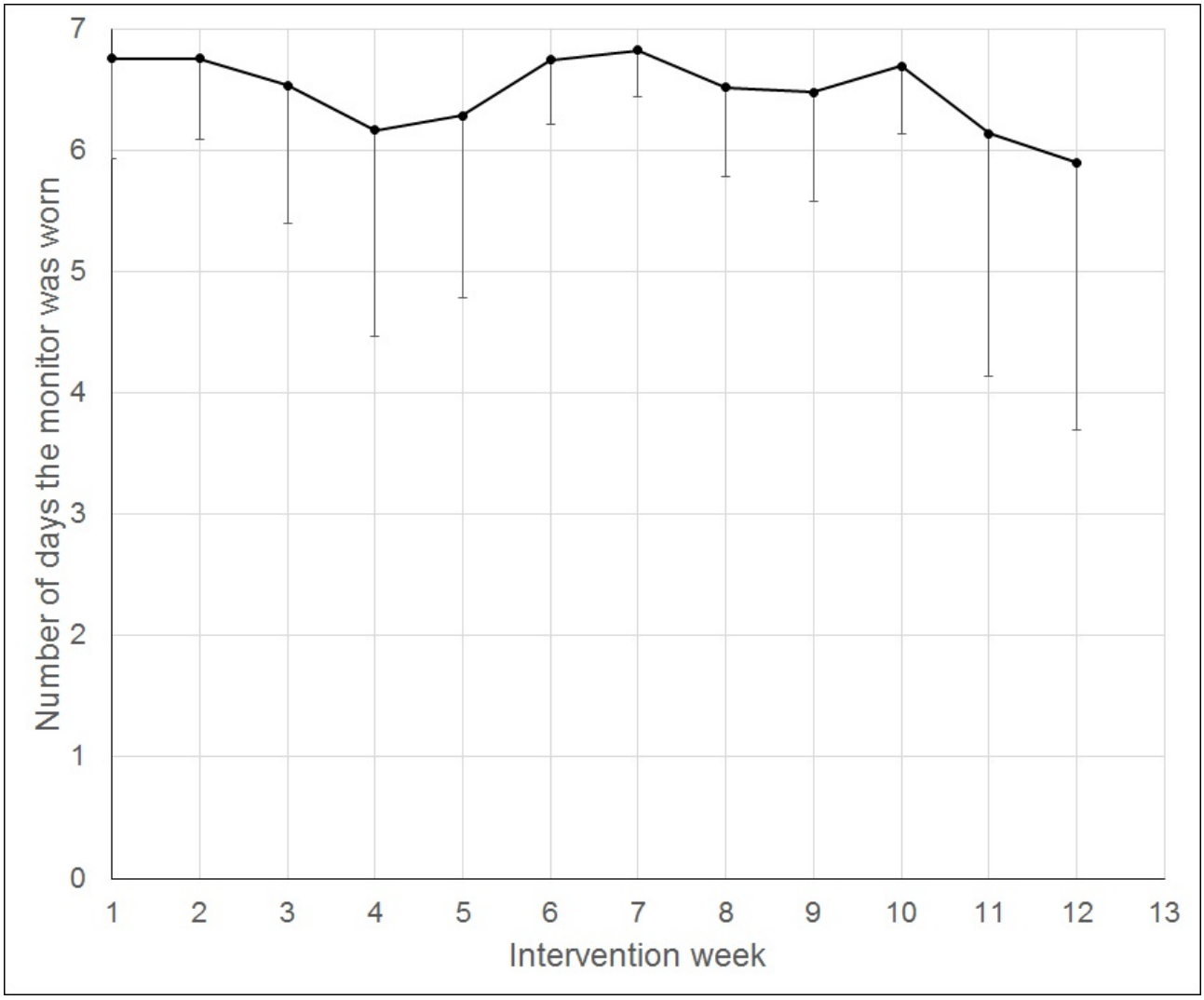
Physical activity, body composition, and anthropometric results for both groups from ANCOVA models are shown in Table 3. Analyses conducted with only the study completers with complete data did not produce substantially different results (eg, effect sizes based on only complete data were 0.40 for minutes and 0.31 for steps as compared with 0.35 and 0.26,

respectively, in the intent-to-treat analysis). Therefore, we have presented the results from the intent-to-treat analysis. When we added a random effect for cohort to these models to account for potential effects of social interaction within cohorts, results did not change meaningfully. Intraclass correlation coefficients ranged from 0 (minutes sedentary, body fat) to 0.10 (weight).

Table 3. Physiological effects of the intervention at 12 weeks.

Outcome	Intervention		Wait list		Effect size d (95% CI)
	Baseline	12 weeks	Baseline	12 weeks	
Stepping time per day (min), mean (SD)	66.33 (23.78)	117.69 (121.37)	60.27 (25.55)	58.08 (33.03)	0.35 (0.02 to 0.68)
Steps per day, mean (SD)	5103.29 (1929.64)	6193.75 (3183.50)	4627.63 (1930.76)	4586.79 (2476.06)	0.26 (−0.07 to 0.59)
Sitting time per day, mean (SD)	1132.04 (127.19)	1088.92 (175.56)	1142.29 (129.93)	1149.44 (147.69)	−0.21 (−0.54 to 0.12)
Body fat, mean (SD)	44.98 (5.28)	44.73 (5.73)	45.17 (5.39)	45.38 (6.06)	−0.17 (−0.50 to 0.17)
Weight (kg), mean (SD)	82.58 (11.96)	81.72 (11.71)	82.14 (9.82)	82.85 (9.77)	−0.33 (−0.67 to 0.00)
Fitness (feet), mean (SD)	1742.92 (217.61)	1729.49 (296.54)	1627.39 (265.20)	1661.16 (267.57)	−0.05 (−0.39 to 0.29)

Figure 3. Changes in wear of the Up24 monitor by week (mean, SD).



Discussion

Principal Findings

This physical activity and sedentary behavior intervention using an electronic activity monitor system with phone counseling was found to be feasible and acceptable in a sample of older adults. The study was also found to produce significant but small changes in total physical activity time and weight favoring the intervention group. Statistical differences between groups were not interpretable due to the underpowered nature of this trial. Effect sizes (0.35 for minutes, 0.26 for steps, 0.21 for sedentary time) suggest that a larger-scale implementation of the intervention will likely produce small but potentially clinically significant improvements in physical activity time and steps taken.

The findings of this study are very similar to the findings of a pilot study of postmenopausal women using a Fitbit system, who increased their steps from approximately 5900 at baseline to 6700 at 16 weeks [16]. Comparing Fitbit One and a brief counseling with a pedometer group, Cadmus-Bertran et al found an effect size of approximately 0.24 for steps, whereas our comparison with a wait-list control produced an effect size about approximately 0.26 (from approximately 5100 to 6200 steps, as compared with approximately 4600 steps at both time points in the control group). Another study that compared Fitbit One with texting with Fitbit One without texting found no significant difference between groups and no increase in steps compared with baseline in either group [40]. A preexperimental study of Fitbit provision among adults more than 60 years of age also found a very similar increase of approximately 1100 steps over 12 weeks [41]. A large-scale study of weight loss that compared a standard behavioral weight loss intervention with and without the use of a BodyMedia wearable monitor found no difference between the 2 on physical activity [17]. The BodyMedia monitor was substantially different from Fitbit and Jawbone in terms of behavior change techniques available in the app [15], which may partially explain this different result. Taken together, these results suggest that wearable electronic activity monitors with sophisticated feedback apps and supplemental guidance can indeed produce a clinically significant increase in physical activity.

Nearly half of our sample (18/40, 45%) self-reported as black, Hispanic, or other race, groups that are at increased risk of inactivity and related negative health outcomes. More than half of the sample (22/40, 55%) were aged above 60 years, with 10 (25%) above 65 years. Baseline fitness estimates also indicated that many of the participants were quite deconditioned. In all, this sample represents a population in critical need of novel and effective interventions to increase physical activity. Ample epidemiological evidence suggests that even small increases in physical activity among sedentary older adults can produce large health improvements [3,42]. Although a standard physical activity intervention might be expected to produce an increase of 1000-2000 steps [12], these interventions are typically much more intensive than the one tested here and thus likely more difficult to disseminate.

Feasibility and acceptability findings showed that participants overall were compliant and reported enjoying the intervention. Based on our findings for broken and lost monitors, researchers may need to purchase extra monitors for any long-term planned implementation. This study required purchase of 6 additional monitors on top of the original 20, which was more than expected. Acceptability findings were high for all components of the intervention, including for participants aged above 60 years. Despite technical issues such as broken monitors (not syncing, not powering on, buttons falling off), participants reported that the monitor, tablet, and app were user-friendly. No participant stated that they would rather use a simple pedometer instead of the provided wearable electronic activity monitor.

These results also raise many questions for future research. The extent to which apps with wearable devices cause increases in physical activity, as compared with telephone counseling or the two in combination, is not clear. We specifically designed brief counseling to address behavior change techniques absent from the app; a study of the Jawbone monitor in isolation may find different results. In addition, we arranged for participant accounts to be “friend”ed with other participants in their cohort to allow for anonymous “likes” and comments. Social interactions, either with participants or with family or friends, could be a powerful tool for increasing the efficacy of these devices.

Limitations

The rigor of this study was limited by several aspects of its study design and by its nature as a small project conducted with very limited financial resources. As a pilot study, it was not fully powered to detect statistically significant differences in its outcomes or long-term behavior maintenance. We also cannot determine feasibility, acceptability, or effects of individual portions of the intervention such as the monitor only or telephone counseling only. Comparing with a wait-list control also limits our ability to interpret feasibility or acceptability as compared with other interventions such as pedometers. Although the effect sizes may be useful for assistance in powering future studies that use wearable electronic activity monitors, we do not report *P* values. A related limitation lies in our study design and analytic plan. We did not anticipate the importance of socializing within the app during our planning process and did not plan for clustering. Because of resource limitations, we were unable to ensure that all participants had equal access to socialization at the same time (ie, some participants had fewer people to talk to in the app for periods of time). We attempted to account for socialization by adding a random effect for cohort into our models, but even that technique cannot truly account for the potential effects of different social opportunities when cohorts do not spend equal time with each other in the app. Future follow-up studies that use the full potential of these apps, which includes online social networking, will need to plan for clustering in their recruitment schedule and analytic plans.

An issue with all studies that use commercially available technology is sustainability. The Jawbone company is no longer manufacturing activity monitors, and it is not clear what the future holds for the Up app. Although other, similar wearables

and apps exist, the number of behavior change techniques and the quality of their implementation differ [15]. In particular, social interaction is implemented quite differently in competitor's products, which could affect future studies' results.

A possible limitation has to do with the ActivPAL research-grade physical activity measurement devices. Comparisons with other physical activity studies in terms of physical activity time are difficult due to differences in how this outcome is estimated. ActivPAL's minute estimates are for any physical activity, not only moderate to vigorous intensity activity. Because our focus here is on replacing sedentary time with any kind of activity, we felt this was the appropriate outcome. However, because many other studies use Actigraphs to measure moderate-vigorous intensity activity as their primary outcome, comparisons across studies for active time are difficult. We have provided both steps and active time to allow for more comparisons with other studies.

Conclusions

An intervention using wearable electronic activity monitors, tablets, and brief phone counseling was found feasible and acceptable in a population of sedentary, overweight middle-aged and older adults. These systems show promise as relatively inexpensive, scalable methods for the delivery of evidence-based behavior change techniques. Future studies are needed to better understand how and why monitor interventions may increase physical activity, for example, by comparing monitors alone with monitors with additional behavior change techniques delivered via counseling.

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Authors' Contributions

EJL developed the study. MCS, ZHL, and EM assisted with implementing the protocol, collecting data, and writing the manuscript. KJ performed statistical analyses and assisted with writing the manuscript. All authors provided edits to the manuscript.

Conflicts of Interest

MCS's spouse has an equity interest in Apple Inc, a company that may potentially benefit from the research results. In addition, ZHL is employed by Beachbody, a company that may potentially benefit from the research results. ZHL's employment began after data collection and analysis. UTMB's Conflicts of Interest Committee has reviewed these conflicts and a management plan was implemented to prevent any appearance of a conflict of interests. Any inquiries regarding this management plan can be directed to UTMB's Office of Institutional Compliance, (409) 747-8701.

Multimedia Appendix 1

Behavior change techniques made available by the Jawbone Up system.

[PDF File (Adobe PDF File), 33KB - mhealth_v5i3e28_app1.pdf]

Multimedia Appendix 2

CONSORT e-health checklist 1.6.

[PDF File (Adobe PDF File), 517KB - mhealth_v5i3e28_app2.pdf]

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Original Paper

Development and Testing of a Mobile Phone App for Self-Monitoring of Calcium Intake in Young Women

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Abstract

Background: Interventions to prevent osteoporosis by increasing dairy intake or physical activity in young women have been limited to increasing osteoporosis knowledge and awareness. However, findings have shown that this does not always lead to a change in behaviors. Self-monitoring using mobile devices in behavioral interventions has yielded significant and positive outcomes. Yet, to our knowledge, mobile self-monitoring has not been used as an intervention strategy to increase calcium intake, particularly in young women, for better bone health outcomes.

Objective: As development and testing of mobile app–based interventions requires a sequence of steps, our study focused on testing the acceptability and usability of Calci-app, a dietary app to self-monitor calcium consumption, before it is used in a behavioral change intervention in young women aged 18-25 years.

Methods: Calci-app development followed 4 steps: (1) conceptualization, (2) development and pretesting, (3) pilot testing, and (4) mixed methods evaluation.

Results: We present the development process of Calci-app and evaluation of the acceptability and usability of the app in young women. Overall, 78% (31/40) of study participants completed the 5-day food record with high compliance levels (defined as more than 3 days of full or partial completion). There was a significant reduction in the proportion of participants completing all meal entries over the 5 days (P=.01). Participants generally found Calci-app easy and convenient to use, but it was time-consuming and they expressed a lack of motivation to use the app.

Conclusions: We present a detailed description of the development process of Calci-app and an evaluation of its usability and acceptability to self-monitor dietary calcium intake. The findings from this preliminary study demonstrated acceptable use of Calci-app to self-monitor calcium consumption. However, for regular and long-term use the self-monitoring function in Calci-app could be expanded to allow participants to view their total daily calcium intake compared with the recommended daily intake. Additionally, to facilitate sustainable lifestyle behavior modifications, a combination of various behavior change techniques should be considered, such as education, goal setting, and advice to participants based on their stage of change. The feedback on barriers and facilitators from testing Calci-app will be used to design a bone health mHealth intervention to modify risky lifestyle behaviors in young women for better bone health outcomes.

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KEYWORDS

behavior therapy; cell phones; health behavior; primary prevention; self care; telemedicine

Introduction

Osteoporosis is an outcome of poor bone health and manifests as porous bone with low bone density and poor bone strength. It was estimated that 4.74 million Australians older than 50 years had osteoporosis or osteopenia in 2012 [1]. These conditions affect more women than men over the age of 55 years [2]. Without intervention, the prevalence of osteoporosis is expected to increase by 31% by 2022 because of population aging [2]. This condition is costly, accounting for Aus $2.75 billion in total costs in 2012 in Australia [1], and it causes significant morbidity and mortality [3].

The conceptualization phase of this study was prompted by the high prevalence and socioeconomic burden of osteoporosis. Emphasis should be placed on preventing this condition by maximizing peak bone mass in young women before bone accrual stops in approximately the third decade of life [4]. During the transitional phase of life (18-24 years), young adults are more likely to practice risky lifestyle behaviors and cultivate bad lifestyle habits that may have deleterious effects on future bone health [5]. Yet young adults tend to be underrepresented in medical and population health research, being highly mobile and more challenging to recruit and retain than both older and younger populations [6]. Nevertheless, this phase of life is viewed as a window of opportunity for the formation of healthy lifestyle habits in order to avoid suboptimal acquisition and maintenance of peak bone mass and, hence, poor bone health in later life.

Interventions to prevent osteoporosis by increasing dairy intake or physical activity in young women have been limited to increasing osteoporosis knowledge and awareness. However, research has shown that this approach does not always lead to a change in relevant behaviors [7-11]. This prompts a call for other intervention methods. Self-monitoring using mobile devices in behavioral interventions has yielded significant and positive outcomes such as weight loss [12], better blood glucose control in patients with type 2 diabetes mellitus [13], and improved depressive symptoms in young people with mild depression [14]. Yet, to our knowledge, mobile self-monitoring has not been used as an intervention strategy to maximize peak bone mass acquisition for better bone health, particularly in young women.

Numerous lifestyle factors contribute to the attainment of optimal peak bone mass, such as physical activity [15], avoidance of smoking [16], and calcium intake [17]. In Australia, less than 40% of women aged 19-50 years have calcium intakes that meet the estimated average requirement of 840 mg/day [18]. Indeed, the typical average calcium intake in young women aged 15-30 years is only 60% of the estimated average requirement [19]. Osteoporosis is a multifactorial disease; therefore, behavior change interventions for better bone health should take into account various lifestyle factors. As development of mobile app–based interventions requires a sequence of steps [20], this study focused on testing one of the apps, *Calci-app*, that we intend to use in future mHealth behavior change interventions. There are commercially available mobile phone apps such as MyFitnessPal and Easy Diet Diary for tracking one's diet and reporting of nutrient intake [21]. However, they emphasize macronutrient intake, particularly caloric intake. At the time when this study was carried out, calcium content was displayed in MyFitnessPal as a total percentage consumed against the daily requirement and it included an American food database. Although Easy Diet Diary used an Australian food database, it did not display calcium intake. Therefore, we developed Calci-app specifically for this study to report the actual calcium levels in food and beverages that are typical of an Australian diet.

Self-monitoring dietary intake involves the recording of the type and amount of food and beverages consumed and this is traditionally done on paper [22]. One of the drawbacks is the burden placed on participants to write down detailed dietary information with paper and pen. With recent technological advances, the burden of self-monitoring on paper diaries has reduced with the use of mobile devices such as mobile phone apps, websites [23], and personal digital assistants (PDAs) [24]. About 77% of Australians carry their mobile phones with them every day [3], and this widespread use of mobile phones can be harnessed for intervention delivery. Research has shown that young people prefer self-monitoring dietary intake on computers and mobile phones over paper [25], and these methods have similar accuracy.

Therefore, our study aimed to assess the usability and acceptability of Calci-app in young women to self-monitor dietary calcium intake and its potential for use in a bone health mHealth behavior change intervention. It should be noted that Calci-app was designed as a monitoring tool for calcium intake, rather than a behavior change intervention in itself. Its functions are consistent with this purpose. It will enable various forms of feedback to users to be added in the implementation of future interventions.

Methods

Initial Development

Calci-app is part of a large observational health study, the Young Female Health Initiative (YFHI), which is being conducted in young women aged 16-25 years living in the state of Victoria, Australia. YFHI is the most comprehensive study yet undertaken to examine young women's health in Australia across many different health domains. YFHI combines Web-based and remote data collection methods with extensive site visits to collect detailed biodata for a wide range of health measures to examine the interplay between the participants' lifestyles, behaviors, physical health, and mental health [26].

Calci-app was developed specifically for this study in collaboration with Nowpos M-Solutions Pvt Ltd (Hyderabad, India). It was developed for both Apple iPhones and Android phones. Development of Calci-app was completed through an iterative process over a period of 16 weeks in 3 phases: (1) initial development, (2) beta testing, and (3) pilot testing. During this period, the research team held weekly progress meetings with Nowpos developers.

In the first phase, Nowpos was provided with (1) a food database [27], (2) app objectives, and (3) a description of expected app graphics, functionalities, and navigation. The main features included in the initial development were (1) food categories, (2) portion size entries, (3) a 48-hour data entry window period, (4) manual submission of completed food entries, and (5) 3 times/day automatic reminders.

The food database was taken from AUSNUT 2007 (Food Standards Australia New Zealand), which contained more than 3800 items. In an initial attempt to simplify food entries for the participants, we sorted the items into 12 categories, such as meat, seafood and fish, and fruit and vegetable. However, as it might create frustration in users having to determine the correct categories, we decided to remove the food categories. Instead, we added a search function for participants to enter keywords that would pull out relevant food items from the database. Portion sizes were automatically entered according to the standard servings provided in AUSNUT 2007, and the quantity could be adjusted by participants using their phones' type pad and the measurement unit could be selected via a drop-down list. Participants were able to view the calcium content next to each of the food or beverage items that they added. In order to minimize recall bias, we set up a window period of 48 hours for data entry, in which entries were restricted to the actual scheduled day plus the following day. After entering their data, participants were required to click on a "submit" button to confirm and send their entries to the backend database.

If no food or drink were consumed, users were asked to click on a button indicating that nothing had been consumed for a particular mealtime. This process was designed to prevent the app from mistaking the blank meal entry as a missing entry. We also set up automatic push notifications that served as reminders for participants to enter data for each meal. These push notifications were programmed to be sent at predefined times (3 times daily) for breakfast, lunch, and dinner. Additional reminders were sent if entries were still not detected at the predefined times.

Besides allowing food/drink and portion size entries, Calci-app also contained a Web dashboard for researchers to view participants' entries, including the calcium levels for each entry. Participants were provided with unique log-in identifiers and passwords to download and access Calci-app from Apple Inc's official app store, iTunes, or the Google Play Store for Android operating systems.

Beta Testing

Nowpos designed the graphic interface, functionalities, and navigation. We agreed on the final app interfaces after several iterations. Nowpos developed a beta version of Calci-app and this was tested on a convenience sample of 10 young women within the research department over 5 days. The participants were given a Web-based diary to complete on each day of the beta test. The 5 main themes in the Web-based diary were (1) layout of interface, (2) ease of navigation and entry, (3) frequency and content of reminders, (4) reasons for noncompliance, and (5) identification of technical flaws.

After reviewing and sorting the participants' responses into themes, we identified the following main issues: (1) difficulty in learning to accomplish basic tasks (10 out of 10 participants), (2) time-consuming to perform basic tasks (9 out of 10), and (3) app design was overall unsatisfying (8 out of 10).

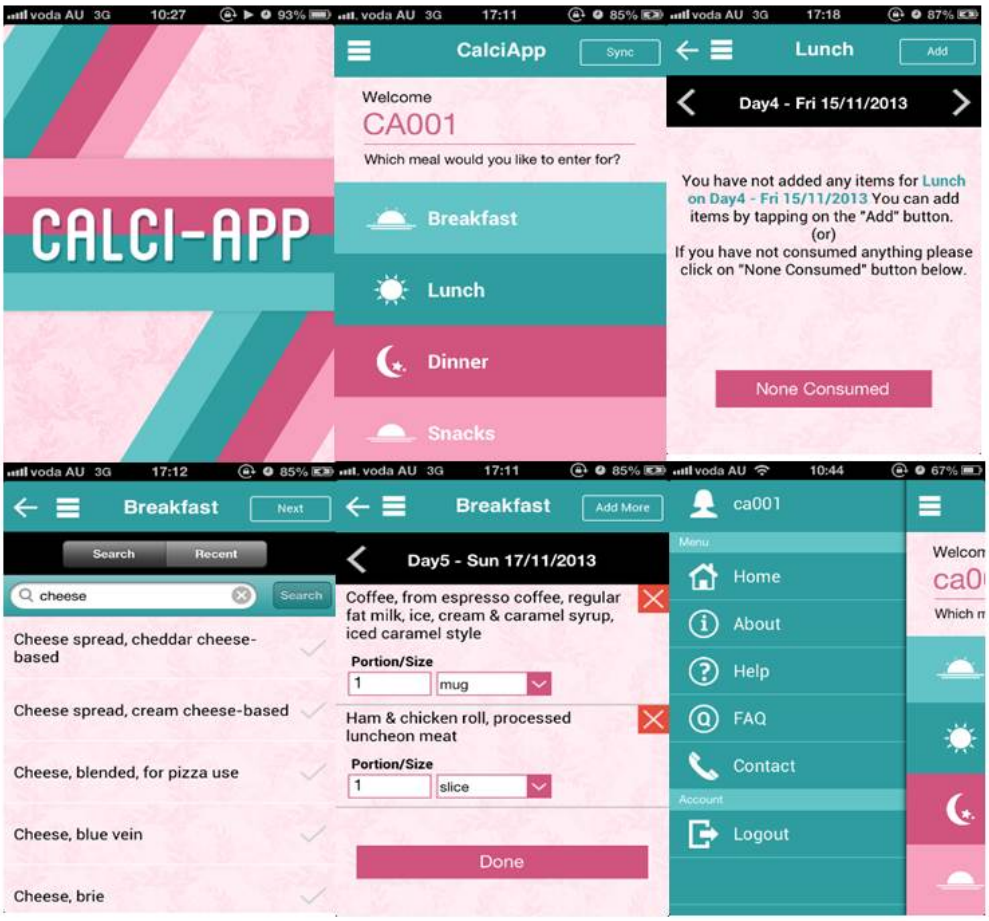
The responses were forwarded to Nowpos and improvements were made in the final version of the app. The main changes were as follows: (1) improvement in search functionality, (2) addition of a summary screen to view completed entries, (3) addition of a "recently added" list, (4) automatic synchronization of entries and backend database, and (5) removal of the window period to allow flexibility in entries. We found it particularly challenging to improve the sensitivity and intuition of the search function and numerous adjustments were required to eventually allow users to search with only keywords, instead of the exact description as specified in the database. The revised build also contained an automatic synchronization function to circumvent issues with poor Internet connectivity by storing entries and uploading data into the backend database when Internet connectivity was available. This function, together with the removal of the 48-hour data entry window, reduced the need for participants to manually submit their entries and prevented missing entries in the database in the event that participants forgot to click on the submit button.

The beta test participants also shared that the push notifications were excessive; therefore, we decided to send only 1 push notification at the end of each day. If no entries were detected, another notification was to be sent the next morning. Unfortunately, these changes required significant modifications to the underlying architecture of the app and would affect development cost and timeline. As such, we only adjusted the timing of the push notifications (to be sent 2 hours after mealtimes and reminders to be sent an hour later if no entries were detected for a particular mealtime).

To assist participants with downloading and navigating the app, we added information and instructions into the app: (1) Calci-app details, (2) instructions or getting started, (3) frequently asked questions, and (4) contact details. Following completion of the informed consent forms, participants were advised to log in to the app, read the information, and complete an assessment of understanding before starting day 1 of data collection.

The final version of Calci-app (see Figure 1) was released for feasibility and usability testing in the pilot study after adjustments from the beta testing were completed.

Figure 1. Screenshots of Calci-app interfaces.



Pilot Testing

Primary Outcome

We explored the level of compliance in young women with completing 5 days of food records in this pilot study.

A high level of compliance was defined as more than 3 days of completed food records and low-level compliance was 3 or fewer days of completed food records. A "completed food record" was one with all meals (breakfast, lunch, and dinner) entered, whereas a food record with either only 1 meal or 2 meals entered was considered a "partial food record."

Secondary Outcome

We explored the acceptability of Calci-app as a mobile dietary calcium intake assessment and self-monitoring method. This was determined by using data collected from the usability questionnaire and mobile focus groups.

Participants for this study were recruited between October 14, 2013, and February 7, 2014, via telephone from the YFHI Launch study, which cross-recruited from previous studies—the YFHI Pilot [26] and Vaccine Against Cervical Cancer Impact and Effectiveness (VACCINE) studies [28]. Participants in these 2 studies responded to targeted advertisements on Facebook and were recruited through their expressions of interest via the study website.

Eligibility criteria for Calci-app were being female, 16-25 years old, resident in Victoria, Australia, and completed the YFHI study. Participants were excluded if they had current or past significant medical condition or conditions, if they were pregnant or breastfeeding, or if they did not own an iPhone or Android phone or were not willing to use them for the study.

Ethics approval was obtained from the Royal Women's Hospital Human Research Ethics Committee (HREC 13/06).

Participants gave their written informed consent in the YFHI study, whereas for Calci-app participants gave their consent electronically. Informed verbal consent to participate was first obtained during telephone recruitment. Subsequently, an electronic copy of the HREC-approved informed consent form was sent to participants via LimeSurvey, an open-source survey tool developed by the University of Melbourne [20]. After receiving full information about the study, respondents provided and documented their consent to participate through LimeSurvey.

After logging in to Calci-app and reading the instructions, participants were asked to complete an assessment of understanding that comprised 5 questions (true or false). The aim of this assessment was to ensure that the participants understood when and how to accurately record their food and drink consumption.

Participants were asked to record their diet using Calci-app for 5 days over a 2-week period. The 5-day food record consisted of 3 nonconsecutive weekdays and 2 nonconsecutive weekend days to cover weekday versus weekend variations. Research has shown that a 3-day food record was sufficient to measure food intake [29]. For our study, we decided on a 5-day collection period to test the extent of compliance, while trying to limit participants' fatigue.

All participants were to begin day 1 of app use on a Saturday and enter their records every alternate day until the fifth day, which fell on a Sunday. Participants were able to view the scheduled dates in Calci-app diary viewer once logged in. At the end of the 5-day food record, the researchers manually emailed the participants' daily total calcium intakes to them.

Usability Questionnaire

After participants completed the 5-day food record, they were asked to complete a usability questionnaire.

Quantitative feedback data about Calci-app was collected in the 5-item usability questionnaire using 5-point Likert scales (strongly agree to strongly disagree). The questionnaire focused on the following themes: (1) ease of use, (2) convenience, (3) intuitiveness, (4) time consumption, and (5) usefulness. The level of burden perceived by the participants was assessed on a scale of 0-10, with 0 being not troublesome at all.

Mobile Focus Group

Completion of the 5-day food record and usability questionnaire was followed by an invitation to participate in a focus group. The topics covered during the interviews included evaluation of technology, integration and impact on everyday routine, acceptability and reasons for noncompliance, perceived impact on health, long-term implementation, and anticipated involvement and perception by others. These topics have been covered in other studies examining the use of mobile phone apps for health interventions [30-34]. The focus groups were conducted using a free mobile phone app called WhatsApp Messenger (Whatsapp Inc) [35] in a chat group created for this purpose.

Statistical Analyses

Statistical analysis was performed with SPSS (IBM Corp, IBM SPSS Statistics for Windows, version 21.0). All quantitative data were analyzed using descriptive analysis and results are reported as n (%). Linear regression was used to assess participants' compliance with food recording during the study time frame.

Thematic analysis was undertaken to analyze qualitative data. All analyses were performed using per-protocol approach.

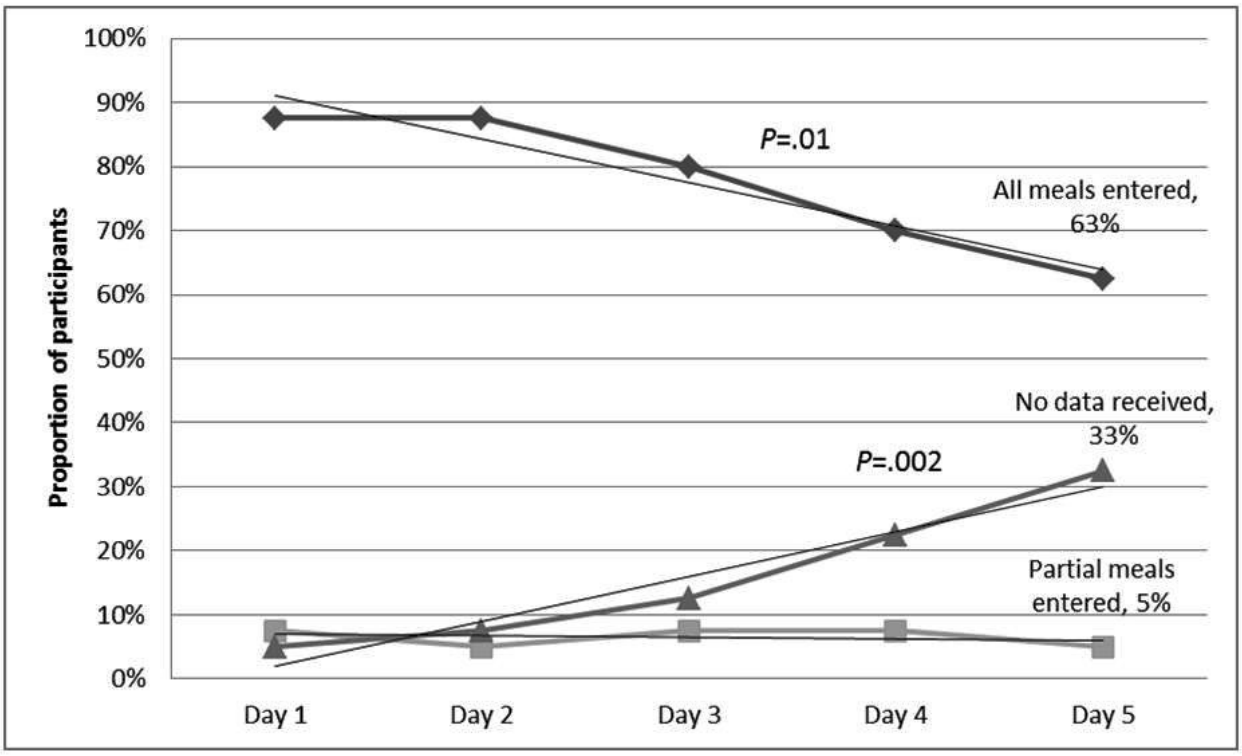
Results

Overall Compliance

On the basis of the eligibility criteria, 129 subjects were excluded (had eating disorder, did not own a mobile phone, were older than 25 years, and did not live in Victoria, Australia). Of the 90 young women who met the eligibility criteria, 54 (60%) agreed to participate. Ultimately, 40 participants completed the study. The other 14 participants withdrew consent (3 participants) and were lost to follow-up (11 participants).

Overall, 78% (31/40) of study participants completed the 5-day food record with high compliance levels (defined as more than 3 days of full or partial completion). There was a significant reduction in the proportion of participants completing all meal entries over the 5 days (P=.01; see Figure 2) and an increase in the proportion of participants who did not enter any data at all over the 5 days (P=.002), especially from day 2 onward. Participants who entered partial meal entries (at least one meal entry) remained constant.

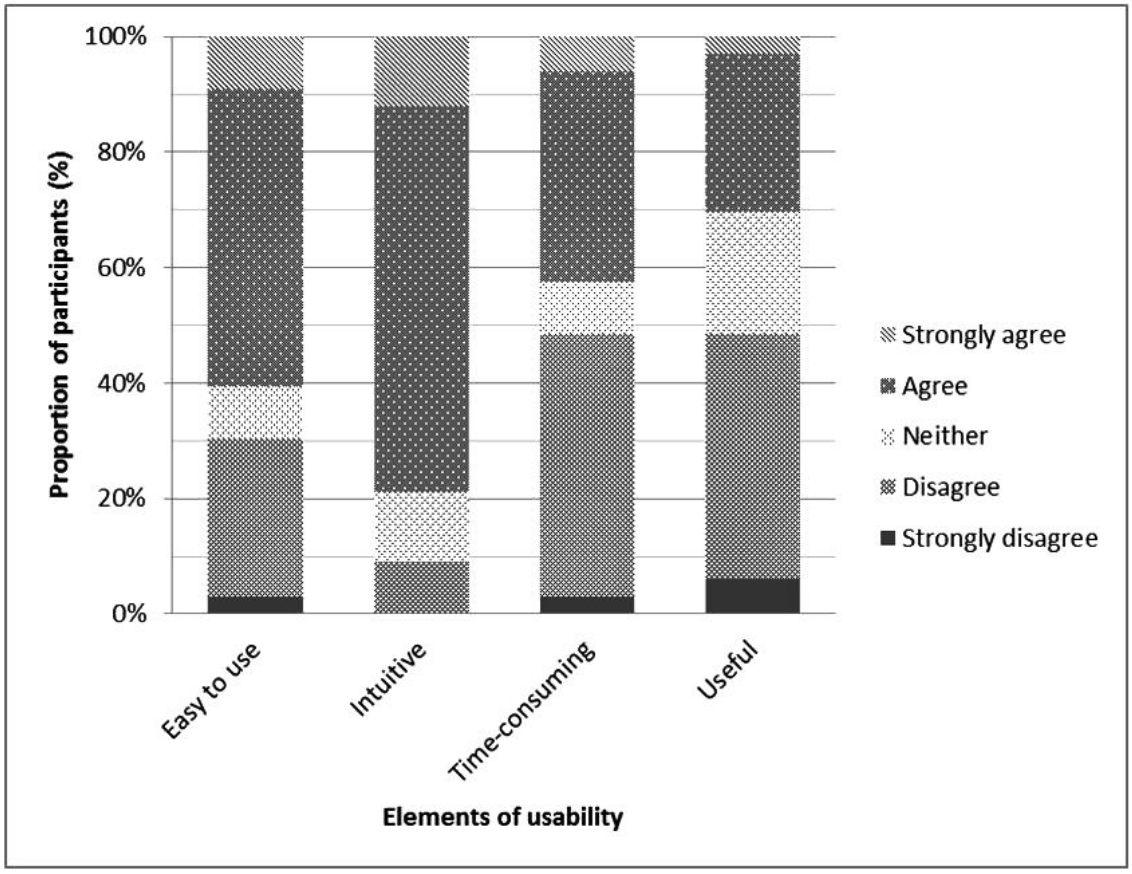
Figure 2. Compliance in meal entries over five days measured by proportion of participants (%) with completed food record, partial food record or no food record (n=40).



Usability Questionnaire

A total of 33 participants (83% of the 40 participants who completed the study) completed the usability questionnaire. Of the 33 participants, 20 respondents (61%) found Calci-app easy and convenient to use, 26 (79%) found the app design intuitive and not confusing to use, 14 (42%) found Calci-app time-consuming, and 10 (30%) found it useful (see Figure 3).

Figure 3. Responses to Calci-app usability questionnaire (n=33).



Mobile Focus Group

A total of 22 participants participated in 5 focus group sessions between January 13, 2014, and February 21, 2014. Each focus group session had 3 to 8 participants and lasted for 30-40 minutes. Of 22 participants, 16 joined the focus group session within 1 month of completing day 5, and 6 of them had the session between 1-2 months after they completed day 5.

Thematic analysis of the focus group interviews aimed at understanding participants' experiences with Calci-app revealed 5 distinct themes: (1) good aesthetics and ease of use promoted app usage, (2) frustration and time consumption reduced app usage, (3) ability to add accurate entries may improve app usage, (4) owning a purpose motivated app usage, and (5) diet concerns hindered app usage (see Table 1).

Table 1. Themes and codes derived from qualitative analysis of Calci-app mobile focus group interviews.

Theme	Codes
Good aesthetics and ease of use promoted app usage	Easy to pick up and use
	Preferred dietary assessment method
	Attractive design
Frustration and time consumption reduced app usage	Slow loading
	Unintuitive search function
	No directive interface
	Lack of database categorization
Ability to add accurate entries may improve app usage	Inaccurate search function
	Portion size cannot be estimated
	Portion size entry not simple and flexible
	Lack of extensive database with basic options
Owning a purpose motivated app usage	Knowing calcium level in food influences choices
	Want comparison between actual and target intake
	Potential for app to provide health education
	Want to see trend of past entries
	Possible data sharing with health professionals
Diet concerns hindered app usage	App usage heightened dietary awareness
	Concerns about diet may lead to eating disorders

Good Aesthetics and Ease of Use Promoted App Usage

The color scheme, graphics, layout, and fonts used in Calci-app were considered attractive to young women, and this created interest in using it. Several positive comments were made regarding the app design, interface (layout), and functions. The letters represent individual respondents.

F: *Designs were nice. Made me want to use it.*

L: *The app was nicely designed and I liked the colour scheme.*

M: *I found the interface really easy to navigate, logically set out and minimal buttons made it simple to use.*

Almost all participants appreciated the simplicity of learning how to use the app and the ease in its daily use. Participants also appreciated the use of a mobile phone food record as a method of dietary assessment.

V: *It is helpful being on your phone, which is always with you.*

S: *Easy to use :) instructions in the email were well written. No worries with navigation! Simple to "get around."*

Q: *It was pretty easy- and I'm quite technologically challenged!*

Frustration and Time Consumption Reduced App Usage

Although the aesthetics of Calci-app and the ease of learning to navigate and use the app might have caught the participants' attention, overall app usage was impeded by a poor and unintuitive search function that produced irrelevant hits.

I: *I found the app very easy to use. It was well designed and the menus made it easy to navigate. One problem was that some search terms (simple things such as raspberries) would return a lot of hits, which was frustrating.*

Q: *I found it easy to navigate but was a bit clumsy when I had to add individual ingredients to a meal and the items I'd actually typed in were at the bottom on the list but the loosely related brand specific items were at the top of the list.*

The participants suggested several improvements to increase usability. They suggested a more intuitive search function with the database categorized to prevent the need to add individual ingredients for a meal and to minimize the list of search hits. They also preferred common food items to appear on the top of the search list to remove the need to scroll and find their selection.

The addition of manual and automated functions would also improve the food entry process, for example, manual entries of food and recipes, bar code scanning, favorites list, and a longer recently added list.

Participants also found that the app was rather slow and it was not clear at times whether it was frozen or was loading. Through their comments, it was apparent that users may only have a short amount of time to enter food records and they may not be particularly patient with an app that is slow.

L: *I agree with the loading being slow at times. Sometimes it could take quite a while to enter a meal so it wouldn't be something that you could do all the time.*

I: *My issues weren't that bad! I'm just impatient and found waiting a minute or so annoying.*

C: *I ended up writing everything down and entering it at the end of the day because of the slow loading.*

Ability to Add Accurate Entries May Improve App Usage

The need for accurate food entries was a repeated theme among the young women and the inability to locate exact food items frustrated them. Furthermore, 3 participants expressed that they

were on special diets (gluten-free, lactose-free) and could not find their products in the database.

T: *I had a lot of trouble finding relevant food. There seemed to be very few gluten free options and sometimes the items listed were so specific that it was hard to find just a basic food item.*

K: *I found it pretty easy to use and understand. However, due to my food allergies not all of the food items or brands I use were listed. So finding similar things was hard at times. So my info may not have been as accurate as it could have been.*

We further analyzed the participants' comments and noted that, besides an unintuitive search function that might cause inaccurate entries, other database limitations were described. These were broken down into 3 main issues:

- Database was not sufficiently extensive
- Items were poorly described
- List of search results was too long and it strained users' attention

Besides imprecise food selection, participants also disliked the inability to accurately estimate portion sizes. Although they found the function of selecting portion measurements simple and basic, they found it frustrating to guess the portion sizes. For example, a cup of milk is subjective and it was not possible for them to estimate the amount in milliliters.

E: *The search style took some getting used to. And the portions options were so inaccurate, how big is a "serve."*

D: *And say I had tomyum soup, it was hard to choose from the list and a "bowl " could mean a wide range of sizes.*

Owning a Purpose Motivated App Usage

When asked whether they could foresee young women using this app, most respondents agreed that only those who have a purpose for using it may use it long term. Examples may include the case of someone with bone problems or those who had been informed by their general practitioners (GPs) that they have low bone density. Many felt that it would be beneficial if the app had a data sharing function for GPs or other health professionals to view their calcium intakes and make recommendations. Many pointed out that they would not use the app if it was just a food diary.

M: *I think most would see it as unnecessary unless diagnosed with a bone problem, I don't think many of my friends would be interested in logging food, many would do so intermittently which almost renders the process useless.*

J: *I'd love my GP to recommend an app like this, or anything that's not just taking tablets.*

Almost all participants said that Calci-app increased their awareness of food selection and that they were encouraged to select food with higher calcium content. However, they would benefit more if Calci-app could present instant feedback on their total daily calcium intake against the recommended levels. Some wanted the app to go beyond a basic food diary and become an informative health intervention app that is able to suggest calcium-rich foods to the users, ring an alarm if calcium intake is low, as well as feature other young women's calcium intake through the use of social media.

D: *Umm we weren't given any values so I was unaware about how much I was consuming but if it gave us a breakdown at say the end of each day that might reflect the choices I make for my next meal.*

F: *Well there isn't any immediate feedback on the actual intake. So it's impossible to know whether you are doing well for the day or not. It did make me more aware of what and when I was eating. I was thinking more whether what I was eating would have high calcium content.*

J: *I was curious of foods other than milk, cheese, cream and yoghurt had dairy, but I still don't really know. And how much others consume, like what's the average calcium intake for my age or bmi.*

U: *And a list of foods with high calcium if we're running low on inspiration.*

Diet Concerns Hindered App Usage

It was of interest that although the use of Calci-app was able to motivate positive food choices to increase calcium intake, the heightened awareness in their diet also led to negative thoughts and emotions, such as guilt and discomfort. A total of 6 participants highlighted a concern that the app may cause potential eating problems in young women, who are often vulnerable to issues with their body image.

R: *Like: it was convenient that I could record meals at any time during the day Dislike: keeping such a close eye on my diet as it made me feel guilty at times.*

S: *To be honest I didn't mind doing it for the study and I know I need more calcium and iron but I wouldn't be comfortable doing it long term.*

Discussion

Principal Findings

Here we described the process of developing Calci-app, designed for self-monitoring of dietary calcium intake in young women. Our goal in this pilot study was to test the usability of Calci-app and to determine the compliance of young women with Calci-app in recording their dietary intake before it is used in an interventional study. This study's outcome reveals the barriers and facilitators in the use of Calci-app by young women to self-monitor dietary calcium intake to bring about an improvement in dietary consumption of calcium.

Our study showed relatively high compliance with dietary intake recording. However, the mobile self-monitoring method did not achieve high-level adherence beyond 3 days of recording. This finding is consistent with another study, which also reported an average of 3 days of dietary recording from participants in a free-living environment [36]. Another study also found low adherence regardless of whether self-monitoring was done on paper or PDA [23]. The compliance seen in our study may be a result of participants simply following the researcher's advice. On the contrary, adherence is a long-term commitment where participants internalize and take ownership to act in order to

produce a therapeutic outcome (ie, self-monitoring, self-therapy, etc) [37]. The use of mobile phone apps is often sporadic and transient [38], which was also echoed by the participants during the focus group. Hence, other strategies may need to be considered to motivate participants to adhere to the intervention.

A possible solution is to personalize the self-monitoring experience by enhancing participants' connection to the intervention and improving support by minimizing negative experiences [39]. Even though participants found Calci-app easy and convenient to use, they described it as time-consuming and not useful to them. Providing a simple and intuitive search function may address the time consumption and technical obstacles that distracted them from using the app. However, it is difficult to instill a need or readiness for behavior change that will motivate young women to use Calci-app continuously. Participants could not identify a purpose for which to use Calci-app and this may be related to their perceived susceptibility to osteoporosis, which is a key component when assessing adherence to a behavioral intervention [40]. Research has shown that young adults perceive a lower susceptibility to osteoporosis [41,42] compared with older adults because osteoporosis is largely an older person's disorder. Moreover, young women do not perceive osteoporosis as a severe problem, thus reducing their sense of urgency to protect themselves from the disease [41]. This barrier may be mitigated by adding a component of education about the potential consequences for bone health with their inaction when they are young. Providing individual feedback on their bone mineral density to individuals may also help to improve engagement [43], but it may be impractical on a large scale because it is relatively expensive and uncommon for young women to have bone mineral density testing.

Participants in our study also reiterated the need for immediate feedback on their actual total calcium consumption and as a comparison against the recommended daily intake levels. Although the technique of self-monitoring and visibility of the calcium content in each food item made them more aware of selecting food with higher calcium levels, knowing their actual consumption against the targeted levels may influence the choices they make at the next meal. Research has established that few entirely mobile phone app–based interventions have been effective. The greatest value is found when education and counseling are combined with feedback and ongoing self-monitoring [12]. This is most apparent in weight loss interventions, where research demonstrated that regular weighing with electronic graphical feedback prevented weight gain in young adults [44], and a Web-based intervention administered with caloric and weight feedback prevented weight gain in college students [44]. Additionally, a recent systematic review of mHealth interventions revealed that interventions that integrate a greater extent of behavior change techniques had the best outcomes [45]. A majority of the successful dietary interventions in young adults used behavior change techniques such as goal setting, personalized feedback, and advice depending on the phase of change that the participant was at [46,47]. However, details of the types of behavior change strategies most effective in our target population are yet to be determined.

It is noteworthy that although we can address the personal barriers in the uptake of Calci-app, such as purpose to use, time constraints, and the lack of motivation, we cannot remove the heightened awareness that dietary monitoring carries. Our study excluded young women with current or past eating disorders, yet our study participants shared that recording their diets made them feel guilty and uncomfortable. Weight management is a major determinant of eating habits [48] and dietary interventions may inadvertently promote eating disorders [47]. Therefore, intervention designs should include components to address body image issues and encourage body satisfaction.

One of the strengths of this study was the use of a mobile method for focus groups. To our knowledge, our study is the first to conduct focus groups using a social media platform (WhatsApp Messenger). Focus groups are traditionally conducted face-to-face and they must be performed at times and locations most suitable for participants. Participants may also feel uncomfortable sharing their opinions freely in a face-to-face group setting [49]. Additionally, focus group sessions are either audio- or video-recorded and the content transcribed by researchers, which can be tedious and time-consuming. One hour of audio recording is equivalent to 8 hours of transcription [49]. Furthermore, the quality of the voice recording is largely dependent on the capabilities of the microphone to capture voice volume variations of the participants and the ability to identify the voices of the speakers [50]. The use of mobile focus groups may overcome these issues. We conducted 5 focus groups in total and had 11 no-shows after excluding the participants who did not complete the usability questionnaire. This is equivalent to approximately 2 to 3 no-show attendees per focus group and it is comparable to previous research findings that suggested that each focus group will likely have 2 no-show attendees [51]. The name of the participant is keyed into WhatsApp Messenger's user profile, which identifies the participant when she responds in the chat group. The focus group conversation is saved in the chat group and can be exported into a .txt file and emailed to the researcher for analysis. However, the mobile focus group is limited by its inability to assess participants' body language and voice tones, and these critical cues therefore are not available in data analysis. We find that this may be moderated by probing and expanding each response to discuss the participants' feelings associated with their opinions. Although we find that the mobile focus group similarly fosters the interactive nature of face-to-face focus group, the participants' ability to share freely may be hindered by the limitation of texting long responses and explanations. Although we only used this social medial platform for mobile focus group, it is yet unknown whether the use of social media can improve effectiveness of interventions. These platforms are far-reaching and not expensive and can be useful tools to encourage content sharing and interactivity [46].

Limitations

Limitations of this study are similar to other studies in self-monitoring for behavioral change [52]. The sample in this study consisted of mainly white young women, and a majority of them were university students. The participants were recruited from a sample of women who volunteered to participate in the YFHI study through an expression of interest. Although research

has shown that educational level did not seem to influence nutrition intervention outcomes [53], there may be inherent characteristics in these volunteers that may lead to the observed outcome of relatively high compliance, such as interest in general health, higher awareness about health issues, and the importance of contributing to research. Therefore, it will be imperative to determine the uptake of Calci-app in a more diverse population living in the "real world" and over a longer time.

The attrition rate in the study was high with 7 participants who did not complete the usability questionnaire and an additional 11 participants who did not attend the focus groups. High attrition rates in eHealth and mHealth interventions are not uncommon [54,55], but the loss of valuable feedback from participants who drop out may have influenced the usability outcomes of the Calci-app that could inform future intervention designs.

Conclusions

We presented a detailed description of the development process of Calci-app and an evaluation of its usability and acceptability to self-monitor dietary calcium intakes. The findings from this preliminary study demonstrated acceptable use of Calci-app to self-monitor calcium consumption. However, for regular and long-term use, the self-monitoring function in Calci-app could be expanded to allow participants to view their total daily calcium intake against the recommended daily intake. Additionally, to facilitate sustainable lifestyle behavior modifications, a combination of various behavior change techniques should be considered, such as education, goal setting, and advice to participants based on their stage of change. Other negative factors limiting adherence to app use such as time consumption, frustrating technical functions, and body image issues also need to be addressed. Although other interventions have used dietary mobile phone apps to improve various lifestyle outcomes, to our knowledge there is no research investigating the use of a mobile phone app to improve risky lifestyle behaviors in young women for better bone health. The feedback on barriers and facilitators from testing Calci-app will be used to design a bone health mHealth intervention to modify risky lifestyle behaviors in young women for better bone health outcomes.

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Conflicts of Interest

None declared.

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Abbreviations

GP: general practitioner
HREC: Human Research Ethics Committee
PDA: personal digital assistant
YFHI: Young Female Health Initiative

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Original Paper

Usability and Acceptability of a Mobile Comprehensive HIV Prevention App for Men Who Have Sex With Men: A Pilot Study

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Abstract

Background: Men who have sex with men (MSM) are the group most impacted by the human immunodeficiency virus (HIV) epidemic and the only subgroup in the United States among which new HIV diagnoses are not decreasing. To achieve the US National HIV/AIDS (acquired immunodeficiency syndrome) Strategy goals of reducing new diagnoses by 25%, high (eg, 30-50%) coverage of multiple HIV prevention interventions is needed in both urban and rural areas. Mobile phone “apps” are an important channel through which prevention services could be provided at scale and at low marginal cost.

Objective: The aim of this study was to evaluate the usability and acceptability of a theory-based Android mobile phone app for HIV prevention.

Methods: The app included self-assessment tools; prevention recommendations; commodity (condoms, HIV self-tests) ordering; reminders to MSM for basic HIV prevention services, HIV testing, condom use, screening for preexposure prophylaxis (PrEP) and nonoccupational postexposure prophylaxis (nPEP); and prevention and treatment provider locators. The study recruited HIV-negative, Android-using MSM in Atlanta and Seattle who were asked to use the app for 4 months and complete a post-use survey. We measured the use of the app and its features, ordering of commodities, self-report of establishing an HIV testing plan, being HIV tested in the community, and starting PrEP or using nPEP. Usability was assessed using the system usability scale (SUS).

Results: A total of 121 MSM were enrolled (59.5%, 72/121 from Atlanta; 40.5%, 49/121 from Seattle). Median age was 28. Nearly half (48.8%, 59/121) were nonwhite, and most (85.9%, 104/121) were gay-identified. Most had tested for HIV in the past (85.1%, 103/121), and 52 (43.0%, 52/121) had a plan to test for HIV regularly. Men used the app for an average of 17.7 minutes over the first 4 months. Over the 4-month period, over half ordered condoms (63.6%, 77/121) and HIV test kits (52.8%, 64/121) on the app. Eight of 86 (9%) PrEP-eligible MSM started PrEP during the 4-month period; of those, 6 of the 8 reported that the app influenced their decision to start PrEP. The mean SUS was 73 (above average).

Conclusions: A theory-based mobile phone app was acceptable to MSM and was rated as having above-average usability. Most men used the commodity-ordering features of the app during the 4-month evaluation period, and nearly 1 in 10 PrEP-eligible men started PrEP, with most attributing their decision to start PrEP in part to the app. A broader, randomized controlled study of the impact of the app on uptake of prevention behaviors for MSM is warranted.

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KEYWORDS

homosexuality, male; mobile applications; pilot projects; sexual minorities; condoms; pre-exposure prophylaxis

Introduction

Human immunodeficiency virus (HIV) prevention has become an HIV sero-status-dependent practice, in which an HIV test is the first step toward either a prevention continuum for HIV-negative individuals, or a treatment and care continuum for those testing HIV-positive. In other words, HIV prevention must rest on a foundation of accurate knowledge of HIV sero-status among key populations, followed by sero-status-specific prevention approaches. For those who are HIV-negative, biomedical interventions such as preexposure prophylaxis (PrEP) hold promise to reduce susceptibility to HIV [1-3].

Men who have sex with men (MSM) are a key risk group in the United States and are disproportionately impacted in terms of HIV prevalence [4-6] and incidence [7-9]. MSM are the only US risk group for whom HIV incidence increased after 2000 [8]; increases are especially alarming among young (15-24 years old) MSM [7] and MSM of color [10]. This has resulted in profound health disparities for both MSM relative to other adult men and within the MSM community, with a burden of HIV infection that is a staggering 67 times greater than for other men in the US population [11]. Disparities are especially pronounced among MSM of color [4].

Multiple models of HIV incidence in MSM suggest that to decrease HIV incidence in MSM, we will need to achieve 30-50% coverage of multiple prevention services and interventions (eg, condom promotion, HIV testing, PrEP, treatment as prevention) in at-risk MSM [12-15]. However, the uptake of routine HIV testing and PrEP is low: less than half of MSM test for HIV yearly [16] and in 2013, <5% were utilizing PrEP [17]. A recent summary of electronic tools for HIV prevention in MSM noted that promotion of certain types of prevention services are most amenable to provision through new technologies. Services for which eligibility can be determined through an algorithm are good candidates to bring to scale with technologies [18]. For example, behavioral eligibility for PrEP has well-described criteria and eligibility algorithms [19,20]. Using technology to promote uptake of prevention services for MSM would also make services more accessible to rural MSM [18]. This is especially important because MSM in rural areas may have lower access to HIV prevention services delivered in community-based organizations [21,22].

Here, we present briefly the development of a comprehensive mobile HIV prevention app for MSM, and describe and report the initial evaluation of the app for usability and acceptability.

Methods

Previous Work and App Development

Needs assessment for an HIV prevention app for MSM was conducted prior to app development using a 3-phase, iterative process [23,24]. Phase 1 consisted of separate focus group discussions with MSM, HIV testing counselors, and key community informants to identify preferences and requirements to consider including in a mobile HIV prevention app. Preliminary data from phase 1 was used to build an alpha version of the app. The alpha version was then theater tested with additional focus group discussions. Data from all phases were then used to develop features, language, and security to build into the beta version of the app. All of the app development was completed by Keymind (McLean, VA), a technology firm that specializes in creating data systems and mobile apps, including apps for health care providers and systems. The authors (PS, RS, JS, and TG) were directly involved in creating the requirements for the app; Keymind staff produced the app.

Theoretical Basis

The app content was developed based on the social cognitive theory of behavior [25]. Briefly, the app features enumerated in the following section were developed to fit into a framework of several health outcome behaviors (eg, making a plan to test regularly for HIV, using condoms, self-screening for PrEP, seeking HIV care for those living with HIV). For each health or prevention behavior, there were specific app features that were designed to promote goal setting, self-efficacy, outcome expectations, and self-regulation. For example, for the behaviors of HIV testing, the “Make a plan” app feature promoted goal setting, the presentation of several testing options and information promoted self-efficacy, information about the benefits of testing promoted positive outcome expectations, and a customizable reminder system for testing promoted self-regulation.

App Features

A list of app features and descriptions are shown in Table 1; screenshots of the app are available in Multimedia Appendix 1. Highlighted features included monthly risk assessment quizzes that offered tailored HIV-prevention related recommendations, quizzes to self-assess PrEP and nonoccupational postexposure prophylaxis (nPEP) eligibility, resources to create and schedule a custom HIV testing plan with reminders, a global positioning system (GPS) enabled map of HIV testing locations with their operational details, and ordering of free condoms and at-home HIV test kits.

Table 1. Features of the HealthMindr app during the pilot study, United States, 2015.

Domain	Features
Initial and Monthly Risk Assessments	Provides tailored, HIV-related prevention suggestions for users to consider based on quiz responses. Monthly Assessments used responses from the previous month's assessment to ask if there had been any changes to give up-to-date suggestions.
PrEP[a] Screener	Assesses PrEP[a] eligibility using seven questions developed by the CDC. The screener asks about time since last HIV[b] test, number of partners in past 3 months, condom use frequency, partner's HIV status, bacterial STIs[c] in the past 12 months, and if engaged in exchange sex.
nPEP[d] Screener	Assesses nPEP eligibility using a three question series about contact with bodily fluids, recency of exposure, and confidence in partners' HIV status [26].
Find My Frequency (HIV Testing)	Suggests HIV testing frequency of every 3 or 6 months based on five questions, including number of partners, partners' HIV status, bacterial STI infections in the last 12 months, and injection drug, meth, or poppers use [27,28].
Compare HIV Tests/ Help Me Choose	Allows users to prioritize the most important aspects of an HIV testing experience based on location type, sample collection method, cost, HIV counseling available, wait time for results, and window period of test. Users can filter tests based on their preferences or complete a quiz for recommendations based on their stated preferences.
My Test Plan	Users can plan an HIV test by date, time, and location. Automated reminders can be set based on a chosen testing frequency. After being tested, users can record their HIV/STI test results within the app to keep a record of testing history.
Reminders	Preferences can be set for how users receive testing and assessment reminders as pop-up notification, email, or neither. Users can choose the text of the reminder from a list of preset phrases or write their own message.
Ordering	Free at-home HIV test kits (OraQuick and Home Access), a variety condom styles, and silicone and water-based personal lubricants were offered.
Location Details & Map	Provides a map and details about testing locations, including address, phone number, type of organization, web address, days/hours of operation, service eligibility requirements (if any), fee information, languages available, and clinical services offered (HIV testing, HIV treatment, PrEP, nPEP, vaccinations, and so on). GPS[e] was enabled to show user's location relative to testing locations. Locations were able to be filtered by the above characteristics to display locations with select characteristics.
FAQs	Frequently asked questions related to HIV were included for users to reference. Users were also able to submit questions via the app to study staff.

[a]PrEP: preexposure prophylaxis.

[b]HIV: human immunodeficiency virus.

[c]STI: sexually transmitted infection.

[d]nPEP: nonoccupational postexposure prophylaxis.

[e]GPS: global positioning system.

Pilot Study Overview

The purpose of this study was to assess the usability and acceptability of the HealthMindr app among MSM living in the metro areas of Atlanta, Georgia, and Seattle, Washington. The 2 cities were chosen because the availability of high-quality, gay-friendly prevention services differs in the 2 cities; we hypothesized that men who live in a city like Seattle where services are readily available and culturally competent might have less interest in accessing services through a mobile app. MSM were recruited on the Web and asked to install HealthMindr on their mobile phone, keep it on their phones for 4 months, and complete an evaluation survey at the end of the study period. Demographic and HIV prevention behaviors were collected during study enrollment. Brief periodic assessments were delivered monthly; the assessment of 10 risk questions allowed for prevention recommendations to be updated based on recent behaviors. App-based usage data was collected for all in-app actions participants made, including in-app button clicks, page views, and assessment or quiz responses. At the end of the participant's study period, a Web-based evaluation survey was sent to participants to assess their HIV-related prevention behaviors during the pilot and app features that they did and did not find useful. Selected participants who were recommended to receive PrEP, including all who started PrEP, were invited to participate in individual in-depth interviews about their decision to start PrEP or not, and how the app influenced their decision-making process.

This study was approved by the institutional review boards of Emory University and the University of Washington. Participants were compensated US $25 each for completion of the baseline and 4-month follow-up surveys and US $5 each for the 3 periodic assessments administered through the app. Men who participated in individual in-depth interviewed were compensated US $40.

Recruitment and Enrollment

Participants were recruited from May 2015 and August 2015 using advertisements on Facebook and a social or sexual networking mobile phone app for MSM. Advertisements targeted adult male Facebook users residing in Atlanta or Seattle who indicated being a man interested in men. Advertisements on the MSM networking app used geolocation to deliver advertisements to men who opened the app on an Android device while in the Atlanta or Seattle metro area.

Interested participants who clicked on an advertisement were taken to a Web-based screening and enrollment survey and presented with a brief description of the study. Men completed an electronic informed consent to be screened for study eligibility and then completed a brief screening survey; to be eligible for the study, participants must have been ≥ 18 years of age, English-speaking, living in the Atlanta or Seattle metropolitan areas, assigned male sex at birth, and identifying as male at the time of the screening; must have had sex with a man in the past year; must have never tested positive for HIV; and must have owned an Android mobile phone device with current service. Eligible men were asked to complete an electronic informed consent for study participation. Disqualified respondents were not given a reason for ineligibility and were provided the principal investigator's contact information.

Consenting participants were next shown a 7-minute introductory video embedded within the enrollment survey (Multimedia Appendix 2). The video introduced study staff members, explained study procedures including compensation schedule, provided detailed instructions with app screenshots on how to download and register the app, and demonstrated different app features. Mobile phone ownership was verified by sending participants an SMS text message (short message service, SMS) with a confirmation number that the participant was required to enter into the enrollment survey before continuing. The last section of the enrollment survey asked for demographic information and HIV testing history during the previous 24 months, use of free condoms in the last year, and whether the participant had ever used PrEP, nPEP, or at-home HIV test kits.

Access to the app was limited to participants through the use of a unique registration code provided only to participants; password and personal identification number (PIN) protection were provided. After successfully registering the app, participants were asked to complete an initial in-app screening assessment, which completed their enrollment into the study. Enrollment completions that were suspected to be fraudulent based on duplicate or similar phone numbers, Internet protocol (IP) addresses, or email addresses were screened and verified by calling and speaking with the participant before accepting him into the study. In all cases, study staff called all study participants within a week of study enrollment to introduce themselves and answer any questions or concerns.

Measures

Enrollment and Baseline Survey

Participants were asked demographic and baseline characteristics during study enrollment; including age in years; city of residence; race or ethnicity; sexual identity; recent HIV testing history; HIV status; plans for future HIV testing; and past use of PrEP, nPEP, condoms, and at-home HIV testing kits.

Evaluation Survey

After 4 months of use, participants were asked about motivation to use the app, HIV testing during the study period, PrEP and nPEP use during the study period, and at-home test kit and condom use for those who placed in-app orders. Participants were also asked to assess the app's features, usability, design, content, and functionality using both Likert scales and optional open text fields. The usability of the app was further assessed using the system usability scale (SUS), a validated, industry standard scale used to evaluate a variety of products and services, including websites, mobile phones, computer software, and more [29]. The scale uses a series of questions to generate a usability score ranging from 0-100. An SUS score below 50 is not considered acceptable while above 70 is above average and >90 is superior [30].

Analysis

The usage log was used to calculate the number of days participants used the app, pages of the app accessed, and the total time spent in the app. Time spent engaged within the app was quantified by calculating time passed between each action a user took and totaling the time for the visit. The longest 1% of time between actions (ie, longer than 2 minutes 38 seconds) was considered to not be representative of active app engagement. Time engaged within the app per person and per person-month was calculated. Descriptive statistics were used to examine app engagement and are reported as mean with range for time and action measurements. Participants' ordering histories were kept for all at-home test kits, condoms, and personal lubricant orders placed. App pages accessed and features used by participants are reported as participant counts with percent. Evaluation responses are reported as percent of users who completed the evaluation survey. SUS results are reported as an aggregate score, using the method by which the scale was validated [30].

All analyses were performed using SAS 9.4 (SAS Institute Inc).

Results

Study Population

Of the 919 Web-based survey responses, 244 (26.5%, 244/919) left the survey after reading the study description, 108 (11.7%, 108/919) did not complete the screening survey, and 257 (28.0%, 257/919) did not meet eligibility requirements. Reasons for ineligibility included not owning an Android phone (42.8%, 110/257), being HIV positive (27.6%, 71/257), and living outside of the study area (18.3%, 47/257). Of the 309 eligible survey responses, 127 (41.1%, 127/309) did not complete the postscreening enrollment survey, 21 (6.7%, 21/309) completed the survey but did not download the app, and 40 (12.9%, 40/309) were determined to be fraudulent attempts to enroll multiple times and were disqualified. Final study enrollment was 121 MSM, including 72 in Atlanta and 49 in Seattle. App usage data were available for 90.0% (109/121) of participants. Ninety-eight (81.0%, 98/121) participants completed the 4-month evaluation survey. Participation in the evaluation survey did not differ by age (median test: P=.34); race (chi-square test: P=.90); or knowing of a local place to be tested for HIV (chi-square test: P=.99).

Table 2. Select baseline characteristics of men who have sex with men (MSM) participating in a 4-month pilot study of a human immunodeficiency virus (HIV) prevention app, United States, 2015.

Characteristic		Total (n=121) n (%)	Atlanta (n=72) n (%)	Seattle (n=49) n (%)
Male		121 (100)	72 (100)	49 (100)
Age in years, median IQR[a]		28 (24-34)	28 (24-35)	28 (23-33)
Race or ethnicity				
	White or Caucasian	62 (51.2)	34 (47.2)	28 (57.1)
	Black or African American	25 (20.7)	24 (33.3)	1 (2.0)
	Hispanic or Latino	10 (8.3)	3 (4.2)	7 (14.3)
	Asian or Pacific Islander	12 (9.9)	5 (6.9)	7 (14.3)
	Multiracial or other	12 (9.9)	6 (8.3)	6(12.2)
Sexual orientation[b]				
	Gay or homosexual	104 (86.0)	64 (88.9)	40 (81.6)
	Bisexual	14 (11.6)	8 (11.1)	6 (12.2)
Times tested for HIV[c] in last 24 months				
	0	12 (9.9)	8 (11.1)	4 (8.2)
	1-2	50 (41.3)	26 (36.1)	24 (49.0)
	3-4	32 (26.4)	23 (31.9)	9 (18.4)
	5+	27 (22.3)	15 (20.8)	12 (24.5)
Most recent HIV test result				
	Negative	103 (85.1)	58 (80.6)	45 (91.8)
	Never tested or unsure	18 (14.9)	14 (19.4)	4 (8.2)
Knows local places to get an HIV test				
	Yes	75 (62.0)	43 (59.7)	32 (65.3)
	No or don't know	24 (19.8)	14 (19.4)	10 (20.4)
	Did not answer	22 (18.2)	15 (20.8)	7 (14.3)
PrEP[d] uptake				
	Never used	106 (87.6)	65 (90.3)	41 (83.7)
	Previously used	4 (3.3)	3 (4.2)	1 (2.0)
	Currently use	11 (9.1)	4 (5.6)	7 (14.3)
nPEP[e] usage				
	Ever used	6 (5.0)	5 (6.9)	1 (2.0)
Free condoms in last 12 months				
	Received and used	55 (45.5)	33 (45.8)	22 (44.9)
	Received and did not use	21 (17.4)	12 (16.7)	9 (18.4)
At-home HIV test				

Characteristic		Total (n=121) n (%)	Atlanta (n=72) n (%)	Seattle (n=49) n (%)
	Ever used	33 (27.3)	14 (19.4)	19 (38.8)

[a]IQR: interquartile range.

[b]1 missing, 1 pansexual, 1 queer for Seattle.

[c]HIV: human immunodeficiency virus.

[d]PrEP: preexposure prophylaxis.

[e]nPEP: nonoccupational postexposure prophylaxis.

Select baseline characteristics of participants are shown in Table 2. The median age of participants was 28 years and did not differ between Atlanta and Seattle. Nearly half of study participants were nonwhite; Seattle had a higher proportion of white participants than Atlanta. Nearly two-thirds knew of a local location to get an HIV test. During the previous 24 months, almost half of participants had tested for HIV 3 or more times; 15.7% (19/121) had never been tested or were unsure of their HIV status. Over 1 in 10 participants had used PrEP before; reported PrEP usage (ever) was higher in Seattle (16%, 8/49) than in Atlanta (10%, 7/72%).

App Engagement

Participants' app engagement is presented in Table 3. Over 4 months, participants used the app on average for 17 minutes 40 seconds and made 133 clicks. There were no differences by median test between participants from Atlanta and Seattle in terms of total time spent on the app (P=.91) or total clicks (P=.62). There were also no differences in total time spent on the app by age (P=.21), race or ethnicity (P=.65), or whether participants knew of a local place to be tested for HIV (P=.99).

Total engaged time ranged from 25 seconds up to 77 minutes. Typically, the first visit was the longest (average first visit time: 7 minutes). Although the number of participants using the app each month declined, returning participants continued to engage with the app consistently with engagement during months 2-4 averaging 6.5 minutes and 49 clicks per month among active users. Most participants returned to the app multiple times over the 4-month period: 35% used the app on between 2 and 4 days, and 42% used the app on 5 or more days. Participants averaged using the app on a mean of 4.9 days.

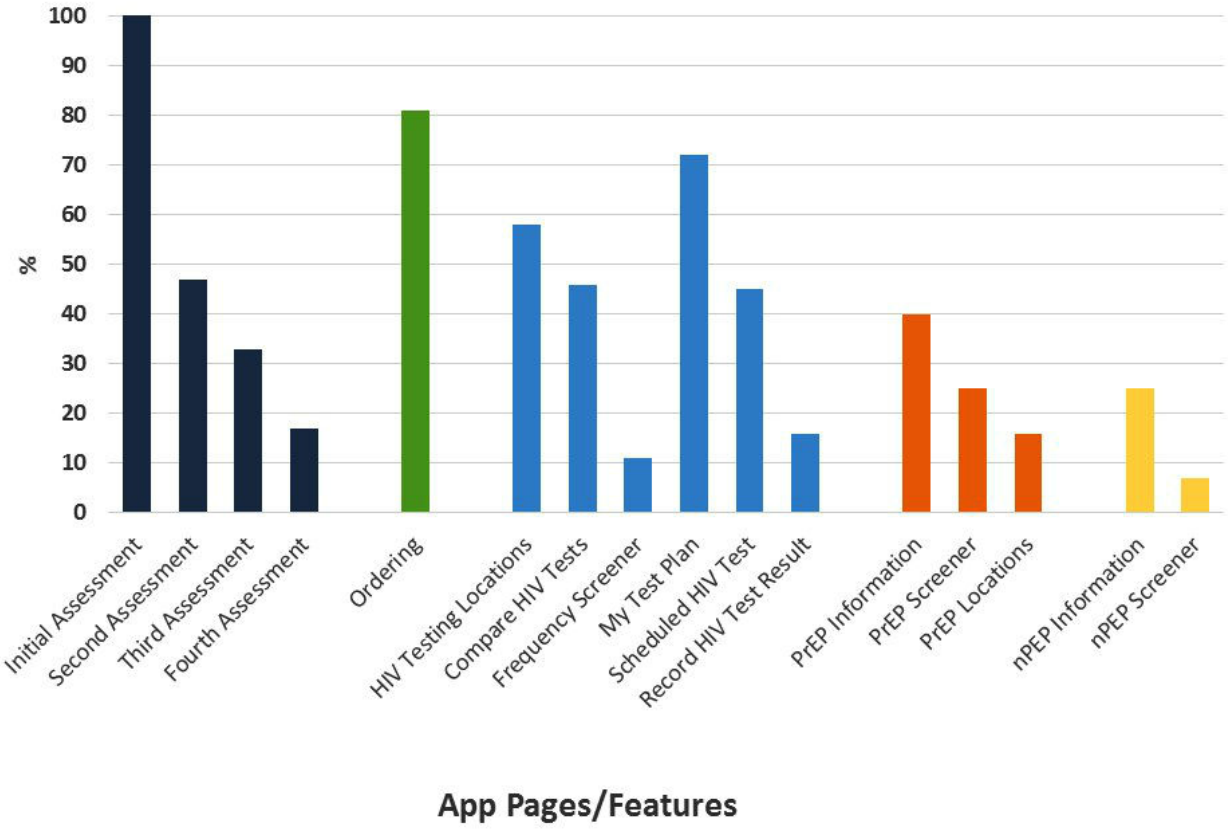
Table 3. Time engaged and user clicks made in a human immunodeficiency virus (HIV) prevention app by men who have sex with men (MSM) participants during 4-month pilot study, United States, 2015.

Criterion			Time engaged		Clicks[a]	
Usage		n	Average (minutes) per user	Range	Average per user	Range
	Total pilot usage	109	17.7	0.4-76.8	133	7-572
	First visit usage	109	7.0	0.4-22.2	52	7-131
Participant no.						
	1	109	11.3	0.4-61.2	85	7-454
	2	47	6.2	1.3-19.6	46	15-184
	3	35	5.7	0.2-20.3	46	2-118
	4	25	8.2	0.8-35.2	61	11-191

[a]Clicks capture all single actions made by a user, including logins, button clicks, and app navigation.

The percent of participants that used app features are reported in Figure 1. All participants completed the initial assessment, a requirement for enrollment into the study. Fewer participants completed the monthly assessments. HIV testing features were frequently accessed; ordering test kits and condoms was the most frequently accessed feature. Forty percent viewed PrEP information, a quarter used the PrEP screener, and nearly 1 in 5 opened the provider map feature from their PrEP screener result to view locations that offered PrEP. nPEP information was accessed by 25% of participants and 7% screened themselves for nPEP eligibility at least once.

Figure 1. Percent of MSM participants that used features or viewed pages in the app during a 4-month pilot study, United States, 2015 (n=109). MSM: men who have sex with men.



Ordering

Orders placed for free condoms and at-home HIV test kits are summarized in Table 4. Nearly two-thirds of men ordered condoms and over half ordered an at-home HIV test kit at least once. Of 154 kits ordered, most (84%, 129/154) were OraQuick kits. Most who placed an order did so on their first visit. Many participants placed multiple orders for condoms (38% of all who ordered) and for at-home HIV test kits (41%). Most at-home HIV test kits received were used by the participants to test themselves; 10% gave their test kit to someone else. Test kit use varied between the cities; 12% of Atlanta participants did not use the test kit compared with 41% of Seattle participants.

Table 4. Condoms and at-home human immunodeficiency virus (HIV) test kit ordered from an HIV prevention app by men who have sex with men (MSM) participants during a 4-month pilot study, United States, 2015.

Characteristic		Total (n=121) n (%)	Atlanta (n=72) n (%)	Seattle (n=49) n (%)
Condom orders[a]				
	On 1st visit	64 (52.9)	38 (52.8)	26 (53.1)
	At least once during pilot	77 (63.6)	47 (65.3)	30 (61.2)
	Place repeat order	29 (24.0)	16 (22.2)	13 (26.5)
At-home HIV test orders[a]				
	On 1st visit	37 (30.6)	28 (38.9)	9 (18.4)
	At least once during pilot	64 (52.9)	39 (54.2)	27 (55.1)
	Placed a repeat order	26 (21.5)	18 (25.0)	8 (16.0)
		n=70	n=45	n=25
Used the ordered condoms[b]				
	Yes	61 (87.1)	40 (88.9)	21 (84.0)
	No	9 (12.9)	5 (11.1)	4 (16.0)
Condoms replaced condoms would have bought or received elsewhere[b]				
	Yes	51 (72.9)	31 (68.9)	20 (80.0)
	No	18 (25.7)	14 (31.1)	4 (16.0)
Had condoms at time of order[b]				
	Yes	40 (57.1)	20 (44.4)	20 (80.0)
	No	30 (42.9)	25 (55.6)	5 (20.0)
		n=50	n=33	n=17
Use of human immunodeficiency virus (HIV) home test[b]				
	Self	34 (68.0)	25 (75.8)	9 (52.9)
	Significant other	3 (6.0)	3 (9.1)	0 (0.0)
	Friend	1 (2.0)	1 (3.0)	0 (0.0)
	Acquaintance	1 (2.0)	0 (0.0)	1 (5.9)
	Not yet used	11 (22.0)	4 (12.1)	7 (41.2)
Prior intentions of at-home HIV test users[b]				
	Not planning to be tested	34 (68.0)	21 (63.6)	13 (76.5)
	Replaced a planned test	16 (32.0)	12 (36.4)	4 (23.5)

[a]Order history analyses include all pilot participants (n=121).

[b]Reported in final evaluation survey (n=98).

Of those who ordered condoms, 87.1% reported using them. When asked about their motivations to place a condom order, participants said it was because the condoms were free (76%), it was convenient to do so in the app (67%), and they wanted to try different condom types (66%). Over two-thirds of participants who ordered test kits said they did not plan on being tested for HIV but ordered an at-home HIV test kit because it was offered in the app.

Outcomes

HIV and sexually transmitted infection (STI) testing behaviors during the pilot study are also shown in Table 5. Almost 80% of participants tested for HIV at least once during the pilot, and 56% tested multiple times. Additionally, almost half were screened for STIs. Three Atlanta participants tested newly positive for HIV. Their ages ranged from 18-29 years; 1 had never been tested for HIV before, and the other 2 had been tested for HIV 3 and 10 months before their enrollment. One participant had ordered and received an HIV test kit from the study. Two of the 3 who tested positive said their main motivation for being tested for HIV was the recommendation of the app to be tested; one said he tested routinely and had planned the test regardless of the app recommendation. Among participants who did not have a set HIV testing schedule at the start of the pilot, 63% had a schedule at the end of the pilot.

Table 5. Human immunodeficiency virus (HIV) and sexually transmitted infection (STI) testing history of men who have sex with men (MSM) participants during a 4-month pilot study of an HIV prevention app, United States, 2015.

Health Behavior at Post-Use Survey		Total (n=98)	Atlanta (n=61)	Seattle (n=37)
		n (%)	n (%)	n (%)
HIV/STI Testing				
	Tested for HIV[a]	75 (77)	48 (79)	27 (73)
	Tested HIV positive	3 (4)	3 (6)	0 (0)
	Tested for STIs[b]	46 (47)	29 (48)	17 (47)
HIV Test Plan				
	Had a previous HIV testing plan	52 (53)	34 (56)	18 (49)
	Did not have a previous plan, but now does	29 (30)	18 (30)	11 (30)
	Does not have an HIV testing plan	17 (17)	9 (15)	8 (19)
Among those never tested or tested > 1 year ago at baseline		n=19	n=12	n=7
	Tested during pilot	13 (68)	8 (67)	5 (71)
	Tested HIV positive	1 (5)	1 (8)	0 (0)
HIV Test Plan				
	Had a previous HIV testing plan	6 (32)	4 (33)	2 (29)
	Did not have a previous plan, but now does	9 (47)	7 (58)	2 (29)
	Does not have an HIV testing plan	4 (21)	1 (8)	3 (43)

[a]HIV: human immunodeficiency virus.

[b]STIs: sexually transmitted infections.

At the beginning of the study, 24% of participants reported not having heard of PrEP and 53% reported not knowing about nPEP. During the app pilot, 9% (8/86) of PrEP-eligible participants not already taking PrEP began taking PrEP, and 1 participant used nPEP. Among the 8 men who started PrEP, 6 reported that the app influenced their decision to start PrEP for one or more reasons (because the participant did not know what PrEP was before using the app [1/8]; because the app recommended PrEP based on behavioral assessments [1/8]; because the app provided information about PrEP [3/8]; because the app allowed them to find a PrEP provider [3/8]).

App Evaluation

The content of the app was thought of positively overall, with 88% finding the level of detail and 81% finding the assessment recommendations to be useful or very useful. Additionally, 66% felt the app content helped them to stick to an HIV prevention plan. Most participants felt the app was a good balance of personal and professional language (71%) and the information was easy to understand (90%). Most participants felt confident in app security (86%), including a password or PIN offering sufficient protection (85%) and the app name and icon not readily associated as an HIV prevention app (84%).

The usability of the app was well received by participants with findings shown in Table 6. Overall, participants found the app

to be easy to use and felt confident that they would be able to learn how to use it quickly and without technical assistance. The average composite score for the app was 73.4 (above average) [30].

Table 6. System usability scale (SUS) scores of an human immunodeficiency virus (HIV) prevention app by men who have sex with men (MSM) participants during 4-month pilot study, United States, 2015 (n=98).

Statement	Mean[a] (SD)	Absolute[b]
I would like to use this app frequently.	3.7 (SD 1.1)	3.7
The app was unnecessarily complex.	2.2 (SD 1.0)	3.8
The app was easy to use.	4.1 (SD 0.8)	4.1
I would need support from a technical person to be able to use this app.	1.8 (SD 1.0)	4.3
Various functions in the app were well integrated.	3.9 (SD 1.0)	3.9
There was too much inconsistency in this app.	2.1 (SD 0.9)	3.9
Most people would learn to use this app very quickly.	4.1 (SD 1.0)	4.1
The app was very cumbersome to use.	2.4 (SD 1.0)	3.6
I felt very confident using the app.	4.0 (SD 0.8)	4.0
I had to learn many things before I could get going with this app.	2.0 (SD 1.0)	4.0
Calculated score	73.4 (SD 16.7)	

[a]Scoring based on a scale from 1=totally disagree to 5=totally agree.

[b]Adjusts scores of negative statements so larger numbers are associated with positive statements.

When participants were asked about future app use, most said they would probably or definitely download the app again (69%), recommend it to a friend (71%), and continue to use it as part of their HIV prevention plan (66%). Very few participants reported they would probably or definitely not download it again (5%), not recommend the app to a friend (3%), or not continue to use the app themselves (13%).

Discussion

Principal Findings

There are many reasons to be excited about the use of mobile apps to increase the uptake of basic HIV prevention services among MSM. Achieving our national strategy goal of reducing new HIV infections by 25% by 2020 will require making substantial improvements in HIV prevention for MSM. Based on current use of HIV prevention services [31], achieving the 30%-50% coverage of basic prevention services that will likely be needed to achieve such reductions would require either broad expansions of funding for existing service provision mechanisms or development of new modes of delivery that can scale with low incremental costs [18]. And the very communities of MSM most impacted by ongoing transmissions—young MSM and MSM of color—are the same men most likely to have mobile phones [32]. In short, there is an intersection of public health need, good fit of technology to programmatic needs, and high coverage of required device ownership among those at greatest need of services. Men in rural areas of the United States are in equal need of HIV prevention services, but are less likely to report receiving HIV testing and condom distribution, and are less likely to be aware of PrEP or have accessed PrEP [17]. Our data indicate that men will use a mobile phone app for comprehensive HIV prevention services, including engagement in HIV testing, condom use, and PrEP assessment, and that such an app is acceptable to MSM at risk for HIV acquisition.

Various metrics have been proposed to characterize engagement with mobile phone apps [[33], although there are very limited data specific to health-related apps. With respect to engagement in the app, our data indicate that there was substantial variation in the extent of engagement with the app. Overall usage time was about 1.5 minutes per week over the period, which suggests that usage of our app was above average (above the median level of engagement observed in a recent analysis of usage of 22,000 mobile phone apps by over 600,000 mobile phone users) [33]. Our user database from the trial participants, 121 users, places our app above the 80th percentile in terms of numbers of users of available apps [33]. Thus, even in this limited implementation, our app shows engagement characteristics that are more favorable than most available apps.

Another way to measure engagement is the ordering and use of commodities by app users. Most users ordered condoms, HIV test kits, or both. It is also significant that most users who ordered condoms or HIV test kits reported using them. In a survey of MSM who received free condoms in bar or club settings, less than three quarters reported using the condoms they received [34]; in our study, nearly 90% of those who ordered condoms used them. It is important to recognize that many health jurisdictions already provide distribution of free condoms, sexual lubricants, and HIV test kits. In most places, this is accomplished through paying staff to distribute commodities in high risk venues. Distributing these prevention commodities by mail to those who want them and order them might offer a more targeted and cost-efficient way to fulfill public health functions of condom distribution and HIV testing promotion.

PrEP is an emerging biomedical approach to reducing HIV acquisition risk in high-risk MSM, but uptake of PrEP among MSM has been slow. Levels of awareness of PrEP are also low, especially among younger MSM and MSM in rural areas [17].

When less than 5% of US MSM have ever used PrEP, it is striking that nearly 10% of PrEP-eligible men initiated PrEP within a 4-month period of app use. According to our theoretical model of the PrEP continuum [35] and our qualitative data, the app likely promoted PrEP uptake by increasing awareness of PrEP (PrEP information features), facilitating access to PrEP providers, and helping men identify their personal risk of HIV infection and indications for PrEP. We recognize that some additional information such as information on costs and clinical procedures are currently lacking from the app, and based on the feedback we received from the participants, we will develop and add new materials to the PrEP component of the app.

According to a broadly accepted standard assessment of usability, our app was assessed as being above average using traditional criteria [30]; using a validated translation to qualitative terms, our app would be assessed as being between good and excellent [36]. Our data also suggest the possibility of social diffusion of the app, when it is made more broadly available: over 7 in 10 participants reported being willing to recommend the app to a friend. MSM have reported that recommendation from a trusted source was a major factor influencing their willingness to use an app [37]. By these standards, we conclude that our app is acceptable to the MSM whom we would have use the app.

Limitations

Our study had several limitations. First, our participants were subject to selection bias across several dimensions. We recruited men who were using Facebook or a Web-based dating app, and who may have been more comfortable using mobile apps than other men. We restricted our study to MSM in Seattle and Atlanta because of the need to provide enhanced resource directories; men in other cities might view and use the app differently. We limited this evaluation to men whose phones used the Android operating system; users of Apple or Windows operating system (OS) phones might have different use experiences or opinions of the app. However, we note that Android phone ownership is higher among Americans of color and among younger Americans, who are the groups with the highest rates of new HIV infections [32]. Our usage might have been overestimated because participants were enrolled in a research study with compensation for study assessments. Our pilot occurred only among MSM in urban areas, so generalizability to other MSM (including those in rural areas) was limited. Although nearly half of our sample was nonwhite, we had limited enrollment of Hispanic MSM. Enrolling racial or ethnic minorities in Web-based prevention research has been historically challenging, and future studies should over-recruit MSM of color, including Hispanic MSM [38].

There is a broad interest in the use of mobile apps for HIV prevention and a scientific evidence base to support the idea that mobile apps can influence health behaviors. We have developed a theory-based mobile phone app to provide a basic package of HIV prevention services to MSM, and found it to be acceptable to users in Seattle and Atlanta. Furthermore, our data on usage of specific components and order of commodities provide examples of how engaging with the app could improve health outcomes and provide baseline estimates of uptake, which can be used to power future randomized studies of the app. We recommend that, because of the high costs of app development, prevention scientists use a staged approach of qualitative formative work, theater testing, and usability or acceptability testing to ensure that mobile apps that are moved into larger, more expensive efficacy trials meet basic standards of acceptability and usability. The HealthMindr app has been demonstrated as being acceptable to MSM, as being usable, and as being associated with use of prevention services. HealthMindr should be considered for further evaluation in a randomized controlled trial with outcomes of the uptake of prevention behaviors.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Screenshots of HealthMindr app.

[PDF File (Adobe PDF File), 1MB - mhealth_v5i3e26_app1.pdf]

Multimedia Appendix 2

Welcome video provided to participants to introduce the study and procedures.

[MP4 File (MP4 Video), 9MB - mhealth_v5i3e26_app2.mp4]

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Abbreviations

AIDS: acquired immunodeficiency syndrome
GPS: global positioning system
HIV: human immunodeficiency virus
MSM: men who have sex with men
nPEP: nonoccupational postexposure prophylaxis
PrEP: preexposure prophylaxis
PIN: personal identification number
STI: sexually transmitted infection
SUS: system usability scale

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Original Paper

Designing Health Apps to Support Dietetic Professional Practice and Their Patients: Qualitative Results From an International Survey

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Abstract

Background: Dietitians are engaging with mobile health (mHealth) technologies, particularly with diet and nutrition apps in their patient care. Despite the plethora of apps available, the majority are not designed with a dietitian's input.

Objective: The aim of this study was to identify the user preferences of dietitians in relation to tools, resources, and design features for smartphone health apps that would support their dietetic professional practice and their patients.

Methods: As part of a larger international Web-based survey of health-app use among dietitians, three open-ended responses were included for specific exploration of app design features and additional resources or tools that could guide the development of apps for use in dietetic practice and patient care. Inductive thematic analysis of responses was conducted using the qualitative data analysis program, NVivo version 11 (QSR International Pty Ltd), to understand the design preferences and features valued by dietitians.

Results: The responses from 381 dietitian respondents were analyzed. Five key themes were identified. Dietitians wanted access to credible apps, suggesting that dietetic associations should have greater involvement in reviewing and endorsing evidence-based apps for use in dietary counseling. Improvements to the usability of apps, relating to their ease of use and design, were also raised, as self-monitoring of dietary behaviors using existing nutrition apps was deemed to be burdensome. Furthermore, apps providing dietitian-oriented support were favored, for example, those with the ability to streamline the dietary assessment process, so that dietitians could spend more time on dietary counseling and negotiating patient goals for dietary and lifestyle behavior change. Provision of patient-oriented support, such as functionality to tailor apps to patient-specific needs, was also considered important. Finally, respondents valued apps that could integrate into their work systems to enhance the quality of the dietitian-patient relationship.

Conclusions: App developers should draw upon the features and characteristics valued by dietitians to guide their development of apps that support dietetic practice and enhance patient care. Moreover, to achieve better dietitian and patient-centered app design, it is imperative that app developers take a collaborative approach with dietitians, their professional associations, and their patients.

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KEYWORDS

dietetics; apps; app design; mHealth; smartphone

Introduction

Smartphone ownership among richer, developed countries is nearing ubiquity. According to the Pew Research Center, a median of 68% of adults in advanced economies reported owning a smartphone in 2015 [1] and 77% of smartphone owners had downloaded smartphone apps [2]. Alongside the digital age, the prevalence of obesity and its associated noncommunicable diseases has rapidly increased [3-5], leading to rising social, health care, and economic costs [6]. Capitalizing on the ubiquitous and accessible nature of smartphones and their associated apps, mobile health (mHealth) strategies have the potential to provide cost-effective and scalable health care solutions to manage the escalating burden of disease. In 2015, there were over 160,000 mHealth apps available in the major app stores (eg, Google Play and Apple App store) [7]; approximately two-thirds of which targeted consumer health and wellness, comprising diet and nutrition, fitness, and other lifestyle and stress apps [8]. However, industry reports indicate that the majority of the 45,000 mHealth publishers had information technology backgrounds [7]. Even when publishers included additional team members with medical competencies, often these members were not sourced from the traditional health care industry [7].

Dietitians are trained and skilled experts in diet and nutrition [9] and have recognized roles in delivering effective lifestyle interventions for weight management through the counseling of health behaviors [10,11]. Their expertise could provide app developers and mHealth publishers with valuable insight into best practice treatment strategies to be incorporated into diet and nutrition apps. Within the literature, some studies have documented the input of dietitians in the development of apps intended for use by the public, such as the weight loss app “My Meal Mate” [12] and the gestational weight monitoring app “Eating4Two” [13]. There have also been a number of apps designed by dietitians for use in research but have not yet been implemented for general usage by dietitians [14-17]. Furthermore, since dietitians are using smartphone health apps and other mHealth technologies in patient care [18-20], understanding their experiences may enhance the ongoing development of apps to support the needs of dietetic practice.

There is a paucity of research that has investigated the design features and characteristics that dietitians seek for inclusion in health apps to support their professional practice. One previous study of Canadian dietitians examined factors affecting app use and recommendation in practice. Factors that were found to affect app use and recommendation included those relating to mobile devices and apps, the person and workplace; however, these findings were more centered on the barriers to app use rather than specific app design recommendations [18]. Dietitians and consumers were consulted during the development of a health platform designed for weight management, MyPace [21]; however, feedback was more relevant to the specific design features of the platform. The app design preferences of mobile phone users more generally, have been more commonly explored. Attractive user interfaces, structure, ease of use, personalized features, and accessibility were valued in weight loss apps [22], and usability, cost, and content quality were valued among wellness apps [23]. Among physical activity apps, some features desirable to users included automatic tracking and monitoring of progress toward physical activity goals and an integrated music feature [24].

We have previously determined from an international survey that 62% of dietitians used health apps as an information resource and for patient self-monitoring [19]. In particular, MyFitnessPal and the Monash University Low FODMAP Diet apps were the most commonly recommended by dietitians [19]. This study reports on the qualitative findings from the larger international survey and specifically aimed to identify dietitians’ user preferences regarding the tools, resources, and design features to be included in smartphone health apps that would support their dietetic practice and their patients.

Methods

Participants

This study was conducted with dietitians from the United Kingdom, Australia, and New Zealand. The dietetic associations for each respective country assisted in recruitment by distributing a link to the Web-based survey via their weekly member electronic newsletters, social media (Facebook) post, or emails directly to each of its members. Eligible participants had to be a Registered Dietitian (United Kingdom, New Zealand) or Accredited Practising Dietitian (Australia). The recruitment process has been described in more detail elsewhere [19]. Approval for this study was granted by the University Human Research Ethics Committee (approval number: 2015/701).

Data Collection

An interpretive paradigm was adopted by this study, which sought to understand the individual experience and the meaning they attribute to their actions [25]. As such, open-ended questions were selected as the research method to elicit new and more diversified information, especially on topics or experiences where there is limited information [26]. Open-ended questions also provide opportunities for respondents to share more rich and detailed opinions than that which could be achieved with close-ended questions alone [26,27]. Therefore, as part of a larger cross-sectional survey aiming to investigate dietitians’ use of smartphone health apps and other mHealth technologies in practice, the 3 open-ended questions shown in Textbox 1 were included to allow more specific exploration of app design features and additional resources or tools which could enable health apps to better support dietetic practice. Detailed methods about the piloting and development of the survey have been described elsewhere [19,28].

Textbox 1. Open-ended questions included on health-app design features that would support dietetic practice.

Questions
What's your ideal for how health apps for smart devices could be designed and can evolve to be most effective in your dietetic practice?
What additional information, education, resources, or tools could be integrated into apps to help you in your dietetic practice?
Do you have any other advice on what you see as features of a good app, for our teams working on developing apps for smart devices relevant to dietetic practice?

Data Analyses

Inductive thematic analysis, guided by the framework described by Braun and Clarke [29], was applied to the survey questions. This involved 6 phases: (1) familiarization with the data, (2) initial code generation, (3) searching for themes, (4) reviewing themes, (5) defining and naming of themes, and (6) writing up of results. Coding of the responses was performed using the NVivo qualitative data analysis software version 11 (QSR International Pty Ltd). One researcher (JC) conducted the analysis, coding all the responses to allow for data immersion and to obtain an overall sense of the entire dataset. Generated codes and subsequent themes were checked through a process of ongoing discussion with a second researcher (MAF) who was familiar with the data, before finalization.

Results

A total of 385 respondents attempted at least one of the 3 open-ended questions included in the larger survey (Q1 n=354; Q2 n=291; Q3 n=234). An additional 185 respondents completed the quantitative study but did not attempt any open-ended questions [19]. Four responses were excluded as they were nonattempts to the questions (eg, ?, -, a, test), thus responses from 381 respondents were analyzed. Table 1 reports the respondent characteristics. Respondents were mainly female (94.8%; 361/381) and aged between 26 and 35 years (41.7%; 159/381). The majority of respondents used health apps in patient care (62.7%; 239/381) and recommended apps to their patients (84.5%; 322/381).

Table 1. Respondent characteristics profile (n=381).

Characteristics		n (%)
Country of dietetic membership		
	United Kingdom	155 (40.7)
	Australia	213 (55.9)
	New Zealand	13 (3.4)
Gender		
	Female	361 (94.8)
	Male	20 (5.2)
Age (years)		
	18-25	35 (9.2)
	26-35	159 (41.7)
	36-45	95 (24.9)
	>46	92 (24.1)
Years in practice (years)		
	<1	28 (7.3)
	1-5	102 (26.8)
	5-10	77 (20.2)
	10-20	99 (26.0)
	>20	75 (19.7)
Setting of dietetic practice[a]		
	Hospital: Inpatient	153 (40.2)
	Hospital: Outpatient	144 (37.8)
	Private Practice	111 (29.1)
	Community	107 (28.1)
	Government and nongovernment organizations for public health	49 (12.9)
	Other[b]	82 (21.5)
Areas of nutrition management[a]		
	Weight management	251 (65.9)
	Diabetes	226 (59.3)
	Gastroenterology	139 (36.5)
	Nutrition support	115 (30.2)
	Allergy and intolerances	97 (25.5)
	Cardiology	95 (24.9)
	Geriatrics	92 (24.1)
	Pediatrics	80 (21.0)
	Oncology	68 (17.8)
	Mental health	51 (13.4)
	Renal	43 (11.3)
	Pregnancy/breast feeding	39 (10.2)
	Other[c]	70 (18.4)
Use of health apps in patient care[d]		
	Yes	239 (62.7)

Characteristics		n (%)
	No	142 (37.3)
Recommend apps to patients		
	Yes	322 (84.5)
	No	59 (15.5)

[a]Respondents were able to make multiple selections for these questions.

[b]Other categories includes responses with less than 10%: research/academia 7%, sports nutrition 4%, corporate 4%, food service management 4%, indigenous health 4%, and food industry 1%.

[c]Other categories includes responses with less than 10%: sport nutrition 9%, neurology/neurosciences 8%, and eating disorder 2%.

[d]Use of health apps in patient care is defined as dietitians using apps for specific purposes in the nutrition care process (eg, as an information resource, for patient self-monitoring, extra support for patients, dietary assessment tool), and extends beyond recommending apps for patients to use in their own self-management of health.

Thematic analyses of the 3 open-ended questions identified 5 major themes: credibility, usability, dietitian-oriented support, patient-oriented support, and integration into dietitian work systems, most with 2 or 3 associated subthemes. The key findings derived from each theme are discussed. Quotes that are representative of the overall sample have been cited, and where exceptions arose, those responses have also been presented.

Credibility

This theme captures dietitians' uncertainty over the credibility of apps, making it difficult for them to recommend apps to their patients. Greater reviewing and endorsement of credible evidence-based apps by dietetic associations and collaboration between app developers and dietitians could improve the confidence of the profession in using and recommending apps in dietetic practice.

Reviewing and Endorsement of Apps by Dietetic Associations

Respondents wanted health apps to be reliable sources of up-to-date evidence-based information and to also have scientific evidence backing their efficacy. However, concerns over the accuracy and validity of these apps produced considerable hesitation among respondents when they were considering whether to recommend health apps to their patients. This was particularly the case if apps were to be used as a standalone tool without the support or guidance of a health professional.

> *However the accuracy of most apps is uncertain and so we always recommend patients use them with caution and in conjunction with the information they receive from us.* [r295]

Some respondents were overwhelmed by the number and range of health apps available and expressed difficulty in remaining up-to-date with those that were most relevant to their practice and credible to recommend to patients. It was suggested that dietitian professional bodies such as dietetic associations should review these apps and endorse those considered to be credible and safe to their members.

> *As a registered dietitian we are also not able to promote one product above another as per our code of conduct. It would be nice to have a product which has been reviewed to be accurate and endorsed by a professional body such as the BDA [British Dietetic Association] to enable more active promotion among patients.* [r293]

Respondents also suggested increased promotion and advertising of the best apps to recommend, such as through distribution of dietetic approved lists of credible apps. Continuing professional development activities, including training workshops, seminars, or webinars could also enhance the profession's knowledge about the functions and features of particular apps.

App Developers to Collaborate With Dietitians

To design credible apps specific to the needs of dietetic practice, respondents proposed greater involvement of dietitians in the app development process. Apps designed in collaboration with dietitians or with dietetic associations were considered to be more acceptable and trusted by the profession.

> *I have more faith in apps designed by dietitians for use by dietitians!* [r287]

> *To have DAA (Dietitians Association of Australia) designed apps - at least the apps are designed by an accredited association.* [r209]

Usability

This theme explores the usability of health apps and the app design features which could enhance their ease of use across a range of users, both for the dietitian and their patients.

Easy to Use

Improvements in app functionality to make them more straightforward and easy to use was prioritized by respondents, especially because more complex apps could cause confusion to patients and detract from their use. With the time constraints of consultations, respondents also affirmed that apps had to be easy to download and set up.

> *Easy to use interface, not too complicated. One with minimal set up time (not one million questions about your health to begin).* [r46]

In describing how food logging and inputting data into an app could be a tedious process for patients, respondents suggested that features such as the ability to duplicate frequently consumed meals and save favorite foods could be more readily incorporated. Tools such as barcode scanners and voice-activated data logging could also make the logging process

quicker, easier, and simpler. Photo logging of meals was also proposed as a less-burdensome alternative method to manual food logging in apps for patients. This method would be further assisted with inclusion of other more advanced technologies, such as image recognition to determine portion sizes or nutrient content of foods.

Usability for All

Respondents mentioned how apps should provide greater accommodation for a range of user demographics, including different ages, literacy levels, and familiarity with technology among patients. Compatibility across different platforms, including both iOS and Android and across a range of smart devices (eg, smartphones, tablets, older phones) was also specified, since lack of compatibility was a barrier to patient use of certain apps recommended by dietitians.

> *Equally available on both iOS and Android platforms - many of my younger patients have Android and not all apps are supported on this platform.* [r244]

It was also commented that apps that should work offline or on little data, particularly to support dietitians servicing patients in remote or rural communities. Respondents also encouraged developers to make apps available for free or at a low cost, citing that paid apps inhibited app uptake by patients.

App Design

Simple, user-friendly app designs with easy to read fonts, and basic layout formats that were still visually appealing were sought after by respondents. Respondents wanted textual information and jargon to be minimized, opting for greater inclusion of visuals as a medium for communicating information to patients. App developers were also recommended to create "all-in-one" apps that could carry out multiple activities, citing greater convenience for both the dietitian and their patients.

> *It would be useful to have an app that had a number of functions - food diary, calorie counter, goal setting and physical activity tracker. It would be easier to recommend one app than three or four to a patient.* [r132]

However, others preferred to have separate apps that were specific to the nutritional management requirements of their patients.

> *Less is often more. Don't try to create an app that can do everything. Have one based on weight loss, a different version for allergies/intolerances etc.* [r146]

Dietitian-Oriented Support

This theme describes the app design considerations which should be addressed with regard to dietary assessment and behavior change and the dietitian-specific tools which should be implemented to support dietitian-oriented tasks.

Dietary Assessment

Respondents recognized the potential of food diary apps to make the dietary assessment process more streamlined through access to computed and analyzed dietary information from app food diaries, thus allowing more time to be spent on discussing strategies with the patient.

> *Patient enters their dietary intake, a full nutritional analysis can be done by a program with results e-mailed to the dietitian – reduces time of collecting and analysis dietary info.* [r198]

However, there was dissatisfaction with the current state of food diary apps. To ensure apps accurately reflected the nutrient composition of the local food supply, respondents emphasized that food databases had to be country specific, rather than being primarily derived from the US-based foods.

> *More UK relevant apps as a lot of apps tend to be USA-centric and foods in these apps are USA-based which then means patient has to find most relevant food which may be way off UK kcals.* [r376]

Dietitians also sought after food-based apps, rather than nutrient-based apps, as this would be more complementary to the dietary counseling advice provided by dietitians. Apps that tracked adherence to dietary guideline recommendations or food groups, as opposed to solely focusing on energy and nutrients were suggested.

> *Those that take food groups into account as opposed to macro- or micro-nutrients, eg, for 1 day there are 3 boxes to tick off, 1 box = a serve of milk/ milk product, 5 boxes for veg etc.* [r192]

Respondents also highlighted that photo functionalities within apps could enhance the dietary assessment process, especially around the estimation and discussion of appropriate portion sizes.

> *It would be great if they could involve pictures of the meal so that I can assess portions. Quite often patients underestimate portions... A visual diary can be a very powerful tool even without kJ information.* [r162]

Behavior Change

Health apps were predominantly reported as tools to promote patient self-monitoring, although mainly of weight, diet, and exercise. Respondents wanted greater flexibility in the outcomes tracked, such that personalized and specific goals negotiated with the dietitian could be entered into the app for patients to monitor. Respondents also communicated a desire for the functionality of health apps to extend beyond mere tracking of health behaviors, suggesting that a broader array of automated in-app feedback and encouragement based on patient performance be included to facilitate behavior change.

> *Offer suggestions when things aren't going well and encouragement when things are, eg, recognizes a goal has/has not been met.* [r340]

Others described how health apps could provide extra support and motivation between consultations. Implementation of push notifications or motivational messages derived from the app could also provide reminders, prompt practice, and action to use the app to achieve goals.

Dietitian-Specific Tools

Calculators for assisting with anthropometric assessment (eg, body mass index) and estimating energy and nutrient requirements were viewed as valuable tools for dietetic practice.

More specifically among respondents working in inpatient hospital settings, there was demand for an app that could calculate and formulate enteral nutrition treatment plans.

> *They could have the complete compendium of all nutritional feeds and used to work out enteral provision based on calculated requirements inputted, ie, fully functional platform for calculating nutrition needs with stress factors and activity and then work out the different ways of meeting those requirements with feeds.* [r254]

Respondents also wanted apps to contain or link into practice guidelines, handbooks, and evidence-based information, such as Practice-based Evidence in Nutrition (PEN).

Patient-Oriented Support

This theme identifies two main strategies for improving patient-oriented support, namely, through the option for tailoring apps to individual needs and by providing patient-specific tools for self-management of health.

Tailored to Patient

Respondents considered that the best apps would be modifiable to suit their own dietetic practice and could be customized to adjust for individual patient preferences. Mostly, respondents wanted personalization to occur within the app and not just only in the settings. For example, apps that could enable patient-negotiated tailored goals to be entered and subsequently tracked were valued by respondents. Others suggested using virtual technologies as a creative method for engaging patients on a personal basis.

> *The ability to personalize in some way - use of an avatar, background design, etc. (to create some 'feel' for the app, and patient buy-in).* [r302]

As dietitians often provide counseling over a range of nutrition management areas, respondents desired apps that would support a range of their patient's conditions (eg, cardiovascular disease, coeliac disease, diabetes, obesity). Respondents also highlighted a gap in the apps that were available for renal patients. They suggested that apps tailored to this patient group should provide analysis of key nutrients, including sodium, potassium, phosphate, and fluids, to allow for the monitoring or management of kidney disease.

> *A good start would be a very simple app for adhering to a fluid restriction. Another good option would be a traffic light system for potassium and phosphate foods, an app for sodium restriction too would be good.* [r218]

Patient-Specific Tools

To increase knowledge and empower patients to self-manage their health, respondents wanted their patients to be able to access to educational resources on different health conditions and nutritional recommendations directly from within the app and for the app to also link to other internet resources. Built-in videos or podcasts in the app were also suggested as a more engaging format to explain diet-disease relationships to patients.

It was also suggested that apps could provide meal or menu plans with attached recipes. This information could then be used to generate shopping lists for general healthy eating and specific diets. Tools that could help patients to make choices about healthier food alternatives, particularly for snack options, or to determine whether a food was appropriate to special dietary needs, were also perceived to be helpful for patients.

> *An app for helping food allergic patients choose safe packaged foods, which is regularly updated as products frequently change.* [r8]

> *Scan grocery items and it flashes Red, Amber or Green depending on the programed nutrient to include or exclude from the diet.* [r19]

Integration Into a Dietitian Work Systems

This theme highlights how sharing of health-app data could improve patient-provider communication and care through enabling greater integration of these mHealth technologies into dietitian work systems.

Sharing of App Data

To improve workflow, respondents commented that patient health-app data should be sharable or exportable from apps for direct viewing in dietitian work systems, citing that reviewing app records on a patient's phone was impractical. Respondents suggested several ways to share this data including email, Bluetooth synchronization, record printouts, and the ability to upload records onto a website or platform. However, ensuring the security and privacy of these app records was emphasized. The efficiency of work processes could also be improved by app data linkage to electronic health records.

> *Direct links to patient's electronic health records for information exchange and capture of information as part of their health records. The ability for patients to get their results, see the goals we've agreed in consultations.* [r249]

Dietitians also felt that having access to patient health-app data would improve patient-provider communication, as well as providing them with more opportunities to provide real-time feedback and support between consultations based on their patient's monitoring.

> *Food diary which allows access remotely to patient information so that it can be analyzed before clinic or as concerns come up.* [r279]

Discussion

Principal Findings

To our knowledge, this study is one of the first to identify design considerations, including features and tools, for apps supportive of dietetic practice. Dietitians prioritized several design aspects, including the credibility and usability, including ease of use and the design of apps. Apps targeted toward dietitian- and patient-oriented support and that could integrate into dietitian work systems were also regarded favorably. These findings provide guidance to app developers about the fundamental

characteristics to address while designing dietitian- and patient-oriented apps.

Dietitians are guided by codes of professional conduct to provide evidence-based practice, which extends also to the promotion of products, including health apps [30-32]. However, recommending apps in a professionally responsible way has been challenging since regulation only exists for apps considered to be medical devices [33-35], and health and wellness apps are left largely ungoverned. Furthermore, there are growing concerns over the credibility and evidence base of a range of mHealth apps that may be recommended in dietetic practice, such as weight management [36-41], diabetes [42-44], and physical activity [45,46] apps. Some studies have attributed the poor credibility of these apps to low health care professional involvement in app development [38,41]. Health care expert involvement in medical urology app development has been found to positively influence app downloads, suggesting that collaboration with health care specialists gives users greater assurance of the safety and credibility of an app [47]. As such, coinciding with our previous recommendations formulated on the basis of the COM-B model [19], involvement of dietitians and dietetic associations in the development as well as reviewing and subsequent endorsement of credible and reputable apps are necessary to enhance the confidence of the profession and their patients in recommending and using apps, respectively. Dietetic associations, such as Dietitians of Canada [48] and the US Academy of Nutrition and Dietetics [49] have headed the development and reviewing of credible apps for patient use and to support the dietetic profession.

According to the Technology Acceptance Model, perceived usefulness and perceived ease-of-use of a technology predicts users' attitudes and behavioral intentions toward accepting the technology, thus affecting subsequent technology use [50]. Usability-related characteristics, such as ease-of-use, were not only valued among our responding dietitians but also were a positive contributor to users' ratings within app stores [51] and were valued by mobile phone users in relation to wellness [23] and popular diet and weight loss apps [22,52]. An app requiring low effort to use is an imperative design consideration since both commercial and researcher-designed health apps typically experience a rapid decline in app use over time and low long-term retention [53-55]. Usability testing of a popular dietary app, MyFitnessPal, revealed users' dissatisfactions over inconveniences in food logging and complex structure which resulted in a loss of interest in using the app [56]. Tools such as barcode scanners and image-based food logging could minimize user burden and allow patients to maintain compliance with tracking, while still providing valid measures of intake [57-59]. Furthermore, to improve adoption of apps, attractive user interfaces and simple to navigate designs should be included. In Web patient portal use, Web aesthetic simplicity (ie, cohesiveness, structure, and easiness to understand) was a significant antecedent variable to patients' acceptance and use of patient portals [60]. App developers also need to engage in more user-testing during the development of apps and incorporate the service user feedback in an iterative design process to produce more dietitian- and patient- oriented apps.

When considering that diet and nutrition apps can automatically calculate energy, macronutrients, and micronutrient values from foods entered, apps present themselves as desirable tools to streamline and support dietitian-led dietary assessment. Yet, app developers should re-evaluate the quantitative approaches to dietary assessment currently implemented within apps, given that few dietitians consider apps as reducing the time for dietary assessment [19] and apps currently appear to lack of effectiveness in improving diet quality [61]. Instead, assessing the overall diet quality and interpreting and translating these dietary patterns into practical and meaningful food-based dietary advice would be more useful to both dietitians and their patients. Echoing conclusions drawn in the literature [36-38,45,62-64], our respondents recommended incorporation of a broader range of behavior change techniques, beyond self-monitoring. Notably, dietitians wanted apps to motivate patients and prompt them to practice health behaviors which could remind and encourage ongoing progress toward goals and encourage behavior change. Inclusion of automated motivational text messages or app push notifications have been found to improve physical activity [65], and when administered as part of a multicomponent mHealth lifestyle intervention, prevented weight gain and improved dietary behaviors [66].

As the health care system shifts away from the delivery of passive care to engaging patients as partners in their own health care, health apps present real-time opportunities to support and empower patients in making positive health behavior choices outside dietetic consultations. However, the absence of tailored goals and feedback is a major shortcoming identified in diet and nutrition apps for weight management [37,38,41]. The ability to input individualized goals within an app, such as those negotiated with dietitians would enable the tracking of more specific health behaviors relevant to the patient. There is only one known app—eaTracker developed by the Dietitians of Canada [67]—that supports the personalization of goals beyond generic pre-set targets of energy intake and weight loss. Additionally, providing personalized nutrition advice via mHealth technologies has been found to significantly improve selected dietary outcomes [68,69] and is an important consideration for developing effective apps. For example, remote and real-time delivery of daily tailored feedback messages significantly reduced energy and saturated fat intake, with changes maintained at 24 months [69]. Use of avatars might also be a method for personalizing the user experience in apps. They have been found to be a highly acceptable medium for modeling weight loss behaviors [70] and may engage and motivate users to change behaviors, such as promoting delayed gratification and dietary regulation [71] through embodying the patient's ideal self.

Individuals have previously expressed that sharing health-app records with their health professional would be useful to their care [72]. Reports, however, indicate limited sharing of these records with health professionals or dietitians [72,73], possibly attributed to individuals' perceptions that health professionals had little interest in their health-app records [72]. Contrary to patient beliefs, our responding dietitians wanted access to their patients' health-app records, particularly to support the dietary assessment process. However, with few commercial mHealth

apps having the capability to export user data [8,38], reviewing of patient progress with health apps has often been an infrequent and informal procedure for dietitians consisting of verbal discussion rather than direct viewing of the health-app data [19]. Enabling patients to synchronize, share, or export health-app data into their dietitian's existing work systems could enhance the two-way communication between dietitians and their patients. The increased connectivity and access to records may create opportunities for dietitians to address patient lapses and deliver more dynamic behavioral strategies to support patient compliance with dietary recommendations. App developers also need to ensure that these functions integrate seamlessly into current practice workflow to avoid imposing addition burdens on time and effort for the dietitian in adopting new systems.

Limitations

Although some respondents explicitly specified having no additional feedback regarding app design, it is not clear whether respondents who did not complete the open-ended questions had no further comments because they were in fact satisfied with the current state of apps, or whether they did not know what answers to provide and so left a blank response. The cross-sectional nature of this survey also poses the possibility of sampling biases, whereby greater willingness to respond to the open-ended questions may have come from more interested individuals and existing app users. However, the demographic profile of these respondents to the open-ended questions is comparable with that of the larger international survey, which was determined to be representative of the wider dietetic profession [19]. Furthermore, although adequate representation of the perspectives of nonusers is necessary, yet without experience in using existing health apps, the scope of suggestions provided by non–app users may be limited. If app developers perceive that the recommendations put forward regarding app design features already exist, they may be less inclined to develop apps further to support dietitian and patient needs. On the contrary, existing app users are likely to have richer and more feasible recommendations to guide and improve app development and design. It should also be noted that although understanding dietitian and user preferences may allow for more suitable apps to be designed for dietetic practice, this does not necessarily guarantee treatment effectiveness. Therefore, interventions studies are required to confirm which specific design features will provide the most support to dietetic practice and elicit significant effects on patient outcomes.

Conclusions

This study provides guidance to app developers of the features and characteristics of smartphone health apps valued by dietitians and highlights improvements for the design of health apps. In particular, dietitians asserted that apps should be credible and easy to use in order for them to more effectively support dietetic practice and dietitian's recommendations of these apps. Greater collaboration between app developers and dietitians or their professional associations were also viewed as critical for achieving dietitian and patient-centered app design and integration into dietitian work systems. However, further investigation is required to determine the app features that offer the most support to dietitians in improving patient health outcomes.

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Conflicts of Interest

None declared for all authors. However, MAF has developed food-based apps but not for weight management.

Authors' Contributions

JC, JL, AB, RH, and MAF contributed to the conception and design of the study. JC conducted the research, analyzed the data, and drafted the first version of the manuscript. JL, AB, RH, and MAF contributed to writing and editing the manuscript. MAF had primary responsibility for the final content of the manuscript. All authors read and approved the final manuscript.

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Abbreviations

mHealth: mobile health
PEN: Practice-based Evidence in Nutrition

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Original Paper

Experiences of Older Adults With Mobile Phone Text Messaging as Reminders of Home Exercises After Specialized Manual Therapy for Recurrent Low Back Pain: A Qualitative Study

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Abstract

Background: Clinical experience of manual therapy for musculoskeletal pain is that patients often suffer from recurrent pain and disorders, but that they do not continue to perform their physical home exercises when they are free from symptoms. The chance of positive long-term effects of manual therapy would probably increase if patients were reminded that they are to continue to perform their exercises. Mobile phone text messaging (short messaging service, SMS) is increasingly used as an innovative intervention to remind patient to exercise. However, there are only a few studies on such interventions in the field of low back pain (LBP). Qualitative studies of patients' experiences of receiving text messages as reminders of home exercises after manual treatment for recurrent LBP have to the best of our knowledge never been published.

Objectives: The aim of this study was to explore older persons' common experiences of receiving reminders of home exercises through mobile phone text messaging after specialized manual therapy for recurrent LBP.

Methods: A total of 7 men and 8 women (67-86 years), who had sought specialized manual therapy (Naprapathic manual therapy) for recurrent LBP were included in the study. Individual one-way text messages as reminders of home exercises (to be performed on a daily basis) were sent to each patient every third day for 3 weeks, then once a week for another 2 weeks. Semistructured interviews with 2 broad, open-ended questions were held and data were analyzed with systematic text condensation, based on Giorgi's principles of psychological phenomenological analysis.

Results: The participants appreciated the messages, which were perceived as timely and usable, and also stimulated memorizing. The messages made the participants reflect on the aim of the exercise, value of being reminded, and on their improvement in pain. During the interviews, the participants created their own routines for continued adherence to the exercises.

Conclusions: It seems plausible that mobile phone text messaging may serve as a useful tool for patient empowerment with regard to recurrent LBP in older persons. Further studies are needed to explore whether future compliance with the exercises will be as large if the participants are not being interviewed.

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KEYWORDS

text messages; older adults; recurrent low back pain; manual therapy

Introduction

Low back pain (LBP) that interferes with normal life is common in the general population [1]. Positive effects from Naprapathic manual therapy (NMT) for LBP and other kinds of musculoskeletal disorders have been found in clinical trials. They include decreased pain, increased physical function, and perceived recovery, both in the short and in the long term [2-4]. The NMT concept is pragmatic; the patients' knowledge about their disorders and their commitment to home exercises are believed to play an important role [5]. The aim of the home exercises is to improve the patients' pain condition and to prevent recurrence, but clinical experience of patients with recurrent pain is that they do not continue to perform the exercises when their pain is not present anymore. If it is possible to increase patients' adherence to home exercises, it may positively impact the long-term effects of the treatment, as well as increase the independence for patients and reduce costs. Therefore, it is necessary to give patients some empowerment over their improvement and to gain knowledge of how they experience being reminded of their home exercises.

Communication technologies are expanding and there are many areas in health care where it may be used for different purposes, for example, reminders of medication, fixing appointments in clinics, and pain assessment [6,7]. Mobile phone apps belong to a growing field of technological inventions that have had a positive impact on the outcomes of different interventions, their feasibility, and usability [8-10]. Responses to surveys can be more easily be given in real time using a mobile phone compared with postal surveys; the compliance is good, and it is also an inexpensive, time-efficient method.

Evaluations of the effects of mobile phone reminders for disease prevention, facilitation of self- management of long-term illnesses, and clinical and healthy behavior interventions are common, and the outcomes are positive in terms of significant improvement and differences regarding medication adherence, clinical management, and health-related behavior modification [11,14]. Mobile phones may also bridge gaps in health disparities; text messages were appreciated by the majority of participants in several studies and effects from text messaging exist across age, minority status, and nationality [11-13]. The majority of studies in this field are conducted in special health care settings; the most frequently studied patient groups are smokers, diabetics and patients with mental health disorders [15]. Research on mobile phone interventions for people with chronic pain in general and for LBP in particular is limited [16,17]; very little is known about preventive strategies and patient empowerment through mHealth, in LBP. Also, studies on vulnerable populations such as the elderly are requested [15]. In striving for increased health for patients with musculoskeletal pain, it is of interest to explore if using text messaging aimed to promote adherence to home exercises might be an appreciated delivery approach. Qualitative studies of patients' common experiences of receiving text messaging about home exercises have never been performed before to the best of our knowledge. The aim of this study was to explore the experiences of the elderly of a one-way reminder program using mobile phone text messaging aimed to promote adherence to home exercises following manual therapy for recurrent LBP.

Methods

Materials

The participants were 8 women (ages: 67, 73, 73, 77, 79, 82, 86, and 86) and 7 men (ages: 67, 71, 73, 75, 78, 81, and 82) who were consecutively treated for recurrent LBP in a clinic for specialized manual therapy (Table 1). Two patients (2 women aged 75 and 78 years) who were asked for participation did not want to be enrolled in the study. One of them did not possess a mobile phone, the other one was not interested in any participation. Another patient (a woman; 80 years) suffered from dementia.

Table 1. Demographics of the study participants or sample information.

Sample characteristics (n=15)		Values
Gender		
	Female	8
	Male	7
Age		
	Mean	76,7
	Range	67-86
Living alone		
	Yes	3
	No	12
Previous profession		
	Light physical load (illustrator, architect, office clerk, laboratory technician)	6
	Medium physical load (nurse, shop assistant, dentist, police, musician, house wife)	8
	Heavy physical load (farmer)	1
Regularly exercising (walking with poles, golfing, going to the gym, doing gymnastics, felling)		
	Yes	11
	No	4
Number of treatments		
	Mean	2,9
	Range	1-5

Intervention

The profession NMT has been a part of the Swedish health and medical care system since 1994. It is defined as a system for specific examination, diagnosis, and manual treatment of soft and connective tissues (massage, stretching, treatment of myofascial trigger points, mobilization, and manual manipulation, combined with physical exercises), which aims to increase the function and to decrease pain and disability in the musculoskeletal system [5]. The treatment concept includes an individually tailored treatment, time to explain the disorders to the patient, and a limited amount of specific home exercises, all of which is believed to have an impact on the long-term effects of the treatment [2,4,18].

Text Messages as One-Way Reminders

All participants possessed a mobile phone. In the present study, 1 or 2 exercises were given, adapted to the patients' conditions (ie, stretching of the ilio-psoas and quadratus lumborum muscles, stretching of the glutei muscles, or breathing technique). The most common exercises were stretching of the ilio-psoas muscle and breathing technique. The one-way text messages were individual for each patient, and the exercises were supposed to be performed on a daily basis. The stretching exercises took a couple of minutes each time, while the breathing technique was supposed to be performed now and then throughout the day. The first reminder was sent 3 days after the final visit. As the patients had their first visit at different occasions, spread over almost a year, reminders were sent consecutively, after the patients' or participants' last visit. The following reminders were sent every third day for 3 weeks, and then once a week for another 2 weeks (ie, a total of 5 weeks). The treatment sessions normally lasted for 2-3 weeks, which makes an average total time of 7-8 weeks from the first visit to the last reminder. The first message read: "Hello! This is the first reminder of your home exercise(s) (eg, breathing technique and stretching of the ilio-psoas muscle or stretching of the glutei muscles). Please text me to verify that you have received this message. Kindly, xxx." All the following reminders, except the last, read: "Hello! This is a reminder of your home exercise(s)! Kindly, xxx." The last message read: "Hello! This is the final reminder of your home exercise(s). I will contact you in 1 week to make a time reservation for the interview. Kindly xxx."

Interviews

The participants were asked 2 broad, open-ended questions in a semistructured interview, in order to focus attention on gathering data about the participants' life worlds (as expressed in phenomenology) and to provide an understanding of the common experiences of the participants [19].

1 . "What have you experienced in terms of the phenomenon SMS reminders of home exercises?"

2. “What contexts or situations have typically influenced or affected your experiences of the phenomenon?”

Follow-up questions were guided by the conversations [20]. For example, “What do you mean by that?”; “If I have understood you correctly….”; and “Could you tell a little more about…?”

The interviews were audiorecorded and transcribed verbatim.

Data Analysis

To understand patients’ experiences of receiving reminders of home exercises after NMT through text messaging, a phenomenological approach with systematic text condensation (STC) according to Malterud was used [20]. A qualitative study was carried out and data were analyzed with STC, deriving from Giorgi’s principles of psychological phenomenological analysis. STC derives from Giorgi’s principles of psychological phenomenological analysis [21]. Phenomenological research can be described as a way to understand the lived relations that human beings have to their world and to other human beings [22]. The reality is comprehended through individual embodied experience and perception, searching for the essence of a phenomenon from the perspective of how it is experienced. It strives to find the participants’ common experience of a phenomenon and significant statements that are valuable. STC is an elaboration of Giorgi’s principles, which includes 4 steps of analysis with specified shifts between decontextualization and recontextualization of data [20]. A limited number of participants [5-15] provide sufficient data for analysis, where the researcher is bracketing his or her presuppositions of the object and moves between identification with, or bracketing, during the different steps of the analysis process.

In the first step, we had an overview of data where the whole transcript was read in order to get a general impression and look for preliminary themes associated with the research question. In the second step, the transcripts were systematically reviewed to identify meaning units. The meaning units were then identified, classified, sorted, and coded according to 3 chosen themes. Data were then reduced to a decontextualized selection of meaning units and sorted into subgroups. The content of the meaning units were thereafter reduced into “a condensate”: an artificial quotation that maintained the terminology used by the participants. A story about the phenomenon with quotations of relevance was then recontextualized. Finally, we searched for data from the transcript that might have challenged our conclusion and compared our findings with existent research findings. We also checked whether our findings challenged our preconceptions.

Preunderstanding

In this study, the first author’s preunderstanding is based on an empirical perspective; experience of 25 years of clinical work both as an employed and as a privately practicing Naprapath. Initially, the patients consisted of young, elite classical ballet dancers (10-20 years) and later of “ordinary people” both groups adolescents; then, people of working age, older adults, and elderly. The researcher has also educated quality assurance in the Naprapathic core and performed research on treatment and cost effects of NMT at the boundary of specialized care [2,18]. The experience of “doing the right thing from the beginning” (as requested in quality assurance) and of treating patients such as ballet dancers (with very high demands on physical capacity) may have had an impact on the way the information was given to the study participants. Experience of quality assurance may have had an impact in terms of a wish that the participants would perform their exercises thoroughly and continue to perform them even after the study was accomplished. The guiding questions in the interviews might have been influenced by the researcher if, for example, the interviewees would tell that they did not continue to perform their exercises. In order to try to avoid influence from the researcher, there was plenty of time and tranquility during the interviews, in order to give space for the participants to reflect. The researcher also tried to pose few follow-up questions, in order to avoid too much guidance of the participants’ answers.

STC was chosen as it strives for “presenting the experience of the participants as expressed by themselves, rather than exploring any possible underlying meaning of what is said” [20]. This seems to set aside (bracket) the author’s preconceptions as much as possible. The author’s explanatory model was that the participants in this study would find the reminders of home exercises positive, yet a little annoying, disturbing them in their everyday life, and that the reminders would give them a bad conscience about neglected home exercises. The explanatory model was also that the participants would not find the exercises important when the text messages did not arrive anymore or when their pain was gone. All authors discussed the inductive analysis and the emerging themes and any discrepancies between coders. They also refined the analysis and commented on drafts of this article.

Ethics

The patients in this study were asked for participation at their last visit to the Naprapathic clinic. They received oral information about the study from the naprapath or researcher as well as a written informed consent to be signed if the patient agreed to participate. The patients had the opportunity to have any questions answered and were informed that they had the right to withdraw from the study at any time, without having to state any particular reason and without any negative consequences for them. The audiorecorded interviews and transcripts were kept in locked safes, separated from each other. The research project was approved by the Research Ethics Committee at Lund University (reference no. 2015/494).

Results

Results of the Treatment Intervention

The patients in this study had sought this treatment method themselves and it was privately financed, which is not the case for most visits to conventional health care in Sweden. All participants suffered from recurrent LBP and were treated with as many sessions as their condition required (an average of 3 treatment sessions), in order to be free from symptoms. The patients were asked for participation in the study at their last treatment session and were recruited consecutively through purposive sampling that was completed when it was possible to identify themes in the material. The home exercises were

thought to help the patients or participants stay pain free and to avoid relapses, and followed normal clinical procedures, in order to aid the transferability of the study.

Results of the Text Messages as One-Way Reminders

The text messages were sent timely, except for the first message for 2 of the participants. They did not receive this message timely, because they were on vacation abroad, and therefore not connected. Nevertheless, both of them replied a couple of days later, when in Sweden again and when they had received their messages. The text messages were perceived as positive by all the participants. The participants were pain-free when the interviews took place and stated that they did not continue with their exercises because they simply forgot to perform them on a regular basis in between the reminders and after the last reminder was sent. This was also the case if they were on a trip and staying away overnight. During the interviews, though, they reflected about their experiences of the text messages and came to think of, (and planned for), the best way to keep up with the exercises when the test period was over. Three subgroups built up 3 altogether different themes (Table 2).

Results of the Interviews

Interviews took place a week after the last treatment session (ie, when the SMS reminder would normally have arrived). The interviews were performed by the researcher, in a place chosen by the participants (ie, the Naprapathic clinic) and lasted for 30-40 min each.

Table 2. Data analysis.

Themes	Subgroups
Appreciation of the support to perform home exercises	Timely arrival of the text messages
	Usable exercises
	Stimulation to practice memorizing
Reflections about the experiences of the mobile phone text messaging	The aim of the exercises
	The value of the exercises
	Improvement in pain
Creation in order to maintain the improvement	Wishing to adhere to the exercises
	Own routines for the exercises
	The need for extended programs

Themes

Appreciation of the Support to Perform Home Exercises (Subgroups: Timely Arrival of the Text Messages, Usable Exercises, Stimulation to Practice Memorizing)

The arrival of the text messages was expected by the participants, as they had all been informed about the routines. The messages were perceived as positive and appreciated by all the participants. They found that the exercises for their back were needed and reasoned that what is good for the health is always positive and worthwhile committing to.

> *To perform the exercises, there is something positive about it. It has only been positive. Everything that affects you positively; at least that's how I reason; that everything that is positive to yourself, you easily commit to it.* [P1]

Also, as compared with disturbing advertisements, the messages were not of commercial character, and therefore, rather than being annoying, the reminders were anticipated and appreciated. The participants' experiences of the reminders were also that they arrived in a timely manner, thus not disturbing.

> *There is nothing annoying when it comes to such things. It is different with all the telephone salesmen...that is when you get upset! This is only positive. [P5]*

The text messages were perceived as easy to handle and the exercises as simple and noninvasive. Therefore, it was possible to perform them as soon as they arrived. As all the participants suffered from recurrent LBP, most of them recognized their given exercises from previous visits in the clinic. It was also appreciated that the exercises were few and perceived as appropriate and effective, and that no equipment was required.

> *I thought that it was really good to be reminded...it was such an easy exercise, compared with when I was to lay on the floor and pick up a ball and make something that took quite some time; I mean, many more exercises...this exercise, I could perform it when I was standing by the oven, waiting for the tea water to boil.* [P3]

The participants found that it was helpful to be reminded as they realized that the reminders were necessary if they were to stay pain-free. This made them feel stimulated and motivated them to practice different ways of memorizing to perform their exercises.

> *Sometimes I had performed my exercise just before the SMS arrived, and then I was very happy that I was ahead, so to say: I had fixed it without the reminder!* [P4]

> *I have been eager to perform the exercises before the reminder, since, thus, it is somehow like a reward!* [P11]

Reflections About the Experiences of the Exercises (Subgroups: The Aim for the Exercises, the Value of the Exercises, and Improvement in Pain)

In the last section of the interviews, the participants expressed reflections about the aim of the exercises, how these were to be performed, and in what way they were useful. It seemed that they reflected more on that during the interviews than during the test period.

> *I haven't thought of it (performing the exercises), more than, eh, what the aim was; or whether I would feel better, or...I have reflected a little about my breathing, whatsoever, how I breathe (laughter). If I breathe through my belly and how I do that, and when I do that, and when I don't. Well, I have had these thoughts...you remind me to breathe in a certain way, and then I wonder a little; how do I breathe, actually...I have never reflected on that before* [P8]

There did not seem to be any doubt that there was a value connected with the exercises. The participants' experiences were that the reminders did have an impact and that they were valuable.

> *It does affect you. It does have a value for me. The thing is that it (to perform the exercises) is valuable to me, myself...* [P5]

Most participants did not suffer from pain or disability when the interviews took place. They stated that, for the time being, they were free—or almost free—from pain, which was somehow surprising to them.

> *I am a little surprised that it, that my back doesn't protest, right now. I play extremely much golf, eh, and, sure, I am stiff and so, in the morning, like I use to be, but since I stress my back as much as I do right now, I am a little surprised that it doesn't protest any more...* [P2]

The participants were also reflective about the fact that their pain and disability had improved, and they wondered whether there was a connection between the exercises and their improvement in pain.

> *Well, eh, if I, it is, like I say, I can feel that they actually...that there is something that...I am a little surprised that my back holds...if it is because of those exercises for my belly, I don't know...* [P13]

More than forgetfulness, the fact that the participants did not suffer from pain or disability anymore was perceived to be the reason they forgot to continue to perform their exercises. This was also the case when going on a trip and staying away overnight, something that is also often recognized in clinical situations.

> *Actually, right now my back is fine, and then it is more difficult to remember to perform them (the exercises), as compared with when having pain…when you feel that your back is tired, or when you are in pain, it is a lot easier to remember the exercises...* [P7]

> *The thing is that I've been away, and then it's more difficult to remember this. Well, it is quite easy when one is at home, in one's everyday life...* [P10]

Creation in Order to Maintain the Improvement (Subgroups: Wishing to Adhere to the Exercises, Own Routines for the Exercises, and the Need for Extended Programs)

Some of the participants were curious to know if the intention was that they would continue with the exercises when the study was completed. They reflected about their own commitment to the exercises and how it would be possible to adhere to them in the future in order to maintain their improvement in pain and disability. This became obvious when the intervals between the reminders became longer and finally ceased to come.

> *In the beginning they (the text messages) came a little more often. Then there were longer intervals, and I ceased to perform my exercises, and when it (the text message) then arrived, I was surprised. By then I had totally forgotten about it. So it...* [P8]

> *I don't claim that I have a routine. I perform the exercises whenever I come to think of them, and it...(laughter) one should have it as a routine, actually; a couple of times every day.* [P6]

Most participants presumed that the exercises should be carried out continuously even when the pain was gone, and they reflected on how it would be possible to make them become a natural and smooth part of their everyday life. When they reflected on the need for continuation, they came to think of quite different solutions to create their own routines. The solutions varied depending on what their everyday lives and routines looked like—if they visited a gym, or a golf club, for example, or if they mostly spent their days at home. They came to think of having specific routines when going to the gym or when warming up before a golf session to perform the exercises at the same time as their daily medication, set mobile phone alerts, or write a diary for the exercises. All in order to make it possible to continue to perform the exercises when the test period was over.

> *But well, I do have certain routines...so it would be...if I would make it a routine, for example in the beginning of each golf session, when I am warming up. There I think that I would do it. Because I use to, eh, try to stretch my back before starting to swing. And there I would think that I could perform those exercises too, at the same time. I would consider that! But not otherwise; you have to connect it to something.* [P2]

> *...one should have it as a routine, actually; a couple of times each day. One should actually have them at each time. "Well, now I have to do it." That it says "pling" and then I have to do them. Of course, this would be possible for me to arrange myself; I have an alert on, in order to take a pill, at a certain time and...I have it continuously, that alert, every day. So I would be able to fix that on my own.* [P5]

> *...I thought then that one alternative to this would be to make a list and to tick it off, and...that you make your own list; that wouldn't be bad, because thus I'd see: "well, I didn't do anything yesterday.* [P3]

Some of the participants even figured that additional exercises would make it possible that they would avoid relapses and to stay pain-free overall, and this is why they requested extended exercises. Thus, it seemed that their creativity was stimulated.

> *There are many exercises that strengthen the back, for example. It would have been nice with some more...one does need some extra practice. More in general, exercising the back and so on...one would need to take action on thatBecause one shouldn't have to be in such pain, because of making a movement that the body is not used to. If you are sufficiently well trained, it shouldn't hurt.* [P1]

> *I associated the exercises in the text messages with other exercises that I have performed previously, so I did all of them when the reminders arrived.* [P14]

Discussion

Principal Findings

The main finding of this study was that reminders in the form of mobile phone text messages for home exercises for elderly patients who have received manual therapy for recurrent LBP were appreciated. It was perceived as positive and valuable to be reminded of home exercises and to practice memorizing. The participants reflected about the aim and the value of the exercises, and in order to maintain their improvement they created their own routines for continued adherence .

Discussion of the Results

There is only a limited amount of published studies that have evaluated text messaging as a method to promote physical activity [23]. Few studies (9 RCTs with small sample sizes) on patients with chronic LBP show reduced catastrophization and improved patient attitudes when using Web-based interventions like, for example, Web-based cognitive behavior therapy (CBT) [24]. These studies contain interactive components and they are quantitative, focused on outcomes, not qualitative (ie, focused on the participants' experiences), and that makes it difficult to compare their outcomes with the outcomes of this study.

The strengths of this study are that the results were distinct, and that the text messages were perceived as positive, simple, and timely. The participants in the present study were pain-free when the interviews were performed, and this is in line with earlier research with positive outcomes in studies where text messaging was used [11-13]. The participants in our study had chosen a private, complement (specialized manual therapy in the shape of Naprapathic manual therapy), and therefore, they may have been extra motivated to limit the number of treatment sessions, as they were expensive, compared with treatments in the reimbursed national health care system. Yet, the intention of our study was to explore how the text messages were perceived, not to measure the effectiveness of the treatment.

A major factor that contributes to increase the adherence to expert advice, according to the concept of health literacy, is improving people's understanding of what is provided in the realm of medical services [25]. Accordingly, the participants in our study were knowledgeable of the treatment option NMT (not available in the national health care system) and had made an active choice, which is a strength. They were thereby also "selected," and maybe more motivated to adhere to the exercises, which is a weakness with regard to the transferability to other groups of patients.

The exercises were perceived as simple, and during the interview the participants reflected on the aim and the value of the exercises and on the fact that the pain was gone. We believe it was because of the exercises because of earlier studies on the effects of text messages, which have concluded that the outcomes of such interventions, in terms of medication adherence, clinical management, and health-related behavior modification are positive changes and significant improvements [13,22].

Meanwhile, the participants realized that they easily forgot to perform the exercises when the reminders ceased to arrive or when the pain was gone. As they found that the exercises were valuable and they appreciated the memorizing practice, they reflected and created their own routines for remembering the exercises to avoid relapses of pain. This is probably the most salient and valuable finding of this study, and it is supported by earlier research, where patient participation and behavior change were important parts of improved self-management in chronic health disorders [26]. This is also in line with another health concept, namely, patient empowerment. The starting point of patient empowerment is that people may improve their health by controlling the conditions that rule health [27]. Positive outcomes of Web-based interventions for patients with chronic LBP in terms of increased patient empowerment and coping strategies have been found in several earlier studies [24]. The choice of treatment and research techniques utilized in this study are strengths, as they have not been studied before. Also, they embrace both health literacy (making an active choice) and patient empowerment (home exercises and reflection about adherence), which may improve peoples' health.

This internalization may be difficult to transfer to if only using text messages (no interviews) though, as it may be that the participants' reflection and creation emerged as a result of the interview. Somebody was interested in the participants' opinions and thoughts; they had a lot of time to reflect during the interview and were being listened to. Previous studies have concluded that text messages combined with other delivery approaches, that is, "face-to-face" interviews and implementation intentions planning in advance are significantly more effective for changing health behavior than one method only [28-30]. Therefore, an important question is, "What will make the participants continue with their exercises when they do not suffer from pain or dysfunction and do not receive the reminders anymore"? Will "creation in order to maintain the improvement" and adherence to the exercises be possible without the interviews, where the participants' creativity emerged [28]?

Patient participation and behavior change may also be easier to achieve when turning to older adults, as their health is more vulnerable compared with younger adults, and because they have a less-stressful everyday life than the working population. They probably have the time to reflect on the exercises and are also probably more motivated than younger people to practice something that stimulates the memory. However, a previously published study on the effects of reminders through text messaging concluded that text messaging was a tool for behavior change across all ages [11]. More rigorous, theory-based intervention research in pediatric and adolescent populations is needed, though [12].

Discussion of the Method

A phenomenological approach and an inductive method were chosen, in order to try to capture the essence of the participants' own experiences as much as possible and what they have in common, and to avoid interpretation of any underlying, latent meanings from the researcher. Looking for similarities might have biased the study though, as the interviewees were all very positive to the phenomenon. Yet, that was not known until the interviews were carried out. Strengths with the study are that the research question is new, the sample was chosen from the "real world" and of almost equal numbers from both genders. Also, it comprised elderly, which is an increasing group of patients, yet not often included in trials.

As mentioned earlier, the sample of participants in the present study was selected. Apart from being older, they had also sought a private clinic for their LBP, which may make it difficult to evaluate the transferability of this study to other contexts, such as hospital settings, for example, to which patients are referred.

The standards with regard to the frequency and duration of the text messages vary compared with former studies (from several times a day to once a month, and for 3-12 months, respectively [11,13]). In this study, the intervals between the reminders were chosen pragmatically; initially they were the same as the intervals between the first and the second treatment sessions (ie, 3 days). This may be considered a weakness; the internalization might have been more evident if the reminders would have arrived more frequently and the test period had lasted longer (ie, more than 5 weeks), yet this has not been confirmed in any previous study. The manual therapist and the interviewer were one and the same person in this study, and the participants are also patients. These are also weaknesses, as patients may want to please their therapist, which increases the risk of bias. Also, the (active) role of the manual therapist or researcher may have an impact when it comes to the patients' reflection and creation. Yet, the method (STC) used in this study appreciates that the researcher in the final analysis reflects on whether the findings challenge the researcher's preconceptions [20]. In this study they did; the participants were expected to find the reminders a little annoying, and their reflection and creation were not expected, which contribute to the reflexivity of the study, hence a strength.

The reminders made the patients reflect on their exercises and why they were pain-free and increased their understanding of sustainability in health. Thus, the study has clinical relevance. It also has technical implications, in that the method is widely available, cheap, and easy to start up, which has also been found before [8-11], and it is possible to elaborate the messages with extended and individually tailored exercises, for example. There is also the possibility of using text messaging the other way around, as found in previous studies, in order to enhance long-term follow-ups in clinical trials [31]. This study may serve as a small, yet an important contribution when striving to find methods that may have an impact on the long-term effects of an intervention.

Further research is needed, both with a technical focus (how often and for how long is it necessary for the text messages to arrive in order for patients to internalize their exercises, and if similar results are possible without interviewing patients?) and with a clinical focus (is it plausible that SMS reminders of home exercises may translate into improved long-term effects of manual therapy?)

Conclusions

Mobile phone text messages as reminders of home exercises after manual therapy for recurrent LBP in the elderly were appreciated among the interviewed study participants. The reminders made the participants reflect about the aim and the value of their exercises and of their improvement in pain. They appreciated that they had to practice memorizing and, in order to maintain their improvement during the interviews they created their own routines for adherence to the exercises. Thus, it seems probable that mobile phone text messaging may serve as a useful tool for patient empowerment with regard to recurrent LBP in older persons.

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Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavior therapy
LBP: low back pain
NMT: naprapathic manual therapy
SMS: short messaging service
STC: systematic text condensation

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Original Paper

Design Considerations for mHealth Programs Targeting Smokers Not Yet Ready to Quit: Results of a Sequential Mixed-Methods Study

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Abstract

Background: Mobile health (mHealth) smoking cessation programs are typically designed for smokers who are ready to quit smoking. In contrast, most smokers want to quit someday but are not yet ready to quit. If mHealth apps were designed for these smokers, they could potentially encourage and assist more people to quit smoking. No prior studies have specifically examined the design considerations of mHealth apps targeting smokers who are not yet ready to quit.

Objective: To inform the user-centered design of mHealth apps for smokers who were not yet ready to quit by assessing (1) whether these smokers were interested in using mHealth tools to change their smoking behavior; (2) their preferred features, functionality, and content of mHealth programs addressing smoking; and (3) considerations for marketing or distributing these programs to promote their uptake.

Methods: We conducted a sequential exploratory, mixed-methods study. Qualitative interviews (phase 1, n=15) were completed with a demographically diverse group of smokers who were smartphone owners and wanted to quit smoking someday, but not yet. Findings informed a Web-based survey of smokers from across the United States (phase 2, n=116). Data were collected from April to September, 2016.

Results: Findings confirmed that although smokers not yet ready to quit are not actively seeking treatment or using cessation apps, most would be interested in using these programs to help them reduce or change their smoking behavior. Among phase 2 survey respondents, the app features, functions, and content rated most highly were (1) security of personal information; (2) the ability to track smoking, spending, and savings; (3) content that adaptively changes with one's needs; (4) the ability to request support as needed; (5) the ability to earn and redeem awards for program use; (6) guidance on how to quit smoking; and (7) content specifically addressing management of nicotine withdrawal, stress, depression, and anxiety. Results generally did not vary by stage of change for quitting smoking (precontemplation vs contemplation). The least popular feature was the ability to share progress via social media. Relevant to future marketing or distribution considerations, smokers were price-sensitive and valued empirically validated programs. Program source, expert recommendations, and user ratings were also important considerations.

Conclusions: Smokers who are not yet ready to quit represent an important target group for intervention. Study findings suggest that many of these individuals are receptive to using mHealth tools to reduce or quit smoking, despite not having made a commitment to quit yet. The preferences for specific mHealth intervention features, functionality, and content outlined in this paper can aid addiction treatment experts, design specialists, and software developers interested in creating engaging interventions for smokers who want to quit in the future but are not yet committed to this important health goal.

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KEYWORDS

tobacco; smoking cessation; telemedicine; mobile health; smartphone; motivation

Introduction

Cigarette smoking is the leading preventable cause of death and illness in the United States [1] and a significant health issue worldwide [2]. In the United States, an estimated 17% of adults are regular smokers [3]. Most of these people (69%) want to quit smoking someday [4] but they are not yet ready to quit or seek treatment. In fact, most current smokers are characterized as being in the precontemplation or contemplation stages of change, meaning they either are not thinking about quitting or have no interest in quitting in the near term. Typically, only a third or less of current smokers report that they are in the preparation stage of change [5-8], meaning they are planning to quit smoking in the next month.

Whereas most smokers are not ready to quit and are not seeking treatment to quit smoking, most public health smoking interventions and nicotine dependence treatment programs—including smoking cessation apps—are designed for those smokers who are ready to quit in the near term. These programs are typically designed to help people take action but do not necessarily include the support, encouragement, or information smokers need to move from a position of wanting to quit someday to being ready to quit now or to help smokers cut back, but not quit, smoking. As a result, these programs may also have little appeal to smokers who are ambivalent about quitting in the near term. Utilization data are limited but it seems unlikely that smokers who are not actively thinking about quitting smoking are downloading or using cessation apps. For example, in a recent multinational survey of smokers who downloaded a cessation app, 77% were ready to quit in the next month (preparation stage of change) [9].

In contrast, we believe smokers who are not ready to quit in the near term may be receptive to mHealth tools if these tools were better designed to address their needs and interests, particularly among people who typically use mobile devices already. In prior research, we found precontemplative and contemplative smokers were receptive to both counseling [10,11] and Internet-based programs [12] when these programs were designed to help them make informed decisions about their smoking behavior (as opposed to quitting, per se), and as a consequence, many ultimately quit smoking. Thus, we hypothesized that smokers who are not yet ready to quit could also be interested in using mHealth apps, if these programs are designed to address their needs and interests and marketed or distributed in a way to encourage their use when people are not actively seeking treatment.

Increasing attention is being focused on how to design appealing and effective mHealth programs for smokers who are ready to quit and on identifying smokers' preferred mHealth features [13-18]; however, little is known about the mHealth needs and preferences of smokers who are not yet ready to quit. This insight is critical to designing appealing and effective mHealth-based, public health interventions in the future.

The goal of this research was to inform the user-centered design of mHealth tools for smokers who are not yet ready to quit by assessing (1) whether these smokers are interested in using mHealth apps to change their smoking behavior; (2) their preferred features, functionality, and content for these programs; and (3) considerations for marketing or distributing these programs to promote their uptake. To our knowledge, this is the first attempt to delineate these issues in this important target group for nicotine dependence intervention.

Methods

Design, Setting, and Review

We conducted a sequential exploratory, mixed methods study [19]. All research activities were conducted at the Group Health Research Institute (GHRI; currently known as the Kaiser Permanente Washington Health Research Institute) and approved by the Group Health Institutional Review Board. Qualitative interviews (phase 1) were conducted from April to May, 2016 to inform whether smokers who were not yet ready to quit were interested in using mHealth tools to modify their smoking behavior and, if so, get a preliminary sense of their desired program content, features, and marketing considerations. The results informed the design of a more comprehensive Web-based survey of smokers conducted from July to September, 2016 (phase 2). The Web-based survey was developed through an iterative process that included review by content experts and field testing with sample users to ensure face validity, user comprehension, and data integrity. All participants from both phases provided informed consent.

Phase 1: Qualitative Interviews

Recruitment and Eligibility

Smokers (n=15) were recruited from the Greater Seattle area via Web-based Craigslist ads, community flyers, and from patients of Group Health Cooperative, a large, regional health care system in Washington state. Respondents were eligible if they (1) were 18 to 60 years old; (2) were current smokers interested in quitting someday, but not in the next month; (3) were able to speak and read in English; (4) had medical insurance; and (5) owned a smartphone which they used to access the Internet. Participants were recruited into 3 age categories: 18-29 years old (n=3), 30-39 years old (n=4), and 40 years or older (n=8). Each person participated in a phone interview and received US $50 as a thank you for their time.

Assessment, Coding, and Analysis

The interview guide was designed to elicit participants' responses regarding their smoking and quit-attempt history, use of smartphones and mHealth apps, and ideal design and content for health-related mHealth apps including apps to help them

cut back or quit smoking. Participants were also presented a list of 17 potential features and functions of an app designed to improve their health or help them stop smoking and asked to indicate which they be would be willing to use (yes or no) and why or why not. Items were modified based on a similar scale recently used with smokers and nicotine dependence clinicians [13]. Finally, participants were asked about how they would like to get or learn about mHealth apps (eg, from the app store, personal doctor, health plan or insurer, friends or family, or other).

Quantitative and demographic data were analyzed using descriptive statistics. Interviews were audio recorded, transcribed, and loaded in ATLAS.ti version 7 (ATLAS.ti Scientific Software Development GmbH) for coding and analysis. Qualitative feedback was analyzed using an inductive, conventional content analysis approach [20] and findings were interpreted in light of the three aims outlined previously (ie, interest in using apps, ideal features, and considerations for marketing or distribution).

Participant Characteristics

Participants were demographically diverse: 53% (n=8/15) were female, 27% (n=4/15) were Hispanic or Latino, 60% (n=9/15) were white, and 53% (n=8/15) had only a high school degree or less. Mean age was 37 years (range 19-54). Participants smoked an average of 12 cigarettes per day (range 4-20). Thirteen participants (87%) had previously tried to quit smoking, but none were interested in quitting in the next month. All participants owned and regularly used a smartphone.

Results

Participants overwhelmingly agreed that they would be interested in an mHealth app to assist them in both determining their readiness to quit smoking and providing assistance to help them successfully do so. Many noted that mHealth apps represent a "new approach," unlike nicotine replacement therapy or quitting cold turkey, methods that several had tried in the past but were not successful. Some participants also noted that an mHealth app that helped them cut back, rather than quit smoking, was particularly appealing. As one participant (P4) stated, such an app, " *would be great, especially to gradually reduce. (Gradually reducing) sounds so much easier than quitting...you ease into it.* "

Based on the open-ended feedback and feature ratings, emergent themes were organized into three broad categories concerning participants' recommendations for and perceptions of the utility of an mHealth app. They valued a program that would: (1) address smoking triggers; (2) build self-efficacy and accountability through social support and coaching; and (3) allow them to track their health behavior, set goals, and earn rewards. Key smoking triggers identified included stress, depression, anxiety, and the environment. One participant (P2) described her ideal program as one that would provide answers to questions like:

> *How would you create a safe environment to quit? How do you make your environment so you can quit? You know what I mean? Like what environment do you need so that you can quit? Like right now I'm talking to you and I didn't want the cigarette.*

Several others suggested the app should provide ideas for alternative activities when they have cravings. For example, one (P7) suggested, " *I would include tips...showing people or telling people other things to do, like craft or clean your house or go do your yard work to keep your mind off (smoking).* " Another (P9) requested the ability to " *contact somebody and get information on smoking, like what I can do or to help me with cravings.*"

In terms of building self-efficacy and accountability, participants described a fear of failure and belief that they did not possess the tools or ability to successfully quit or cut back on their smoking. In response, all but one said they would use an app that allowed them to talk with a health coach or counselor through private text messaging (short message service, SMS) or secure email built into the app. Two-thirds of participants were interested in receiving support from others. As one participant shared (P11), this type of outside support " *might help me have more confidence to undertake something very difficult, you know, a little outside input that says, 'You're ready' when I'm unsure on some level.* "

Another person (P2) said they would like " *networking with other people to quit...somewhere you can vent and whine. You never know, people might say something that might strike a chord with you like yeah, that's so true.*"

But others were not interested in peer support or qualified their interest. For example, P7 commented, " *If it were something like (a text message or email), I would be interested. But like say, joining a support group or even chatting online with other smokers? I don't think I would do something like that.*" Another participant would only be interested in peer support if it did not come from family or friends. As this person (P13) explained, *"You don't really want to show your friends you're weak and need help, you want it to be more private.*"

Most participants were also interested in setting health goals, tracking their smoking and cigarette spending, or earning incentives for cutting back or quitting smoking. All of them said they would use a tool to track their smoking. This was seen as a way to help them cut back on their smoking, assess their readiness to quit, and monitor how much they smoke or spend over time.

> *An app to track how much I'm smoking would be great...like every time you smoke you tap a button and then over the course of a couple of weeks or even months it can tell you the ebb and flow* [P11]

> *...where it logs exactly, 'Hey, you smoked this many cigarettes a day' and then it turns it into a price...'You smoked $8 a day' or whatever the case may be. And when you have something to look at and it expresses it to you, when somebody actually points out your fault, you're like, 'Wow, I need to pay attention to that.' It would let you know, 'You know what? You over-smoked today. You've overspent.'* [P1]

Others suggested including features that allow users to track the health impacts of their smoking or quitting, *"...like 'now*

that you've quit for this long, your lungs have regained this much' so (it is) kind of like a motivator thing." [P15]

When asked how they would want to learn about an mHealth app for reducing smoking, most—but not all—participants identified their doctors as trusted informants. These participants described a scenario in which their doctors would introduce the app, but participants would download it themselves from the app store. One participant further described:

> *That would be so great if (the app recommendation) was on my going-home papers from (my health provider). If I saw (this), I would download it. There's always the quit smoking plan in the back of my after visit summaries, so if there was information about this app, that would be even more incentive than the number to call (to get help quitting).* [P4]

Participants who were reluctant to get the app from their doctor expressed concerns about cost. Another participant shared that she had not and was unwilling to tell her doctor she smoked, as she feared that her health care costs would go up. But there was a general willingness to download the app from an app store, either based on one's own interest or at the suggestion of family or friends. One participant felt the app's popularity could be spread through social networks:

> *Word of mouth is a great sales (tool) itself. If you really believe in your product or that app. My swamp game that I play, it's the dumbest game in the world, but...I got all my friends playing it just because of word of mouth.* [P1]

Additional participant preferences for each of the 17 features assessed are presented in Table 1. Of all of the potential features and topics assessed, smokers had the least interest in apps to help manage their diet or physical activity.

Table 1. Participant preferences for mHealth features.

Feature domain		Yes n (%)	No n (%)
Addressing smoking triggers			
	Advice for coping with cravings to smoke that is tailored specifically for you based on your needs or preferences	14 (93)	1 (7)
	Advice for handling stress that is tailored specifically for you based on your needs or preferences	13 (87)	2 (13)
Building self-efficacy and accountability through social support and coaching			
	The ability to talk with a health coach or counselor through private text messaging or secure email built into the app	14 (93)	1 (7)
	Information about the risks of smoking or benefits of quitting	12 (80)	3 (20)
	Information about stop-smoking medications, how they work, or how to get them	11 (73)	4 (27)
	Stories or videos from others talking about how they successfully changed their lifestyle and improved their health	11 (73)	4 (27)
	Social support from people other than your friends or family, like others who are trying to quit smoking or have successfully quit already	10 (67)	5 (33)
	Social support from people other than your friends or family, such as other people trying to change their diet or physical activity	9 (60)	6 (40)
	Social support from friends or family to help you stop smoking	9 (60)	6 (40)
	Social support from friend or family to help you change your diet or physical activity[a]	6 (40)	8 (53)
Tracking health behavior, setting goals, and earning rewards			
	A tool to track how many cigarettes you've smoked	15 (100)	0 (0)
	A tool to track how much money you spend on cigarettes or have saved by not smoking	13 (87)	2 (13)
	The ability to get points or credit for using the app and exchange them for rewards	13 (87)	2 (13)
	A tool to track your medication use	11 (73)	4 (27)
	A tool to track your physical activity	10 (67)	5 (33)
	A tool to track your diet	8 (53)	7 (47)
	Information about how to change your diet or physical activity[a]	7 (47)	7 (47)

[a]Totals do not add to 100% as 1 participant refused this question.

Phase 2: Survey

Recruitment and Eligibility

Survey participants (n=116) were recruited via Craigslist ads and through ResearchMatch.org, a Web-based service funded by the US National Institutes of Health Clinical and Translational Science Award (CTSA) program which matches prescreened volunteers with relevant medical research studies. Advertisements were placed in 21 states representing all US geographic regions, but focused more heavily on states in the southeast and midwest due to higher smoking prevalence in these regions [21]. Persons interested in learning more about the study were directed to a study website where they were screened for eligibility, provided consent, and completed the survey. Completely Automated Public Turing test to tell Computers and Humans Apart (CAPTCHA) verification was used to exclude nonhuman respondents. Persons were eligible if they (1) were 18-60 years old; (2) were current smokers interested in quitting someday, but not in the next month; (3) were able to speak and read in English; (4) owned a smartphone; and (5) used any app on their phone. Participation was limited to 1 survey per person, enforced with a combination of cookies and cross-referencing participant names and email addresses to ensure that there were no duplicates. A total of 250 people were screened for eligibility; of which, 123 screened ineligible (primarily because they were trying to quit smoking or had plans to quit within the month; n=92), and 1 person broke off before completing screening. Additionally, 10 eligible respondents declined participation, leaving 116 enrolled participants. Participants were provided a US $20 Amazon gift card code as a thank you for their time.

Assessment Measures

Participants were asked about their demographics, smoking and quit attempt history, use of smartphones and mHealth apps, interest in smoking-focused mHealth apps, and reasons they were or were not interested in these tools. Participants were presented a list of 42 specific mobile app features, functionality, and content topics and asked to rate how important or how appealing they found each of them. Item selection was based on a similar scale previously used to assess interest in mHealth app content and features among smoking cessation treatment experts and smokers [13,14], but modified to include additional response options based on the target audience, phase 1 results, and input from the authors. Importance and appeal were each rated on a 4-point Likert scale ranging from "not at all" to "very" important or appealing. Participants could also write in additional desired features, functions, or content.

Analysis

Survey responses were analyzed using SPSS version 22 (IBM Corporation). Descriptive statistics were used to summarize overall results. Preferences for mHealth features, functions, and content were also compared by stage of change (precontemplators vs contemplators) using Pearson chi-square analyses given the categorical nature of the ratings. Multiple comparisons were adjusted using the Bonferroni correction. Write-in comments were coded for common themes and summarized.

Phase 2 Results

Participants

Demographics and Smoking

Participant demographics and smoking characteristics are presented in Table 2. Most were moderate smokers, middle-aged, female, white, had a college degree, and a household income under US $50,000 a year. Participants were recruited from a total of 29 states and Washington, the District of Columbia. States represented all geographic regions of the continental United States. Few used tobacco other than cigarettes. Forty participants (34.5%, 40/116) were recruited via Craigslist and 76 (65.5%, 76/116) via ResearchMatch.org.

Interest in Reducing or Quitting Smoking

One-third (37.1%, 43/116) had attempted to quit smoking in the past year. Whereas participants were not actively attempting or planning to quit smoking in the near term, most agreed that they would cut back on their smoking if they knew where to find help (59.4%, 69/116) and nearly half said they would quit smoking if they knew where to find help (47.4%, 55/116).

Mobile Phone Use

Participants were predominantly Android users (75.0%, 87/116); only 29 (25.0%, 29/116) owned an iPhone. The majority actively used their mobile phones for accessing the Internet (97.4%, 113/116), taking pictures (97.4%, 113/116), sending email (95.7%, 111/116) and text messages (93.1%, 108/116), downloading apps (92.2%, 107/116), playing games (86.2%, 100/116), and listening to music (84.5%, 98/116).

Table 2. Participant characteristics.

Characteristics		Participants (N=116)
Gender, n (%)		
	Female	84 (72.4)
Race and Ethnicity, n (%)		
	Hispanic or Latino	8 (6.9)
	White	80 (69.0)
	Black	19 (16.4)
	Asian	5 (4.3)
	American Indian or Alaska Native	2 (1.7)
	Other	5 (4.3)
	Decline	5 (4.3)
Education, n (%)		
	High school degree or general educational development (GED) certificate	48 (41.4)
	College degree	58 (50.0)
	Graduate degree	8 (6.9)
	Household income < US $50,000	65 (56.1)
Other regular nicotine or tobacco use, n (%)		
	Electronic cigarettes	16 (13.8)
	Cigars or cigarillos	9 (7.8)
	Hookah	14 (12.1)
	Quit attempt in past year (yes)	43 (37.1)
Stage of change, n (%)		
	Precontemplation	37 (32.2)
	Contemplation	78 (67.8)
Age, mean (SD)		38.1 (11.7)
Cigarettes per day, mean (SD)		15.5 (12.9)

Interest in mHealth Apps

Approximately half (55.2%, 64/116) had used an app to manage 1 or more common health-related issues. Nearly half (45.7%, 53/116) had used a physical activity app. Twenty-five people (21.6%, 25/116) had used an app to track their food, calories, or weight. Eight people (6.9%, 8/116) had used a stress reduction app, 11 (9.5%, 11/116) used an app to track their sleep, 9 (7.8%, 9/116) used an app to help them manage their mood, and 3 people (1.2%, 3/116) had used another health-related app. However, only 4 (3.4%, 4/116) had ever downloaded an app to help them stop smoking.

In contrast, most (75.0%, 87/116) said they would consider downloading an app to help them stop smoking. Among those who said they would not consider this or were unsure whether they would ever consider this, many (44%, 11/25) expressed uncertainty that an app could help them change their behavior. Comments included, "*Other health apps I have used have not been particularly helpful*," " *I'm unsure how an app would aid in the prevention of smoking*," and "*I don't consider technology to be a good source to make someone do something*." Less frequent concerns expressed included cost, a reticence to download apps in general, and a lack of interest in quitting smoking.

More people (87.9%, 102/116) were interested in an app that could help them reduce their smoking than stop smoking (75%, 87/116). This interest was driven by a desire to improve one's health 71.6%, 83/116), protect one's future health (62.9%, 73/116), and save money (61.2%, 71/116). Similarly, nearly all participants expressed interest in an app that could help them decide "if, when, or how" to quit smoking (90.5%, 105/116). Of these 3 topics, more people were interested in knowing how to quit (51.7%, 60/116) than getting help deciding if they were interested in quitting (11.2%, 13/116) or when would be a good time to quit (26.7%, 31/116). People who already owned health-related apps were more willing to download an app to help them decide if, when, or how to quit smoking than those who did not own health apps (51.8%, 61/116 vs 41.9%, 44/116;

X^2_4 [n=116]=22.0, *P*<.001). A similar relation was observed for willingness to download an app to help people reduce their smoking. More people who already owned health-related apps were interested in this than people who did not own health apps (57.8%, 59/116 vs 41.9%, 44/116; X^2_4 [n=114]=12.2, *P*=.02). Willingness to use a smoking reduction app did not vary by education, income, race, or age. Interest in an app to help people decide if, when, or how to quit smoking varied by income, but not by education, age, or race. Most of the participants who were interested in this type of app reported an annual household income between US $25,000 to US $50,000 (30.8%, 32/116; X^2_{10} [n=115]=18.4, *P*=.05).

Preferred Features, Functionality, and Content of mHealth Smoking Apps

Privacy and Security Features

Participants rated the importance of various privacy and security features they would want to see in an app to help them change their smoking behavior (Table 3). They did not express a clear preference for blocking access to personal information stored in other apps versus allowing the app to access this information with permission; both were rated as important features. Similarly, they did not express a clear preference for whether their program information should be stored locally on their phone or saved in "the cloud" to allow access from other devices; both of these were seen as less important than other privacy and security considerations. Overall, password protection was viewed as important, with 41% of participants rating this as "very important." Preferences for these features did not vary significantly by stage of change.

Table 3. Perceived importance of privacy and security features. Items are measured on 4-point Likert scale from "not at all" to "very" important.

Feature	Mean (SD)	Rated "very important" n (%)	Rated "not at all important" n (%)
App does not access personal information on phone (eg, contacts, calendar, Facebook)	3.09 (0.97)	51 (44)	8 (6.9)
App can access personal information on phone, but I can decide which	3.07 (0.95)	46 (39.7)	10 (8.6)
App is password protected	2.99 (1.03)	48 (41.4)	12 (10.3)
My data is stored in "the cloud" so I can access from other devices	2.62 (1.05)	30 (25.9)	20 (17.2)
My data is stored on phone and not in "the cloud"	2.38 (1.07)	22 (19.0)	30 (25.9)

Functionality

Participants also rated the relative appeal of a range of potential app functionality (Table 4). Tracking functions were viewed as relatively important overall, with a 38% to 54% of participants rating these functions as "very appealing." Participants preferred content that could dynamically update to match their changing needs and interests, were interested in receiving rewards, and liked the idea of being able to request support or advice through the program when they needed it or to get immediate advice after answering a brief survey, but other forms of support and connectivity were rated as less appealing overall. In particular, smokers rated the ability to share updates with family or friends via social media or to video chat with other smokers or treatment experts as least appealing; 34% to 47% of participants rated these features as "not at all" appealing.

Participants were asked what type of rewards they would want to receive in exchange for points accumulated from viewing program content or completing tasks. Most (87.0%, 100/115) preferred a gift card or money, 9 people (7.8%, 9/115) wanted nicotine replacement patches, 3 (2.6%, 3/115) preferred free advice from a stop-smoking counselor or doctor, 2 (1.7%, 2/115) were interested in receiving another app of their choosing, and 1 person (0.9%, 1/115) simply wrote "gold."

There was a significant relationship between stage of change and the appeal of reporting one's progress on social media (X^2_3 [n=114]=13.1, *P*<.01). More precontemplators rated the ability to share their progress on social media as "not at all" or only "somewhat" appealing (83.7%, 31/116) compared with 66.2% (51/116) of contemplators. Other item comparisons by stage of change were not significantly different.

Table 4. Perceived appeal of potential app functions. Items were measured on 4-point Likert scale from "not at all" to "very" appealing.

Function domain		Mean (SD)	Rated "very appealing" n (%)	Rated "not at all appealing" n (%)
Tracking				
	Tracks how much I save by not smoking	3.34 (0.83)	63 (54.3)	2 (1.7)
	Tracks how much I spend on smoking	3.26 (0.88)	57 (49.1)	6 (5.2)
	Tracks how much I smoke	3.06 (0.92)	44 (37.9)	8 (6.9)
Static versus dynamic				
	Content adapts over time to my needs or interests	3.17 (0.75)	40 (34.5)	3 (2.6)
	Content stays the same and does not change	2.14 (0.89)	8 (6.9)	30 (25.9)
Support and connectivity				
	Lets me request support or advice when I need or want it	3.16 (0.84)	48 (41.1)	3 (2.6)
	Can get immediate advice after answering a brief survey	2.92 (0.90)	34 (29.3)	8 (6.9)
	Includes advice from stop-smoking experts	2.88 (0.89)	31 (26.7)	8 (6.9)
	Includes stories from other smokers with support and advice	2.63 (1.01)	27 (23.3)	18 (15.5)
	Sends me motivational or supportive messages via text message	2.63 (0.99)	24 (20.7)	18 (15.5)
	Let me text or email other smokers for support and advice	2.60 (1.03)	27 (23.3)	20 (17.2)
	Can request advice, but may wait 24-48 hours for response	2.43 (1.03)	20 (17.2)	26 (22.4)
	Sends me motivational or supportive messages via email	2.42 (1.00)	20 (17.2)	23 (19.8)
	Lets me send private messages to my doctor	2.39 (0.97)	18 (15.5)	22 (19.0)
	Lets me share my progress with family and friends	2.18 (1.00)	13 (11.2)	35 (30.2)
	Lets me video chat with stop-smoking experts	2.14 (1.05)	17 (14.7)	39 (33.6)
	Lets me video chat with other smokers	2.03 (1.04)	13 (11.2)	47 (40.5)
	Lets me share my progress on Facebook, Twitter, or social media[a]	1.90 (1.01)	10 (8.6)	55 (47.4)
Rewards				
	Lets me earn points to redeem for free gifts	3.45 (0.83)	74 (63.8)	3 (2.6)
	Lets me earn points or badges to track progress	3.11 (0.94)	50 (43.1)	8 (6.9)

[a]Significant difference by stage of change.

Content and Focus

Participants rated the appeal and perceived importance of different content which might be included in an app to help them either reduce their smoking or decide if, when, or how to stop smoking (Table 5). Nearly half (47%) said that an app to help them decide how to stop smoking was "very appealing" and more than half (53%) rated help managing nicotine withdrawal as "very appealing." A substantial portion of participants (ranging from 39%-53%) also thought it was very important that a smoking-focused app should also include

information about related issues like stress reduction, help managing depression and anxiety, or help managing their weight. However, the appeal of stress management content varied by stage of change (X^2_2 [n=114]=7.9, *P*=.02). This feature was viewed as "very important" by 70.3% (26/116) of precontemplators versus 44.2% (34/116) of contemplators. Whereas not statistically significant (X^2_3 [n=114]=7.0, *P*=.07), more precontemplators rated help managing stop-smoking medication side-effects as appealing or very appealing (72.9%, 27/116 vs 57.2%, 44/116).

Games were considered relatively important among everyone (mean=2.85 out of 4), but overall, fewer people considered these "very important" than considered health related content as "very important" (Table 5).

Participants were asked what other features they would like to see in an app designed to help them cut back or quit smoking. Twenty three stated they had no additional suggestions. Seventy-seven participants provided written suggestions. Among these, the most common theme (n=15) was the ability to track one's behavior (cigarettes smoked, purchased), health status (improvements over time), or money (amount spent on cigarettes or saved by not smoking). The second most common themes, each endorsed by 5 people, was the ability to earn rewards by using the program or to somehow distract themselves from smoking. Four respondents requested a place to journal about their experience or record their own positive affirmations and 4 people wanted some type of interaction with other smokers. Suggestions for the latter included stories from other smokers, the ability to get advice from others, and the ability to track others' milestones without having to personally interact with them. The remaining responses were only endorsed once each and included offering standard treatment content such as information on the risks and benefits of smoking, as well as more controversial suggestions such as providing "electric shock" and including images of smokers' diseased lungs.

Table 5. Perceived appeal and importance of content. Items were measured on 4-point Likert scale from "not at all" to "very."

Content domain		Mean (SD)	Rated "very appealing" n (%)	Rated "not at all appealing" n (%)
Focus				
	Guides me "how" to quit	3.26 (0.84)	55 (47.4)	4 (3.4)
	Helps me cut-back but not quit	2.95 (0.86)	34 (29.3)	5 (4.3)
	Helps me decide "if" I want to quit	2.57 (0.97)	21 (18.1)	18 (15.5)
Stop-smoking content				
	Helps me manage nicotine withdrawal	3.35 (0.78)	61 (52.6)	1 (0.9)
	Helps me manage medication side-effects	2.78 (0.95)	30 (25.9)	12 (10.3)
	Includes information on stop-smoking medications	2.63 (0.87)	19 (16.4)	11 (9.5)
Nonsmoking content				
	Helps manage stress[a]	3.40 (0.74)	61 (52.6)	18 (15.5)
	Helps manage anxiety	3.30 (0.85)	59 (50.9)	3 (3.4)
	Helps manage depression	3.17 (0.85)	47 (40.5)	5 (4.3)
	Helps manage weight	2.97 (1.01)	45 (38.8)	12 (10.3)
	Games for fun or distraction from smoking	2.85 (0.93)	34 (29.3)	8 (6.9)

[a]Significant difference by stage of change.

Considerations for Marketing and Distribution

Source and Reputation

Participants rated the importance of different reputational factors that might influence their decision to use a smoking-related app (Table 6). Based on the mean Likert scale score, most of the reputational metrics assessed were deemed "important," but fewer people rated a recommendation from their personal doctor as "very important" than the other considerations assessed. The most important consideration, rated as "very important" by 48% of people, was that the app be research-tested. Opinions on source and reputation did not vary by stage of change.

Table 6. Perceived importance of reputational metrics. Items were measured on 4-point Likert scale from "not at all" to "very" important.

Metrics	Mean (SD)	Rated "very important" n (%)	Rated "not at all important" n (%)
Research tested	3.22 (0.88)	56 (48.3)	4 (3.4)
Recommended by treatment experts	3.16 (0.88)	50 (43.1)	5 (4.3)
Highly rated by others	3.06 (0.95)	50 (43.1)	6 (5.2)
Developed by a trusted source	3.04 (0.95)	47 (40.5)	7 (6.0)
Recommended by my doctor	2.70 (1.03)	34 (29.3)	15 (12.9)

Price

Most smokers were not willing to pay much for an app to help them cut back on their smoking or decide if, when, or how to quit (Table 7). One third said they would not be willing to pay anything. Fewer than 4% would pay more than US $10 for this intervention program. No difference was observed by stage of change.

Table 7. Maximum price willing to pay for smoking-related mHealth apps.

Maximum willing to pay	App to reduce smoking n (%)	App to decide if, when, or how to quit n (%)
US $0	46 (39.7)	39 (33.6)
US $1	13 (11.2)	14 (12.1)
US $2	23 (19.8)	21 (18.1)
US $5	23 (19.8)	24 (20.7)
US $10	7 (6.0)	13 (11.2)
US > $10	4 (3.4)	5 (4.3)

Discussion

To our knowledge, this is the first report to assess whether smokers who are not yet ready to quit are interested in using mHealth apps to change their smoking behavior or inform their decisions about smoking. Others have examined technology use among smokers who are not motivated to quit, but did not look at use of smoking cessation apps specifically [22]. Similarly, increasing attention is being focused on how to design appealing and effective mHealth programs for smokers [13-18] but this work has focused on smokers who are ready to quit. As such, this paper makes a unique contribution to the literature.

Principal Findings

All phase 2 survey participants were smartphone owners and most regularly used apps; however, relatively few had used common mHealth apps and only 3% (4/116) had ever downloaded a cessation app. This supports our contention that smokers who are not yet ready to quit are not likely to proactively download and use traditional cessation-focused smoking apps. Similar results were found in a recent survey of US smokers; only 6% of smartphone owners who smoked and were not motivated to quit had used a cessation app versus 24% of those who were motivated to quit [22].

As in our prior research with smokers who are not yet ready to quit [10-12], both phase 1 and phase 2 participants were interested in getting assistance in changing their smoking behavior, even though they were not ready to commit to quitting. Notably, 88% of phase 2 survey respondents expressed interest in an app to help them reduce their smoking and 91% expressed interest in an app to help them decide "if, when, or how" to quit, with nearly half of participants saying that learning how to quit was "very appealing." This suggests that mHealth tools targeting this population should have a broader focus than cessation, even though the content should still help users understand the process of quitting for when they are ready. It is equally notable that almost a third of participants wanted a tool to simply help them cut back on their current smoking and nearly 1 in 5 would like a tool to help them decide "if" they want to quit. Thus, the optimal program for this population needs to address a range of user goals.

Participants rated their preferences for a variety of potential mHealth features, functions, and content. We suggest that items with a mean score of 3 out of 4 (indicating an average rating of "important or appealing" or "very important or appealing") reflect items most highly valued. With little exception, these items were also rated as "very" important or appealing by at least 40% of respondents. Using this metric, the app features, functions, and content rated most highly were: (1) security of personal information (eg, password protection and no or limited access to personal information on one's phone); (2) the ability to track smoking, spending, and savings; (3) content that adaptively changes with one's needs and preferences; (4) the ability to request support as needed; (5) the ability to earn and redeem awards for program use; (6) guidance on how to quit smoking; and (7) content specifically addressing management of nicotine withdrawal, stress, depression, and anxiety. Many of these themes emerged during the phase 1 interviews as well. With the exception of the security features and incentives, these are standard components of cognitive behavioral nicotine

dependence programs [23]. In that respect, smokers not yet ready to quit are interested in much of the same information known to be important with smokers who are ready to quit but the way this information is framed may need to differ to appeal to smokers who are still unsure of their quitting goals. For example, 1 phase 2 participant commented, " *I like that you are asking 'if' I want to quit rather than stopping right away*." This illustrates the importance of respecting that not everyone is ready to quit or necessarily wants to stop smoking, even if they do want to cut back or change their smoking behavior. Thus, apps designed for this target group should acknowledge that ambivalence.

Participants' interest in tracking tools was a consistent theme in phases 1 and 2 and was echoed in the phase 2 write-in comments. In fact, tracking was the most common write-in theme endorsed. In addition to tracking the typical financial and smoking metrics, participants suggested they would like to track health changes over time. A similar theme emerged during the phase 1 interviews. As wearable sensors become more advanced and available, we could envision a future system that might track users' heart rate, pulse, or oxygen saturation as relevant indices of health improvement when one cuts back or quits smoking. Our phase 1 participants indicated this type of feedback would be motivating, although it is worth pointing out that using biologically-based metrics of harm exposure or risk to motivate behavior change, including smoking cessation, has yielded mixed results when empirically studied [24-28]. Thus, these features may sound appealing but the potential for their actual impact on cessation is unclear. However, remote sensors could be used to monitor smoking events and event geolocation of these events. In turn, this information could be used to help smokers better understand when, where, and perhaps why they smoke. This insight may be useful in quitting.

Perhaps equally important to participants' preferred features and functions was their lack of interest in sharing their progress via social media; nearly half rated this as "not at all" appealing and it received the lowest overall mean score (1.9 out of 4). This finding echoes the opinion of smokers in another recent survey [13] and reflects the sentiment shared by one of the phase 1 participants that, " *You don't really want to show your friends you're weak and need help, you want it to be more private.*" In contrast, many recent studies are testing social media platforms to intervene with smokers [29-33]. These programs may ultimately be most appealing when sharing is limited to a closed group of users and not shared broadly with one's friends and family. It is also possible that social media will have greater appeal among younger smokers than older smokers, since younger people may be more comfortable sharing personal information over social media, in general. But it remains unclear if even younger smokers who have not yet committed to quit smoking will be interested in sharing their experiences in this way.

Finally, we sought to better understand future marketing or distribution considerations. This will perhaps be the greatest challenge of intervening with precontemplative and contemplative smokers, as it is unclear if smokers who are not yet ready to quit will voluntarily seek out tools to help them decide if or how to quit, even though they expressed interest in these tools in our survey. Whereas our findings do not fully inform how to connect smokers with these tools, it is clear that cost will be a barrier. Sixty percent of respondents said they would be willing to pay but our data suggest the cost should be under US $5. This is consistent with a general trend of price sensitivity for mobile apps. Program source, expert recommendations, empirical validation, and user ratings also appear important considerations for smokers and should be highlighted in promotional materials. Opinions about the role of health care providers in distributing these materials differed between the phase 1 and 2 participants but doctors, health care systems, and insurers could play a role in educating patients about the availability of a relevant mHealth app, even if not directly distributing it.

Strengths and Limitations

This work has a number of strengths including the use of a sequential exploratory mixed-methods analysis, nationwide recruitment, inclusion of smokers who are active smartphone users, and its focus on smokers who are not yet ready to quit. The latter makes up the majority of smokers, yet little is known about how best to engage these individuals in treatment or their preferences for using mHealth tools.

The chief limitation of this study is the small sample size, which limits generalizability. Compared with all US smokers assessed via the 2012-2014 National Health Interview Survey (NHIS) [34], our sample included more females (72.4% vs 45.3%) but fewer Hispanics (6.9% vs 10.3%) and whites (69.0% vs 81.0%). Slightly more than half (55.9%) of the people in our sample had a college degree or higher education compared with slightly less than half (44.7%) of those in the NHIS sample who had some or more college education. The groups also differed in terms of age (for those age groups included in our sample, we excluded people over 60 years). Among all US smokers, 12.8% are aged 18-25 years versus 11.2% of our sample, 45.3% are aged 25-44 years versus 56.0% of our sample, and 40.1% are aged 45-64 years compared with 32.8% of our sample. However, the groups are comparable in terms of the percentage of persons who smoke 20 or more cigarettes a day (28.9% NHIS vs 28.5% in our sample). These differences are not surprising since our sample was limited to adult smokers who regularly use smartphones and were not yet ready to quit smoking. Since nationally-representative data are not available on this specific subgroup of smokers, we cannot say to what extent the findings will generalize to this population of interest. However, the consistency of themes observed across phases 1 and 2 lend credence to the general validity of the results among similar US smokers.

Finally, we note that the preferences expressed by smokers in this study are based on the features and functionality they expect they would like. User preferences could be different if assessed in reaction to an actual app reflecting these preferred features, particularly if reactions are assessed based on "real-world" user conditions. But the results of this study provide some initial guideposts for developing these tools in the future.

Conclusions

This mixed-methods study confirmed that smokers who are not yet ready to quit are receptive to using mHealth tools to reduce or quit smoking. As such, these smokers represent an important target group for mHealth delivered interventions. In addition to being designed with an understanding of best practice nicotine dependence treatment, mHealth apps should be designed to appeal to smokers who have not yet committed to quitting. Findings from this study can provide insight into how to achieve this goal and may aid addiction treatment experts, design specialists, and software developers interested in creating new public-health focused smoking cessation apps in the future.

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Conflicts of Interest

None declared.

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Abbreviations

mHealth: mobile Health

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Original Paper

Content, Usability, and Utilization of Plain Language in Breast Cancer Mobile Phone Apps: A Systematic Analysis

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Abstract

Background: Breast cancer is one of the leading contributors to preventable illness and death among women. Although mobile phone apps provide unprecedented opportunity to engage women along the cancer continuum, little is known about the availability, content, and usability of breast cancer mobile phone apps.

Objective: This study analyzed the content and adherence to literate design standards of all breast cancer-related apps available on the App Store and Google Play, as well as the relationship between their content, user ratings, and price.

Methods: Following identification and downloading of all available breast cancer mobile phone apps in October 2015, 101 apps were confirmed as focusing on breast cancer. Based on prior research, we adapted and applied a content analysis scheme that was specific to breast cancer apps, including their main purpose, relevance to the cancer care continuum, and adherence to usability standards outlined by the Institute of Medicine (IOM).

Results: The most common aim of apps was educational (73/101, 72.3%), followed by behavior change (24/101, 23.9%), fundraising (20/101, 19.8%), and advocacy (14/101, 13.9%). On the cancer continuum, primary prevention (strategies to prevent cancer cells from occurring) was mentioned in almost one-third of the apps (30/101, 29.7%). Less than half of the apps (46/101, 45.5%) presented information about mammography and/or breast clinical exam, and 53 apps (52.5%) discussed breast self-exam (which is no longer recommended). Symptoms of cancer prediagnosis, such as a lump, were discussed in almost half of the apps (48/101, 47.5%) and a similar number of apps included information about genetic risk for breast cancer (47/101, 46.5%). Information about breast cancer diagnosis was included in 42 apps (41.58%) and 43 (42.6%) apps discussed treatment options. Survivorship issues were addressed in 17 (16.8%) apps. Only one (1.0%) app discussed hospice. Adherence to usability recommendations was low. The median composite score was 3 (mean 2.60, SD 1.20) of the six recommended usability items. With eight plain language items, the median of the composite health literacy score was 5 (mean 5.06, SD 2.00). Most apps did not use easy-to-understand words (44/101, 43.6%) and few (24/101, 23.8%) defined key terms.

Conclusions: Current breast cancer apps provide important information about breast cancer, but the most common topic covered is breast self-examination, a non-evidence-based screening strategy. Apps that focus on evidence-based strategies on the cancer continuum are needed, with a notable pressing need for apps that would address survivorship and end of life. Finally, developers of breast cancer apps should adhere to IOM standards to meet the needs of diverse populations and reduce current disparities.

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KEYWORDS

mobile phones; mobile apps; breast cancer; cancer-related content

Introduction

Overview, Rationale, and Goals

More than 1,677,000 women worldwide are diagnosed with breast cancer and more than 522,000 die of it annually [1], making it the most commonly occurring cancer and the principal cause of death from cancer among women globally [2]. Breast cancer constitutes a major contributor to preventable cancer burden [3,4], which refers to the morbidity and mortality that can be reduced by health behavior change, access, and utilization of screening and treatment services. Notably, most of the inequity in cancer health outcomes, including international and interethnic differences in breast cancer incidence and mortality, are attributed to preventable causes [5,6]. Although evidence-based comprehensive programs have documented successes in increasing breast cancer survival rates in high resources settings, much work is needed in increasing their reach, particularly among medically underserved populations in the United States and beyond [7].

Mobile health technology, or mHealth, holds great potential in reducing disparities in cancer-related health outcomes. With nine of 10 Americans owning at least one cell phone, and a majority (63%) of these devices providing access to mobile Internet service [7], it has tremendous penetration. Unlike previous communication technologies [8], these devices are disproportionally used by members of low-resources communities, with minority users more likely to access the Internet exclusively from their mobile phone [9]. Further, well-designed mHealth holds great potential in promoting health in low-resources communities in developing [10] and developed countries [11]. In view of the international and national burden of breast cancer and the potential of mHealth in improving medical and public health practices [12], it is important to understand the use of breast cancer-related apps across the cancer care continuum. However, although half of cell phone users reported downloading apps in 2013 [13], little is known about these apps' design, availability, and health-related use in general and in the context of breast cancer in particular. To date, studies have examined content of cancer-related apps using content analysis of apps' descriptions on the App Store [14], of cancer-related apps available on iPhone only [15], and of studies reporting on educational cancer apps [16], yet the specific content of breast cancer-related apps available to consumers along the cancer care continuum [17] has not been examined. Studies of mHealth reveal that although apps offer beneficial functions [18], consumers are faced with a "bewildering array" of available health apps [19], with varied and often dubious quality [20,21]. Of apps that focus on cancer awareness, few discuss evidence-based preventive health behaviors [14], a deficiency that is likely because of a lack of medical professional involvement in design of apps [22]. Furthermore, cancer-related apps can pose a danger; for instance, skin cancer-related apps accurately assessed melanoma only 10% of the time [23].

To reach individuals from low-resources communities who are disproportionally affected by preventable cancer burden, literate principles should be followed in the design of apps. The Institute of Medicine (IOM) published guidelines on mHealth-literate design strategies, including plain language and appropriate usability features [24]. However, it is unknown to what degree these standards are implemented in the design of breast cancer-related apps [24].

In view of the importance of breast cancer as a public health concern, the goal of this study was to systematically analyze the availability and content of breast cancer apps available on the main platforms of Google Play and the App Store, and their main features, including content on the cancer care continuum, goals, adherence to the IOM literacy guidelines, price, and user ratings. The following sections review past research on these factors as they relate to breast cancer mHealth.

Prevention

A growing body of evidence documents mHealth interventions' effectiveness in engaging users in cancer preventive measures [25]. For instance, text message reminders to female patients before scheduled breast cancer screenings were found to greatly increase screening attendance [26]. Apps have also been shown to successfully increase breast cancer screenings in rural areas as well as disseminate important breast cancer information where cultural and social constraints prevent the spread of accurate breast health information [27,28].

Treatment

Apps are also utilized to enhance care delivery during cancer treatment. These apps work as information management tools where patients can check appointments, journal symptoms, and log medications [29]. These apps and devices can also reduce the communication gap between patients and providers, expedite treatment, allow patients to more easily report side effects of chemotherapy and other treatments to health care providers in a timely manner [10,30], provide information about postchemotherapy side effect management, and assist cancer patients with medication adherence [11]. Although mHealth has great potential for cancer supportive care during treatment (eg, management of symptoms), research has not explored its role in improving patient quality of life [23,31].

Survivorship

Survivorship is another important area for mHealth cancer care interventions. In addition to cancer recurrence, breast cancer survivors are at a greater risk of comorbid conditions, such as obesity, osteoporosis, cardiovascular disease, and diabetes [32], and many breast cancer survivors do not meet healthy lifestyle recommendations [32]. Several mHealth interventions on nutrition quality, physical activity, and improved eating self-efficacy have addressed this problem and were found to facilitate significant short-term weight loss, decrease waist circumference, and increase self-efficacy in breast cancer survivors [33]. It has been suggested that lifestyle interventions for cancer survivors, including breast cancer survivors, should

incorporate text messages and mobile phone apps to augment existing survivorship interventions [34]. In addition, researchers noted the potential of apps to increase physical activity for breast cancer survivors [35] and the successful reduction of stress among breast cancer survivors in a technology-based self-management intervention [36] further demonstrates the promise of technology-based survivorship interventions.

mHealth Literacy

User skills are key to effective utilization of mHealth, particularly among underserved communities. Digital health literacy is related to one's ability to seek, locate, comprehend, and assess health information from electronic sources [37]. The concept of digital literacy draws on health literacy, defined as the ability to understand and use health information, communicate needs to health providers, and understand information from health care institutions [38]. Health literacy is strongly related to health outcomes, including cancer communication [39]. Similarly, digital health literacy is related to age and education, as well as to better outcomes as a result of health information seeking [40]. Use of mobile technology is dependent on both health and digital literacy skills. Digital literacy is crucial to engage in health maintenance, change behavior, and utilize health care services [41]. People with low literacy are less likely to access the Internet to seek information about health concerns [20], despite strong information needs following cancer diagnosis [42,43]. Patients with low health literacy are less likely to use health apps or perceive them as easy or useful, and hence are less likely to benefit from this technology [31]. Understanding different literacy levels is consistent with research by Second-Level Digital Divide [36] that examined different skill levels of using digital communication technologies. Health-literate apps can bridge the digital divide by improving quality and usefulness of health information and interventions that would ultimately lead to better health outcomes [24].

The price of apps is an additional factor in apps' dissemination and adoption of health promotion messages. Paid diabetes apps demonstrated better adherence to IOM standards compared to free apps [44]. Such advantage of paid apps has the potential to limit the dissemination of health information and to increase health disparities because most users are reluctant to pay for apps [45]. However, it is unknown whether these differences are manifested in apps in other health-related content areas, including breast cancer.

Finally, although systematic reviews aim at addressing availability and analyzing the content and features of the analyzed apps use [46], mHealth allows some insight into users' experiences by featuring user ratings of apps. User ratings have been shown to be correlated with professional quality ratings of apps [47]; therefore, exploring their association with adherence to literate app design has the potential to shed light on the relationship between design and user experience.

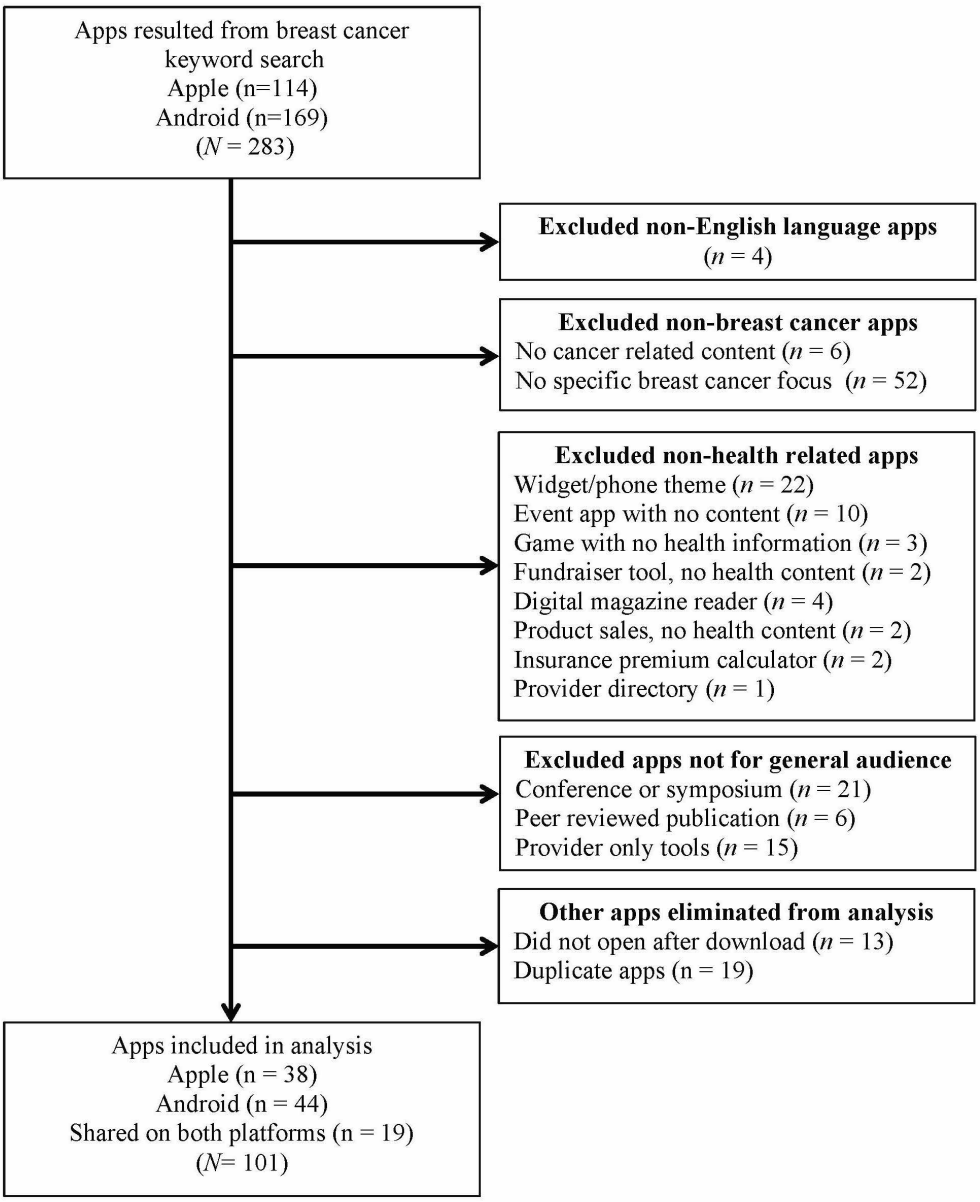
In view of the preceding research, the goal of this study is to evaluate the availability and content of existing breast cancer-related apps. In particular, we assessed apps' content for intended purpose, consistency with the breast cancer care continuum, adherence to IOM plain language and usability standards, and the association between adherence to standards and apps' prices and users' reviews.

Methods

Sampling

The study did not involve recruitment of human population; therefore, ethics committee approval was not required. Following previous content analyses of mHealth apps [44,48], a list of breast cancer apps was generated in October 2015. Apple apps were searched directly from the App Store using an iPad device. Android apps were searched on Google Play Android App Store using an Android tablet device. The "any price" (Apple App Store) and "all price" (Google Play Android App Store) search options were selected to include both free and paid (fee-based) apps in the search results. The search term "breast cancer" on both platforms resulted in 264 unique apps (105 Apple apps, 131 Android apps) and 28 apps that were available on both platforms. Apps were chosen for analysis if they met the following inclusion criteria: (1) English-language app, (2) focused on breast cancer, (3) health related (as opposed to apps that included entertainment only, such as ringtones), and (4) intended for a general audience of consumers rather than health care professionals. A total of 163 apps were excluded (see Figure 1 for information on reasons for exclusion). One app had both a free and an upgraded paid version and the content was found to be different, so both versions were coded. The final sample of apps that were downloaded and coded in this analysis was 101, including 44 unique Android apps, 38 unique Apple apps, and 19 apps that were available on both platforms. Most of the apps were free (85/101, 84.1%) and only a minority (16/101, 14.8%) were paid apps. See Figure 1 for the process of inclusion and exclusions of apps.

Figure 1. App Exclusion Chart.



Coding Process

At the time of the study, only one prior study explored content of apps and adherence to IOM standards in diabetes-related apps [44]. Consequently, no coding scheme was available for use in the context of breast cancer. This previous IOM-related coding scheme [44] was applied, and its content-related scheme was adapted to the breast cancer context based on past literature and in particular the focus of this study on the cancer continuum. TG created the initial adaptation based on the literature and her experience as a cancer communication researcher, and three additional authors provided input based on their knowledge and experience in cancer communication, including clinical experience of the last author. Following discussions between the researchers, the coding scheme was finalized (see Table 1 for the coding scheme). Two trained graduate research assistants downloaded each app to an iPad or an Android tablet. After reviewing the app's features, they entered information into an electronic database. The coding process began with coding general characteristics listed in the App Store and Google Play. Then, coders coded cancer-related content and adherence to the IOM recommendations (see Table 1 for a list of variables) for designing health-literate mobile apps. The coders were trained by TG for two sessions lasting a total of 5 hours and then they coded the apps individually. Two independent coders coded a sample of 30 apps (29.7% of the total sample) to test intercoder reliability. Any coding disagreements were discussed collectively with the first author until agreement was reached. For each variable, intercoder reliability was assessed using Krippondorf alpha (see Table 1).

Table 1. Variable categories, names, definitions, and intercoder reliabilities.

Category and name	Definition	Intercoder reliability, Krippendorf α[a]
Purpose		
Information/education	Content to inform/educate	1.0
Behavior change/maintenance	Content to motivate, encourage behavior change	1.0
Fundraising	Raising money, donations	0.88
Advocacy	Other than fundraising	0.86
Cancer continuum primary prevention		
Primary prevention	Health promotion activities, diet, and exercise	1.0
Genetic risk/screening		
Risk	Genetic risk (eg, BRCA discussed)	0.89
Screening	Genetic screening discussed	1.0
Screening evidence-based		
Mammography	Mammography discussed	0.90
Non-evidence-based clinical breast exam	Clinical breast exam discussed	1.0
Breast self-exam	Breast self-exam discussed	1.0
Symptoms prediagnosis	Cancer symptoms prediagnosis discussed/explained	0.90
Diagnosis		
Stage	Cancer stages discussed	0.89
Tumor type	Types of tumors discussed	0.90
Prognosis	Prognosis discussed, including survival	1.0
Treatment		
Treatment options	Breast cancer treatment discussed	1.0
Side effects/symptoms	Treatment side effects discussed	1.0
Medication care management	Information on medication types/brands	1.0
Chemotherapy prevention	Chemotherapy prevention medication	1.0
Survivorship	Life after cancer discussed	N/A
End of life	End-of-life/hospice information	N/A
Breast cancer care		
Breast cancer continuum care	Breast cancer continuum care and or behaviors discussed	0.89
Research/Science		
Biological process	Information on biological process of breast cancer	1.0
Trial recruitment	Clinical trial recruitment	N/A
Research referenced	App cites medical research studies	0.74
Adherence to literate principles design plain language		
Common, everyday words	Common plain language used	1.0
Personal pronouns	Personal pronouns such as “you” used	0.90
Defined terms	Terms explained/defined	1.0
Active voice	Use of active voice	1.0
Action words	Direct action language used	1.0
Present tense	Present tense used	1.0
Short sentences	Sentences 15-20 words max	1.0

Category and name	Definition	Intercoder reliability, Krippendorf α[a]
Limited paragraph size	Short paragraphs, use of bullets/lists	1.0
Usability		
Images for learning	Use images that facilitate learning	1.0
Bold colors/background	Use bold colors with contrast; avoid dark backgrounds	0.71
Home/menu page	Enables easy access to home/menu page	0.71
Back button	Back button identified as arrow or labeled	0.85
Simple search	Utilizes simple search tool	0.71
Browsing	Easy browsing/navigating through app	0.75
Technology		
Email	Connected with device email option/in-app email options	0.71
Calendar	Connected with device calendar	0.53
Reminders/notifications	Offered device notifications	0.78
Maps/GPS	Offered maps/GPS options	0.87
Print	Included print options	0.65
Save options	Save content as .doc, PDF, image files	N/A
Interactivity		
Personal information	Contact information input	1.0
Personal statistics	Input of height, weight, etc	1.0
Expert interaction	Interactions with medical professionals	1.0
Peer support	Interaction with other app users	N/A
Connect with event	Link user with event source	1.0
Audio/video features	Use of sound bite/video content	1.0
New media	Use of social media and/or text	0.90

[a] N/A: Krippendorff alpha could not be calculated due to lack of variance.

Coding Scheme

General Characteristics

Basic information was captured from the App Store and Google Play, such as the provider or seller, price (if any), age rating, app category, and numbers for both ratings and reviews for each coded app and its price.

Purpose of the App

For perceived purpose of the app content, coders noted one or more of the following four categories: (1) information/education (eg, reference/glossary of breast cancer terms), (2) behavior change/maintenance (eg, becoming more physically active, participating in screening), (3) fundraising, and (4) advocacy (eg, awareness-raising campaigns).

Cancer Continuum-Related Content

To examine the apps' foci on the cancer care continuum, one or more of the following variables were coded: (1) primary prevention; (2) evidence-based cancer screening (mammography, clinical breast exam); (3) diagnosis, including information about cancer staging, type of tumor, and information about prognosis, such as survival rate; (4) disease management/therapeutics, including information about treatment, side effects of treatments, and treatment medications and chemo prevention to prevent recurrence; (5) survivorship; and (6) end-of-life care. In addition, the following prediagnosis categories were coded: (1) genetic risk (eg, family history of cancer) and (2) breast self-exam and symptoms of breast cancer prediagnosis. Finally, the coding scheme included research and scientific-related content, which was comprised of information on the biological process of cancer, references to research, and discussions of clinical trials.

Adherence to IOM Literate Design Principles

To assess the apps' adherence to the IOM mHealth literacy guidelines [24], we used the coding scheme developed and tested by Caburnay and colleagues [44]. Plain language variables included the presence or absence of the following: (1) common everyday words, (2) the pronoun "you" (second person voice), (3) use of present tense, (4) defined technical terms, (5) use of active voice, (6) use of action words, (7) use of short sentences (15-20 words), and (8) limited paragraph length (including bullet points and short lists). Each of these eight variables was coded

(0=not present; 1=present), and the results were summed to create a composite plain language score.

Usability was measured as a composite of (1) avoidance of dark backgrounds, (2) easy access to home page (eg, home/menu button), (3) clearly labeled back button, (4) in-app simple search, (5) enabled browsing, and (6) use of images that facilitate learning (eg, diagrams of breast anatomy). Each of these six variables was coded (0=not present; 1=present) and summed to create a composite usability score [24,44].

Variables on graphics and technology use were also recorded and were composed of integration with other device apps (email, calendar, maps, reminders, GPS) and save/print options. Interactivity variables included user-tailored/interactive content (eg, input contact information, measures such as weight and height, expert interactions, online peer support, connect user with event), use of audio and video features, and use of new media or texting (eg, Facebook, Twitter).

Statistical Analysis

We used SPSS version 23 (IBM Corp, Armonk, NY, USA) to calculate descriptive statistics; *t* tests to identify associations between app characteristics, price (free vs paid), and user ratings; and Pearson correlations to examine the relationship between IOM guidelines and user ratings. Significance was determined at a level of alpha=.05.

Results

Road Map

Our goal in this study was to better understand availability and content of breast cancer-related apps available to the public, with a focus on their purpose, cancer continuum-related content, adherence to IOM literate design standards, price, and user ratings.

Sample Description and General Characteristics

The final sample of apps that met our selection criteria and was used in the final analysis (N=101) included 44 apps (43.7%) that were available on Google Play only, 28 (27.7%) apps that were available exclusively on the App Store, and 19 (18.8%) that were available on both platforms (see Table 2 and Figures 2-5). Most apps were free (85/101, 84.2%). Of the 16 (15.8%) paid apps, prices ranged from US $0.99 to US $4.99 with a mean of US $2.15. User ratings were provided for 49 apps; the median number of ratings per app was 6 (mean 25.16, SD 74.50), and the median star rating was 4.5 of 5 (mean 4.00, SD 1.27). In total, 40 of 101 apps (39.6%) were either rated for all ages or for ages 4 years or older. Another 19 (18.8%) were rated for 12 years and older, and 17 (16.8%) were rated for 17 years and older. The categories in which the apps were placed most often were health and fitness (24.8%, 25/101) and medical (31.7%, 32/101).

Table 2. Characteristics of breast cancer-related apps on the App Store and Google Play (N=101).

App characteristics	n (%)
Type of apps	
Android	44 (43.6)
Apple	38 (37.6)
Android & Apple	19 (18.8)
Free apps	85 (84.1)
Paid apps	16 (14.8)
Purpose	
Information/education	73 (72.3)
Behavior change/maintenance	24 (23.8)
Fundraising	20 (19.8)
Advocacy	14 (13.9)
Cancer continuum	
Primary prevention	
Prebiological onset	30 (29.7)
Genetic risk/screening	
Risk	47 (46.5)
Screening	29 (28.7)
Evidence-based screening	
Mammography	45 (44.6)
Clinical exam	38 (37.6)
Non-evidence-based screening	
Breast self-exam	53 (52.5)
Symptoms prediagnosis	48 (47.5)
Diagnosis	
Stage	30 (29.7)
Tumor type	35 (34.7)
Prognosis	19 (18.8)
Management/Therapeutics	
Treatment	38 (37.6)
Side effects	19 (18.8)
Care management	31 (30.7)
Chemotherapy prevention	14 (13.9)
Survivorship	17 (16.8)
End of life	1 (1.0)
Research/Science	
Biological information	40 (39.6)
Trial recruitment	5 (5.0)
Research referenced	24 (23.8)
Literate principles adherence	
Plain language	
Common everyday words	44 (43.6)
Personal pronouns	60 (59.4)

App characteristics	n (%)
Defined terms	24 (23.8)
Active voice	78 (77.2)
Action words	75 (74.3)
Present tense	84 (83.2)
Short sentences	78 (77.2)
Limit paragraph size	68 (67.3)
Usability	
Images that facilitate learning	44 (43.6)
Bold colors, no dark backgrounds	89 (88.1)
Home/Menu pages	51 (50.5)
Back button	37 (36.6)
Simple search	9 (8.9)
Browsing	33 (32.7)
Technology	
Email	32 (31.7)
Calendar	11 (10.9)
Reminders	17 (16.8)
Maps/GPS	4 (4.0)
Print	3 (3.0)
Save	8 (7.9)
Interactivity	
Personal information	15 (14.9)
Personal statistics	19 (18.8)
Expert interaction	2 (2.0)
Peer support	8 (7.9)
Connect to an event	15 (14.9)
Incorporate Audio and Visual	31 (30.7)
Integrate social media or text messages	42 (41.6)

Figure 2. App characteristic percentages on App Store and Google Play: content/goal, primary prevention genetic risk/screening, screening/early detection, and diagnosis (N=101).

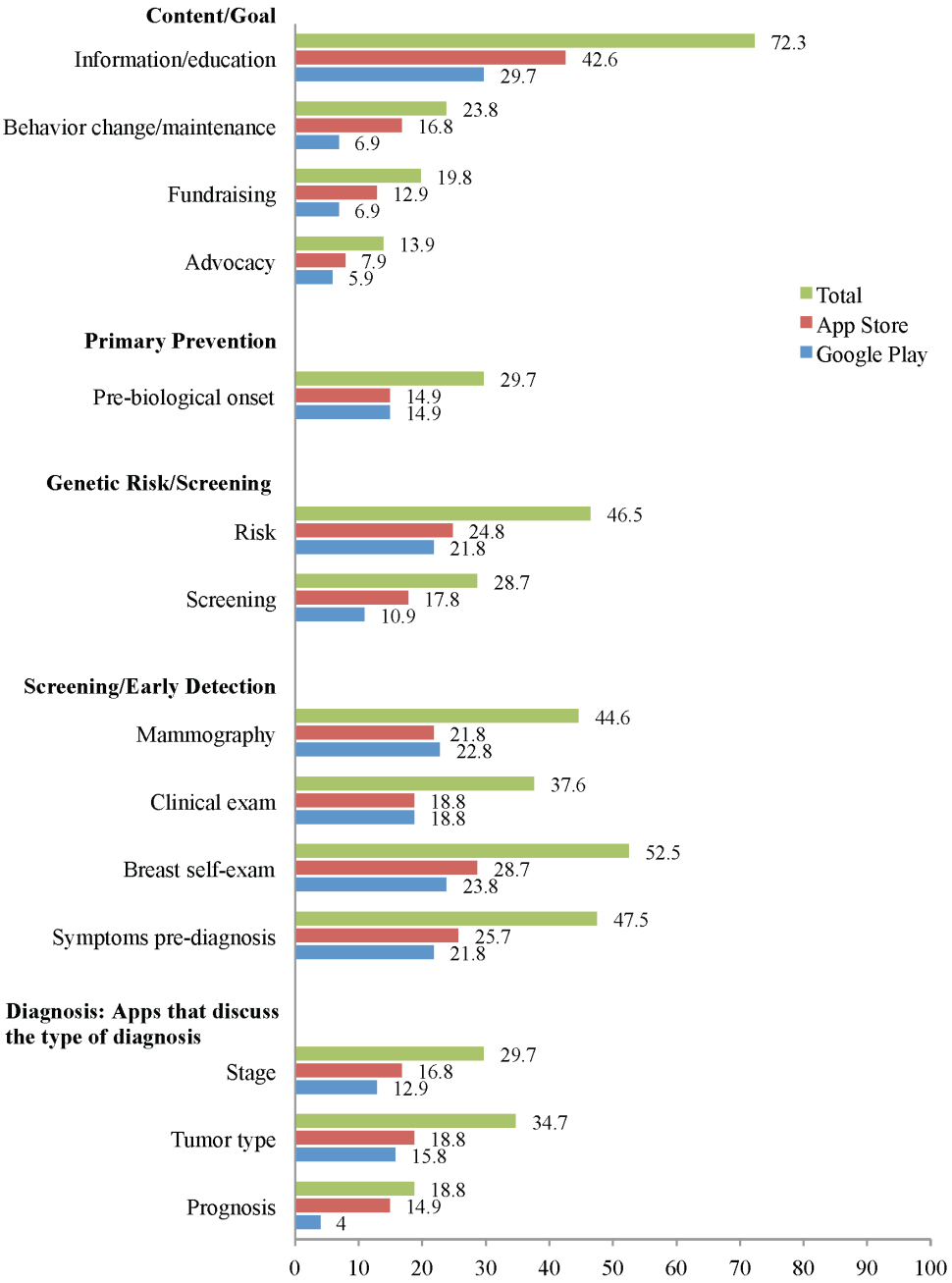


Figure 3. App characteristic percentages on App Store and Google Play: management/therapeutics, postcare/end of life, breast cancer care, and research/science (N=101).

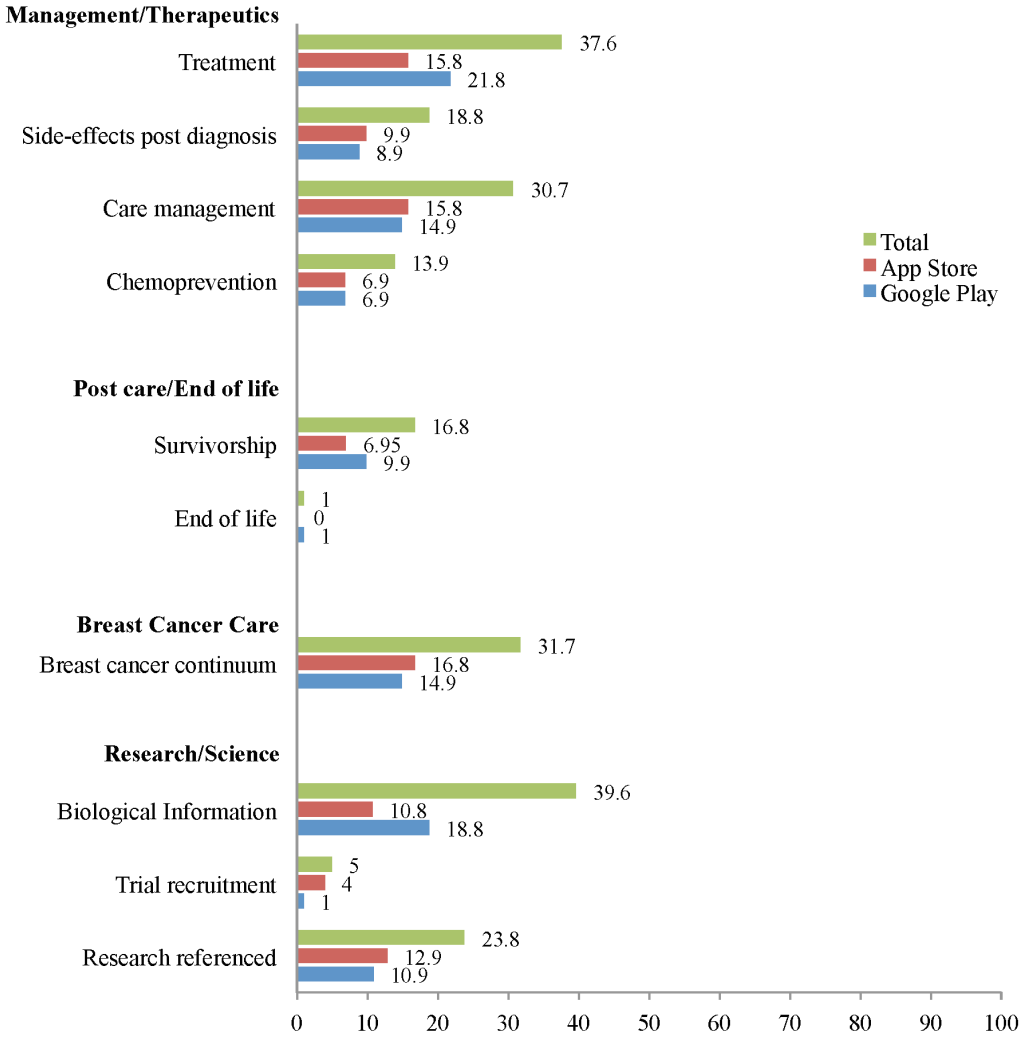


Figure 4. App characteristic percentages on App Store and Google Play: plain language and usability (N=101).

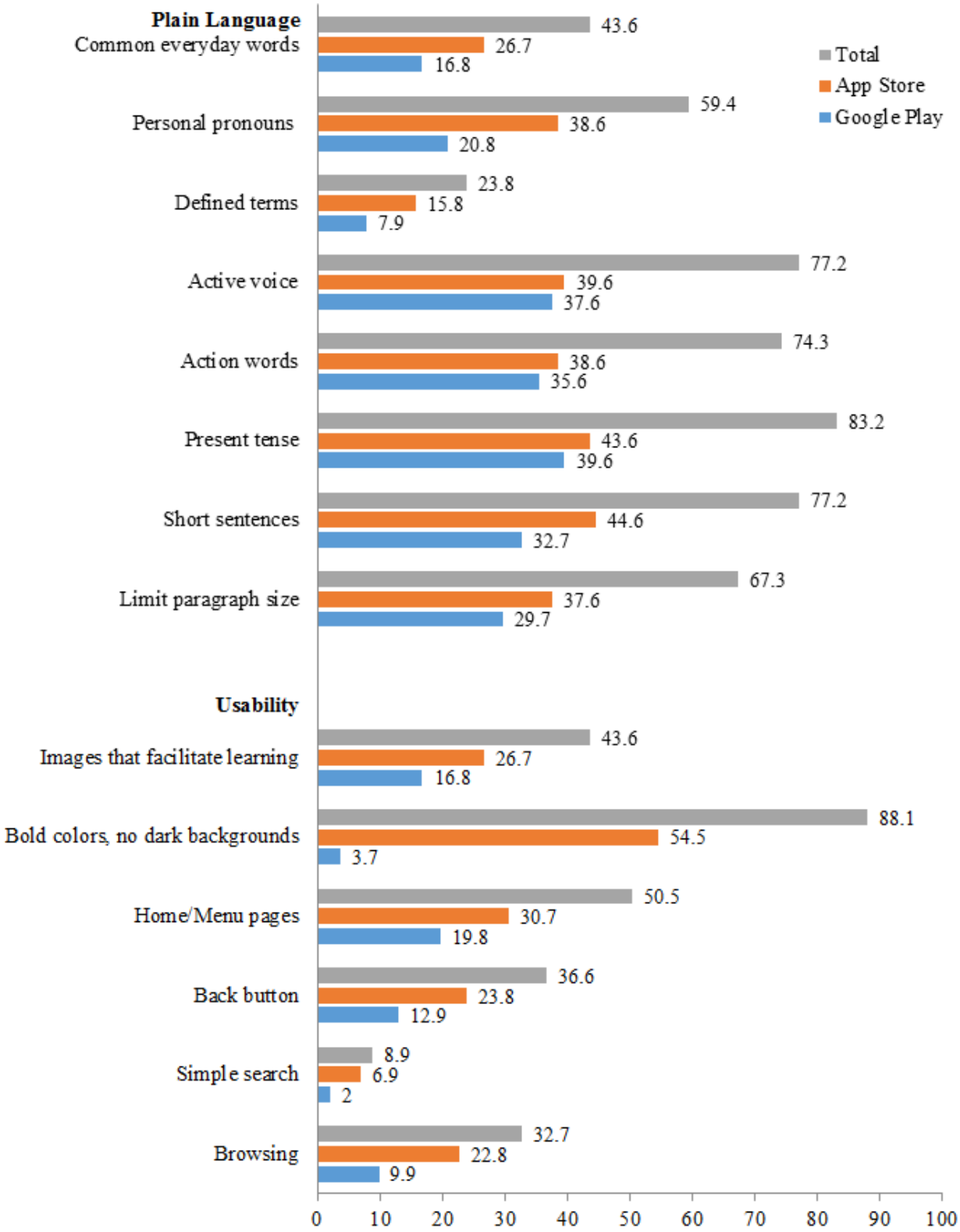
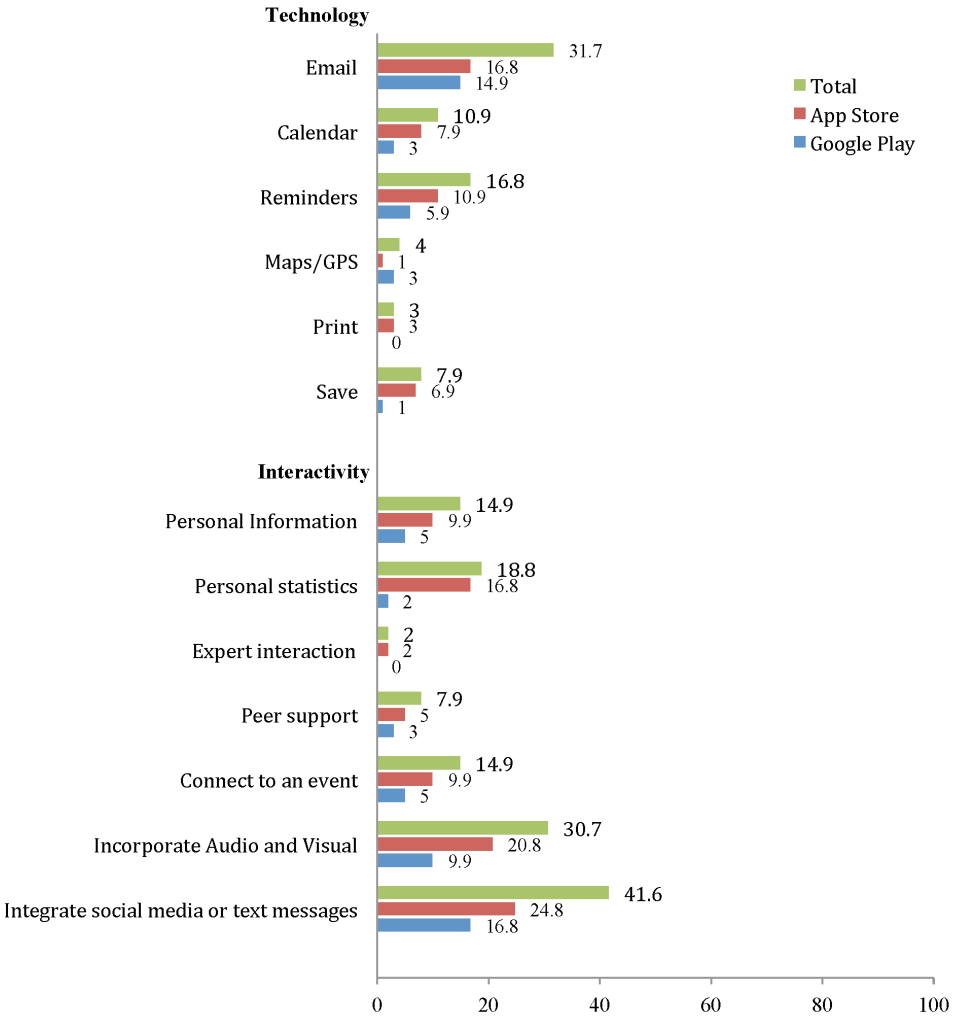


Figure 5. App characteristic percentages on App Store and Google Play: technology, interactivity, and approach/theoretical underpinning (N=101).



Purpose of the Apps

The analysis included the classification of the apps' goals by four main categories, according to the messages they advanced: (1) aimed at providing information and education about breast cancer, (2) targeted behavior change related to breast cancer, (3) included messages about fundraising, and (4) aimed at breast cancer advocacy. Most of the apps contained information/education messages (73/101, 72.3%), approximately one-quarter (24/101, 23.9%) targeted behavior change, one-fifth (20/101, 19.8%) aimed at fundraising, and a one-sixth of the apps (14/101, 13.9%) were related to advocacy. More than half of the apps focused on only one of these categories (56/101, 55.4%), 26 (25.7%) on two categories, five (5%) included three categories, and two apps included all categories. Most apps that targeted behavior change also included informational/educational goals (18/101, 75%).

Breast Cancer Continuum

Primary Prevention

Almost one-third of the apps (30/101, 29.7%) presented information about primary prevention of breast cancer, such as information about diet and exercise.

Screening

Less than half of the apps in our sample (46/101, 45.5%) presented information about evidence-based methods of breast cancer screening (mammography and breast clinical exam). Of this subsample, 37 apps (80.4%) included information about both mammography and clinical breast exam. Eight apps contained information about breast mammography alone (17.39%), and only one contained information about clinical breast exams (2.17%).

In all, 53 apps (52.5%) discussed breast self-exam. Additional prediagnosis variables included symptoms of cancer

prediagnosis, such as a lump (48/101, 47.5%) and genetic risk for breast cancer (47/101, 46.5%).

Diagnosis

Information about breast cancer diagnosis was included in 42 apps (41.6%). Of these apps, 15 (36%) provided information about stages of breast cancer, prognosis, and types of breast cancer tumor together; 10 apps (24%) discussed stages of breast cancer and types of breast cancer tumors together; and two (5%) provided information about stages of cancer as well as prognosis. In addition, 11 (27%) provided information about types of breast cancer tumors only, three (7%) communicated information about stages of breast cancer only, and two (5%) addressed prognosis only.

Treatment

Of the 101 apps, 43 (42.6%) discussed various treatment options for breast cancer patients. Of these, 18 (17.8%) provided concurrent information on (1) different treatment options, (2) possible side effects of treatment, and (3) care management of breast cancer; eight (8%) discussed treatment options and side effects; and one (2%) provided information on different treatment options and care management of breast cancer together. Eleven (26%) apps provided information about different treatment options only, and five (12%) discussed care management only.

Survivorship and End of Life

Seventeen of 101 apps (16.8%) discussed issues related to survivorship, such as care coordination after completion of therapeutic treatment for cancer, financial burden of cancer, late and long-term effects of breast cancer diagnosis and treatment, or health promotion after a breast cancer diagnosis. Only one of 101 apps (1.0%) discussed end-of-life hospice.

Research and Scientific-Related Information

In all, 40 of 101 apps (39.6%) provided biological information about breast cancer, such as the mechanism of tumor development in the breast. Only 24 apps (23.8%) cited scientific research or evidence-based guidelines to support their information. Five apps (5.0%) discussed clinical trials.

Adherence to IOM Literate Design Principles

Plain Language

The median of the composite health literacy score was 5 (mean 5.06, SD 2.00), and only 13 (13%) apps had a composite plain language score of 8 of 8. A majority of the apps used present tense (84/101, 83.2%), active voice (78/101, 77.2%), short sentences (78/101, 77.2%), action words (75/101, 74.3%), short paragraph size (68/101, 67.3%), and personal pronouns such as "you" (60/101, 59.4%). However, fewer than half of the apps primarily used common and easy-to-understand words (44/101, 43.6%) and only 24 (23.8%) defined terms.

Usability

The median composite usability composite score was 3 (mean 2.60, SD 1.20). None of the apps contained all six usability items recommended by the IOM. Five apps (5.0%) had a composite usability score of 5 of 6. The most common usability feature was the use of bold colors without dark backgrounds (89/101, 88.1%). In all, 51 (50.5%) apps provided easy access to home/menu pages, 44 (43.6%) used images that facilitated learning, 37 (36.6%) had a back button, 33 (32.7%) were easy to browse, and nine (8.9%) had a simple search option available.

Graphics and Technological Features

The most common technological feature was the ability to share content via email through the app (32/101, 31.7%). In addition, eight (7.9%) apps had the option to save documents. Four apps (4.0%) connected users to maps or GPS and three (3.0%) provided users the option to print directly from the apps.

Interactivity

Most apps (93/101, 92.1%) did not allow the user to customize information (ie, input weight, height, and other personal measures); only eight (7.9%) offered peer support and two (2.0%) provided an "ask the expert" option.

Adherence to IOM Plain Language and Usability Guidelines by Content Area and Goals

There was no statistically significant difference in the composite plain language scores of apps that focused on information/education content (mean 5.10, SD 1.89) and apps that did not (mean 4.96, SD 2.41; $t_{40.34}$=0.26, P=.80). Similarly, although the composite usability scores of apps containing information/education messages (mean 2.71, SD 1.12) were somewhat higher than other apps (mean 2.32, SD 1.25), these differences were not statistically significant (t_{99}=1.52, P=.13) (see Table 3).

Table 3. Adherence of apps to literate principles (N=101).

Content	Composite plain language score			Composite usability score		
	Mean (SD)	*t* (*df*)	*P*	Mean (SD)	*t* (*df*)	*P*
Information/education content		–0.26 (40.34)	.13		–0.26 (99)	.77
No information/ education content	4.96 (2.41)			2.32 (1.25)		
With information/education content	5.10 (1.89)			2.71 (1.12)		
Behavior change content		–2.80 (99)	.006		–0.30 (99)	.77
No behavior change content	4.75 (2.00)			2.58 (1.21)		
With behavior change content	6.04 (1.85)			2.67 (1.05)		
Fundraising content		–3.47 (99)	.001		0.23 (99)	.82
No fundraising content	4.73 (1.97)			2.62 (1.11)		
With fundraising content	6.40 (1.73)			2.55 (1.39)		
Advocacy content		–2.19 (99)	.031		0.11 (99)	.91
No advocacy content	4.89 (2.07)			2.61 (1.20)		
With advocacy content	6.14 (1.41)			2.57 (0.94)		
Apps		0.80 (99)	.43		–2.73 (99)	.007
Free	5.13 (2.09)			2.47 (1.17)		
Paid	4.69 (1.70)			3.31 (0.87)		

Apps aimed at behavior change scored higher on use of plain language (mean 6.04, SD 1.85) than apps that did not aim at behavior change (mean 0.75, SD 2.00) and the relationship was statistically significant (t_{99}=2.80, *P*=.006). Although these type of apps also ranked slightly higher in usability (mean 2.67, SD 1.05) than the apps that did not include behavior change messages (mean 2.58, SD 1.21), the difference was not significant (t_{99}=0.30, *P*=.77) (see Table 3).

The *t* test analysis also revealed that apps with a fundraising purpose had a higher composite plain language score (mean 6.40, SD 1.73) than those without a fundraising purpose (mean 4.73, SD 1.97) and the relationship was statistically significant (t_{99}=3.47, *P*=.001). There was no significant difference in usability between apps that targeted fundraising (mean 2.55, SD 1.39) and those that did not (mean 2.62, SD 1.11; t_{99}=–0.23, *P*=.82) (see Table 3).

Apps that included advocacy for breast cancer causes scored higher for plain language (mean 6.14, SD 1.41) compared to those that did not advocate for breast cancer causes (mean 4.89, SD 2.07) and the relationship was statistically significant (t_{99}=2.19, *P*=.03). In contrast, advocacy-related apps (mean 2.57, SD 0.94) and apps that did not include advocacy (mean 2.61, SD 1.20) did not differ in their usability (t_{99}=–1.12, *P*=.91) (see Table 3).

Differences Between Free and Paid Apps in Adherence to IOM Guidelines

Of the 73 apps that had information/education content, 58 (79%) were free and 15 (21%) were paid. Most of the 24 apps that targeted behavior change were free (21/24, 88%), and three (13%) were paid. All 20 (100%) of the apps that aimed at fundraising were free. Of the 14 apps that that included breast cancer advocacy, 12 (86%) were free, and two (14%) were paid (see Table 3).

Free apps (mean 5.13, SD 2.09) did not differ significantly from paid apps in use of plain language (mean 4.69, SD 1.70; t_{99}=–0.80, *P*=.43). In contrast, paid apps scored higher on usability (mean 3.31, SD 0.87) than free apps (mean 2.47, SD 1.17). The difference was statistically significant (t_{99}=2.73, *P*=.007) (see Table 3).

IOM Guidelines and User Ratings

Pearson correlations and *t* tests were used to examine the relationship between how well apps followed the IOM guidelines and how highly users rated those apps. Approximately half (49/101) of the apps in the sample were rated by users. There was a significant positive correlation between apps' user ratings and their composite scores on the health literacy scale (*r*=.33, *P*=.02).

Average ratings were significantly higher for apps that used action words (mean 4.26, SD 1.07) than for apps that did not (mean 3.42, SD 1.52; t_{47}=–2.20, *P*=.03). Ratings were also higher for apps that used the present tense (mean 4.27, SD 1.03) than for those that did not (mean 3.08, SD 1.63; $t_{12.39}$=–2.28, *P*=.04).

There was no significant correlation between an app's user rating and its composite usability score (*r*=.02, *P*=.85).

Discussion

Principal Findings

This study examined the availability of breast cancer-related apps, their purpose, cancer continuum-related content, adherence to literate principles design, price, and user ratings. At the time

of data collection, 101 apps focusing on breast cancer were available to the public. The majority of these apps were available on Android. The proportion of Apple-only apps in the sample represented their respective share of the cellular market of 28% at the time of data collection [49], albeit not the increased likelihood of iPhone users to download apps [50]. This distribution of apps documented in this study demonstrates increasing efforts from developers to provide apps for both Android and iPhone platforms.

Although apps often have multiple purposes, the majority are designed to provide information and education. Consistent with past studies [14], these findings reveal the limited potential of the current apps available to advance breast cancer-related behavior change. Research has shown that information is important yet insufficient in changing multifaceted health behaviors [51]. The high number of apps that included information/educational content without clear guidelines for behavior change suggests limited utility of currently available apps in behavior change, despite the relative advantage of mHealth in providing interactive features that can support such change. Moreover, the content of most apps does not support evidence-based, comprehensive breast cancer-related behavior change in specific areas. These findings align with past research on cancer apps that identified few evidence-based preventive messages [14]. For instance, although research and consequently clinical guidelines in North America in the past decade concluded that breast self-examination is an ineffective and often harmful screening strategy [52,53], this strategy was featured in more apps compared to the evidence-based strategies of mammography and clinical breast exams. Involving medical professionals in design of apps [22] may improve the quality of the information they provide.

The findings also indicate that provision of information in support of treatment-related decision making emerges as an area of need. Less than half of the apps that provided information on treatment included information about possible side effects and of treatment options. This deficiency might be explained by the reluctance of developers to include medical information due to paucity of clinical expertise involvement in development of mHealth [50]. However, extant literature documented the importance of such information for women with breast cancer [54], including availability of relatively easy-to-use decision tools [55].

The analysis of the content of the apps on the cancer continuum reveals that, in contrast to primary breast cancer prevention, screening, and treatment, only a few apps focused on survivorship and only one included information about hospice care. No apps covered other aspects of end-of-life decisions and care. It is possible that information and support on end-of-life decisions and care are available on apps that are not breast cancer-specific (and consequently in apps that were not included in this sample), past research on cancer-related apps did not document such focus [56]. Therefore, these findings lend support to the need for apps that would provide evidence-based information and support behavior change and decision making following breast cancer diagnosis, with extreme need for apps on end-of-life decisions and care.

The analysis further underscores that greater adherence to literate design strategies continues to be a pressing need in breast cancer app development. Adherence to most usability design standards was low. It is possible that this low adherence relates to lack of experience or training of developers working on this relatively new platform. For instance, the literacy design principle that was most closely adhered to included use of colors, which is consistent with design of websites. In contrast, features that are arguably more significant in-app design, such as an easy browse and use of images, were not frequently included in the apps.

Similarly, the findings underscore the importance of greater attention to using plain language principles in the design of breast cancer apps. Notably, of the plain language characteristics, text level was still too high in the vast majority of apps, which demonstrates that mHealth developers, like developers of print information [57] and of Web-based information [58], are not effective in bridging the literacy divide using principles such as defining concepts. Therefore, it is evident that the need for more appropriate plain language materials persists. However, behavioral change, advocacy, and fundraising apps demonstrated higher adherence to plain language principles. It is possible that these differences indicate greater degree of professionalism of these apps' developers.

Consistent with past studies that examined diabetes-related apps [44], paid apps were more likely than free apps to adhere to literacy guidelines. In this case, paid apps featured usability principles more frequently than free apps. As the vast majority of mobile phone users are reluctant to pay for apps [59], this finding also points at the potential for persistence of disparities between users who are able to use paid apps and those who are restricted to using only free apps. In addition, this study provides additional support to the potential of using reviewer ratings to learn about user experiences. In past research, user ratings were correlated with professional quality ratings of apps [47], but in this study they were correlated with apps' adherence to plain language principles, thus lending further empirical support to the importance of plain language. To our knowledge, this is the first study to document such an association. In contrast, user ratings were not related to usability. Future studies should explore users' expectations from apps' usability in the context of breast cancer.

This study contributes to research on the use of mHealth to advance breast cancer-related education and behavior change in a few ways. First, this is the first study to focus solely on breast cancer apps. In view of the unique information, education, treatment, and support needs before and following breast cancer diagnosis [60], this focus can advance understanding on the degree to which these apps have the potential to meet these needs. In addition, past studies that examined cancer apps were limited to analyzing only iPhone apps [15], apps' descriptions in the App Store [14], or reviews of the literature reporting on cancer-related mHealth interventions [16]. By analyzing relevant, working, uploaded apps available on both Android and iPhone platforms, this study provides a more comprehensive analysis of availability to consumers. Moreover, past studies did not examine design of cancer-related apps, including adherence to literacy design principles, and did not focus on

breast cancer, whereas this study provides important insights on implementation of literate design strategies.

Limitations

As in any research project, the methodologies utilized in this study hold inherent limitations. Specifically, systematic content analyses are helpful in providing an overview on the content available to users and its adherence to scholarly and professional standards, but are limited in their ability to shed light on users' experiences. Moreover, previous researchers noted that content analysis of mHealth cannot link user information to app use [46]. In addition, information about the sources of the apps was not available; therefore, analysis of the relationship between app-related factors such as release dates, content source, organizational affiliation, or country of origin was not possible. Similarly, because we included only apps that focused on cancer, we did not examine other apps that might be used for cancer prevention purposes or that people might use to manage symptoms after diagnosis with cancer or survivorship and end of life. Finally, this study was conducted in the United States and, therefore, does not demonstrate availability of breast cancer-related apps in other markets or in languages other than English.

Conclusions

Despite exciting potential for consumer engagement along the cancer continuum, availability of evidence-based breast cancer information and integration of literate design strategies to mHealth users is limited. This current state reveals that mHealth has not met its potential in engaging consumers with evidence-based information and design necessary to reduce preventable breast cancer burden and its associated disparities in health outcomes. Specifically, breast cancer-specific apps represent a limited spectrum on the cancer continuum. Therefore, this study is important in supporting the need for better-designed breast cancer apps that would adhere to evidence-based as well as to plain language and usability standards, with an extreme need for apps that focus on information necessary for medical decision making, most notably side effects, survivorship, and end of life.

As a systematic review, the goal of this study was to provide an overview of availability of breast cancer apps and their adherence to evidence-based content and design principles. Such systematic analyses are time consuming and cannot be performed by users. Further, the characteristics of such users at this point are unknown and are likely very diverse, including cancer-free individuals, cancer patients, and cancer survivors, because different apps target women at different stages on the cancer continuum. Future studies should apply additional, user-centered research methods, including surveys and community-based studies to learn about users' experiences using apps along the breast cancer continuum.

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Conflicts of Interest

None declared.

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Abbreviations

IOM: Institute of Medicine

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Original Paper

Mobile App-Based Interventions to Support Diabetes Self-Management: A Systematic Review of Randomized Controlled Trials to Identify Functions Associated with Glycemic Efficacy

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Abstract

Background: Mobile health apps for diabetes self-management have different functions. However, the efficacy and safety of each function are not well studied, and no classification is available for these functions.

Objective: The aims of this study were to (1) develop and validate a taxonomy of apps for diabetes self-management, (2) investigate the glycemic efficacy of mobile app-based interventions among adults with diabetes in a systematic review of randomized controlled trials (RCTs), and (3) explore the contribution of different function to the effectiveness of entire app-based interventions using the taxonomy.

Methods: We developed a 3-axis taxonomy with columns of clinical modules, rows of functional modules and cells of functions with risk assessments. This taxonomy was validated by reviewing and classifying commercially available diabetes apps. We searched MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials, the Chinese Biomedical Literature Database, and ClinicalTrials.gov from January 2007 to May 2016. We included RCTs of adult outpatients with diabetes that compared using mobile app-based interventions with usual care alone. The mean differences (MDs) in hemoglobin A_{1c} (HbA_{1c}) concentrations and risk ratios of adverse events were pooled using a random-effects meta-analysis. After taxonomic classification, we performed exploratory subgroup analyses of the presence or absence of each module across the included app-based interventions.

Results: Across 12 included trials involving 974 participants, using app-based interventions was associated with a clinically significant reduction of HbA_{1c} (MD 0.48%, 95% CI 0.19%-0.78%) without excess adverse events. Larger HbA_{1c} reductions were noted among patients with type 2 diabetes than those with type 1 diabetes (MD 0.67%, 95% CI 0.30%-1.03% vs MD 0.37%, 95% CI –0.12%-0.86%). Having a complication prevention module in app-based interventions was associated with a greater

HbA_{1c} reduction (with complication prevention: MD 1.31%, 95% CI 0.66%-1.96% vs without: MD 0.38%, 95% CI 0.09%-0.67%; intersubgroup *P*=.01), as was having a structured display (with structured display: MD 0.69%, 95% CI 0.32%-1.06% vs without: MD 0.69%, 95% CI –0.18%-0.53%; intersubgroup *P*=.03). However, having a clinical decision-making function was not associated with a larger HbA_{1c} reduction (with clinical decision making: MD 0.19%, 95% CI –0.24%-0.63% vs without: MD 0.61%, 95% CI 0.27%-0.95%; intersubgroup *P*=.14).

Conclusions: The use of mobile app-based interventions yields a clinically significant HbA_{1c} reduction among adult outpatients with diabetes, especially among those with type 2 diabetes. Our study suggests that the clinical decision-making function needs further improvement and evaluation before being added to apps.

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KEYWORDS

mobile health; mHealth; mobile applications; mobile apps; diabetes mellitus; classification

Introduction

Diabetes mellitus poses enormous challenges to China's health care system due to its mortality, prevalence, and costs. Of 8.3 million deaths in China in 2010, 37.3% (3.1 million) were attributable to cardiovascular disease, which was also one of the leading causes of disability-adjusted life-years [1]. Diabetes is not only an independent risk factor for cardiovascular disease [2], but also associated with increased mortality from a range of cardiovascular diseases (eg, ischemic heart disease and stroke), as well as noncardiovascular diseases (eg, infections) among Chinese adults [3]. In 2008, the estimated prevalence of diabetes was 9.7%, accounting for 92.4 million adults with diabetes [4]. A more recent cross-sectional survey reported an even larger estimate (11.6% among Chinese adults, ie, 113.9 million) in 2010 [5]. In addition, expenditures for the medical care of patients with diabetes were 3.38 times higher than for people with normal glucose tolerance [6].

Once diabetes is diagnosed, lifetime diabetes self-management is critical to glycemic control and is associated with the long-term prognosis for patients with diabetes. Diabetes self-management includes self-monitoring blood glucose, making healthy lifestyle choices (healthy eating, physical activity, tobacco cessation, weight management, and coping with stress), taking and managing medications, preventing diabetes complications (self-monitoring of foot health; active participation in screening for eye, foot, and renal complications; and immunizations), and setting self-selected behavioral goals [2]. In China, diabetes self-management education and support are provided during outpatient visits and are a huge burden on patients, their families, and the health system. Hence, a more cost-effective way to provide diabetes self-management education and support is essential for reducing the socioeconomic burden of diabetes.

Mobile apps are the computer programs or software installed on smart mobile devices, with computing and connectivity capability built right into an operating system. With the rapid and ongoing growth in wireless connectivity, more than 500 million Chinese were smartphone and apps users in 2016 [7]. In addition to their universality, apps provide real-time interactions and data transmission, which can be used in providing diabetes self-management education and support [8-10]. Accordingly, the American Diabetes Association (ADA) guideline has stated that mobile apps may be a useful element of effective lifestyle modification to prevent diabetes [2].

In the iTunes App Store for iOS and Google Play for Android, diabetes is one of the top-ranked categories [11,12], with more than 1100 different apps available for download. In contrast, according to a recent systemic review [13], there were only 5 randomized controlled trials (RCTs) assessing the effectiveness of apps in diabetes self-management. The contrast between the number of commercially available apps and the number of RCTs of apps demonstrates a shocking lack of evidence to support the recommendation of a specific app for diabetes self-management. Consequently, it is extremely difficult for clinicians and patients to choose a safe and effective one among the thousands of available apps [14].

Despite their variety and complexity, apps for diabetes self-management always share a limited number of basic functions, which can be classified into several simple categories (eg, self-monitoring, education, alerts and reminders, and communication) [15]. Therefore, indirect evidence from systematic reviews of existing RCTs can give insight into the efficacy of each app function, which is helpful in estimating the effectiveness of a specific app and making recommendations for effective functions. Nevertheless, prior systematic reviews involving mobile app-based interventions with multiple functions have not attempted to investigate their differential effectiveness [16-18]. As a result, it remains unclear how their functions contribute to the efficacy of apps.

To address functional efficacy, a classification of app functions is required [19]. Moreover, the classification should be comprehensive, with not only considerations of functions but also recommendations for clinical practice [15], as well as risk assessment [20,21]. However, existing classifications are inconsistent, and they primarily focus on functions [16,17,20,22-30]. Inconsistency and incompleteness have limited their use in classifying functions of diabetes self-management apps.

The aims of this systematic review of RCTs were to (1) develop and validate a taxonomy of apps for diabetes self-management, (2) perform a meta-analysis investigating the effects of mobile app-based interventions on glycemic control in adults with diabetes, and (3) explore the contribution of different functions to the glycemic efficacy of entire app-based interventions using the taxonomy and subgroup analyses.

Methods

Taxonomy Development and Validation

We developed a preliminary taxonomy based on previous classifications, evidence-based guidelines, and authoritative recommendations, and validated it by reviewing commercially available apps for diabetes management. The contents of the taxonomy were confirmed if all functions of the available apps could be classified. After validation, we proposed a final taxonomy for diabetes management apps. Multimedia Appendix 1, part A, shows the flow chart of taxonomy development. Multimedia Appendix 1, part B, shows the review of previous classifications [16,17,20,22-30].

The preliminary taxonomy was validated by a review of commercially available diabetes apps, as shown in Multimedia Appendix 1, part D. We searched the iTunes App Store (Apple Inc, Cupertino, CA, USA) and Google Play (Google Inc, Mountain View, CA, USA) (for the United States and China, February 1, 2016) using the terms "diabetes" OR "blood glucose" to identify apps for diabetes management. Apps with real-time interactions and any functions supporting self-monitoring of blood glucose were included. We excluded apps that were duplicated or were designed for health care providers. Apps that did not have English or Chinese versions and that had not been updated for at least 5 years were also excluded.

Data Sources and Searches

We searched MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL), and the Chinese Biomedical Literature Database using the terms "diabetes mellitus," "blood glucose," "blood glucose self-monitoring," "mobile applications," and "cell phones" from January 1, 2007, to May 30, 2016. We also searched for ongoing studies via ClinicalTrials.gov and checked the reference lists of relevant reviews and trials. Multimedia Appendix 2 lists the search strategy for MEDLINE. Necessary adjustments were made for searching other databases.

Eligibility Criteria

We selected RCTs that compared mobile app-based interventions with standard care (free of app-based interventions) in adult outpatients with diabetes. Mobile app-based interventions were those that could provide real-time interactions with users through apps running on smart mobile devices.

Our primary outcome was the change in hemoglobin A_{1c} (HbA_{1c}) concentration (%) from baseline. Our secondary outcomes were severe hypoglycemia (defined as the need for assistance from another person or very low glucose concentrations; this was study specific, eg, <2 mmol/L) and any other adverse events. We did further quantitative meta-analyses of primary and secondary outcomes if relevant data were available.

We excluded studies without any available data on HbA_{1c}. We also excluded studies if their participants were children, adolescents, or pregnant women who required different therapeutic strategies for a more challenging or strict glycemic control [2]. Studies of apps for continuous glucose monitoring or continuous subcutaneous insulin infusion were excluded due to their medical devices nature. We excluded interventions without real-time interactions (eg, frequent interactions or passive interactions).

Two reviewers (YW and YD) independently screened titles and abstracts and then full texts to select eligible studies. Reviewers resolved disagreements through discussion or, if necessary, through discussion with an arbitrator (SL).

Data Extraction and Quality Assessment

For each trial, 2 reviewers (YW and YD) independently extracted data using a structured abstraction form and classified functions according to our taxonomy. Then, 2 reviewers (YW and YD) independently used the Cochrane Collaboration's tool to assess the risk of bias of included studies [31]. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was used to assess the quality of evidence for primary and secondary outcomes [32]. Reviewers resolved discrepancies by discussion or, if required, through adjudication by a third reviewer (SL).

Data Synthesis and Analysis

We used a random-effects meta-analysis to pool the overall mean difference (MD) of the HbA_{1c} changes and the risk ratios of adverse events due to the possible clinical heterogeneity of each included study. For trials with unreported change-from-baseline standard deviations, we imputed by standard deviations at the baseline and at the end of the intervention using the formula $SD_{change}=\sqrt{SD^2_{baseline}+SD^2_{final}-(2\times Corr \times SD_{baseline}\times SD_{final})}$. The correlation coefficient (Corr) was calculated with the reported change-from-baseline standard deviations using the formula $Corr=(SD^2_{baseline}+SD^2_{final}-SD^2_{change})/(2\times SD_{baseline}\times SD_{final})$ [31]. Publication bias was examined in Begg funnel plots and with the Egger linear regression test [33,34]. We assessed the consistency of the results across the studies by the statistical heterogeneity with the I^2 statistic [35]. The effect of the presence and absence of each function was examined in an exploratory subgroup analysis. We also conducted subgroup analyses of interventions that applied distinct technologies and had different risk levels. Statistical analyses were performed using RevMan version 5.3.0 (the Cochrane Collaboration) and STATA version 9.0 (StataCorp LLC). GraphPad Prism version 7.0 (GraphPad Software, Inc) was used to generate the figures included in this study.

Results

Taxonomy of Apps for Diabetes Self-Management

We designed a preliminary taxonomy with a functional axis, a clinical axis, and a risk axis as shown in Multimedia Appendix 1, part C. The functional axis consisted of 5 technical modules (ie, log, structured display, general education, personalized feedback, and communication) whose descriptive details were refined by previous classifications. The clinical axis consisted of 5 diabetes management modules (ie, monitoring, medication

management, lifestyle modification, complication prevention, and psychosocial care) referring to the ADA guideline [2]. Functions were specified by crossing the functional axis (module) and the clinical axis (module), where we made sure that each function belonged to a functional or clinical classification, or both.

We developed the risk axis based on the US Food and Drug Administration (FDA) risk-based recommendation [36]. This recommendation classifies functionalities of mobile health technology into 3 categories: administrative (eg, general-purpose communication and population health management), which pose limited or no risk to patient safety; health management (eg, some clinical decision support and medication management), which pose potential but generally low risks; and medical device (eg, medical device accessories and medical device clinical decision support software), which present a relatively higher risk to patient safety. We assessed the risks of functions as low, potential, and high, accordingly.

During validation, we identified 1559 apps by searching the iTunes App Store and Google Play and excluded 1414 apps that were duplicated, were not for diabetes-management, were without English or Chinese versions, and had not been updated for at least 5 years. The remaining 145 eligible apps were downloaded onto smart mobile devices. After excluding those without real-time interactions and designed solely for health care providers, we included 96 apps and classified them by the preliminary taxonomy. As we could well classify all functions among the included apps by the taxonomy, and we identified all modules in the taxonomy in the included apps, we proposed the final taxonomy after this validation (Table 1).

Table 1. Taxonomy of apps for diabetes self-management.

Functional modules	Diabetes management modules				
	Monitoring[b]	Medication management[c]	Lifestyle modification	Complication prevention	Psychosocial care
Log[b]	⊕ Recording self-monitoring parameters[d]; ⊕⊕ Recording other medical parameters[e]	⊕⊕ Recording used medications and side effects	⊕ Recording activities, diets, and weight[f]	⊕ Recording complication-related status[g]; ⊕ Recording appointments with doctors	⊕ Recording mood
Structured display	⊕ Displaying data in a structured way				
General education	⊕ Instructions for monitoring; ⊕⊕ Interpreting the parameters	⊕⊕ Diabetes process and treatment options; ⊕⊕ Using medications safely and effectively	⊕ Incorporating nutritional management and physical activity into lifestyle	⊕⊕ Preventing, detecting, and handling acute complications and chronic complications[h]	⊕ Addressing psychosocial issues and promoting behavior change
Personalized feedback	⊕ Reminding to monitor; ⊕ Off-target alert; ⊕⊕ Setting targets	⊕⊕ Reminding to take medications; ⊕⊕⊕Clinical decision making[i]	⊕ Reminding to eat healthily and be active; ⊕⊕ Self-management decision making[j]	⊕ Reminding to quit smoking, visit doctors, and prevent acute complications	N/A[k]
Communication	⊕ General communication, connecting users with their peers and families through social networking, chat forums, or websites; ⊕⊕ Patient-clinician communication, in-app access to health care providers for medical support or consultation.				

[a]Risk assessment of a function: low risk (⊕), potential risk (⊕⊕), and high risk (⊕⊕⊕). The overall risk assessment of an app was determined by the highest risk of included functions.

[b]Monitoring and log are basic modules.

[c]Medications for diabetes include insulin, oral antidiabetic agents, aspirin, antihypertensives, lipid-lowering medications, and vaccines.

[d]Self-monitoring parameters include blood glucose, blood pressure, heart rate, and pulse.

[e]Other medical parameters include cholesterol levels, hemoglobin A_{1c}, urine test, and ketones.

[f]Activities include steps, duration, heart rate, and consumed calories; diets include food, water, nutritional values, carbohydrate counting, and calorie calculator; weight includes body mass index, body fat, and circumference.

[g]Complication-related status includes smoking, drinking, snoring, feet, eyes, teeth, and sensory status.

[h]Acute complications include hypoglycemia and hyperglycemia; chronic complications include cardiovascular disease and microvascular complications (ie, nephropathy, retinopathy, neuropathy).

[i]Clinical decision making is recommending treatment (eg, oral agents and insulin) by algorithms alone without the participation of health care providers.

[j]Self-management decision making is decision making on lifestyle modification by algorithms.

[k]N/A: not applicable.

Characteristics and Classifications of Included Trials

We identified 3131 references using our search strategies and identified 544 references by checking the reference lists of relevant articles, 68 of which underwent a full-text review. This process excluded 55 studies, with the reasons listed in Multimedia Appendix 3. We included 12 trials from 13 references in a qualitative systematic review, evaluating 12

independent app-based interventions involving 974 outpatients with diabetes. Figure 1 shows the flow of study selection.

Across the 13 included references, the HbA_{1c} was obtained from 12 trials with 974 participants after a median follow-up period of 6 (range 3-12) months, and severe hypoglycemia was extracted from 4 trials of 346 participants after a median follow-up of 6 months. There were 5 trials that enrolled patients with type 1 diabetes mellitus (T1DM), 5 with type 2 diabetes mellitus (T2DM), and 2 with both types of diabetes.

Of the 12 included mobile app-based interventions, 1 is available in the iTunes Store and Google Play at the time of our study [37]. After taxonomic classification, all 12 included interventions had monitoring as a diabetes management module, followed by lifestyle modification (11/12, 92%), medication management (8/12, 67%), and complication prevention (2/12, 17%). Psychosocial care was not distinguished in any of the included interventions. For functional modules, all 12 interventions had a log as a basic functional module, followed by communication (9/12, 75%), a structured display (8/12, 67%), personalized feedback (8/12, 67%), and general education (6/12, 50%). To be noted, the included interventions only had patient-clinician communication instead of general communication.

Various technologies were applied for data transmission between users and mobile devices. Across the 12 included trials, 6 (50%) used wireless transmission through Wi-Fi, Bluetooth, near-field communication, or public switched telephone network, 5 (42%) used manual entry, and 1 (8%) used wire transmission through a data port connection.

Of the 12 included app-based interventions, we determined 3 (25%) to be of high risk due to having a clinical decision-making function. The definition of the clinical decision-making function was recommending treatment (eg, oral agents and insulin) by algorithms alone without the participation of health care providers. We determined that the other 9 interventions (75%) carried potential risk. Table 2 summarizes the modules, risks, and technologies of the mobile app-based interventions included in the meta-analysis [37-49].

Table 2. Characteristics, modules, risk assessments, and technologies of the included mobile app-based interventions.

Study	Country	No. patients: baseline/end	Diabetes type	Follow-up (months)	Mean (SD) HbA_{1c}[a], %: baseline; end; change	Intervention	FM[b]	DMM[c]	Risk assessment[d]	Technology
Hsu, 2016 [38]	US	I[e]: 20/15; C[f]: 20/16	2	3	I: 10.8 (1.0); 7.7 (1.6); –3.2 (1.5) C: 10.9 (0.9); 8.9 (2.2); –2.0 (2.0)	Cloud-based diabetes management program	L, StD, GE, Co	M, MM, LM, CP	Potential	Wireless
Baron, 2017 [39]	UK	I: 45/40; C: 36/31	Both	9	I: 9.1 (1.8); 8.6 (1.6); C: 8.9 (1.7); 8.9 (1.6)	Mobile telehealth	L, StD, GE, PF, Co	M, MM, LM	Potential	Wireless
Drion, 2015 [40]	Netherlands	I: 31/30; C: 32/32	1	3	I: 7.73 (NR[g]); 7.91 (NR); C: 7.82 (NR); 7.91 (NR)	Diabetes Under Control (DBEES)	L, StD	M, MM, LM	Potential	Manual entry
Holmen, 2014 [41]; Torbjornsen, 2014 [42]	Norway	I: 51/39; C: 50/41	2	12	I: 8.1 (1.1); 7.8 (0.9); C: 8.3 (1.2); 8.2 (1.1)	Few Touch Application (FTA)	L, StD, GE, PF, Co	M, LM	Potential	Wireless
Waki, 2014 [43]	Japan	I: 27/24; C: 27/25	2	3	I: 7.1 (1.0); 6.7 (0.7); C: 7.0 (0.9); 7.1 (1.1)	DialBetics	L, StD, GE, PF, Co	M, LM	Potential	Wireless
Kirwan, 2013 [37]	Australia	I: 36/28; C: 36/32	1	9	I: 9.1 (1.2); 8.0 (0.7); C: 8.5 (0.9); 8.4 (1.0)	Glucose Buddy	L, StD	M, MM, LM	Potential	Manual entry
Rossi, 2013 [44]	Italy	I: 63/55; C: 64/57	1	6	I: 8.4 (NR); 7.9 (NR); –0.5 (NR); C: 8.5 (NR); 8.1 (NR); –0.5 (NR)	Diabetes Interactive Diary	L, PF, Co	M, MM, LM	High	Manual entry
Charpentier, 2011 [45]	France	I: 60/56; C: 61/60	1	6	I: 9.2 (1.1); 8.6 (1.1); C: 8.9 (0.9); 9.1 (1.2)	Diabeo system	L, StD, PF, Co	M, MM, LM	High	Manual entry
Rossi, 2010 [46]	Italy	I: 67/58; C: 63/61	1	6	I: 8.2 (0.8); 7.8 (0.8); –0.4 (0.9); C: 8.4 (0.7); 7.9 (1.1); –0.5 (1.0)	Diabetes Interactive Diary	L, PF, Co	M, MM, LM	High	Manual entry
Yoo, 2009 [47]	Korea	I: 62/57; C: 61/54	2	3	I: 7.6 (0.9); 7.1 (0.8); C: 7.4 (0.9) 7.6 (1.0)	Ubiquitous Chronic Disease Care (UCDC) system	L, GE, PF	M, LM	Potential	Wire
Istepanian, 2009 [48]	UK	I: 72/NR; C: 65/NR	Both	9	I: 7.9 (1.5); 7.8 (NR); C: 8.1 (1.6) 8.4 (NR)	Mobile phone telemonitoring system	L, Co	M	Potential	Wireless

Study	Country	No. patients: baseline/end	Diabetes type	Follow-up (months)	Mean (SD) HbA_{1c}[a], %: baseline; end; change	Intervention	FM[b]	DMM[c]	Risk assessment[d]	Technology
Quinn, 2008 [49]	US	I: 15/13; C: 15/13	2	3	I: 9.5 (NR); 7.5 (NR); C: 9.1 (NR); 8.4 (NR)	WellDoc Communications	L, StD, GE, PF, Co	M, MM, LM, CP	Potential	Wireless

[a]HbA_{1c}: hemoglobin A_{1c}.

[b]FM: functional modules are communication (Co), general education (GE), log (L), personalized feedback (PF), and structured display (StD).

[c]DMM: diabetes management modules are complication prevention (CP), lifestyle modification (LM), monitoring (M), and medication management (MM).

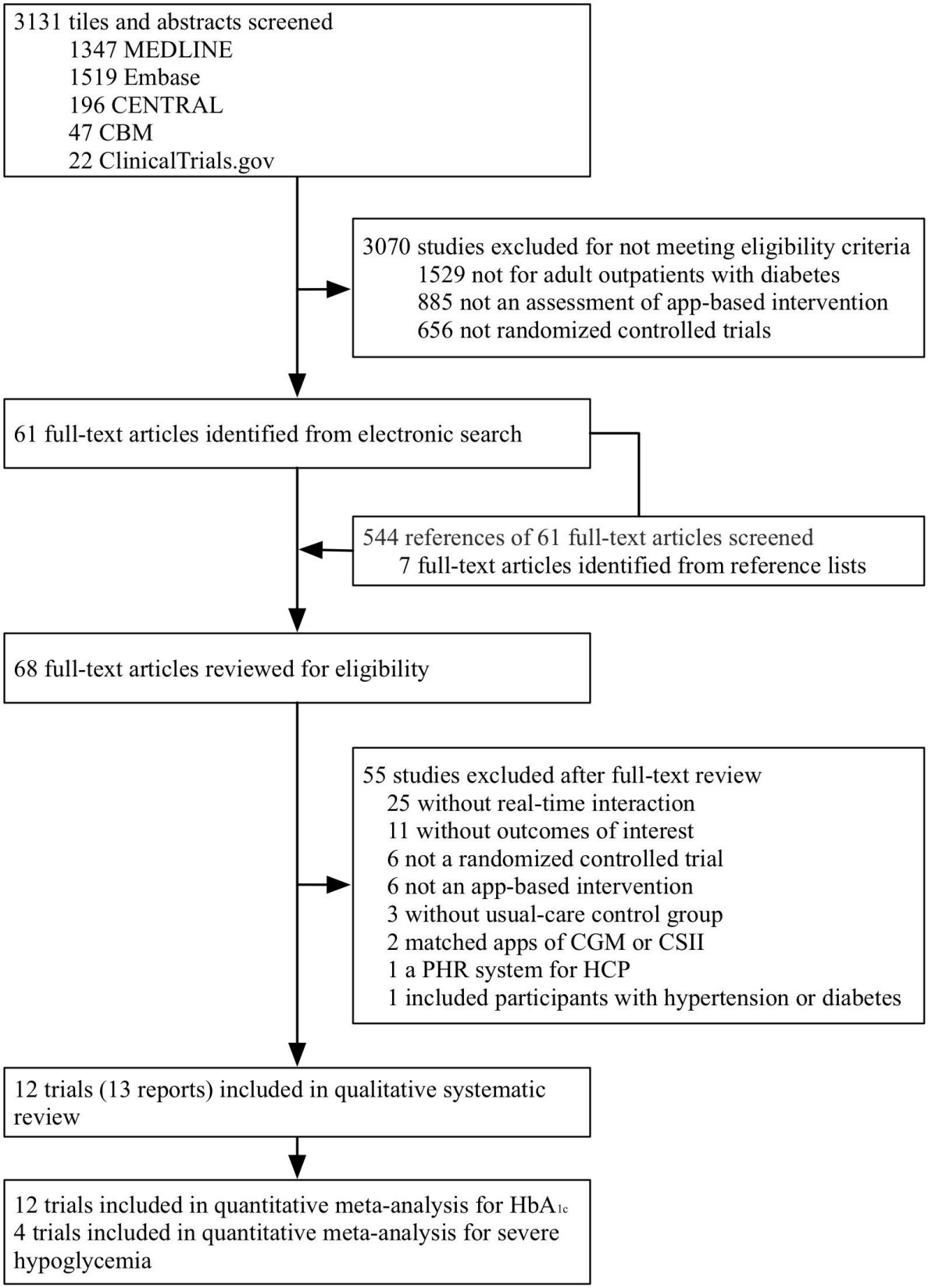
[d]The overall risk assessment of an intervention was determined by the highest risk of its functions.

[e]I: intervention group.

[f]C: control group.

[g]NR: not reported.

Figure 1. Study selection. CBM: Chinese Biomedical Literature Database; CENTRAL: Cochrane Central Register of Controlled Trials; CGM: continuous glucose monitoring; CSII: continuous subcutaneous insulin infusion; HbA_{1c}: hemoglobin A_{1c}; HCP: health care provider; PHR: personal health record.



Risks of Bias of Included Trials

Only 67% (8/12) of the trials adequately reported allocation sequence generation, and 58% (7/12) adequately reported concealing the allocation sequence. As an objective outcome, all trials adequately blinded the assessment of the primary outcome (HbA_{1c} changes). The corresponding proportion for incomplete outcome data was 25% (3/12), for selective reporting

was 25% (3/12), and for other sources of bias was 50% (6/12). Figure 2 and Figure 3 present the risk-of-bias assessments of the primary outcome (HbA_{1c} changes) for each domain of each included study. Multimedia Appendix 4 lists the detailed characteristics, taxonomic classification, and risk of bias of each included trial.

Figure 2. Risk of bias for the primary outcome (hemoglobin A_{1c} changes): review authors' judgments about each risk-of-bias item presented as percentages across all included studies.

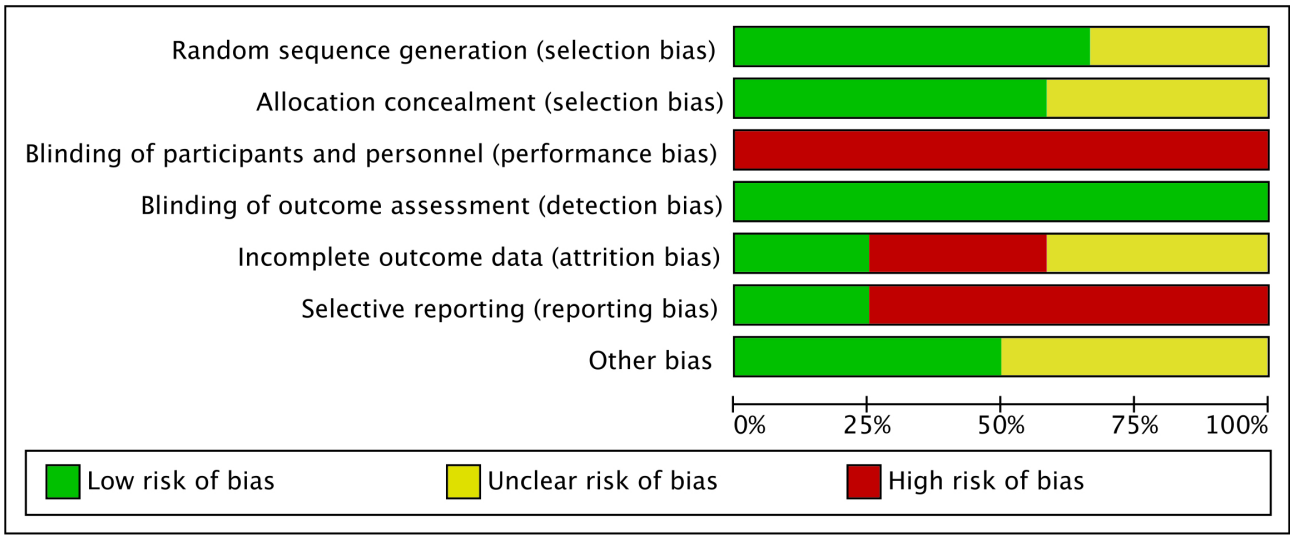
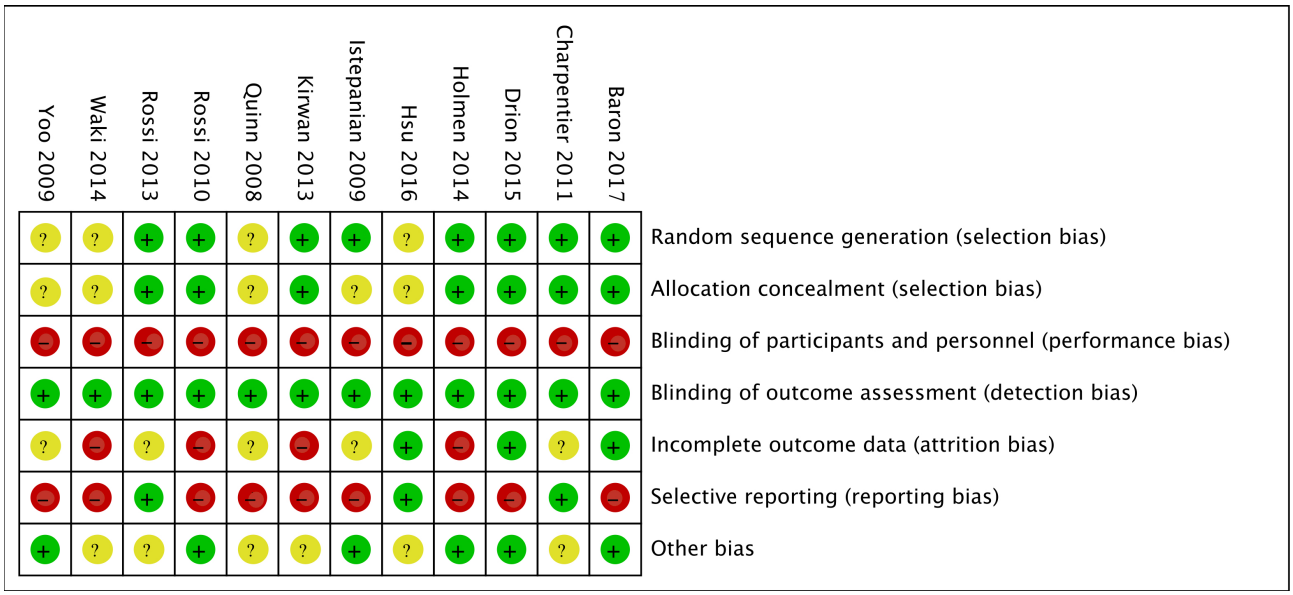


Figure 3. Risk-of-bias summary for the primary outcome (hemoglobin A_{1c} changes): review authors' judgments about each risk-of-bias item for each included study.



Effects of Mobile App-Based Interventions on HbA1c

The use of mobile app-based interventions was associated with a clinically significant HbA_{1c} reduction of 0.48% (95% CI 0.19%-0.78%, I^2=76%, P<.001) compared with standard care alone, as Figure 4 shows. However, the funnel plot was found to be asymmetrical (Multimedia Appendix 5), with Egger test indicating a potential publication bias (P=.008). Overall, we used the GRADE approach to rate the quality of the evidence for HbA_{1c} as low due to the potential publication bias and study limitations (lack of allocation concealment, lack of blinding of participants and personnel, incomplete outcome data, selective reporting, and other biases as shown in Figure 2 and Figure 3; Multimedia Appendix 6).

We performed a post hoc exploratory analysis for 5 trials enrolling patients with T1DM and 5 trials enrolling patients with T2DM. The use of app-based interventions did not achieve statistical significance among patients with T1DM (MD 0.37%, 95% CI –0.12%-0.86%, I^2=86%, P<.001). Larger HbA_{1c} reductions were noted for patients with T2DM (MD 0.67%, 95% CI 0.30%-1.03%, I^2=47%, P=.11). The intersubgroup difference was not significant (P=.30) (Figure 5).

Figure 4. Effects of app-based mobile health interventions on hemoglobin A_{1c} (HbA_{1c}). MD: mean difference.

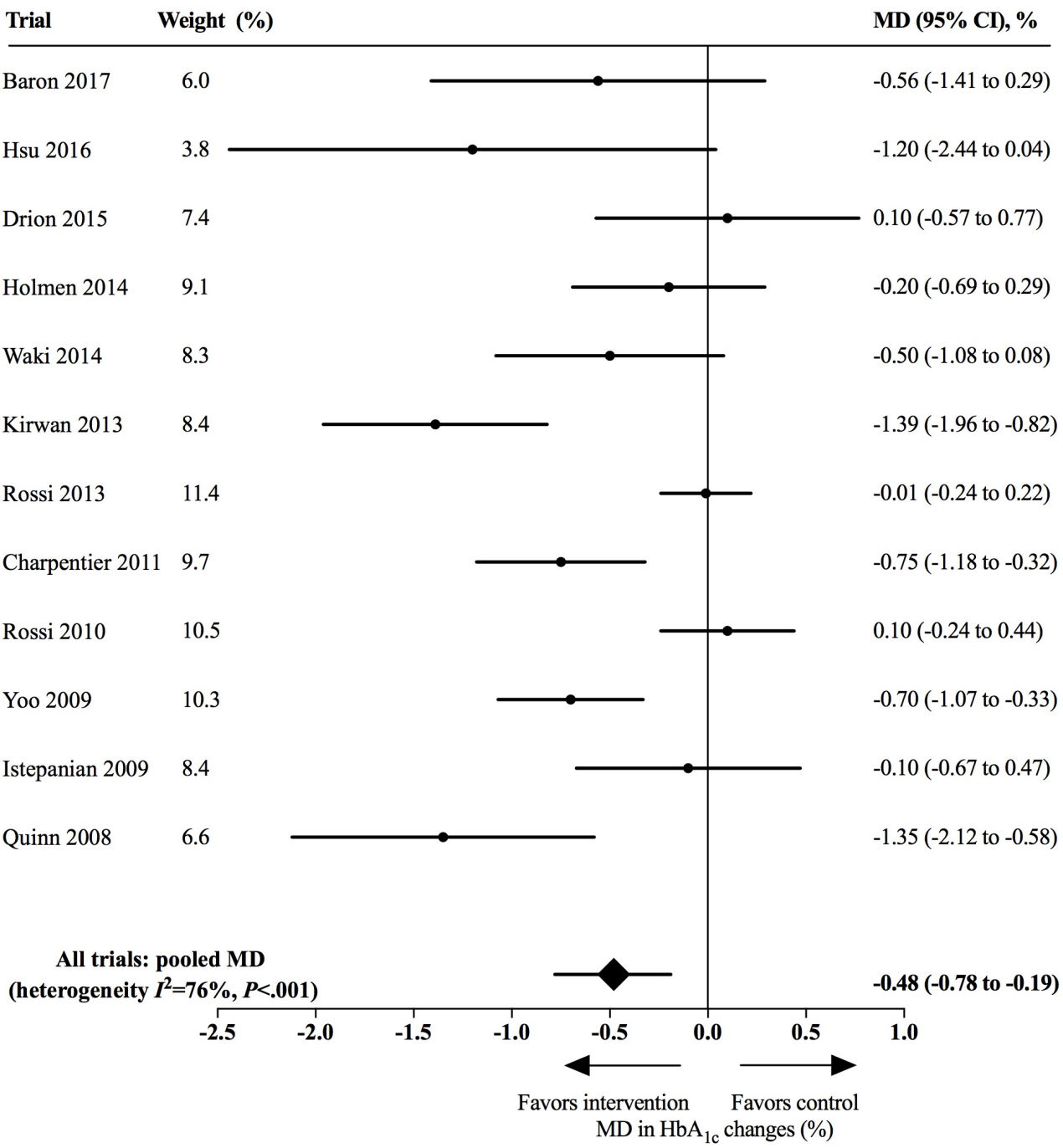
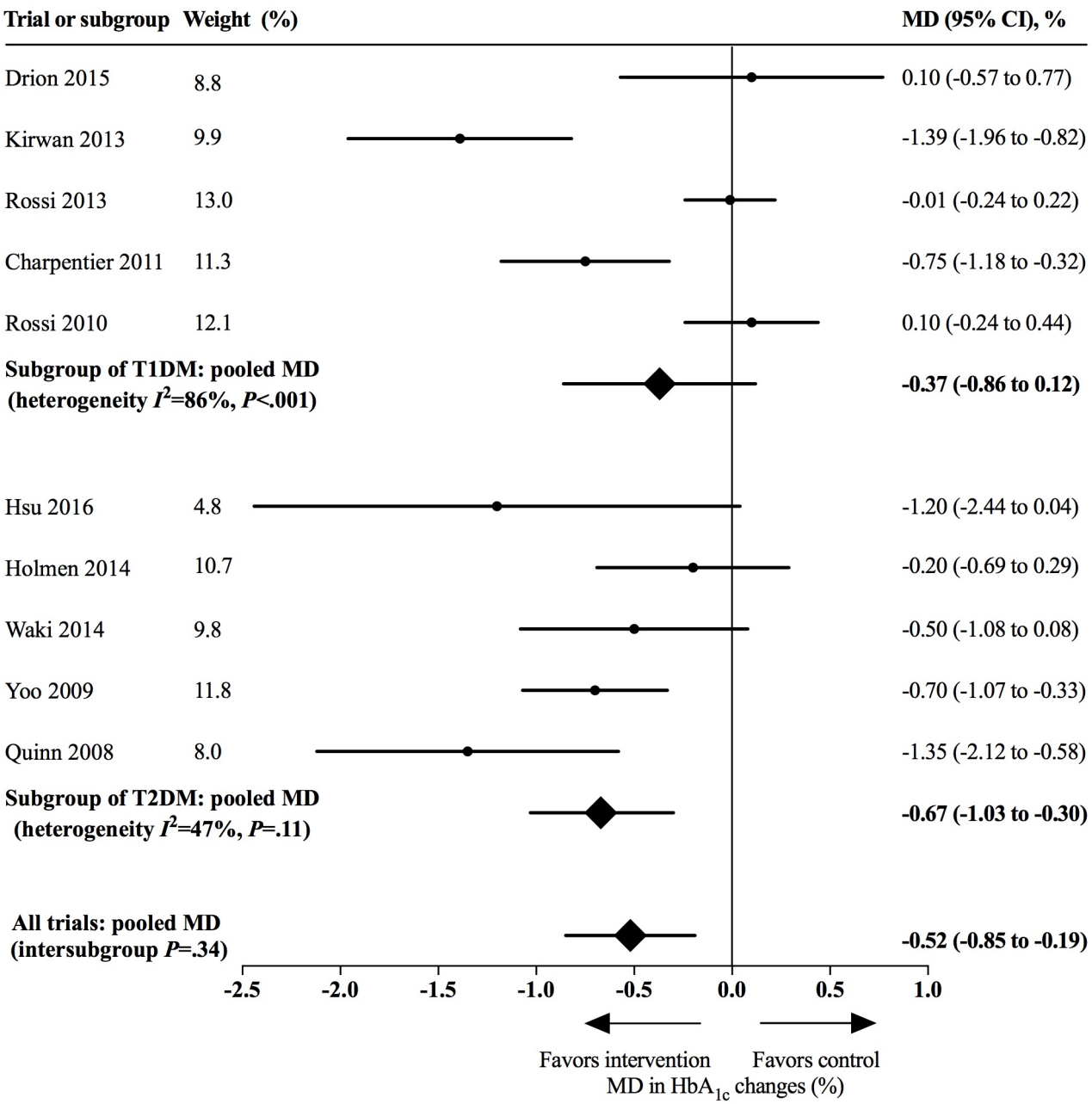


Figure 5. Effects of app-based mobile health interventions on hemoglobin A_{1c} (HbA_{1c}) for patients with type 1 diabetes (T1DM) and type 2 diabetes (T2DM). MD: mean difference.



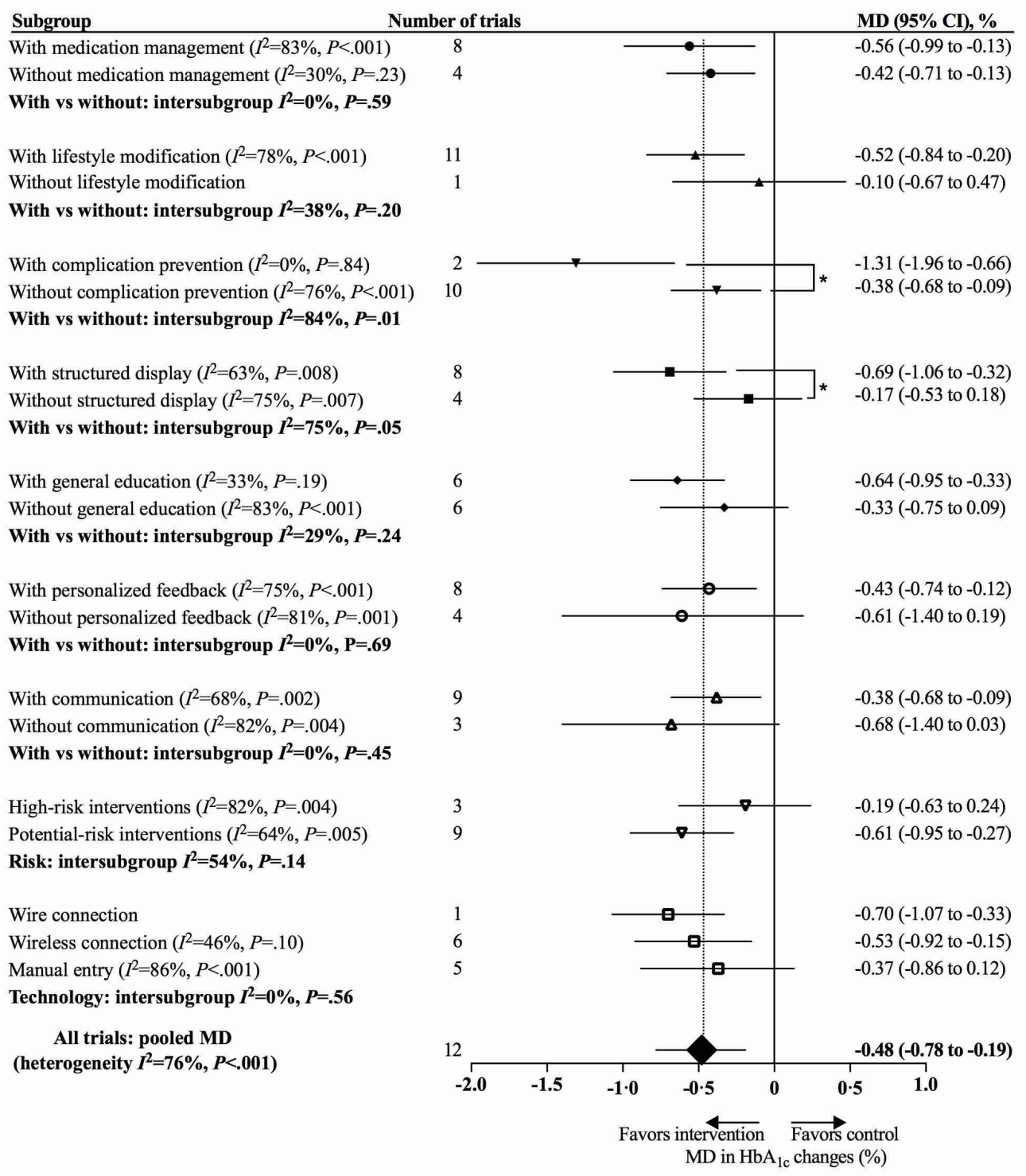
Effects of Modules, Risks, and Technologies of App-Based Interventions on HbA1c

We noted a greater HbA_{1c} reduction when interventions included a complication prevention module (with complication prevention: MD 1.31%, 95% CI 0.66%-1.96%, I^2=0%, P=.84 vs without: MD 0.38%, 95% CI 0.09%-0.68%, I^2=76%, P<.001; test for subgroup difference P=.01). Having a structured display was also associated with a larger HbA_{1c} reduction (with structured display: MD 0.69%, 95% CI 0.32%-1.06%, I^2=63%, P=.008 vs without: MD 0.17%, 95% CI –0.18% to 0.53%, I^2=75%, P=.007; test for subgroup difference P=.05).

For high-risk interventions with a clinical decision-making function, the reduction of HbA_{1c} was 0.19% (95% CI –0.24%-0.63%, I^2=82%, P=.004), while the reduction was 0.61% (95% CI 0.27%-0.95%, I^2=64%, P=.005) for potential-risk interventions without clinical decision making (test for subgroup difference P=.104.

Interventions using manual entry showed an associated lower HbA_{1c} reduction without statistical significance (wire connection: MD 0.70%, 95% CI 0.33%-1.07% vs wireless connection: MD 0.53% CI 0.15%-0.92%, I^2=46%, P=.10 vs manual entry: MD 0.37%, 95% CI –0.12%-0.86%, I^2=86%, P<.001; test for subgroup difference P=.56) (Figure 6).

Figure 6. Effects of modules, risks, and technologies of app-based mobile health interventions on hemoglobin A_{1c} (HbA_{1c}). MD: mean difference.



Adverse Events of Included Trials

Adverse events were reported variably among the 5 included studies [38,41,44-46]. One study reported no adverse clinical event but several undesired technical events in the automatic data transmission between the glucometer and the app [41]. A total of 4 studies reported the participants or the proportion of participants with, or the incidence of severe hypoglycemia and overall hypoglycemia [38,44-46]. None of the studies reported any other kinds of adverse events or death.

For severe hypoglycemia, 1 study reported significantly fewer episodes in the intervention group (0.33 vs 2.29 events/patient-year) [44]; 3 studies reported no severe hypoglycemia in either the intervention or control group [38,41,46]. Of the 5 studies, 4 reported that 3 participants in the intervention group and 3 in the standard-care group had severe hypoglycemia episodes, with a pooled risk ratio of 1.07 (95% CI 0.23%-5.09%) [38,41,45,46]. The pooled risk ratio was 1.62 (95% CI 0.48%-5.40%) for the 3 trials reporting overall hypoglycemia [38,41,46] (Multimedia Appendix 7).

Overall, we rated the quality of the evidence for severe hypoglycemia as low due to imprecision (wide confidence intervals including null effect) and study limitations (risk of bias in 4 trials), and as very low for adverse events owing to inconsistency (substantial diversity in the definitions of outcome measures), imprecision (small sample sizes and low event rates), and study limitations (risk of bias in 5 trials) (Multimedia Appendix 5).

Discussion

Principal Findings

As most commercially available apps for diabetes self-management were not tested by RCTs, both the patients and the clinicians needed indirect evidence to guide their assessment while choosing apps. The purposes of this review were to investigate the glycemic efficacy of mobile app-based interventions, and to explore the differential effectiveness of their functions. We could not use existing classifications for the functions of the app-based interventions because of inconsistency and incompleteness. As a result, we developed and validated a comprehensive taxonomy for the functions of diabetes self-management apps. To our knowledge, this is the first comprehensive taxonomy with clinical, functional, and risk axes, and this is the first review exploring the contribution of each function to the effectiveness of entire apps.

The meta-analysis of 12 RCTs demonstrated that app-based interventions were associated with a statistically and clinically significant HbA_{1c} reduction of 0.48% (95% CI 0.19%-0.78%). We noted larger HbA_{1c} reductions for patients with T2DM (MD 0.67%, 95% CI 0.30%-1.03%) than those with T1DM (MD 0.37%, 95% CI –0.12%-0.86%). The exploratory subgroup analyses showed that having a clinical decision-making function in app-based interventions was not associated with a greater HbA_{1c} reduction (with clinical decision making: MD 0.19%, 95% CI –0.24%-0.63% vs without: MD 0.61%, 95% CI 0.27%-0.95%; intersubgroup P=.14). There were no excess adverse events related to the included app-based interventions.

Comparison With Prior Work

Consistent with previous reviews involving mobile app-based interventions [16-18], our study indicated that the use of mobile app-based interventions is associated with a clinically significant HbA_{1c} reduction in the diabetes management of adult outpatients. Our results suggested that glycemic control of adult outpatients with diabetes can benefit from apps. A subgroup analysis of diabetes types showed a larger HbA_{1c} reduction in patients with T2DM than in those with T1DM. This difference is consistent with a previous review [17] and may be explained, at least in part, by the complexity of the management of T1DM [2]. Patients with T1DM, especially those at a young age, require intensive management, which increases the burdens placed on the management of T1DM. Our result suggested that current apps may not be good enough to support the intensive management of T1DM.

Our study developed a 3-axis taxonomy for diabetes apps, with rows of functional modules, columns of diabetes management modules, and cells of functions with risk assessments. The functional, clinical, and risk axes were developed based on previous classifications, the ADA's guidelines, and the FDA's risk recommendation, respectively. The 3-axis design of the taxonomy is comprehensive and decreases the possibility of misclassification. Additionally, this 3-axis design is applicable for diseases other than diabetes by adjusting the modules in the clinical axis. The validation process guarantees that our taxonomy can be used to classify commercial diabetes apps. Differences in the detected effect sizes in subsequent subgroup analyses indicated the utility of our taxonomy.

Our taxonomy has some advantages. First, it is a comprehensive taxonomy with functional, clinical, and risk axes. The taxonomy permits subsequent exploratory subgroup analyses of multifunction apps, which give insights into the efficacy and risk of each module in diabetes apps. Comparatively, existing classifications appear to be incomplete or inconsistent. Previous classifications have mainly focused on the functions of apps, which, as a result, have made them applicable only for functional evaluation [16,17,22-25,27-30]. Some similar functions in these classifications have diverse definitions and descriptive details. Moreover, some functions lack clinical considerations, such as education, feedback, and decision support [16,17,23-25,27-30]. Only 1 classification addresses risk assessment [20]. These classifications, on the one hand, demonstrate a requirement to classify apps comprehensively, and on the other hand, they indicate the limitation of each independent classification.

Second, our taxonomy can be of some help in the development and evolution of diabetes apps. App developers are usually technicians without a clinical background. As a result, the evidence-based guidelines for diabetes management are easily ignored during app development. For example, we found that complication prevention and psychosocial care were uncommon in the app-based interventions we examined. However, complication prevention behaviors and emotional well-being are associated with positive diabetes outcomes according to the guidelines [2]. Previous reviews also suggested that diabetes apps lacked essential modules and neglected evidence-based guidelines [15,50]. With a clinical axis of diabetes management modules developed based on guidelines, our taxonomy makes it straightforward for app developers to follow evidence-based guidelines during the design and development of diabetes apps.

Third, our taxonomy permits subsequent exploratory subgroup analyses of multifunction apps, which give insights into the efficacy and risk of each module in diabetes apps.

Our exploratory subgroup analyses suggested a limited efficacy of clinical decision making, which was defined as recommending treatment (eg, oral agents and insulin) by algorithms alone without the participation of health care providers and was determined to be high risk according to our taxonomy. Traditionally, clinical decisions are made during a face-to-face interview after a complete assessment. Built-in clinical decision support systems, however, are less likely to collect data and assess status as thoroughly as face-to-face consultations do. Without adequate data and well-designed algorithms, clinical decision-making functions can make inappropriate decisions and pose risks to patients [51,52].

Additionally, complex data collection may cause technical difficulties. Despite the above-mentioned issues, clinical decision making can be found in diabetes apps both in trials [44-46] and in app stores [23,28]. Therefore, we suggest that app developers should employ caution to add clinical decision making into diabetes apps, and patients should consult with health care providers on using apps for diabetes self-management.

Our subgroup analyses indicated that having a complication prevention module in the apps was associated with a greater HbA_{1c} reduction. Complication prevention behaviors such as smoking cessation and hypoglycemia prevention are critical components of diabetes management according to current guidelines [2]. However, only 2 included app-based interventions had a complication prevention module. Further studies are needed to confirm the efficacy of a complication prevention module. Meanwhile, having a structured display module was associated with a larger HbA_{1c} reduction. The structured display module may improve blood glucose self-monitoring behaviors by displaying structured self-monitoring of blood glucose profiles. Having a structured display is consistent with current clinical guidelines, in which self-monitoring of blood glucose is a critical element in the management of diabetes [2].

Having a lifestyle modification in app-based interventions was associated with a trend toward reduced HbA_{1c}, as was having a general education module. The modules of lifestyle modification and general education may raise awareness of lifestyle change and self-management. Since these 2 modules pose limited risks to patients with diabetes, it might be reasonable to add lifestyle modification and general education to diabetes apps.

The data suggested limited glycemic efficacy of having a personalized feedback module. However, considerable uncertainty and limitations exist regarding its efficacy. Given that the personalized feedback module has a relatively high risk, further evaluation is required before adding a personalized feedback module to diabetes apps. Consistent with a previous review [15], our review found that none of the interventions included a general communication function. Particular attention should be paid to the complexity and variety of the patient-clinician communication function as shown in Multimedia Appendix 8. As for the technologies, direct data transmission between users and mobile devices using wire or wireless connections was associated with a trend toward reduced HbA_{1c}, which could be explained by the convenience and accuracy of the technology.

Limitations

Our study also has some limitations. First, the exploratory and observational nature of our subgroup analyses and the possibility of misclassification prevented us from drawing a solid conclusion about the modular efficacies and risks. Second, we examined only 12 trials in our study, which may limit the strength of this systematic review. Third, we noted the asymmetry of the funnel plot, which indicated a potential risk of publication bias in our systematic review.

Conclusions

In our study, we developed a 3-axis taxonomy for diabetes self-management apps. Mobile app-based interventions improve glycemic control in adult outpatients with diabetes, especially in those with T2DM. Our analyses suggest that clinical decision making requires further improvement and evaluation before being added to apps. Safety issues such as hypoglycemia and other adverse events are being overlooked and need attention in future investigations.

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Authors' Contributions

YW, XY, HT, and SL conceived this study. YW and YD contributed to data extraction and quality assessment. YW and XY contributed to the Web-based searches of the literature and apps. YW and SL wrote the report. YW, JK, and LL conducted the statistical analysis. GV, AN, and XS guaranteed the study methodology. All authors discussed and interpreted the results and reviewed the manuscript before submission.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Taxonomy development and validation.

[PDF File (Adobe PDF File), 578KB - mhealth_v5i3e35_app1.pdf]

Multimedia Appendix 2

MEDLINE search strategy.

[PDF File (Adobe PDF File), 29KB - mhealth_v5i3e35_app2.pdf]

Multimedia Appendix 3

List of excluded references with reasons for exclusions.

[PDF File (Adobe PDF File), 66KB - mhealth_v5i3e35_app3.pdf]

Multimedia Appendix 4

The detailed information, taxonomic classification, and risk of bias of included trials.

[PDF File (Adobe PDF File), 164KB - mhealth_v5i3e35_app4.pdf]

Multimedia Appendix 5

Funnel plot.

[PDF File (Adobe PDF File), 61KB - mhealth_v5i3e35_app5.pdf]

Multimedia Appendix 6

GRADE for primary and secondary outcomes.

[PDF File (Adobe PDF File), 44KB - mhealth_v5i3e35_app6.pdf]

Multimedia Appendix 7

Meta-analyses for adverse events.

[PDF File (Adobe PDF File), 160KB - mhealth_v5i3e35_app7.pdf]

Multimedia Appendix 8

Classifications of the patient-clinician communication function.

[PDF File (Adobe PDF File), 27KB - mhealth_v5i3e35_app8.pdf]

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Abbreviations

ADA: American Diabetes Association
CENTRAL: Cochrane Central Register of Controlled Trials
FDA: Food and Drug Administration
GRADE: Grading of Recommendations Assessment, Development and Evaluation
HbA1c: hemoglobin A1c
MD: mean difference
RCT: randomized controlled trial
T1DM: type 1 diabetes mellitus
T2DM: type 2 diabetes mellitus

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Original Paper

Remote Monitoring of Hypertension Diseases in Pregnancy: A Pilot Study

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Abstract

Background: Although remote monitoring (RM) has proven its added value in various health care domains, little is known about the remote follow-up of pregnant women diagnosed with a gestational hypertensive disorders (GHD).

Objective: The aim of this study was to evaluate the added value of a remote follow-up program for pregnant women diagnosed with GHD.

Methods: A 1-year retrospective study was performed in the outpatient clinic of a 2nd level prenatal center where pregnant women with GHD received RM or conventional care (CC). Primary study endpoints include number of prenatal visits and admissions to the prenatal observation ward. Secondary outcomes include gestational outcome, mode of delivery, neonatal outcome, and admission to neonatal intensive care (NIC). Differences in continuous and categorical variables in maternal demographics and characteristics were tested using Unpaired Student's two sampled *t* test or Mann-Whitney *U* test and the chi-square test. Both a univariate and multivariate analysis were performed for analyzing prenatal follow-up and gestational outcomes. All statistical analyses were done at nominal level, Cronbach alpha=.05.

Results: Of the 166 patients diagnosed with GHD, 53 received RM and 113 CC. After excluding 5 patients in the RM group and 15 in the CC group because of the missing data, 48 patients in RM group and 98 in CC group were taken into final analysis. The RM group had more women diagnosed with gestational hypertension, but less with preeclampsia when compared with CC (81.25% vs 42.86% and 14.58% vs 43.87%). Compared with CC, univariate analysis in RM showed less induction, more spontaneous labors, and less maternal and neonatal hospitalizations (48.98% vs 25.00%; 31.63% vs 60.42%; 74.49% vs 56.25%; and 27.55% vs 10.42%). This was also true in multivariate analysis, except for hospitalizations.

Conclusions: An RM follow-up of women with GHD is a promising tool in the prenatal care. It opens the perspectives to reverse the current evolution of antenatal interventions leading to more interventions and as such to ever increasing medicalized antenatal care.

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KEYWORDS

pregnancy; gestational hypertension disorders; eHealth; remote monitoring

Introduction

Background

Gestational hypertensive disorders (GHD) remain one of the most significant and intriguing unsolved problems in obstetrics [1,2]. It is estimated that 5-10% of pregnancies are complicated by this disease, and it is one of the major causes of maternal and fetal morbidity and mortality [1,3,4]. GHD is defined as new onset hypertension (diastolic blood pressure ≥90 mmHg and systolic blood pressure ≥140 mmHg), with or without proteinuria (≥300 mg in 24-h urine collection) at or after 20 weeks of gestation [1]. The most common management for GHD in Belgium is an admission to the prenatal observation unit for diagnostic and therapeutic follow-up before induction of labor or discharge at home. In severe cases, premature birth is indicated [1].

As part of the Hasselt University and the Limburg Clinical Research Program (LCRP), Ziekenhuis Oost-Limburg (Genk, Belgium) initiated in January 2015 a remote monitoring (RM) program for women with or at risk for GHD. RM is an alternative approach in medical management (dating back to the early 1990s) facilitating patients' management at home [5]. It is defined as the use of telecommunication technologies to assist the transmission of medical information and services between health care providers and patients. The use of this 2-way telecommunication technology, using multimedia and computer networks, to assist medical management is a growing trend internationally [6].

In this paper, we report our first clinical results of RM in GHD, obtained retrospectively during the year of technical installation of remote communication between hospital doctors or midwives and pregnant women at home.

Related Work

RM has already shown benefits in Cardiology and Pneumology [7,8]. In the prenatal care, RM has also shown an added value to improve maternal and neonatal outcomes. Various studies reported a reduction in unscheduled patient visits, low neonatal birth weight, and admissions to neonatal intensive care (NIC) for pregnant women who received RM compared with pregnant women who did not receive these devices. Additionally, RM can contribute to significant reductions in health care costs. RM was also demonstrated to prolong gestational age and to improve feelings of self-efficacy, maternal satisfaction, and gestational age at delivery when compared with a control group which did not received RM [9-16]. Unfortunately, some of the previous mentioned studies are dating back to 1995 and no more recent work is available. This is in contradiction with the rapid technological advancements that have been seen in the last decade. Further, no studies are published about the added value of RM in pregnant women with GHD. To our knowledge, this is the first publication about a prenatal follow-up program for pregnant women with GHD to date.

Methods

Subjects

All women diagnosed with GHD who delivered at the outpatient prenatal clinic of Ziekenhuis Oost-Limburg (Genk, Belgium) during 2015 were included. Women received RM on demand of the responsible obstetrician before admission or after discharge from the prenatal observation ward. The criteria to initiate RM were GHD at gestational age ≥20 weeks where an intensive follow-up until delivery was desirable. Women without a mobile phone, a gestational age less than 20 weeks, a fetus with congenital malformations, and women who refused informed consent were excluded and received conventional care (CC).

Between January 1, 2015 and December 31, 2015, there were 2058 women who had prenatal care and delivery at Ziekenhuis Oost-Limburg. It was found that 166 women were diagnosed with GHD, 53 of them received CC added with RM. The remaining 113 pregnant women with GHD did not receive RM but only CC.

Interventions in the Remote Monitoring Group

Women consenting for RM received obstetric surveillance by a Withings Wireless Blood Pressure Monitor, Withings Smart Body Analyzer, and a Withings Pulse O² (Withings, Issy-les-Moulineux, France). Pregnant women participating in the prenatal remote follow-up program were asked to perform one blood pressure measurement in the morning and one in the evening, one weight measurement a day, and wear an activity tracker day and night until delivery or hospital admission (see Figure 1).

The data from the monitor devices were transmitted to a Web-based dashboard developed by the Mobile Health Unit of the University of Hasselt. Predetermined alarm signals were set; one midwife performed remote follow-up of all transformed data at the dashboard. She had to discriminate normal and alarm signals of systolic blood pressure >140 mmHg, diastolic blood pressure >90 mmHg, or weight gain >1 kg/day. Alarm events were communicated with the obstetrician in charge to discuss management options before contacting and instructing patients at home. Type of interventions were (1) expectant management, (2) ambulatory blood sampling and 24-h urine collection at home, (3) adjustment of the antihypertensive therapy or physical activity, (4) admission to the antenatal ward, and (5) induction of labor. Therapeutic interventions were according to local management.

The hospital's Medical Ethics Committee approved the study.

Figure 1. The equipment used in the remote monitoring group.

Maternal Demographics

Maternal demographics and characteristics of the patients in the RM group were collected at study entry. In the CC group, these data were obtained by manual search through the electronic medical records.

Primary Outcome: Prenatal Follow-Up

Total numbers of prenatal consultations were collected from 10 weeks of gestation onwards: ultrasound scans, cardiotocographics (CTG), admission to the prenatal ward, total days of hospitalization, and the number of admissions until delivery. These data were retrospectively collected from the electronic medical records after the delivery of the women in both the RM and CC group. These data were checked with the hospital administration and billing records.

Secondary Outcomes: Delivery Outcomes

Maternal parameters collected at birth were gestational age at delivery and mode of delivery. Neonatal outcomes collected were birth weight, birth weight percent, length, Apgar at 1′ and 5′, and number of admissions to NIC.

Statistical Analysis

Differences in continuous and categorical variables in maternal demographics and characteristics were tested using Unpaired Student's two sampled *t* test or Mann-Whitney *U* test and the chi-square test. Both univariate and multivariate analyses were performed for analyzing prenatal follow-up and gestational outcomes. Beta coefficients and 95% CI were calculated for multivariate analysis. All statistical analyses are done at nominal level, Cronbach alpha=.05. Statistical analysis was performed with Statistical Package for Social Sciences release 22.0 (IBM SPSS Inc).

Results

Participant Demographics

Of the 2058 deliveries in Ziekenhuis Oost-Limburg in 2015, 18.06% (166/2058) were diagnosed with GHD and had both prenatal care and birth in the same hospital. A total of 31.92% (53/166) (31.92%) of the GHD pregnancies had RM. Of these, 3.01% (5/53) were excluded from analysis because of missing data (n=4) and fetal loss (n=1). In total, 28.92% (48/166) RM women were eligible for analysis. The other 68.08% (133/166) GHD pregnancies had CC. Of these, 9.04% (15/133) women were excluded because of missing data, leaving 59.04% (98/166) eligible for analysis. Figure 2 shows the study population in a flowchart.

Table 1 shows the maternal demographics and characteristics of the women diagnosed with GHD. In CC, there were more primigravidas and smokers than in RM: 66.32% (65/98) versus 41.66% (20/48) and 10.20% (10/98) versus 0% (0/48), respectively.

Table 1. Maternal demographics and characteristics.

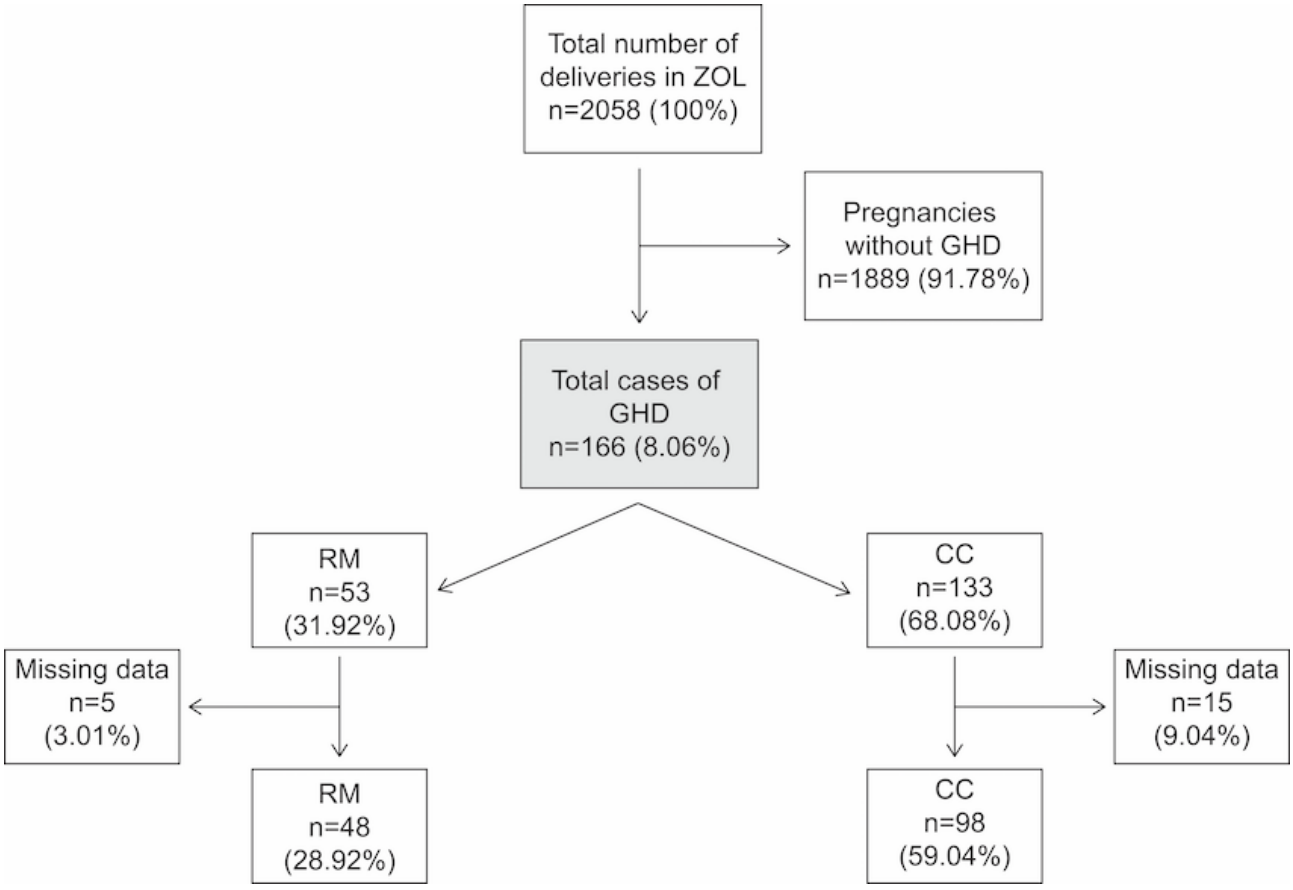
Variable	RM[a] group (n=48)	CC[b] group (n=98)	Statistical significance (2-tailed), *P* value
Maternal age in years, mean (SD)	31.69 (4.25)	31.94 (4.77)	.73
Pre pregnancy weight (kg), mean (SD)	72.00 (17.99)	76.80 (19.74)	.11
Height (cm), mean (SD)	166.00 (6.94)	167.08 (6.86)	.38
BMI (kg/m²), mean (SD)	25.54 (5.58)	27.08 (6.92)	.32
Primigravidity, n (%)	20 (41.66)	65 (66.32)	.005
Concomitant diseases, n (%)			
Cardiovascular disorders	0 (0)	1 (1.02)	.48
Blood coagulation disorder	1 (2.08)	1 (1.02)	.61
Endocrine disorders	2 (4.16)	5 (5.10)	.81
Immunological disorders	1 (2.08)	2 (2.04)	.99
Smoking, n (%)	0 (0)	10 (10.20)	.02
GA[c] first visit in weeks, mean (SD)	10.10 (5.36)	11.21 (7.60)	.66

[a]RM: remote monitoring.

[b]CC: conventional care.

[c]GA: gestational age.

Figure 2. The study population.



Prenatal Follow-Up: Comparison Between RM and CC

Data on prenatal follow-up balance are shown in Table 2. The number of prenatal hospital admissions and admissions until delivery were lower in RM than in CC when a univariate analysis is performed: 56.25% (27/48) versus 74.49% (73/98), and 27.08% (13/48) versus 62.24% (61/97). This was not significant in multivariate analysis. For both uni- and multivariate analysis was the prevalence of gestational hypertension higher in RM than in CC (81.25% vs 42.86% and beta=6.62), but the prevalence of preeclampsia was lower (14.85% vs 43.87% and beta=.24).

Table 2. Prenatal follow-up.

Variable	Univariate analysis			Multivariate analysis		
	RM[a] group (n=48)	CC[b] group (n=98)	*P* value	RM versus no RM (beta)	95% CI[c] for beta	*P* value
Total number of prenatal visits, mean (SD)	8.77 (4.12)	8.86 (3.51)	.90	−.56	−1.74 to 9.14	.54
CTG's, mean (SD)	2.23 (2.05)	1.89 (1.70)	.46	−.08	−1.12 to 0.53	.48
Echo's, mean (SD)	3.95 (2.00)	3.67 (2.12)	.08	.07	−0.56 to 1.19	.48
Prenatal admission, n (%)	27 (56.25)	73 (74.49)	.03	.46	0.18-1.45	.09
Days hospitalized, mean (SD)	5.74 (8.98)	4.73 (5.69)	.57	.10	−1.62 to 4.81	.32
Prenatal admission until delivery, n (%)	13 (27.08)	61 (62.24)	<.001	.38	0.12-1.22	.11
Gestational outcome, n (%)						
Essential hypertension	1 (2.08)	9 (9.18)	.11			
Gestational hypertension	39 (81.25)	42 (42.86)	<.001	6.62	2.40-18.27	<.001
Preeclampsia	7 (14.58)	43 (43.87)	<.001	0.24	0.08-0.71	.01
HELLP[c]	1 (2.08)	4 (4.08)	.53			

[a]RM: remote monitoring.

[b]CC: conventional care.

[c]HELLP: hemolysis elevated liver enzymes and low platelets.

In order to investigate the influence of the maternal demographics and characteristics on the prenatal follow-up, a multiple linear regression analysis and a multivariate logistic regression analysis is performed. A detailed overview of these data is proved in Multimedia Appendix 1.

Delivery Outcomes: Comparison Between RM and CC

Delivery outcomes are shown in Table 3. For both uni- and multivariate analyses, in the RM group, the number of spontaneous start of the birth process was higher compared with CC group: 60.24% (29/48) versus 31.63% (31/98) and beta=3.25. Also, the number of inductions was lower in RM group compared with CC group: 25.00% (12/48) versus 48.98% (48/98) and beta=.36. Neonates in RM group did have a shorter length compared with the CC group when performed a multivariate analysis (beta=.23). Finally, neonates in the RM group, compared with CC group, were less likely to be admitted to the NIC department when performed a univariate analyses (10.42%, 5/48 vs 27.55%, 27/98) but not in multivariate analyses (beta=.34). Despite the significant differences in the start of the birth process, there are no differences in the mode of delivery between the two groups.

Table 3. Delivery outcomes.

Variable	Univariate analysis			Multivariate analysis		
	RM[a] group (n=48)	CC[b] group (n=98)	*P* value	RM versus no RM (beta)	95% CI for beta	*P* value
GA[c] delivery in weeks, mean (SD)	37.49 (2.52)	37.20 (3.20)	.94	−.21	−1.29 to 0.06	.85
Start birth process, n (%)						
Spontaneous	29 (60.42)	31 (31.63)	.001	3.25	1.36 to 7.78	.001
Induction	12 (25.00)	48 (48.98)	.006	.36	0.14 to 0.89	.03
Primary cesarean section	7 (14.54)	19 (19.39)	.48	.67	0.21 to 2.18	.51
Mode of delivery, n (%)						
Vaginal	32 (66.67)	58 (59.18)	.38	1.06	0.44 to 2.54	.90
Instrumental	4 (8.33)	8 (8.16)	.97	2.34	0.47 to 11.64	.30
Primary cesarean section	7 (14.54)	19 (19.39)	.48	.67	0.21 to 2.18	.51
Secondary cesarean section	5 (10.42)	13 (13.27)	.63	.49	0.11 to 2.10	.33
Birth weight in g, mean (SD)	3058.54 (692.60)	2953.09 (874.80)	.36	.11	−162.71 to 535.33	.29
Length in cm	49.53 (2.85)	48.33 (3.52)	.07	.23	0.02 to 3.45	.05
Apgar 1′, mean (SD)	8.11 (1.20)	7.91 (1.63)	.86	.08	−0.38 to 0.88	.43
Apgar 5′, mean (SD)	9.13 (0.80)	9.03 (1.27)	>.99	.06	−0.37 to 0.65	.59
Admission NIC[d], n (%)	5 (10.42)	27 (27.55)	.02	.34	0.10 to 1.14	.08

[a]RM: remote monitoring.

[b]CC: conventional care.

[c]GA: gestational age.

[d]NIC: neonatal intensive care.

In order to investigate the influence of the maternal demographics and characteristics on the delivery outcomes, a multiple linear regression analysis and multivariate logistic regression analysis is performed. A detailed overview of these data is proved in Multimedia Appendix 2.

Discussion

Principal Findings

We sought to determine whether RM was an added value to facilitate the prenatal follow-up and to improve the delivery outcomes in patients diagnosed with GHD. To our knowledge, this is the first publication about a prenatal follow-up program for pregnant women with GHD.

The findings show us a reduced appearance of preeclampsia, but an increased appearance of gestational hypertension in the group of women who received a prenatal RM program when compared with women who received CC. Women in the RM group, when compared with CC group, had a lower number of prenatal hospitalizations, prenatal hospitalizations until delivery, and their neonates were less likely to be admitted to the NIC department in univariate but not in multivariate analysis. In both analysis, spontaneous deliveries were more likely and inductions less likely to occur in the RM group when compared with CC group.

Strengths and Limitations

Despite the potential benefits, the use of RM in obstetrical care is still very limited and is not integrated into healthcare systems. The Commission of the European Communities has, in 2012, written an eHealth Action Plan [17] in which they foster a spirit of innovation in eHealth in Europe as the way forward to ensure better health. Our study is one of the first studies in the obstetrical care for women at risk for GHD which meets this requirement. Additionally, one of the strengths of this study is the fact that all patients had antenatal care and delivery in the same hospital with electronic medical records in line with administration files. Also, all patients had antenatal care according to uniform local management protocols. Finally, the percentage of missing data for RM group and CC group is 3.01% and 9.04% respectively, which is a low value.

Our study has three main limitations. First, the data collection was done retrospectively so selection bias cannot be excluded. Second, in CC group, there were more primigravida and women

who smoked during their pregnancy when compared with RM group. Although, our multivariate analysis did not show any influence of these parameters on our principal findings, nulliparous women are known to have a higher risk for the development of preeclampsia superimposed on chronic hypertension [1,13] and smoking during pregnancy carries adverse outcomes; however, a reduced risk of developing GHD in women who smoke is shown by many studies [1,3]. The last limitation is the interference from family doctors or community midwives which cannot be excluded.

Comparisons With Previous Trials

To our knowledge, this is the first publication about a prenatal follow-up program for pregnant women with GHD to date. There are a few publications about a RM program during prenatal follow-up in the management for pregnant women at risk for preterm labor or with the diagnosis of gestational diabetes mellitus. When looking at their maternal outcomes, the results of these studies are not in line with our findings. Compared with the usual care, these studies report no significant difference in prenatal hospitalizations [14] and mode of delivery [10,11] in RM group. When looking at the neonatal outcomes, some contradictions were found: the study of Corwin et al [9] and Morrison et al [12] states that infants born to monitored women were less likely to be admitted to a NIC compared with women without a RM follow-up program, which are in line with our findings. The Collaborative Home Uterine Monitoring Study Group [15] and Homko et al [16] did not find any difference between the two groups in neonatal hospitalization to the NIC. A side note which has to make is that some of the mentioned studies are dating back to 1995, which is in contradiction with the rapid technological advancements that have been made in the last decade.

Possible Explanations

A possible hypothesis of the differences in admission to the prenatal observational ward, admission to the NIC and the gestational outcomes is the hypothesis that preeclampsia is possibly a result of gestational hypertension or essential hypertension [18-20]. This may be due to the possibility to start or adjust an antihypertensive drugs therapy to reduce a high systolic or diastolic blood pressure which can be picked up by RM. There are some studies which mentioned a reduced risk of developing severe hypertension and preeclampsia associated with the use of antihypertensive drugs [21-24]. However, these results are in contradiction with the review of Duley [25], who states that antihypertensive drugs may be effective at reducing the risk of severe hypertension, but not of preeclampsia. Further examination of the influence of antihypertension drugs therapy on the development of severe hypertension or preeclampsia when moderate hypertension is diagnosed, is necessary to obtain clarification herein.

When women are diagnosed with preeclampsia, an induction of labor is often necessary for the prevent of further complications [26,27]. The explanation of more inductions in CC could be the higher number of women diagnosed with preeclampsia in this group. Gestational hypertension is not often a requirement to induce women, and a spontaneous onset of their labor is preferred. This can be the cause of the higher number of spontaneous start of labor in RM.

Additionally, our study shows that there are no differences in prenatal consults between RM and CC. These findings are in contradiction with the statement that medicalization of childbirth has gone too far, which arises from different angles [28-33]. Our study showed that adding RM devices to standard prenatal care does not mean an increase of total amount of echo's, CTG's or other prenatal consultations. In addition, RM opens the perspective to timely initiative and monitor antihypertensive treatments for gestational hypertension. As stated in the review of Gyselaers et al [34], offering RM to a high risk group allows timely identification of most cases of alarm events without increasing ambulatory or in-hospital interventions. This also opens perspectives to reverse the current evolution of antenatal interventions leading to more interventions and as such to ever increasing medicalized antenatal care.

Recommendations for Further Research

Although women in the RM group were invited for an extra prenatal consult to evaluate fetal and maternal wellbeing when events occurred, no statistical significant difference is present in prenatal consultations (total number of consultations, total number of CTG's, and total number of echo's) in the RM group versus the CC group. This indicates that RM does not cause extra prenatal consultations but, when further implemented, can ensure a reduction in this number when obstetricians and gynecologists are more familiar with this system. A study to evaluate the cost-effectiveness of a RM follow-up program needs to be performed later. Additionally, early detection of GHD in the monitoring group demonstrated the value of objective measurements of increase in blood pressure by a remote blood pressure monitoring device. The patients not receiving these devices relied on standard prenatal care, where a GHD mostly will be discovered by chance or when the patient comes to the hospital with self-reported complaints, for example, headache or blurred vision. In these cases, the degree of the GHD is often severe and an active management is necessary [1]. Recent resources showed that providing information about GHD enables women to spot signs and symptoms of these diseases. This leads to earlier diagnoses and management, and reduces morbidity and mortality rates [35]. It is possible that combining patient education and a remote prenatal follow-up program could make morbidity and mortality rates further decrease, but this requires further research. Finally, more research should be done to the influence of antihypertension drugs therapy on the development of severe hypertension or preeclampsia when moderate hypertension is diagnosed. When the effect of the medication is clarified, the added value of RM in the prenatal care of women diagnosed with GHD will be more apparent.

Conclusions

Prenatal RM follow-up is linked with an increased prevalence of a spontaneous start of the birth process, when compared with CC. This may relate to a trend for less maternal and neonatal hospitalizations in RM group compared with the CC group. This study illustrates that RM opens perspectives to timely initiate and monitor antihypertensive treatments for gestational

hypertension, and early identifications of alarm events without increasing ambulatory or in-hospital interventions. To our knowledge, this is the first publication about a prenatal follow-up program for pregnant women with GHD to date. Further examinations about the effect of a prenatal RM follow-up program for women at risk for the development of GHD needs to be done in a randomized controlled trial to confirm these results.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Multivariable model for the prediction of prenatal follow-up using maternal demographics and characteristics.

[PDF File (Adobe PDF File), 36KB - mhealth_v5i3e25_app1.pdf]

Multimedia Appendix 2

Untitled.Supplementary file 2: Multivariable model for the prediction of gestational outcomes using maternal demographics and characteristics.

[PDF File (Adobe PDF File), 40KB - mhealth_v5i3e25_app2.pdf]

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Original Paper

mHealth Interventions for Health System Strengthening in China: A Systematic Review

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Abstract

Background: With rapidly expanding infrastructure in China, mobile technology has been deemed to have the potential to revolutionize health care delivery. There is particular promise for mobile health (mHealth) to positively influence health system reform and confront the new challenges of chronic diseases.

Objective: The aim of this study was to systematically review existing mHealth initiatives in China, characterize them, and examine the extent to which mHealth contributes toward the health system strengthening in China. Furthermore, we also aimed to identify gaps in mHealth development and evaluation.

Methods: We systematically reviewed the literature from English and Chinese electronic database and trial registries, including PubMed, EMBASE, Cochrane, China National Knowledge of Infrastructure (CNKI), and World Health Organization (WHO) International Clinical Trials Registry Platform. We used the English keywords of mHealth, eHealth, telemedicine, telehealth, mobile phone, cell phone, text messaging, and China, as well as their corresponding Chinese keywords. All articles using mobile technology for health care management were included in the study.

Results: A total of 1704 articles were found using the search terms, and eventually 72 were included. Overall, few high quality interventions were identified. Most interventions were found to be insufficient in scope, and their evaluation was of inadequate rigor to generate scalable solutions and provide reliable evidence of effectiveness. Most interventions focused on text messaging for consumer education and behavior change. There were a limited number of interventions that addressed health information management, health workforce issues, use of medicines and technologies, or leadership and governance from a health system perspective.

Conclusions: We provide four recommendations for future mHealth interventions in China that include the need for the development, evaluation and trials examining integrated mHealth interventions to guide the development of future mHealth interventions, target disadvantaged populations with mHealth interventions, and generate appropriate evidence for scalable and sustainable models of care.

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KEYWORDS

mHealth; China; health care systems

Introduction

Burden of Disease and Health System in China

In the last decade, China has undergone a continuing epidemiological transformation from infectious diseases to chronic and noncommunicable diseases (NCDs) [1,2]. NCDs caused over 80% of China's total disability-adjusted life years in 2013 and accounted for China's largest burden of disease [3]. Chronic and NCDs pose special challenges to existing health systems as the long-term ongoing management of such conditions requires a shift from institutional care to community-based care, with an increased focus on self-management with or without peer or family support [4]. Despite the four major rounds of health care reforms since mid-1980s in China, many health equity and system level challenges remain [4,5]. Responding to those challenges, the health system needs to be adjusted to provide more effective solutions. The portability and connectivity of mobile health (mHealth) can potentially serve as an effective tool in facilitating this adjustment and to allow the health care delivery to reach hard-to-reach population. mHealth has been variably defined. The World Health Organization (WHO) definition is medical and public health practice supported by mobile devices, such as mobile phones, personal digital assistants (PDAs), and other wireless devices [6]. mHealth involves the use of a wide range of functionalities incorporated by such mobile devices, including standard voice, short message service (SMS), Web browsing, and applications on different operating systems.

Chinese Mobile Market and the Potential for mHealth

The unprecedented uptake of mobile phones with an ever growing telecommunications infrastructure has driven the development of mHealth innovation around the globe. In China, mobile phone penetration reached 94.5 per 100 people in 2014 [7]. Cellular signals now cover almost all residential areas from densely populated cities to remote villages, with increasing penetration of 3G and 4G networks. Penetration of smartphones has also increased rapidly, reaching 90% in urban areas and 32% in rural areas in 2015 [8]. The rapid development of this mobile infrastructure has created significant potential for mHealth interventions in China.

The rapid adoption of mobile phones may be explained by the diffusion of innovation theory, which is one of the most popular theories for studying adoption of information technologies and understanding how information technology innovations spread within and between communities [9].

Prior Work and Objectives

Although there were several reviews documenting the mHealth interventions in low- and middle-income countries (LMICs) [10-12], no systematic reviews of the scope and value of mHealth initiatives in the largest developing country exist. The specific aims of this systematic review were to (1) characterize mHealth interventions across all disease areas in China, (2) evaluate the extent to which mHealth interventions focus on health system strengthening, and (3) identify gaps in mHealth intervention development and evaluation that need to be addressed in the future.

Methods

Database Search

A systematic search of the literature in both Chinese and English published from May 26, 2008 to December 17, 2015, was performed following Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [13] using the following electronic databases: PubMed, EMBASE, Cochrane, and China National Knowledge of Infrastructure (CNKI). We also searched for registered trials in the WHO International Clinical Trials Registry Platform, which included 15 approved trial registries and supplementary searches in Chinese Clinical Trial Registry (CHICTR), and Clinicaltrials.gov. English keywords used in these searches included the following: mHealth, eHealth, telemedicine, telehealth, mobile phone, cell phone, text messaging, and China. The Chinese keywords used include "ShouJi" (mobile phone or cell phone), "DuanXin" (text messaging), "YiDongJiangKang" (mHealth), and "Yi Dong Yi Liao" (mobile medicine). Multimedia Appendix 1 lists the detailed search strategy for each database.

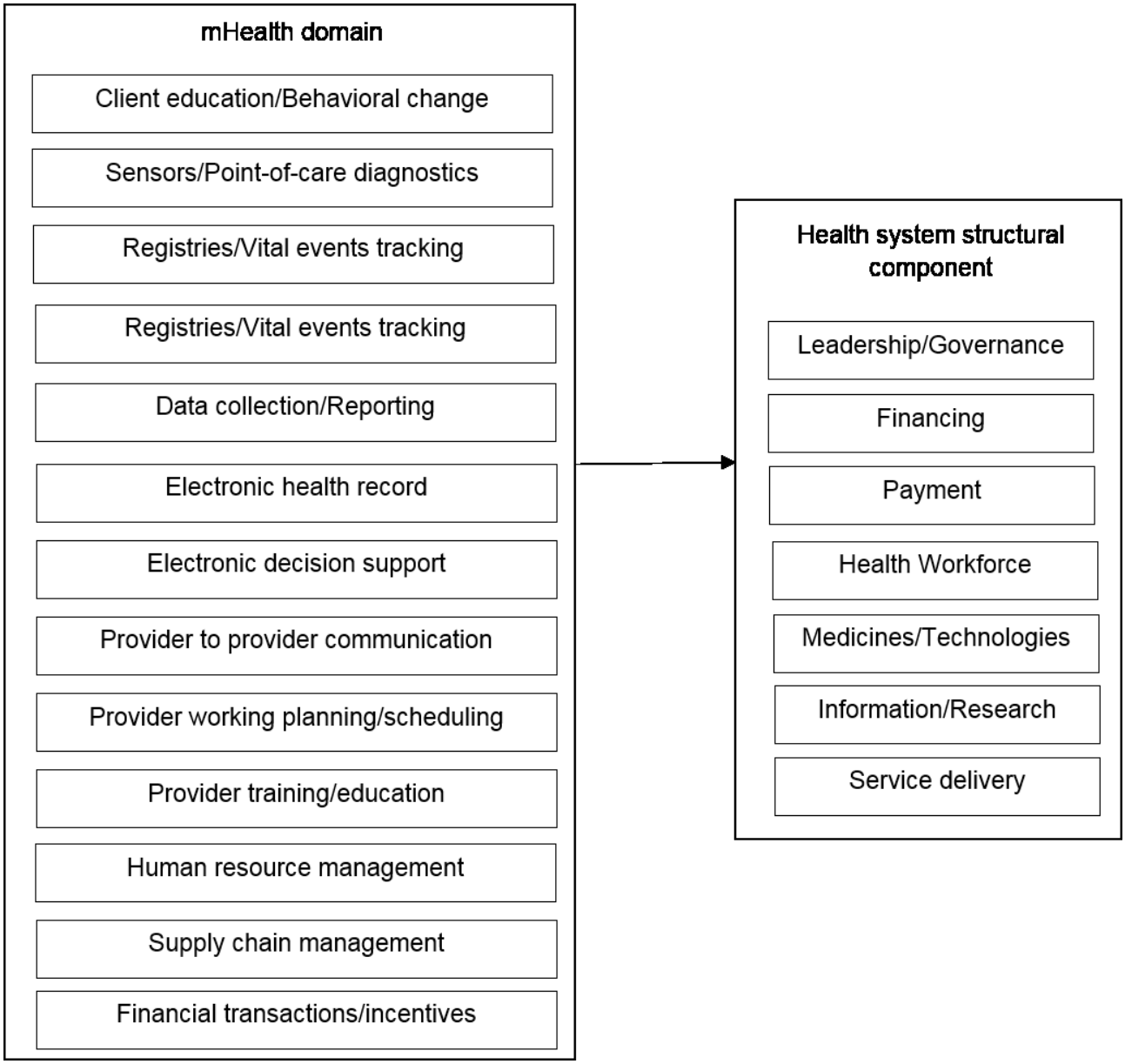
Inclusion and Exclusion Criteria

We included all articles related to health care management using mobile technology in China. Any type of the following articles with full texts was included: (1) randomized controlled trials (RCTs), (2) quasi-experimental studies, (3) descriptive studies without any outcome measured, or (4) registered RCTs. We only included studies written in English or Chinese, and articles related to telemedicine or telehealth were only included if mobile technologies were used as part of the intervention. We excluded all articles describing technology development, review articles, protocol papers, and any studies using fixed landline phone or the Internet using a desktop computer as part of the intervention. A total of 5 reviewers independently evaluated and excluded articles at the abstract review stage. Full-text articles whose abstracts met the inclusion criteria were then reviewed by 3 reviewers.

Analytical Framework

We utilized an adapted health system framework to evaluate the role of mHealth interventions as a health system strengthening tool (Figure 1) [14-16]. In this framework, there were two dimensions: (1) the function of mHealth intervention categorizing into one of the 12 mHealth tools proposed by Labrique et al [14], and (2) the corresponded health system frame work as developed by Hsiao and WHO [15,16]. Assessing both dimensions of the mHealth intervention allowed us to identify where the gaps were in the mHealth interventions from a health systems perspective.

Figure 1. Adapted health system framework for evaluating mHealth interventions.



Data Extraction

A spreadsheet was developed for entering extracted data that included study characteristics, the mHealth domain, and the health system domain using the aforementioned analytical framework [16]. An agreement was reached on the definitions and interpretation of each variable in the data extraction template among the reviewers before data collection. Three reviewers independently extracted the data into the template and cross-reviewed. Disagreements in this step were resolved by consensus.

Quality Assessment

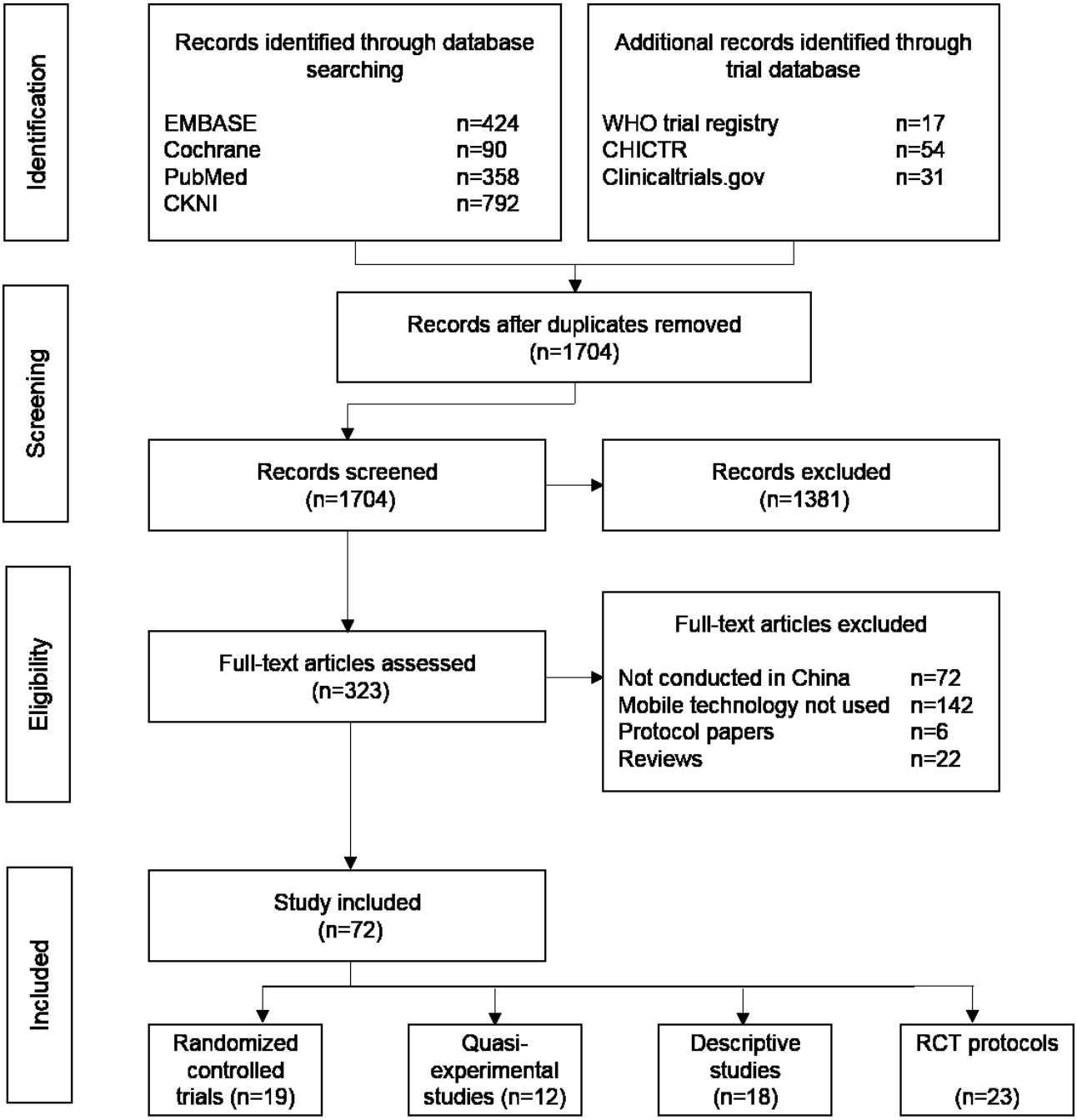
For RCTs, methodological quality was assessed using the Cochrane Risk of Bias Assessment Tool [17]. We assessed the random sequence generation, allocation concealment, blinding of participants, personnel and outcome assessors, incomplete outcome data, selective outcome reporting, and other sources of bias. Any discrepancies in article inclusion, data extraction, and bias assessment were discussed and resolved by team consensus.

Results

Included Studies

We retrieved 1704 articles using the search terms, and 323 articles were selected for full-text review (Figure 2). Of those, 251 studies were excluded for the following reasons: not conducted in China (n=81), not using the mobile technology (n=142), protocol papers (n=6), and review articles (n=22).

Figure 2. Study flowchart.



Study Characteristics

The study characteristics, mHealth domain, and health system domain of the nonprotocol articles (n=49) are summarized in Table 1. The majority of the studies were conducted in an urban setting (n=34) [18-51], with only 6 focusing on a rural population [28,51-55]. The most common disease focus was on NCDs (n=15) [22,25,26,29,30,34,37-39,42,45,46,52,56,57], whereas 12 studies focused on infectious diseases [33,41,51,53,54,58-64] and 8 studies were designed for maternal and child health [36,40,43,47-49,55,65]. A wide range of study designs was used to evaluate or describe the mHealth intervention, including 18 exploratory studies that described, validated, or pilot-tested mHealth interventions without any quantitative outcome assessment [18-28,58-62,64,66]. A total of 31 studies quantitatively evaluated the mHealth intervention [29-57,63,65], of which 19 utilized a RCT design [29-35,38-40,43,47,51-53,56,57,63,65] whereas the remainder used a quasi-experimental study design (n=12). In most cases, the primary mobile technology was a regular mobile phone (n=36) [18,19,21,25,29-49,51,53-57,59,62-65]. Only 12 studies utilized smartphone technology for the intervention [20,22-24,26-28,50,52,58,61,66].

Table 1. Study characteristics, mHealth domain, and health system domain of nonprotocol articles.

Author	Setting	Disease area	Population (n)	Study description	Type of device	mHealth domain	Health system domain
Descriptive Studies							
Deng [18]	Urban	Others -patients for sedation gastrointestinal endoscopy (SGIE)	908 outpatients in the anesthesia clinic for SGIE	Feasibility to use SMS to improve the adherence for SGIE appointment	R^	Client education and behavior change	Service delivery
Chen [19]	Urban	Others -suicide attempters	15 suicide attempters from the emergency department	Feasibility to SMS to decrease recidivism for suicide attempters	R	Client education and behavior change	Service delivery
Li [58]	Not described	Infectious disease	Not described	A decision support system for the responses to infectious disease emergencies	S*	Electronic decision support	Leadership/governance
Zhao [20]	Urban	Not mentioned	Not described	A case report describing development of a shared community health information system	S	Electronic medical record	Leadership/governance
Li [59]	Not described	Infectious disease -hand, foot, and mouth disease	Not described	Use of SMS to develop automated alert and response system for hand, foot, and mouth disease	R	Registries and vital event tracking	Leadership/governance
Guo [60]	Not described	Infectious disease	Not described	A mobile phone-based infectious disease reporting system in earthquake-affected area	PDA[a]	Data collection and reporting	Information
Mao [21]	Urban	Not mentioned	100 patients admitted from general hospital	Use of SMS to deliver individualized pharmaceutical care	R	Client education and behavior change	Service delivery
Yang [61]	Not described	Infectious disease	495 health care agencies in earthquake-affected area	Use of mobile phone as a surveillance tool to monitor infectious disease	S	Data collection and reporting	Information
Jun [22]	Urban	Noncommunicable disease -adolescent Idiopathic Scoliosis	64 adolescent idiopathic scoliosis patients	Use of smartphone to measure the axial trunk rotation	S	Sensors and point-of-care diagnosis	Medicines/technologies
Zhang [64]	Not described	Infectious disease -schistoscomajaponicum infection	Not described	Use of SMS to send alert the fishermen to avoid the schistosome infection	R	Registries and vital event tracking	Leadership/governance
Ma [62]	Not described	Infectious disease	Not described	Development of SMS-based emergency response system for infectious disease	R	Registries and vital event tracking	Leadership/governance
Guan [23]	Urban	Others -voiding diary monitoring	20 healthy volunteers	Development of smartphone-based remote voiding diary monitoring system	S	Data collection and reporting	Service delivery
Ye [24]	Urban	Others -slitlampbiomicroscopy	Not described	Use of smartphone camera for teleophthalmology	S	Sensors and point-of-care diagnosis	Service delivery

Author	Setting	Disease area	Population (n)	Study description		Type of device	mHealth domain	Health system domain
Yu [66]	Not described	Not mentioned	11 volunteers	Health examination toolkit involving sensors and data upload into an Android phone		S	Sensors and point-of-care diagnosis	Service delivery
Yin [25]	Urban	Noncommunicable disease -dialysis patients	Not described	Development of mobile phone-based follow up system		R	Client education and behavior change	Service delivery
Yang [65]	Urban	Noncommunicable disease -facial acne	80 patients with facial acne	Use of mobile phone to grade the severity of facial acne		S	Sensors and point-of-care diagnosis	Service delivery
Wang [27]	Urban	Others -dietary intake assessment	35 healthy volunteers	Development of dietary intake assessment using mobile phone camera function		S	Data collection and reporting	Medicines/technologies
Smith [28]	Rural and urban	Not mentioned	110 healthy adults	Development of a smartphone-assisted 24-h recall to assess beverage consumption		S	Data collection and reporting	Medicines/technologies
RCT				**Intervention**	**Follow-up**			
Tian [52]	Rural	Noncommunicable disease -cardiovascular disease	2086 high cardiovascular risk patients	A smartphone based electronic decision support system focusing on two medication use and two lifestyle modifications	12 month	S	Electronic decision support	Service delivery
Lin [29]	Urban	Noncommunicable disease -obesity	123 overweight adults	SMS-assisted lifestyle weight loss intervention	6 month	R	Client education and behavior change	Service delivery
Liu [51]	Rural and urban	Infectious disease -tuberculosis	4173 pulmonary TB[b] patients	SMS reminders and medication monitoring	6 month	R	Client education and behavior change	Service delivery
Sabin [63]	Not described	Infectious disease -HIV[c]	120 HIV patients	Real time SMS reminders triggered by the electronic medication storage device	6 month	R	Client education and behavior change	Service delivery
Liu [30]	Urban	Noncommunicable disease -cardiovascular disease	589 workers without known CVD[d]	Mobile-phone based lifestyle intervention	12 month	R	Client education and behavior change	Service delivery
Shi [31]	Urban	Others -smokers	179 adolescent smokers	Smoking cessation lifestyle intervention delivered by the SMS	12 week	R	Client education and behavior change	Service delivery
Chen [53]	Rural	Infectious disease -Viral infections affecting upper respiratory tract and otitis media	977 township level health workers	SMS based health worker training	1 month	R	Provider training and education	Health workforce
Deng [32]	Urban	Others -outpatients for sedation gastrointestinal endoscopy	2200 outpatients	SMS reminders to attend medical examination	Not mentioned	R	Client education and behavior change	Service delivery
Lv [56]	Not described	Noncommunicable disease -asthma	150 outpatients with asthma	SMS reminders for asthma self-management	12 week	R	Client education and behavior change	Service delivery

Author	Setting	Disease area	Population (n)	Study description		Type of device	mHealth domain	Health system domain
Wang [57]	Not described	Noncommunicable disease -allergic rhinitis	50 outpatients with allergic rhinitis	SMS reminders to improve adherence to medication and treatment	30 days	R	Client education and behavior change	Service delivery
Chai [33]	Urban	Infectious disease -H1N1	1992 residents in Shanghai	SMS-based health education for H1N1 prevention	10 days	R	Client education and behavior change	Service delivery
Lin [65]	Not described	Maternal and child health	258 parent-child pairs with child having cataract	SMS reminders to attend medical appointment	4 days	R	Client education and behavior change	Service delivery
Dai [34]	Urban	Noncommunicable disease -diabetes	80 type-2 diabetes patients	SMS based health education	12 month	R	Client education and behavior change	Service delivery
Shi [35]	Urban	Others -smokers	176 adolescent smokers	SMS based health education for smoking cessation	3 month	R	Client education and behavior change	Service delivery
Zhang [40]	Urban	Maternal and child health	166 children with asthma	SMS-based health promotion	3 month	R	Client education and behavior change	Service delivery
Wei [38]	Urban	Noncommunicable disease -chronic kidney disease	108 patients with chronic kidney disease	SMS-based medication adherence intervention	3 month	R	Client education and behavior change	Service delivery
Li [43]	Urban	Maternal and child health	82 pregnant women	SMS-based dietary recommendation during pregnancy	Not mentioned	R	Client education and behavior change	Service delivery
Chen [74]	Urban	Maternal and child health	155 pregnant women	SMS-based breastfeeding promotion	16 week	R	Client education and behavior change	Service delivery
Qu [25]	Urban	Noncommunicable disease -schizophrenia	178 patients with schizophrenia	SMS-based medication adherence intervention	12 month	R	Client education and behavior change	Service delivery
Quasi-experiment								
Jiang [49]	Urban	Maternal and child health	582 expectant mothers	SMS-based intervention about infant feeding	12 month	R	Client education and behavior change	Service delivery
Fang [42]	Urban	Noncommunicable disease -hypertension	599 hypertensive patients	SMS-based health education for hypertension management	12 month	R	Client education and behavior change	Service delivery
Zhao [46]	Urban	Noncommunicable disease -diabetes	64 type-2 diabetes patients	SMS-based medication adherence and health education program	3 month	R	Client education and behavior change	Service delivery
Qin [44]	Urban	Others -dialysis	92 dialysis patients	SMS-based health education for dialysis patients delivered by the nurse	53-612 days	R	Client education and behavior change	Service delivery
Xie [45]	Urban	Noncommunicable disease -diabetes	196 type-2 diabetes patients	SMS-based health promotion for diabetes management	12 month	R	Client education and behavior change	Service delivery
Chen [54]	Rural	Infectious disease -schistosomiasis	501 healthy residents	SMS-based health promotion for schistosomiasis prevention	10 month	R	Client education and behavior change	Service delivery

Author	Setting	Disease area	Population (n)	Study description		Type of device	mHealth domain	Health system domain
Chen [48]	Urban	Maternal and child health	180 children with allergic rhinitis	SMS-based health education for allergic rhinitis management	12 month	R	Client education and behavior change	Service delivery
Xu [41]	Urban	Infectious disease -HIV	71 HIV patients	SMS-based medication adherence intervention	12 month	R	Client education and behavior change	Service delivery
Ni [36]	Urban	Maternal and child health	460 pregnant women	SMS-based health education	5 month	R	Client education and behavior change	Service delivery
Liu [37]	Urban	Noncommunicable disease -acute coronary syndrome	82 ACS[e] patients	SMS based medication adherence intervention	1 month	R	Client education and behavior change	Service delivery
Zhou [55]	Rural	Maternal and child health	N250 pregnant women	SMS-based health education for HIV prevention	1 month	R	Client education and behavior change	Service delivery
He [50]	Urban	Others -general health	100 residents with smartphone	Smartphone-based pedometer “app”	6 months	S	Sensors and point-of-care diagnosis	Service delivery

[a]PDA: personal digital assistant.

[b]TB: tuberculosis.

[c]HIV: human immunodeficiency virus.

[d]CVD: cardiovascular disease.

[e]ACS: acute coronary syndrome.

[^]R: regular mobile phone.

[*]S: smartphone.

The search of registered clinical trials identified 23 additional mHealth registered RCTs (Multimedia Appendix 2). Although 12 of these studies were listed as completed, we were only able to find 5 studies with published results. All 5 studies were identified during the original systematic review of the literature [29,32,51,52,65]. Consistent with the published RCTs, the majority of the interventions described in the registry focused on client education and behavior change using simple text messaging.

Role of mHealth in the Health System

Applying the adapted health system framework (Table 2), we found the client education and behavioral change communication was the most commonly targeted mHealth domain (n=32) [18,19,21,25,29-49,51,54-57,63,65]. It was found that 5 interventions addressed sensors and point-of-care diagnostics [22,24,26,50,66], 5 interventions focused on data collection and reporting [23,27,28,60,61], 3 interventions involved registries and vital events tracking [59,62,64], 2 interventions focused on electronic decision support [52,58], 1 intervention involved electronic health records [20], and 1 intervention delivered provider training and education [53]. There were no interventions identified in the domains of provider to provider training, provider work planning and scheduling, human resources management, supply chain management, or financial transactions and incentives. From a health systems perspective, most studies targeted service delivery (n=38) [18,19,21,23-26,29-52,54-57,63,65,66]. Few interventions focused on the provision or management of information (n=2) [60,61], health workforce support (n=1) [53], medicines and technologies (n=3) [22,27,28], or leadership and governance (n=5) [20,58,59,62,64].

Risk of Bias Assessment

For the RCTs, risk of bias was mostly classified as either low or unclear (Table 3). Four studies did not provide sufficient information to assess risk [34,35,43,47].

Table 2. Health system framework assessment of the mHealth interventions.

mHealth Functionality	Health System Structural Component							
	Leadership/ Governance	Financing	Payment	Health Workforce	Medicines/ Technologies	Information	Service Delivery	Sub-total
Education/behavioral							32	32
Sensors/point-of-care devices					1		4	5
Registries/vital events tracking	3							3
Data collection and reporting					2	2	1	5
Electronic health records	1							1
Electronic decision support	1						1	2
Provider to provider communication								
Provider work planning/scheduling								
Provider training/education				1				1
Human resources management								
Supply chain management								
Financial transactions/incentives								
Sub-total	5			1	3	2	38	

Table 3. Risk of bias assessment for randomized controlled trials.

Author	Sequence generation	Allocation concealment	Blinding of participants, personnel, and outcome assessors	Incomplete outcome data	Selective outcome reporting	Other sources of bias
Tian [52]	Low	Low	Low	Low	Low	Low
Lin [29]	Low	Low	Low	Low	Unclear	Low
Liu [51]	Low	Unclear	Unclear	Unclear	Unclear	Low
Sabin [63]	Low	Low	Unclear	Low	Unclear	Low
Liu [30]	Low	Low	Low	Low	Unclear	Low
Shi [31]	Unclear	Unclear	Unclear	Low	Unclear	Low
Chen [53]	Low	Low	Low	Low	Unclear	Low
Deng [32]	Low	Low	Low	Unclear	Unclear	Low
Lv [56]	Low	Unclear	Unclear	Unclear	Unclear	Low
Wang [57]	Low	Low	Low	Unclear	Unclear	Low
Chai [33]	Low	Unclear	Low	Unclear	Unclear	Low
Lin [65]	Low	Low	Low	Low	Unclear	Low
Dai [34]	Unclear	Unclear	Unclear	Unclear	Unclear	High
Shi [35]	Unclear	Unclear	Unclear	Unclear	Unclear	High
Zhang [40]	Low	Unclear	Unclear	Unclear	Unclear	Unclear
Wei [38]	Low	Unclear	Unclear	Unclear	Unclear	Unclear
Li [43]	Unclear	Unclear	Unclear	Unclear	Unclear	High
Chen [47]	Unclear	Unclear	Unclear	Unclear	Unclear	High
Qu [39]	Low	Low	Low	Low	Unclear	Low

Discussion

Principal Findings

In this study, we reviewed studies and registered trials for studies published in the peer-reviewed journals involving mHealth interventions in China. We particularly focused on the extent to which mHealth interventions had the capacity to contribute to health care strengthening in the context of a rapidly evolving disease burden. Although we did observe an increasing focus on NCDs, there was little evidence of the development of mHealth interventions that were likely to substantially strengthen health care systems. We also noted a large disparity in the development of mHealth interventions that were focused on rural as opposed to urban areas. In addition, the quality of evidence provided in relation to effectiveness of such interventions is generally poor.

Comparison With Other Reviews

Beratarrechea et al [11] conducted a review to examine the role of mHealth intervention on the management of NCDs in LMICs, with a focus on the use of SMS and automated voice interventions. The study found that there were significant improvement on certain clinical outcomes and processes of care. Peiris et al further performed a review to explore the impact of all mHealth interventions on health care quality for NCDs in LMICs. Similar to our findings, there were few high-quality studies, and most of the studies used the SMS for patient behavior change. Very few studies addressed the mHealth intervention as a health system strengthening tool.

Health System Strengthening

On the basis of the literature we have identified, the development of mHealth interventions by academia in China remains relatively under-developed, in terms of both scope and capability. Interventions mostly utilized a texting tool to provide client education and behavior change. We identified a focus on only 7 of the 12 mHealth domains, with no interventions concentrating on interprovider communication or health service management, including financial transactions. In addition, all the interventions were developed as stand-alone tools to deliver health services, with little or no exploration of how integration within existing or developing health systems can be achieved.

Health Equality

Equitable access to quality health services is an important dimension of an effective health system. In China, around 50% of the population is based in rural regions, where health outcomes are, in general, poorer than those among urban communities. Addressing such inequities is a public health priority, and mHealth strategies may provide a particular opportunity to reduce gaps that relate to weaker health systems. As China's mobile network reaches far and deep into its rural areas, mHealth solutions provide a real opportunity to strengthen rural health systems. Despite the huge potentials of mHealth help in closing the health equity gap, few academic studies in China has chosen to focus on this area. The regional imbalance identified in this review may be explained by the greater convenience of conducting studies in urban communities. However, the potential for mHealth to impact on health outcome inequities cannot be addressed if the digital gulf between those who have access to mobile technology in urban areas and those who do not have access in rural areas is not reduced. Similar considerations are relevant to other disadvantaged subgroups of population, including those with relatively low literacy or socioeconomic status.

Quality of Evidence

A key objective of mHealth research should be to provide useful and reliable evidence for end users, including policy-makers in the context of those innovations aimed at improving health outcomes through deployment in the public health care system. Our review found that published and planned mHealth studies in China largely have not and will not produce such outcomes. Fewer than 40% of the published studies utilized an RCT design and all were of uncertain or poor quality based on objective measures. The majority of the reports were descriptive, with no apparent attempt to determine efficacy or effectiveness. Study outcomes were largely the product of low-quality and small-scale experiments, which provided little understanding of the true impact of an intervention with large-scale real-world implementation within complex health systems.

Limitations

There are several limitations to this review. Firstly, we were not able to conduct a quantitative meta-analysis of the outcomes due to the heterogeneity of the RCTs. We identified a number of ongoing trials from the trial registry. The published results of those trials will enable to provide increased power to determine the size of the effect of mHealth interventions on health outcomes. Second, although the adapted health system framework was useful to evaluate the mHealth intervention as a health system strengthening tool, a single study may address multiple mHealth domains or health system domains. We only reported the primary functionality of the mHealth intervention and the key aspect that the intervention addressed in the health system. Finally, this review mainly targeted academic studies in the literature. We should note that China is experiencing rapid development in mHealth technology in the commercial world, many of which may have health system implications that we had limited ability to evaluate in this review.

Conclusions

mHealth has the potential to overcome some of the challenges due to the rapid changing environment of health care needs and provision in China. However, this potential can only be realized through the continual development of mHealth interventions to strengthen the health system, utilizing a subsequent rigorous approach to generating high-quality evidence about the likely implications of "real world implementation." Therefore, we outline three recommendations for future mHealth research and development in China: (1) mHealth studies should not be conducted as the standalone technical study evaluating its efficacy in the vacuum of the social context, (2) promote the development of integrated mHealth interventions as a tool to serve the existing health system, (3) focus on developing and evaluating mHealth interventions with the potential to reduce health outcome disparities within the population, and (4) conduct large-scale rigorously designed "real world" evaluation of

mHealth interventions focused on health system strengthening. Specific public and private investment into such research is a priority.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Detailed search strategy for each database used.

[PDF File (Adobe PDF File), 27KB - mhealth_v5i3e32_app1.pdf]

Multimedia Appendix 2

Table: Registered randomized controlled trials in clinical trials database.

[PDF File (Adobe PDF File), 27KB - mhealth_v5i3e32_app2.pdf]

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Abbreviations

ACS: acute coronary syndrome
CHICTR: Chinese Clinical Trial Registry
CNKI: China National Knowledge of Infrastructure
COPD: chronic obstructive pulmonary disease
CVD: cardiovascular disease
HIV: human immunodeficiency virus
LMICs: low- and middle-income countries
NCDs: noncommunicable diseases
PDA: personal digital assistant
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCTs: randomized controlled trials
SGIE: sedation gastrointestinal endoscopy
SMS: short message service
TB: tuberculosis
WHO: World Health Organization

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Original Paper

Estimating Accuracy at Exercise Intensities: A Comparative Study of Self-Monitoring Heart Rate and Physical Activity Wearable Devices

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Abstract

Background: Physical activity tracking wearable devices have emerged as an increasingly popular method for consumers to assess their daily activity and calories expended. However, whether these wearable devices are valid at different levels of exercise intensity is unknown.

Objective: The objective of this study was to examine heart rate (HR) and energy expenditure (EE) validity of 3 popular wrist-worn activity monitors at different exercise intensities.

Methods: A total of 62 participants (females: 58%, 36/62; nonwhite: 47% [13/62 Hispanic, 8/62 Asian, 7/62 black/ African American, 1/62 other]) wore the Apple Watch, Fitbit Charge HR, and Garmin Forerunner 225. Validity was assessed using 2 criterion devices: HR chest strap and a metabolic cart. Participants completed a 10-minute seated baseline assessment; separate 4-minute stages of light-, moderate-, and vigorous-intensity treadmill exercises; and a 10-minute seated recovery period. Data from devices were compared with each criterion via two-way repeated-measures analysis of variance and Bland-Altman analysis. Differences are expressed in mean absolute percentage error (MAPE).

Results: For the Apple Watch, HR MAPE was between 1.14% and 6.70%. HR was not significantly different at the start (P=.78), during baseline (P=.76), or vigorous intensity (P=.84); lower HR readings were measured during light intensity (P=.03), moderate intensity (P=.001), and recovery (P=.004). EE MAPE was between 14.07% and 210.84%. The device measured higher EE at all stages (P<.01). For the Fitbit device, the HR MAPE was between 2.38% and 16.99%. HR was not significantly different at the start (P=.67) or during moderate intensity (P=.34); lower HR readings were measured during baseline, vigorous intensity, and recovery (P<.001) and higher HR during light intensity (P<.001). EE MAPE was between 16.85% and 84.98%. The device measured higher EE at baseline (P=.003), light intensity (P<.001), and moderate intensity (P=.001). EE was not significantly different at vigorous (P=.70) or recovery (P=.10). For Garmin Forerunner 225, HR MAPE was between 7.87% and 24.38%. HR was not significantly different at vigorous intensity (P=.35). The device measured higher HR readings at start, baseline, light intensity, moderate intensity (P<.001), and recovery (P=.04). EE MAPE was between 30.77% and 155.05%. The device measured higher EE at all stages (P<.001).

Conclusions: This study provides one of the first validation assessments for the Fitbit Charge HR, Apple Watch, and Garmin Forerunner 225. An advantage and novel approach of the study is the examination of HR and EE at specific physical activity intensities. Establishing validity of wearable devices is of particular interest as these devices are being used in weight loss interventions and could impact findings. Future research should investigate why differences between exercise intensities and the devices exist.

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KEYWORDS

motor activity; physical exertion; exercise; monitoring, physiologic; energy metabolism; heart rate; photoplethysmography

Introduction

Prior Research

The *Physical Activity Guidelines for Americans* suggest adults achieve 150 minutes of moderate to vigorous physical activity (MVPA) per week [1]. According to self-report data, the proportion of adults meeting the guidelines was 62.0%, but this dropped to 9.6% for accelerometry measures of activity [2], which illustrates the importance of objective measures of activity. Commercial physical activity tracking wearable devices have emerged as an increasingly popular method for consumers to assess their daily activity and calories expended. In addition to physical activity and energy expenditure (EE), more recent wearable models are designed to measure heart rate at the wrist. In 2015, 232 million wearable electronic devices were sold worldwide, with a projected 18.4% increase in sales for 2016 [3]. With the increase in popularity, wearable-based behavioral change interventions are becoming more prevalent [4-7]. As monitors grow as an intervention tool, questions of validity become paramount and it is important to assess their accuracy for this purpose.

Accuracy is measured by evaluating the device against a research-grade criterion measure. Most research has primarily focused on the accuracy of estimates of EE [7-12]. However, given the pace of technological change, these existing studies have largely been completed on devices that would be considered outdated, such as earlier Fitbit models (One, Zip, Flex, Ultra), Jawbone Up, and the Nike FuelBand. It is important to validate current devices, especially those that are most popular. To this end, our study assesses the Apple Watch, Fitbit Charge HR, and Garmin Forerunner 225. These devices were selected based on review of sales data in 3 categories of wearable devices—smart watches, basic wearable bands, and portable navigation devices [13-16]. However, it should be noted that these devices are not the only commercial devices in the market. These more recent wearable physical activity devices, which include a measure of heart rate, utilize photoplethysmography (PPG) to measure heart rate. PPG is a simple and low-cost optical technique that detects blood volume changes in the microvascular bed of tissue [17]. PPG uses a light source to illuminate the tissue of the wrist and a photodetector to measure variations in light intensity associated with changes in perfusion.

There have been limited validity studies regarding these more recent devices. Fitbit Charge HR has been found to underestimate heart rate and EE [18] with further examination showing the device to have the greatest error in light to moderate physical activity and least amount of error in vigorous physical activity [19]. For Garmin devices, most validation studies focus on the Garmin Vivofit, although Forerunner models have been used in built environment studies. For example, the Forerunner was used to show that, in children, decreased time spent in outdoor environments is associated with increased body weight and lower levels of MVPA [20]. We can find no efforts to validate the Garmin Forerunner 225. Moreover, although the Apple Watch has become very popular, it has only been used in one validation study. The Apple Watch was found to underestimate both heart rate and EE, with a tendency to underestimate calories expended by more than 100 calories [18]. The need for validation is especially important as each of these represent additional technology for behavioral interventions.

To date, most studies analyze accuracy over an entire activity bout in comparison to assessing heart rate accuracy in response to different levels of physical activity intensity. Assessing accuracy in this way may lead to inaccurate results, as over a range of intensities there may be both underestimation and overestimation of feedback. In the few studies that have assessed differences between exercise intensities, results have been mixed depending on device and type of physical activity. Investigators have found that heart rate measurement error increases with activity intensity for the Omron HR-500U and Mio Alpha when jogging, stair climbing, and using the stationary bike [21]. Conversely, another study examining heart rate error during treadmill activities found the highest percentage error in light walking and the least error in running for Mio Alpha, Fitbit Charge HR, Basis Peak, Microsoft Band, and TomTom devices [19]. Therefore, more research is needed to determine the accuracy of these devices in response to various physical activity intensities. Thus, this study will examine 3 popular wearable devices during sedentary behavior, light activity, moderate activity, and vigorous activity to understand the accuracy differences that may occur between intensities.

This Study

Individual heart rate monitoring during physical activity greatly expands the options for intervention design. Heart rate response to exercise has been shown to be moderated by both knowledge about suggested levels of intensity as well as feedback in meeting those levels [22]. In addition, heart rate feedback has been shown to increase overall daily activity and percentage of time spent in MVPA [23]. Finally, participants who monitored their heart rate following exercise were able to significantly lower their heart rate during recovery, compared with participants who did not have access to monitors [22]. Decreased heart rate recovery rate, or the ability for heart rate to fall rapidly during early recovery after exercise, is associated with increased overall mortality [24]. Thus, if proved accurate, use of heart rate monitors in these devices provides a potentially novel point of intervention during recovery.

Wearable activity monitors are both popular and of increased interest as a component of physical activity interventions. However, little research exists regarding whether these wearable devices—particularly those that measure heart rate—are reliable and valid for these purposes. Thus, the purpose of this study was to compare 3 popular wearable activity monitors with regard to their accuracy in assessing heart rate and estimates of EE at various physical activity intensities. The findings from this study will do much to guide researchers in the selection of wearable activity monitors for future studies' intervention design.

Methods

Participants

A total of 62 students (36 females, 47% nonwhite) aged 18-38 (mean 22.6) years drawn from kinesiology and health courses at a large southwestern university participated in the study. Participants began the testing day after being caffeine-free for 12 hours and having fasted for 3 hours. Those who were current smokers, had a disability that was contraindicated for exercise, or had tattoos, piercings, or braces where the device would be worn were excluded from participation. Participants were compensated with extra credit for their class upon completion of the study. Approval for the study was obtained from the Institutional Review Board at The University of Texas at Austin. Before beginning, all participants provided written informed consent.

Wearable Devices

Participants simultaneously wore 3 wearable physical activity monitors during testing: Apple Watch, Fitbit Charge HR, and Garmin Forerunner 225. The location of each of the 3 devices (ie, right or left) was randomized before participation.

Apple Watch

The Apple Watch (Apple Inc, Cupertino, CA, USA) is an accelerometer-based device that provides estimates of heart rate, distance traveled, calories expended, activity minutes, and standing time. While using the associated Workout app, Apple Watch measures heart rate continuously during a workout, using PPG to calculate beats per minute through green LED lights paired with light-sensitive photodiodes [25]. The heart rate sensor is also designed to compensate for low signal levels by increasing both LED brightness and sampling rate [25]. Calories expended are reported in both active calories and total calories.

Fitbit Charge HR

The Fitbit Charge HR (Fitbit Inc, San Francisco, CA, USA) is a triaxial accelerometer–based device that provides estimates of heart rate, steps, calories expended, distance traveled, floors climbed, and sleep quality. The Fitbit Charge HR uses a technology that they label "PurePulse," which uses LED lights to measure heart rate. Fitbit suggests wearing the device higher on the wrist, 3 finger widths above the wrist bone, to improve accuracy. Calories expended are reported in total calories.

Garmin Forerunner 225

The Garmin Forerunner 225 (Garmin, Ltd, Schaffhausen, Switzerland) is an accelerometer-based device that provides estimates of heart rate, steps, calories expended, distance traveled, and sleep time. The device uses GPS (Global Positioning System) and has a built-in optical sensor based on Mio Heart Rate Technology to measure heart rate at the wrist. Mio Heart Rate Technology tracks heart rate using proprietary algorithms for LED light sampling. The frequency at which heart rate is measured varies and depends on the level of activity—as activity increases, the optical heart rate monitor uses a higher sampling rate [26]. Calories expended are reported in total calories.

Criterion Measures

In addition to the 3 wearable physical activity monitors, participants wore a series of devices to provide criterion measures against which to judge the accuracy of the wearable activity monitors.

Polar Heart Rate Monitor

Polar T31 transmitter monitor (Polar Electro, Kempele, Finland) was used as the criterion measure of heart rate as it is a validated and reliable measure for heart rate compared with 12-lead ECG (electrocardiogram) [27]. The heart rate sensor is worn around the chest and transmits real-time heart rate of the user to a wristwatch ECG.

Parvo Medics TrueOne 2400

Parvo Medics TrueOne 2400 (Parvo Medics Inc, Sandy, UT, USA) metabolic measurement system was used as the criterion measure for EE in this study. TrueOne 2400 uses a Hans Rudolph pneumotachometer to measure ventilation. EE was estimated from a direct measurement of oxygen consumption and carbon dioxide production. TrueOne 2400 volume and gas were calibrated before each trial. TrueOne 2400 has been previously found to be a reliable measure of EE for research [28].

Other Measures

Physical Activity Intensity

ActiGraph GT3X+ (ActiGraph, Pensacola, FL, USA) accelerometers were used to assess physical activity intensity.

Height

A Perspective Enterprises stadiometer (Perspective Enterprises, Portage, MI, USA) was used to measure height to the 0.25 cm. Each participant's height was measured in workout clothes and without shoes before participation. Height was measured twice, and an optional third measurement was taken if the 2 measurements differed by 0.25 cm. Height was entered into each wearable device and metabolic cart before participation.

Weight

Weight was measured using the Tanita BWB-800 scale (Tanita Corporation of America, Arlington Heights, IL, USA). Weight was measured to the nearest 0.1 kg for each participant before participation and the scale was calibrated before each trial. Participants' weights were measured in workout clothes and without shoes. Weight was measured twice for each participant, and an optional third measurement was taken if the 2 measurements differed by 0.1 kg. Weight was entered into each wearable device and metabolic cart before participation.

Ratings of Perceived Exertion

The Borg Rating of Perceived Exertion (RPE) scale was used to measure the participant's perceived intensity of exercise. The scale value ranges from 6 to 20 and can be used to denote heart rates ranging from 60 to 200 beats per minute [29]. The scale is anchored by no exertion (6), light (11), somewhat hard (13), hard (15), very hard (17), and maximal exertion (20). Participation was suspended if participants indicated they were at maximal exertion.

Procedures

Participants completed the consent form, a demographic information survey, and were screened for fasting and caffeine consumption before the start of the study. Their participation was rescheduled if the participants did not comply with this criterion. Trained graduate research assistants performed anthropometric measurements. These measurements were used to initialize the wearable devices as well as the metabolic cart for each individual before testing.

To avoid unanticipated problems with device functionality, 2 devices for each product (ie, Fitbit #1 and Fitbit #2) were available for each testing period. The specific device selected (ie, Fitbit #1 or Fitbit #2) and location for each of the 3 devices (ie, right or left arm) were randomized across participants. First, the Polar heart rate strap was placed around the chest and the accelerometer was placed on a belt, positioned on the right hip. Each of the 3 wearable devices was then placed and participants were then fitted with the mouthpiece and nose plug for the metabolic cart. Although accelerometers were used for physical activity intensity validation, this study did not compare EE from this device and therefore will not be used in any analyses.

Protocol

Initial measures were taken during a 10-minute seated baseline assessment. This was followed by 4 stages of treadmill exercise. Each stage was 4 minutes in length. The final stage was a 10-minute seated recovery period. The activity routine consisted of an unmeasured warm-up walking period and measured stages of walking at 2.5 mph, brisk walking at 3.5 mph, and jogging at 5.5 mph. There was a 1-minute break between each stage. RPE was measured at 1 minute and 3 minutes into each 4-minute stage. To allow sufficient time for participants to reach steady state, heart rate was assessed 3.5 minutes into each stage of activity. These were collected in a random order across devices and averaged together to provide a measure of heart rate for each device during that stage. EE was assessed using the metabolic cart. Activity EE estimates were measured for all stages. Each device was evaluated against the EE estimate of the metabolic cart. Exercise intensity for each participant was evaluated through accelerometry.

Statistical Analyses

Descriptive statistics were used to examine associations with the criterion measures. Pearson correlations were computed to examine overall group-level associations. Mean absolute percentage error (MAPE) values were calculated as the average absolute value of the errors of each device relative to the criterion measures. Repeated-measures analysis of variance (ANOVA) and Bland-Altman analyses were performed to compare the accuracy of the wearable devices to measure each outcome relative to the criterion measures. Bland-Altman plots were examined for proportional bias. Two-factor ANOVA was performed to compare the effects of sex, body mass index (BMI), and age on the devices. Significant findings were followed with paired-samples *t* tests. Mauchly's tests were used to test the assumption of sphericity. When violated, degrees of freedom were corrected using Greenhouse-Geisser estimates. Cohen's *d* effect size measures were calculated for each comparison.

Results

Participant Characteristics

A total of 62 individuals completed the protocol. Of these, 58% were female (36/62) and 47% were nonwhite (13/62 Hispanic, 8/62 Asian, 7/62 Black/African American, 1/62 other). Ages ranged from 18 to 38 years (mean 22.6 years). BMI ranged from 17.1 to 45.0 (mean 24.6 kg/m^2). Descriptive statistics for the sample population are provided in Table 1.

Table 1. Physical characteristics of participants (N=62).

Characteristics	All (n=62)			Male (n=26)			Female (n=36)		
	Mean	SD	Range	Mean	SD	Range	Mean	SD	Range
Age, years	22.55	4.34	18-38	21.89	2.7	18-29	23.03	5.21	18-38
Height, m	1.70	0.11	1.50-1.92	1.79	0.08	1.58-1.92	1.64	0.09	1.50-1.88
Weight, kg	72.02	18.99	46.36-150.59	85.03	18.77	50.44-150.59	62.63	12.63	46.36-95.62
Body mass index, kg/m^2	24.60	4.77	17.14-45.02	26.47	5.08	18.36-45.02	23.25	4.1	17.14-33.11

Heart Rate Overview

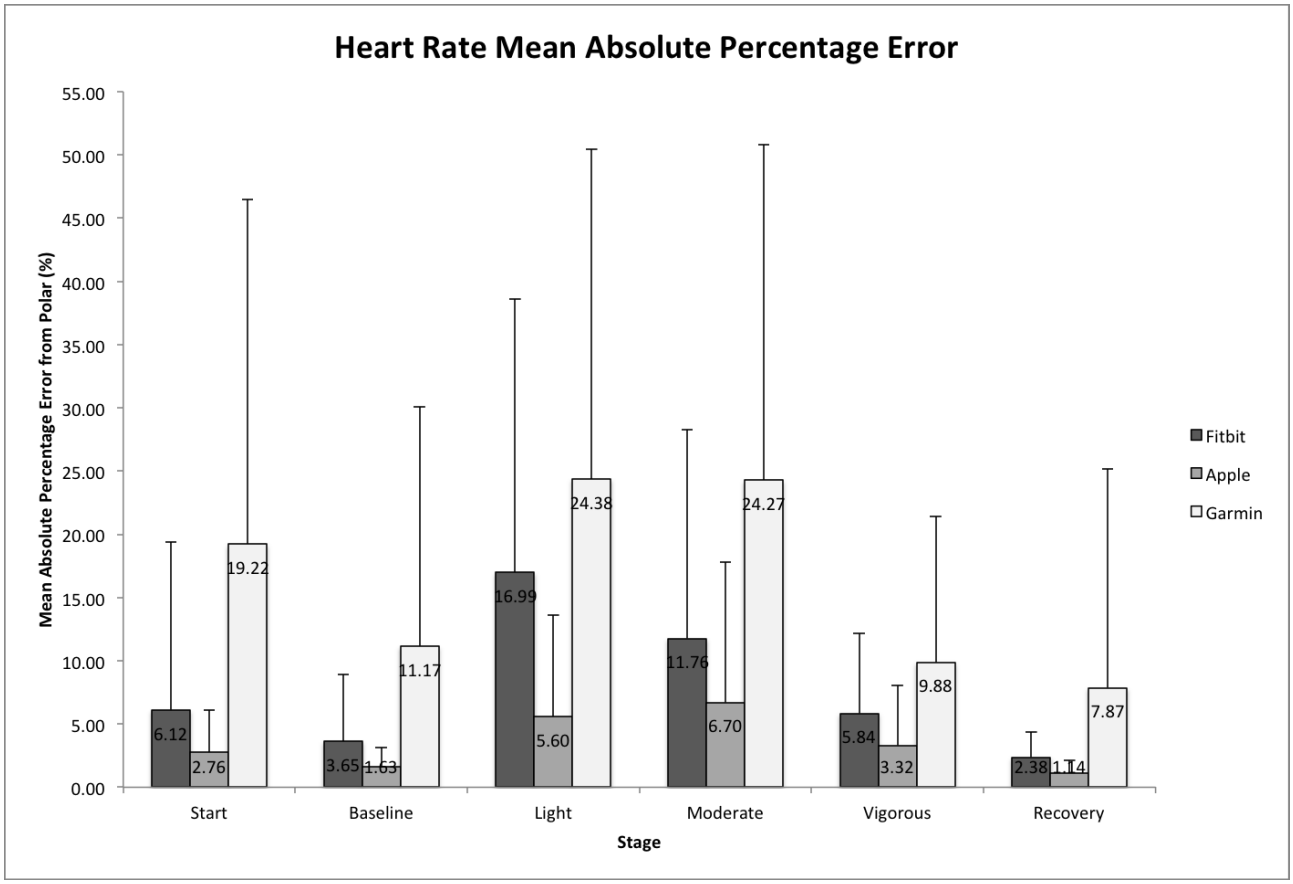
The correlations between the criterion scores from the Polar heart rate monitor and the readings from the devices indicate the strongest association with Apple Watch (*r*=.59-.99), followed by the Fitbit Charge HR (*r*=.16-.99), and finally Garmin Forerunner 225 (*r*=.05-.75). Table 2 provides descriptive statistics of heart rate by exercise intensity per device.

Table 2. Average heart rate (beats per minute) by exercise intensity per device.

Stage	Device	Mean	SD	Minimum	Maximum	Cohen's *d*
Start	Polar T31	72.32	12.20	46.67	106.00	
	Fitbit Charge HR	73.08	10.44	55.00	102.33	0.07
	Apple Watch	72.84	12.08	43.00	108.00	0.04
	Garmin Forerunner 225	84.90	22.73	58.00	181.33	0.69
Baseline	Polar T31	72.99	11.30	45.00	103.83	
	Fitbit Charge HR	71.36	10.74	47.67	103.33	−0.15
	Apple Watch	73.07	11.45	45.00	105.17	0.01
	Garmin Forerunner 225	80.32	18.38	56.33	169.33	0.48
Light intensity	Polar T31	92.45	13.66	72.00	139.00	
	Fitbit Charge HR	103.11	17.45	73.67	179.33	0.68
	Apple Watch	89.19	11.94	65.00	117.67	−0.25
	Garmin Forerunner 225	108.31	25.69	73.67	166.67	0.77
Moderate intensity	Polar T31	106.84	16.44	78.00	152.00	
	Fitbit Charge HR	110.06	16.71	78.67	162.00	0.19
	Apple Watch	101.01	16.48	68.00	133.00	−0.35
	Garmin Forerunner 225	126.50	23.40	85.33	184.33	0.97
Vigorous intensity	Polar T31	150.63	21.26	112.00	197.67	
	Fitbit Charge HR	144.65	17.35	107.67	192.00	−0.31
	Apple Watch	150.87	19.17	112.00	194.67	0.01
	Garmin Forerunner 225	147.85	21.80	96.67	203.67	−0.13
Recovery	Polar T31	84.47	15.16	46.83	123.17	
	Fitbit Charge HR	82.57	15.17	46.83	119.83	−0.13
	Apple Watch	84.02	15.27	45.17	119.83	−0.03
	Garmin Forerunner 225	87.23	12.48	60.50	120.67	0.20

Figure 1 shows the MAPE for these devices for heart rate by exercise intensity. The magnitude of errors across all stages was least for the Apple Watch (1.14%-6.70%), followed by the Fitbit Charge HR (2.38%-16.99%) and the Garmin Forerunner 225 (7.87%-24.38%). All repeated-measures ANOVA omnibus *F* tests were significant at the .05 level; therefore, only pairwise comparisons between device (Apple Watch, Fitbit Charge HR, and Garmin Forerunner 225) and criterion measure (Polar heart rate monitor) are reported.

Figure 1. Mean absolute percentage error (MAPE; %) of the devices for heart rate from the Polar heart rate monitor criterion. MAPE values are presented by exercise intensity per device. Error bars represent one standard deviation from the mean score.



Fitbit Charge HR

Fitbit Charge HR was not significantly different from Polar heart rate monitor at the start (P=.67) or during moderate intensity (P=.34). There was no proportional bias found in Bland-Altman analyses. Fitbit Charge HR measured significantly lower heart rate during baseline (P<.001, d=0.15), vigorous intensity (P<.001, d=0.31), and recovery (P<.001, d=0.13). During light intensity, Fitbit Charge HR measured significantly higher heart rate readings (P<.001, d=0.68).

Apple Watch

Apple Watch was not significantly different from Polar heart rate monitor at the start (P=.78), during baseline (P=.76), or vigorous intensity (P=.84). There was no proportional bias found in Bland-Altman analyses. Apple Watch measured significantly lower heart rate readings during light intensity (P=.03, d=0.25), moderate intensity (P<.001, d=0.35), and recovery (P=.004, d=0.03).

Garmin Forerunner 225

Garmin Forerunner 225 was not significantly different from Polar heart rate monitor during vigorous intensity (P=.35). There was no proportional bias found in Bland-Altman analysis. Garmin Forerunner 225 measured significantly higher heart rate readings at the start (P<.001, d=0.69) and during baseline (P<.001, d=0.48), light intensity (P<.001, d=0.77), moderate intensity (P<.001, d=0.97), and recovery (P=.04, d=0.20).

Energy Expenditure Overview

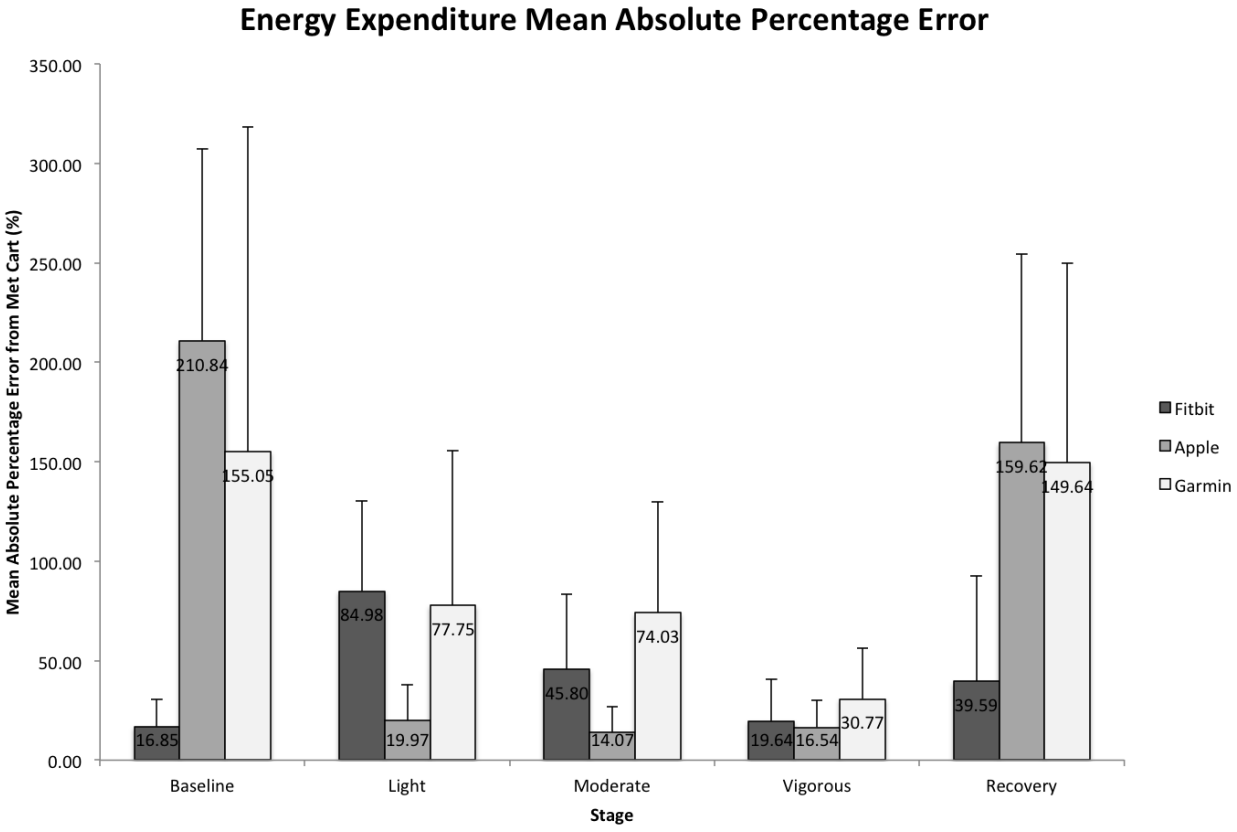
The correlations between the criterion scores from Parvo Medics TrueOne 2400 and the readings from the devices indicate the strongest association with Apple Watch (r=.59-.87), followed by the Fitbit Charge HR (r=.42-.66), and finally Garmin Forerunner 225 (r=.18-.73). Table 3 provides descriptive statistics of EE by exercise intensity per device.

Table 3. Average energy expenditure (kcal) by exercise intensity per device.

Stage	Device	Mean	SD	Minimum	Maximum	Cohen's *d*
Baseline	Metabolic cart	12.97	3.02	9	25	
	Fitbit Charge HR	11.80	2.79	8	19	−0.40
	Apple Watch	40.41	16.82	17	103	2.27
	Garmin Forerunner 225	32.36	19.27	8	126	1.41
Light intensity	Metabolic cart	14.44	4.14	9	32	
	Fitbit Charge HR	26.32	7.52	15	45	1.96
	Apple Watch	17.15	6.08	9	39	0.52
	Garmin Forerunner 225	24.97	12.98	8	73	1.09
Moderate intensity	Metabolic cart	19.62	4.98	12	32	
	Fitbit Charge HR	27.9	7.68	13	46	1.28
	Apple Watch	21.49	7.24	10	48	0.30
	Garmin Forerunner 225	33.75	10.80	16	69	2.27
Vigorous intensity	Metabolic cart	37.28	9.75	22	64	
	Fitbit Charge HR	38.34	13.63	20	88	0.09
	Apple Watch	40.35	12.51	23	81	0.27
	Garmin Forerunner 225	47.23	16.36	16	92	0.74
Recovery	Metabolic cart	16.61	4.27	10	28	
	Fitbit Charge HR	19.76	12.99	8	64	0.33
	Apple Watch	43.03	19.92	17	105	1.83
	Garmin Forerunner 225	42.65	20.59	13	84	1.75

Figure 2 shows the MAPE for these devices for EE by exercise intensity. The magnitude of errors across all stages was least for the Fitbit Charge HR (16.85%-84.98%), followed by the Apple Watch (14.07%-210.84%), and the Garmin Forerunner 225 (30.77%-155.05%). All repeated-measures ANOVA omnibus *F* tests were significant at the .05 level; therefore, only pairwise comparisons between device (Apple Watch, Fitbit Charge HR, and Garmin Forerunner 225) and criterion measure (Parvo Medics TrueOne 2400) are reported.

Figure 2. Mean absolute percentage error (MAPE; %) of the devices for energy expenditure from the TrueOne 2400 metabolic cart criterion. MAPE values are presented by exercise intensity per device. Error bars represent one standard deviation from the mean score.



Fitbit Charge HR

Fitbit Charge HR was not significantly different than Parvo Medics TrueOne 2400 during vigorous intensity (P=.70) or recovery (P=.10). However, Bland-Altman analysis revealed there was bias for overestimation. Fitbit Charge HR measured significantly higher EE during baseline (P=.003, d=0.40), light intensity (P<.001, d=1.96), and moderate intensity (P<.001, d=1.28).

Apple Watch

Apple Watch measured significantly higher EE than the criterion measure (Parvo Medics TrueOne 2400) during baseline (P<.001, d=2.27), light intensity (P<.001, d=0.52), moderate intensity (P<.001, d=0.30), vigorous intensity (P<.01, d=0.27), and recovery (P<.001, d=1.83). The two-factor ANOVA showed a significant interaction effect of sex and device at baseline, $F_{1,47}$=16.74, P<.001. The device measured higher EE for males, t_{24}=12.63, P<.001, and females, t_{33}=10.64, P<.001, as compared with the Parvo Medics TrueOne 2400. However, the magnitude of the effect is greater for males (d=2.46) than females (d=1.6). The two-factor ANOVA showed a significant interaction effect of BMI and device at baseline $F_{3,47}$=9.08, P<.001. Paired-samples t test indicated all BMI categories were significantly different than the criterion. However, the magnitude of the effect is greater for those who were classified as overweight (d=3.05), followed by obese (d=2.95) and normal weight (d=2.92). During moderate intensity, the two-factor ANOVA showed a significant interaction for BMI and device for Apple Watch, $F_{3,48}$=8.57, P<.001. Paired-samples t test determined that overweight and obese BMI categories were significantly different from the criterion; however, normal weight was not significantly different (P=.96). The magnitude of the effect is greater for obese (d=0.99) than overweight (d=0.57) category. During recovery, the two-factor ANOVA revealed a significant interaction for sex and device for the Apple Watch, $F_{1,49}$=4.96, P<.05; both males, t_{23}=10.32, P<.001, and females, t_{33}=7.3, P<.001, measured higher EE than the criterion. However, the magnitude of the effect is greater for males (d=2.58) than females (d=1.7). The two-factor ANOVA also revealed a significant interaction for BMI and device for the Apple Watch, $F_{3,49}$=8.01, P<.001; paired-samples t test indicated that all BMI categories were significantly different from the criterion. However, the magnitude of the effect is greater for overweight (d=2.60), followed by obese (d=2.55) and normal weight (d=2.26) categories.

Garmin Forerunner 225

Garmin Forerunner 225 measured significantly higher EE than Parvo Medics TrueOne 2400 during baseline (P<.001, d=1.41), light intensity (P<.001, d=1.09), moderate intensity (P<.001, d=2.27), vigorous intensity (P<.001, d=0.74), and recovery (P<.001, d=1.75).

Discussion

Principal Findings

This study investigated the accuracy of consumer-grade activity monitors for estimating heart rate and EE during stages of sedentary, light, moderate, and vigorous physical activity. Similar to previous heart rate research [19], this study found the highest measurement error for all devices (Apple Watch, Fitbit Charge HR, Garmin Forerunner 225) in light and moderate physical activity stages. The Apple Watch provided the most accurate measure of heart rate relative to the criterion Polar heart rate monitor, as MAPE was between 1.14% and 6.70% for all stages. Fitbit Charge HR showed reasonable results with MAPE between 2.38% and 16.99%. The Garmin Forerunner 225 was the least accurate of the wearable devices, with MAPE between 7.87% and 24.38%. The results indicate the most favorable outcomes for the Apple Watch; however, it measured significantly lower heart rate than the criterion measure during light and moderate physical activity. Fitbit Charge HR produced reasonably accurate results during moderate physical activity but measured significantly higher heart rate readings during baseline and light physical activity and lower heart rate readings during vigorous physical activity. Garmin Forerunner 225 read accurately during vigorous physical activity but measured significantly higher heart rate readings at all other intensities. Results of the Fitbit Charge HR are similar to previous research, which found the highest percentage error in moderate-intensity treadmill activity and the lowest percentage error during vigorous activity [19].

The performance of the devices to measure EE was not accurate either. Apple Watch and Garmin Forerunner 225 report considerably more calories expended than the Parvo Medics TrueOne 2400 metabolic measurement system, which was used as the criterion measure. Fitbit Charge HR measured significantly higher EE for all stages except in vigorous physical activity and recovery. One previous study [10] found MAPE for Fitbit Zip (10.1%) and Fitbit One (10.4%) to be much lower than the results from this study, where MAPE was between 16.85% and 84.98%. Apple Watch has been previously found to underestimate calories by more than 100 calories [18], whereas our study found the device to overestimate calories expended. The differences in results could be due to the previous studies analyzing overall EE and not reporting EE at specific bouts of physical activity intensities. In regard to specific exercise intensity, this study supports previous research that found the Fitbit device to overestimate EE during moderate activity [8]. In our study, the error for EE was the highest for Fitbit Charge HR at light and moderate physical activity.

There are a number of factors that might impact accuracy, such as design, materials, and engineering specifications. Proper placement for optimal sampling from most devices is weak or unknown. Fitbit specified placement higher on the wrist, but there were no instructions for other devices. It may be that varying the location of placement may serve to improve accuracy. Differences in devices in the sampling rate of PPG may also be a cause of variation. Garmin reports varying sampling rate with physical activity intensity [26], but this did not serve to enhance accuracy relative to the other devices. Additionally, the specific algorithms to determine EE for each device are not provided. The increased error from previous studies for the Fitbit device [8,10] suggests that the Fitbit Charge HR may utilize heart rate in determining EE. Errors in heart rate readings would therefore contribute to errors in EE accuracy. The devices are initialized through user's age, height, and weight measurements. The lack of further anthropometric measures (ie, body fat percentage, waist to hip ratio) to aid in EE assessment could lead to increased errors in estimation. Future research should examine whether additional anthropometric measurements reduce the error in these devices.

Implications

Behavioral interventions utilizing Fitbit devices have found increased step count and daily physical activity minutes in both adults [5,30,31] and older adults [32]. Likewise, heart rate feedback has been found to increase overall activity and percentage of time spent being vigorously active [23]. Thus, the addition of heart rate monitoring allows further opportunities for researchers to utilize these devices for interventions to increase physical activity and physical activity intensity. However, these data would suggest that, although these are useful as a stimulus to increase activity, each device is limited as an outcome measure or indicator of change in physical activity. As such, researchers would do well to continue to utilize accelerometers or similar well-validated devices for measures of physical activity. The inaccuracy with estimates of EE may be more problematic. Self-monitoring of EE is significantly associated with weight loss and increased daily exercise [33]. However, it is less clear whether wearable physical activity devices aid in weight loss. For example, in one weight loss intervention study, there were no changes in weight for those participants who wore a wearable physical activity device and tracked intake through a food tracking website compared with participants who completed MVPA and food diaries [6]. It could be possible that the wearable devices reported inaccurate EE and consequently participants were consuming more calories than recommended for weight loss. Therefore, questions remain about how the accuracy of these trackers impact interventions. Thus, users and researchers need to be aware of the measurement error for EE within these devices.

To our knowledge, this is the first study to establish the validity of popular wearable devices at distinct physical activity intensities. Most studies establishing validity only assess the overall physical activity intensity for an entire bout of physical activity [18]. Thus, it is difficult to tease apart the differences in heart rate and EE from each wearable device at specific physical activity intensities. Additionally, establishing validity over an entire bout at various physical activity intensities may overestimate accuracy, as the wearable devices may overestimate or underestimate the heart rate and EE at different intensities. In our study, Fitbit Charge HR underestimated heart rate at resting and vigorous intensities but overestimated heart rate at light and moderate intensities. If examined overall, these differences would cancel each other and show minimal differences. Therefore, establishing validity at specific physical

activity intensities increases accuracy that we would lose if examined as an overall bout of activity.

Inclusion of specific physical activity intensities is also an advantage as most physical activity or exercise bouts typically stay within certain physical activity intensities. For example, light-intensity activities are of particular importance as older adults tend to spend a greater portion of their day performing at this physical activity level [12], with walking as the most prevalent activity reported among all sociodemographic statuses [34]. Following walking, participation in aerobics is most prevalent in younger women and running most prevalent among younger men [34]. Thus, it is critical to evaluate these devices across different intensities. Unfortunately, this analysis did not find these devices to accurately measure heart rate and EE during light-intensity walking.

Limitations

There are limitations to this study. This study was conducted in a laboratory setting and therefore may not be generalizable to free-living activities. However, it is necessary to establish validity in a controlled setting, such as in a laboratory, in order to compare potential confounders that might be experienced in a field setting. This laboratory-based study was the necessary first step in device validation against each criterion. Given the observed heart rate variability between the Garmin Forerunner 225 relative to the Polar heart rate monitor, it is probably unnecessary to test in field-based studies, as it does not meet the standards of the criterion in highly controlled settings. However, because of the relative accuracy with heart rate, it is reasonable to suggest further field-testing with the Apple Watch and Fitbit Charge HR for heart rate.

Another limitation is the use of Apple Watch's EE activity tracking. Using the Workout app, all stages in this study were tracked under "indoor run." Operating indoor run could be a reason the Apple Watch measured significantly higher EE at baseline and recovery stages. Other activities included in the Workout app are, but not limited to, indoor walk, outdoor walk, elliptical, and other. The differences in algorithms for obtaining EE under various activities may lead to varying EE estimates. However, in order to decrease variability between participants within the study and given that there are no other ways to track EE than operating the Workout app, indoor run was utilized. The Apple Watch also reports both active and total calories per activity. We used total calories in our statistical analyses and did not use active calories because of the generalizability toward the other devices, which all reported overall calories per stage. Further investigation is needed to determine the impact of the Workout app activities on EE.

The Garmin device's ability to track workouts is a limitation of the device. According to Garmin Ltd, the Forerunner 225 is a GPS running watch, which suggests that the EE algorithm is based solely on running activities, which may be associated with the overestimation at baseline and recovery stages. However, while the differences were significant, both the Apple Watch and Garmin Forerunner 225 devices recorded little to no distance measured during these sedentary activities. As such, the practical impact is likely minimal.

One final limitation is that companies are constantly introducing new updates of activity tracking wearable devices. However, these changes are often aesthetic, with no modification of the underlying technology. For example, while Fitbit models have changed over time, the basic error rate has been similar across studies and devices [8,10]. This suggests that although the devices used in this study underwent software updating, the effect was likely insignificant.

Conclusions

Despite these limitations, this was one of the first studies to examine the accuracy of consumer-grade activity tracking wearable devices in regard to heart rate. The study used a novel approach to measure accuracy of these devices for heart rate and EE at specific bouts of physical activity intensities. The results of this study provide consumers, researchers, and clinicians the error measurement of 3 popular consumer brands: Apple Watch, Fitbit Charge HR, and Garmin Forerunner 225. Future research should continue to reflect the existing technology and determine why differences between the devices exist. Interventions targeting physical activity through the use of wearable devices should consider these results when selecting a wearable device as an objective measure of physical activity.

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Conflicts of Interest

None declared.

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Abbreviations

ANOVA: analysis of variance
BMI: body mass index
ECG: electrocardiogram
EE: energy expenditure
GPS: Global Positioning System
MAPE: mean absolute percentage error
MVPA: moderate to vigorous physical activity
PPG: photoplethysmography
RPE: Rating of Perceived Exertion

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